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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. and BOEHRINGER INGELHEIM INTERNATIONAL GMBH **Plaintiffs,** **v.** **ANOBRI PHARMACEUTICALS US, LLC, NANCHANG ANOVENT PHARMACEUTICAL CO., LTD., and SHANGHAI ANOVENT PHARMACEUTICAL CO., LTD.,** **Defendants.**	**Case No. 2:24-cv-09135-CCC-LDW** Honorable Claire C. Cecchi, U.S.D.J. Honorable Leda D. Wettre, U.S.M.J.

DEFENDANT ANOBRI PHARMACEUTICALS US, LLC'S AMENDED ANSWER

Defendant Anobri Pharmaceuticals US, LLC hereby responds to the Complaint for Patent Infringement filed by Plaintiffs Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH (collectively, "Boehringer" or "Plaintiffs"), against Anobri Pharmaceuticals US, LLC (formerly known as Anovent Pharmaceutical (U.S.), LLC) ("Anobri"),

Nanchang Anovent Pharmaceutical Co., Ltd. ("Nanchang Anovent"), and Shanghai Anovent Pharmaceutical Co., Ltd. ("Shanghai Anovent") (collectively, "Defendants") as follows:

RESPONSES TO ALLEGATIONS PERTAINING TO THE 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 and e), arises from Defendants' submission of Abbreviated New Drug Application (ANDA) No. 218956 to the United States Food and Drug Administration (FDA). Through this ANDA, Defendants seek approval to market a generic version of the pharmaceutical product STIOLTO® Respimat® prior to the expiration of United States Patent Nos. 7,396,341 ("the '6,341 patent"), 9,027,967 ("the '967 patent"), 7,837,235 ("the '235 patent"), and 8,733,341 ("the '3,341 patent") (collectively, "the patents-in-suit"). Boehringer seeks injunctive relief against infringement, attorneys' fees, and any other relief the Court deems just and proper.

ANSWER:

Anobri admits that the Complaint purports to assert an action for patent infringement pursuant to the patent laws of the United States, 35 U.S.C. § 1, et seq. Anobri admits that it has submitted ANDA No. 218956, seeking approval to market a tiotropium bromide and olodaterol hydrochloride inhalation spray, 2.5 mcg/2.5 mcg/actuation, (hereafter "Anobri's ANDA Product"), referring to reference listed drug STIOLTO ® Respimat®, before the expiration of the patents-in-suit. Anobri admits that both Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956. Anobri admits that Boehringer seeks the recited relief. Otherwise denied.

2. This is also an action under 28 U.S.C. §§ 2201 and 2202 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.

ANSWER:

Paragraph 2 contains legal conclusions to which no response is required. To the extent a response is required, denied.

3. 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:

Upon information and belief, Anobri admits that Boehringer Ingelheim Pharmaceuticals, Inc. has a place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Anobri is without information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3 and therefore denies them.

4. 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:

Upon information and belief, Anobri admits that Boehringer Ingelheim International GmbH has a place of business at Binger Strasse 173, 55216 Ingelheim, Germany. Anobri is without information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4 and therefore denies them.

5. On information and belief, Shanghai Anovent Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of China, having a place of business at 3rd Floor, Block B, Building 3, No. 299 Kangwei Road, Kangqiao Town, Pudong District, Shanghai, 2000, China.

ANSWER:

The allegations of Paragraph 5 appear to be directed to Shanghai Anovent Pharmaceutical Co., Ltd., and a response from Anobri is not required. To the extent Anobri is required to respond, Anobri admits that Shanghai Anovent Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of China, having a place of business at 3rd Floor, Block B, Building 3, No. 299 Kangwei Road, Kangqiao Town, Pudong District, Shanghai, 2000, China. Otherwise denied.

6. On information and belief, NanChang Anovent Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of China, having a place of business at Building

B1, Lianbo Science and Technology Park, 888 Jingkai Avenue, Nanchang Economic and Technological Development District, NanChang City, 330013 Jiangxi Province, China.

ANSWER:

The allegations of Paragraph 6 appear to be directed to Nanchang Anovent, and a response from Anobri is not required. To the extent Anobri is required to respond, Anobri admits that Nanchang Anovent is a corporation organized and existing under the laws of China, having a place of business at Building B1, Lianbo Science and Technology Park, 888 Jingkai Avenue, Nanchang Economic and Technological Development District, NanChang City, 330013 Jiangxi Province, P.R. China. Otherwise denied.

7. On information and belief, NanChang Anovent Pharmaceutical Co., Ltd. is a subsidiary of Shanghai Anovent Pharmaceutical Co., Ltd.

ANSWER:

The allegations of Paragraph 7 appear to be directed to Nanchang Anovent, and a response from Anobri is not required. To the extent Anobri is required to respond, Anobri admits that Nanchang Anovent is a subsidiary of Shanghai Anovent. Otherwise denied.

8. On information and belief, Anobri Pharmaceuticals US, LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at One Gateway Center, Suite 2600, Newark, New Jersey 07102. On information and belief, Anobri Pharmaceuticals US, LLC amended its certificate of formation on July 23, 2021, to identify this address as the location of its principal office, and Anobri Pharmaceuticals US, LLC has since used this address in patent assignments recorded at the U.S. Patent and Trademark Office (USPTO), including as recently as June 13, 2023.

ANSWER:

Anobri admits that it is a limited liability company formed and existing under the laws of Delaware, having its principal place of business at One Gateway Center, Suite 2600, Newark, New Jersey, 07102. Anobri admits that its original name was Anovent Pharmaceutical (U.S.), LLC. Anobri admits that its certificate of formation was amended on July 23, 2021, to add this address

as its principal office and that Anobri has used this address in patent assignments recorded at the USPTO as recently as June 13, 2023. Anobri admits that certain patent assignments filed with the USPTO inadvertently included incorrect corporate information and that corrective assignments have since been filed for Anobri's pending patent applications and issued patents. Otherwise denied.

9. On information and belief, Anobri Pharmaceuticals US, LLC is a wholly owned subsidiary of NanChang Anovent Pharmaceutical Co., Ltd.

ANSWER:

Denied.

10. On information and belief, Anobri Pharmaceuticals US, LLC, in collaboration with NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd., prepared and submitted ANDA No. 218956 ("Defendants' ANDA"), and they continue to collaborate in seeking FDA approval of Defendants' ANDA.

ANSWER:

Anobri admits that it prepared and submitted ANDA No. 218956. Anobri also admits that both Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No.218956. Anobri admits that it is seeking FDA approval of ANDA No. 218956 and does not presently know what collaboration may be needed from Shanghai Anovent and Nanchang Anovent. Otherwise denied.

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

ANSWER:

Anobri admits that it will not commercially manufacture, market, offer for sale, and sell the product described in ANDA No. 218956 without FDA approval, but FDA approval is not the only condition upon which Anobri will commercially market its product. Anobri will decide

whether and when to commercially market its product once the FDA approves its ANDA in view of numerous factors, including the progress of this lawsuit. Otherwise denied.

RESPONSES TO ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

12. 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 the patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, and 2201–02.

ANSWER:

Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, Anobri states that for the purposes of this civil action only, it does not contest that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338. Anobri admits that the Complaint purports to assert an action for patent infringement of the patents-in-suit pursuant to the patent laws of the United States, including 35 U.S.C. § 271. Otherwise denied.

13. On information and belief, this Court has personal jurisdiction over Anobri Pharmaceuticals US, LLC because it is a limited liability company with a principal place of business in New Jersey and is the agent of NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. On information and belief, Anobri Pharmaceuticals US, LLC is acting as the agent of NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. with respect to Defendants' ANDA.

ANSWER:

Paragraph 13 contains conclusions of law for which no response is required. To the extent a response is required, Anobri states that for the purposes of this civil action only, it does not contest personal jurisdiction, but denies that this Court has jurisdiction over Shanghai Anovent and Nanchang Anovent. Anobri admits that it is a limited liability company with a principal place of business in New Jersey. Otherwise denied.

14. On information and belief, this Court has personal jurisdiction over NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met: (a) Boehringer's claims arise under federal law; (b) NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent

Pharmaceutical Co., Ltd. are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. have sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products to be distributed throughout the United States, such that this Court's exercise of jurisdiction over NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. satisfies due process.

ANSWER:

Paragraph 14 contains conclusions of law for which no response is required. To the extent a response is required, denied.

15. On information and belief, this Court also has jurisdiction over Defendants because, *inter alia*, this action arises from actions of Defendants directed toward New Jersey and because Defendants have purposefully availed themselves of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. On information and belief, Anobri Pharmaceuticals US, LLC has a principal place of business at One Gateway Center, Suite 2600, Newark, New Jersey 07102. On information and belief, Anobri Pharmaceuticals US, LLC amended its certificate of formation on July 23, 2021, to identify this address as the location of its principal office, and Anobri Pharmaceuticals US, LLC has since used this address in patent assignments recorded at the USPTO, including as recently as June 13, 2023. Anobri Pharmaceuticals US, LLC also represented to the USPTO that it was incorporated in New Jersey, at this address, during the time that Defendants were developing the ANDA Product.

ANSWER:

Paragraph 15 contains conclusions of law for which no response is required. To the extent a response is required, Anobri states that for the purposes of this civil action only, it does not contest personal jurisdiction, but denies that this Court has jurisdiction over Shanghai Anovent and Nanchang Anovent. Anobri admits that it has a principal place of business at One Gateway Center, Suite 2600, Newark, New Jersey 07102. Anobri admits that its certificate of formation was amended on July 23, 2021, to add this address as its principal office and that Anobri has used this address in patent assignments recorded at the USPTO as recently as June 13, 2023. Anobri admits that certain patent assignments filed with the USPTO inadvertently included incorrect corporate

information and that corrective assignments have since been filed for Anobri's pending patent applications and issued patents. Otherwise denied.

16. On information and belief, Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Boehringer, which manufactures STIOLTO® Respimat® for sale and use throughout the United States, including this Judicial District. On information and belief, Anobri Pharmaceuticals US, LLC has submitted, caused to be submitted, or aided and abetted in the preparation or submission of Defendants' ANDA, including activities undertaken from One Gateway Center, Suite 2600, Newark, New Jersey 07102. On information and belief, in the event that FDA approves Defendants' ANDA, Anobri Pharmaceuticals US, LLC, with the participation of NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd., intends to commercially manufacture, import, market, offer for sale, and sell the ANDA Product throughout the United States and in this Judicial District.

ANSWER:

Paragraph 16 contains conclusions of law for which no response is required. To the extent a response is required, Anobri states that for the purposes of this civil action only, it does not contest personal jurisdiction, but denies that this Court has jurisdiction over Shanghai Anovent and Nanchang Anovent. Anobri admits that Plaintiffs manufacture and sell STIOLTO ® Respimat® in the United States. Anobri admits that it submitted ANDA No. 218956 to FDA seeking approval to market and sell Anobri's ANDA Product within the United States. Anobri admits that it will not commercially manufacture, market, offer for sale, and sell the product described in ANDA No. 218956 without FDA approval, but FDA approval is not the only condition upon which Anobri will commercially market its product. Anobri will decide whether and when it will commercially market its product once the FDA approves its ANDA in view of numerous factors, including the progress of this lawsuit. Anobri admits that activities relating to preparing and submitting ANDA No. 218956 were undertaken from One Gateway Center, Suite 2600, Newark, New Jersey 07102. Anobri admits that Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956. Anobri admits that filing ANDA No.

218956 with paragraph IV certifications to the '6,341, '967, '235, and '3,341 patents is an artificial act of infringement, but Anobri denies that there is any merit to Plaintiffs' substantive claims of infringement. Otherwise denied.

17. At least because, on information and belief, Anobri Pharmaceuticals US, LLC has a regular and established place of business in New Jersey, committed act(s) of infringement in New Jersey, and is acting as the agent of NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd., venue is proper in this Judicial District as to Anobri Pharmaceuticals US, LLC pursuant to 28 U.S.C. § 1400(b).

ANSWER:

Paragraph 17 contains conclusions of law for which no response is required. To the extent a response is required, Anobri admits that it does not contest venue for the purposes of this civil action only. Otherwise denied.

18. At least because, on information and belief, NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. are foreign corporations, venue is proper in this Judicial District as to NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b).

ANSWER:

Paragraph 18 contains conclusions of law for which no response is required. To the extent a response is required, Anobri denies the allegations in Paragraph 18.

19. Anobri Pharmaceuticals US, LLC has not disputed venue or jurisdiction in this Judicial District in Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Anobri Pharmaceuticals US, LLC, et al., Civil Action No. 2:23-cv-03530-CCC-LDW (consolidated), in which Boehringer has accused Anobri of infringing the patents-in-suit on the ground that Anobri seeks approval to market generic versions of SPIRIVA® Respimat® and COMBIVENT® Respimat®.

ANSWER:

Paragraph 19 contains conclusions of law for which no response is required. To the extent a response is required, Anobri admits that it does not contest venue or personal jurisdiction for the purposes of this civil action only, but denies that this Court has jurisdiction over Shanghai Anovent and Nanchang Anovent. To the extent a response is

required, Anobri denies the remaining allegations in Paragraph 19.

RESPONSES TO ALLEGATIONS PERTAINING TO PLAINTIFFS' APPROVED STIOLTO® RESPIMAT® DRUG PRODUCT AND PATENTS-IN-SUIT

20. Boehringer makes and sells STIOLTO® Respimat®, a product that is a combination of an anticholinergic agent and a long-acting beta2-adrenergic agonist, and that is indicated for the long-term, once-daily maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). A true and correct copy of the prescribing label for STIOLTO® Respimat® is attached hereto as Exhibit A.

ANSWER:

Anobri admits that Plaintiffs attached a document that appears to be prescribing information for STIOLTO® Respimat® as Exhibit A to the Complaint. Anobri further admits that STIOLTO® Respimat® (tiotropium bromide and olodaterol hydrochloride inhalation spray) currently is described as an anticholinergic indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; that STIOLTO® Respimat® is indicated to reduce exacerbations in COPD patients; and that STIOLTO® Respimat® is not indicated for the relief of acute bronchospasm. For the remaining allegations in Paragraph 20, Anobri is without knowledge or information sufficient to admit or deny such allegations, and therefore denies them.

21. Boehringer Ingelheim Pharmaceuticals, Inc. is the holder of New Drug Application (NDA) No. 206756 for STIOLTO® Respimat® and a licensee of the patents-in-suit. FDA first approved NDA No. 206756 for STIOLTO® Respimat® in May 2015.

ANSWER:

Anobri admits that the United States Patent and Trademark Office ("USPTO")'s Patent Assignment database identifies Boehringer Ingelheim Pharmaceuticals, Inc. as the assignee of the patents-in-suit. Anobri admits that, according to FDA website Drugs@FDA, Boehringer Ingelheim Pharmaceuticals, Inc. is the holder of NDA No. 206756, which is sold under the trade name for STIOLTO® Respimat®. Anobri further admits that FDA's Orange Book lists an

approval date of STIOLTO® Respimat® as May 21, 2015. Anobri is without knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 21, and therefore denies them.

22. Boehringer Ingelheim International GmbH owns the '6,341 patent, which is listed in the Orange Book for STIOLTO® Respimat®.

ANSWER:

Anobri admits that the '6,341 patent is listed in the Orange Book for STIOLTO® Respimat®. Anobri is without knowledge or information sufficient to admit or deny the remaining allegations of Paragraph 22, and therefore denies same.

23. The '6,341 patent is entitled "Blocking Device for a Locking Stressing Mechanism having a Spring-Actuated Output Drive Device" and was duly and lawfully issued by the USPTO on July 8, 2008. The '6,341 patent is attached hereto as Exhibit B.

ANSWER:

Anobri admits that the '6,341 patent is titled "Blocking Device for a Locking Stressing Mechanism having a Spring-Actuated Output Drive Device," and that it issued on July 8, 2008. Anobri admits that what purports to be a true and correct copy of the '6,341 patent is attached to the Complaint as Exhibit B. Anobri denies that the '6,341 patent was lawfully issued. Anobri is without knowledge or information sufficient to admit or deny the remaining allegations of Paragraph 23, and therefore denies same.

24. Boehringer Ingelheim International GmbH owns the '967 patent, which is listed in the Orange Book for STIOLTO® Respimat®.

ANSWER:

Anobri admits that the '967 patent is listed in the Orange Book for STIOLTO® Respimat®. Anobri is without knowledge or information sufficient to admit or deny the remaining allegations of Paragraph 24, and therefore denies same.

25. The ’967 patent is entitled “Device for Clamping a Fluidic Component” and was duly and lawfully issued by the USPTO on May 12, 2015. The ’967 patent is attached hereto as Exhibit C.

ANSWER:

Anobri admits that the ’967 patent is titled “Device for Clamping a Fluidic Component,” and that it issued on May 12, 2015. Anobri admits that what purports to be a true and correct copy of the ’967 patent is attached to the Complaint as Exhibit C. Anobri denies that the ’967 patent was lawfully issued. Anobri is without knowledge or information sufficient to admit or deny the remaining allegations of Paragraph 25, and therefore denies same.

26. Boehringer Ingelheim International GmbH owns the ’235 patent, which is listed in the Orange Book for STIOLTO® Respimat®.

ANSWER:

Anobri admits that the ’235 patent is listed in the Orange Book for STIOLTO® Respimat®. Anobri is without knowledge or information sufficient to admit or deny the remaining allegations of Paragraph 26, and therefore denies same.

27. The ’235 patent is entitled “Device for Clamping a Fluidic Component” and was duly and lawfully issued by the USPTO on November 23, 2010. The ’235 patent is attached hereto as Exhibit D.

ANSWER:

Anobri admits that the ’235 patent is titled “Device for Clamping a Fluidic Component,” and that it issued on November 23, 2010. Anobri admits that what purports to be a true and correct copy of the ’235 patent is attached to the Complaint as Exhibit D. Anobri denies that the ’235 patent was lawfully issued. Anobri is without knowledge or information sufficient to admit or deny the remaining allegations of Paragraph 27, and therefore denies same.

28. Boehringer Ingelheim International GmbH owns the ’3,341 patent, which is listed in the Orange Book for STIOLTO® Respimat®.

ANSWER:

Anobri admits that the '3,341 patent is listed in the Orange Book for STIOLTO® Respimat®. Anobri is without knowledge or information sufficient to admit or deny the remaining allegations of Paragraph 28, and therefore denies same.

29. The '3,341 patent is entitled "Atomizer and Method of Atomizing Fluid with a Nozzle Rinsing Mechanism" and was duly and lawfully issued by the USPTO on May 27, 2014. The '3,341 patent is attached hereto as Exhibit E.

ANSWER:

Anobri admits that the '3,341 patent is titled "Atomizer and Method of Atomizing Fluid with a Nozzle Rinsing Mechanism," and that it issued on May 27, 2014. Anobri admits that what purports to be a true and correct copy of the '3,341 patent is attached to the Complaint as Exhibit E. Anobri denies that the '3,341 patent was lawfully issued. Anobri is without knowledge or information sufficient to admit or deny the remaining allegations of Paragraph 29, and therefore denies same.

RESPONSES TO ALLEGATIONS PERTAINING TO DEFENDANTS' ANDA

30. Boehringer Ingelheim International GmbH owns additional patents that are listed in the Orange Book for STIOLTO® Respimat® for which Defendants have not provided a Paragraph IV certification ("Unchallenged Patents"). Defendants do not seek approval to market a generic version of STIOLTO® Respimat® prior to expiration of the Unchallenged Patents, including any associated pediatric exclusivity. The Unchallenged Patents are: (i) U.S. Patent No. 7,284,474, entitled "Piston-Pumping System Having O-Ring Seal Properties," which expired on August 26, 2024, but benefits from pediatric exclusivity until February 26, 2025; (ii) U.S. Patent No. 7,896,264, entitled "Microstructured High Pressure Nozzle with Built-in Filter Function," which expires on May 26, 2025; (iii) U.S. Patent No. 7,220,742, entitled "Enantiomerically Pure Beta Agonists, Process for the Manufacture Thereof and Use Thereof as Medicaments," which expires on May 12, 2025; (iv) U.S. Patent No. 7,727,984, entitled "Medicaments for the Treatment of Chronic Obstructive Pulmonary Disease," which expires on January 19, 2027; and (v) U.S. Patent No. 8,034,809, entitled "Enantiomerically Pure Beta Agonists, Process for the Manufacture Thereof and Use Thereof as Medicaments," which expires on May 12, 2025.

ANSWER:

Upon information and belief, Anobri admits that additional patents are listed in the

Orange Book, including (i) U.S. Patent No. 7,284,474, entitled "Piston-Pumping System Having O-Ring Seal Properties," which expired on August 26, 2024, but benefits from pediatric exclusivity until February 26, 2025; (ii) U.S. Patent No. 7,896,264, entitled "Microstructured High Pressure Nozzle with Built-in Filter Function," which expires on May 26, 2025; (iii) U.S. Patent No. 7,220,742, entitled "Enantiomerically Pure Beta Agonists, Process for the Manufacture Thereof and Use Thereof as Medicaments," which expires on May 12, 2025; (iv) U.S. Patent No. 7,727,984, entitled "Medicaments for the Treatment of Chronic Obstructive Pulmonary Disease," which expires on January 19, 2027; and (v) U.S. Patent No. 8,034,809, entitled "Enantiomerically Pure Beta Agonists, Process for the Manufacture Thereof and Use Thereof as Medicaments," which expires on May 12, 2025. Anobri is without knowledge or information sufficient to admit or deny the allegations that Boehringer Ingelheim International GmbH Anobri owns these patents, and therefore denies that allegation. Anobri admits that its ANDA No. 218956 does not contain Paragraph IV certifications to the Unchallenged Patents. Anobri admits that both Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956. Otherwise denied.

31. Thus, Defendants do not seek final FDA approval to market a generic version of STIOLTO® Respimat® prior to January 19, 2027.

ANSWER:

Anobri admits that it has submitted ANDA No. 218956, seeking approval to market Anobri's ANDA Product, referring to reference listed drug STIOLTO ® Respimat®, before the expiration of the '6,341, '967, '235, and '3,341 patents. Anobri admits that both Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956. Anobri denies the remaining allegations in Paragraph 31.

32. On information and belief, Defendants have submitted or caused to be submitted Defendants' ANDA to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of tiotropium bromide and olodaterol hydrochloride inhalation spray as a purported generic version of STIOLTO® Respimat® prior to the expiration of the patents-in-suit.

ANSWER:

Anobri admits that it has submitted ANDA No. 218956 to FDA pursuant to 21 U.S.C. § 355(j), seeking approval to manufacture, use, sell, offer for sale, or import Anobri's ANDA Product prior to the expiration of the patents-in-suit. Anobri admits that Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956. Anobri denies the remaining allegations in Paragraph 32.

33. On information and belief, on or about July 30, 2024, Defendants mailed Boehringer a letter regarding "notice and information required by 21 U.S.C. §§ 355(j)(2)(B)(i) and (ii)" ("Notice Letter"). The Notice Letter represented that Defendants had submitted to FDA Defendants' ANDA and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in Defendants' ANDA before the expiration of the patents-in-suit, which are listed in the Orange Book for STIOLTO® Respimat® Hence, Defendants' purpose in submitting Defendants' ANDA is to manufacture and market the ANDA Product before the expiration of the patents-in-suit.

ANSWER:

Anobri admits that it mailed its Notice Letter on or about July 30, 2024. Anobri admits that its Notice Letter notified Boehringer that FDA deemed acceptable for filing Anobri's ANDA No. 218956 for Anobri's ANDA Product, notified Boehringer that ANDA No. 218956 contained a Paragraph IV certification as to each of the patents-in-suit. Anobri admits that it seeks FDA approval to engage in the commercial manufacture, use, or sale of Anobri's ANDA Product before the expiration of the patents-in-suit. Anobri also admits that the patents-in-suit are listed in the Orange Book for STIOLTO® Respimat®. Otherwise denied.

34. Defendants' Notice Letter contained a purported offer of confidential access ("Defendants' Offer"). Pursuant to Defendants' Offer, Defendants produced only limited information about the proposed inhaler from Defendants' ANDA. Specifically, Defendants

produced only a single, 19-page document from their ANDA. Defendants thus have not provided reasonable access to Defendants' ANDA, and Defendants' actions have impeded Boehringer's ability to evaluate Defendants' contentions that the proposed inhaler does not infringe certain of the patents-in-suit.

ANSWER:

Anobri admits that, pursuant to 21 U.S.C. §§ 355(j)(2)(B)(i) and (ii), it notified Plaintiffs through its Notice Letter that FDA deemed acceptable for filing Anobri's ANDA No. 218956 for Anobri's ANDA Product, through which Anobri seeks FDA approval to engage in the commercial manufacture, use, or sale of Anobri's ANDA Product before the expiration of the patents-in-suit. Anobri admits that the Notice Letter contained the Defendant's Offer. Otherwise denied.

35. Upon information and belief, the inhaler device of Defendants' ANDA is the same as the device at issue in Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Anobri Pharmaceuticals US, LLC, et al., Civil Action No. 2:23-cv-03530-CCC-LDW (consolidated).

ANSWER:

Anobri admits that the inhaler device at issue in Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Anobri Pharmaceuticals US, LLC, et al., Civil Action No. 2:23-cv-03530-CCC-LDW (consolidated) is the same as the inhaler device described in Anobri's ANDA No. 218956. Anobri denies the remaining allegations in Paragraph 35.

36. On information and belief, Defendants have participated in the preparation and submission of Defendants' ANDA, have provided material support to the preparation and submission of Defendants' ANDA, and intend to support the further prosecution of Defendants' ANDA.

ANSWER:

Anobri admits that it prepared and submitted ANDA No. 218956 to FDA. Anobri admits that Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956. Anobri admits that it is seeking FDA approval of ANDA No. 218956 and does not presently know what further support may be needed from Shanghai Anovent and Nanchang

Anovent in prosecuting ANDA No. 218956. Anobri denies the remaining allegations in Paragraph 36.

37. On information and belief, if FDA approves Defendants' ANDA, Defendants 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:

Anobri admits that it will not commercially manufacture, market, offer for sale, and sell the product described in ANDA No. 218956 without FDA approval, but FDA approval is not the only condition upon which Anobri will commercially market its product. Anobri will decide whether and when it will commercially market its product once the FDA approves its ANDA in view of numerous factors, including the progress of this lawsuit. Otherwise denied.

38. Alternatively, on information and belief, if FDA approves Defendants' ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product within the United States, including within New Jersey, or will import the ANDA Product into the United States, including New Jersey. On information and belief, Defendants. ANDA Product is especially adapted for a use that infringes one or more claims of the patents-in-suit and there is no substantial noninfringing use for Defendants' ANDA Product.

ANSWER:

Anobri admits that it will not commercially manufacture, market, offer for sale, and sell the product described in ANDA No. 218956 without FDA approval, but FDA approval is not the only condition upon which Anobri will commercially market its product. Anobri will decide whether and when it will commercially market its product once the FDA approves its ANDA in view of numerous factors, including the progress of this lawsuit. Anobri denies that its ANDA Product is especially adapted for a use that infringes one or more claims of the patents-in-suit and denies that there is no substantial non-infringing use for its ANDA Product. Otherwise denied.

39. This action is being filed within forty-five days of Boehringer's receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER:

Admitted.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT I

40. Boehringer incorporates by reference paragraphs 1–39 as if fully set forth herein.

ANSWER:

Anobri repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

41. On information and belief, Defendants have submitted or caused the submission of Defendants' ANDA to FDA and continue to seek FDA approval of Defendants' ANDA.

ANSWER:

Anobri admits that it submitted ANDA No. 218956 to FDA and continues to seek FDA approval of Anobri's ANDA No. 218956. Anobri also admits that Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956. Otherwise denied.

42. Defendants have infringed the '6,341 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV certification and seeking FDA approval of Defendants' ANDA prior to the expiration of the '6,341 patent.

ANSWER:

Denied.

43. On information and belief, if Defendants' ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of New Jersey, directly infringing one or more claims of the '6,341 patent.

ANSWER:

Denied.

44. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the '6,341 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218956, Defendants 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 '6,341 patent.

ANSWER:

Denied.

45. Defendants had actual knowledge of the '6,341 patent prior to submitting Defendants' ANDA and were aware that the submission of Defendants' ANDA with the request for FDA approval prior to the expiration of the '6,341 patent would constitute an act of infringement of the '6,341 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the '6,341 patent.

ANSWER:

Anobri admits that it had knowledge of the '6,341 patent before the submission of Anobri's ANDA No. 218956. Otherwise denied.

46. In addition, Defendants submitted Defendants' ANDA without adequate justification for asserting the '6,341 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the '6,341 patent thus renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER:

Denied.

47. Boehringer will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '6,341 patent. Boehringer does not have an adequate remedy at law and, considering the balance of hardships between Boehringer and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT II

48. Boehringer incorporates by reference paragraphs 1–47 as if fully set forth herein.

ANSWER:

Anobri repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

49. On information and belief, Defendants have submitted or caused the submission of Defendants' ANDA to FDA and continue to seek FDA approval of Defendants' ANDA.

ANSWER:

Anobri admits that it submitted ANDA No. 218956 to FDA and continues to seek FDA approval of Anobri's ANDA No. 218956. Anobri also admits that Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956. Otherwise denied.

50. Defendants have infringed the '967 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV certification and seeking FDA approval of Defendants' ANDA prior to the expiration of the '967 patent.

ANSWER:

Denied.

51. On information and belief, if Defendants' ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of New Jersey, directly infringing one or more claims of the '967 patent.

ANSWER:

Denied.

52. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the '967 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218956, Defendants 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 '967 patent.

ANSWER:

Denied.

53. Defendants had actual knowledge of the '967 patent prior to submitting Defendants' ANDA and were aware that the submission of Defendants' ANDA with the request for FDA approval prior to the expiration of the '967 patent would constitute an act of infringement of the '967 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the '967 patent.

ANSWER:

Anobri admits that it had knowledge of the '967 patent before the submission of Anobri's ANDA No. 218956. Otherwise denied.

54. In addition, Defendants submitted Defendants' ANDA without adequate justification for asserting the '967 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the '967 patent thus renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER:

Denied.

55. Boehringer will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '967 patent. Boehringer does not have an adequate remedy at law and, considering the balance of hardships between Boehringer and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT III

56. Boehringer incorporates by reference paragraphs 1–55 as if fully set forth herein.

ANSWER:

Anobri repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

57. On information and belief, Defendants have submitted or caused the submission of Defendants' ANDA to FDA and continue to seek FDA approval of Defendants' ANDA.

ANSWER:

Anobri admits that it submitted ANDA No. 218956 to FDA and continues to seek FDA approval of Anobri's ANDA No. 218956. Anobri also admits that Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956 Anobri denies the remaining allegations in Paragraph 57.

58. Defendants have infringed the '235 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV certification and seeking FDA approval of Defendants' ANDA prior to the expiration of the '235 patent.

ANSWER:

Denied.

59. On information and belief, if Defendants' ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of New Jersey, directly infringing one or more claims of the '235 patent.

ANSWER:

Denied.

60. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the '235 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218956, Defendants 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 '235 patent.

ANSWER:

Denied.

61. Defendants had actual knowledge of the '235 patent prior to submitting Defendants' ANDA and were aware that the submission of Defendants' ANDA with the request for FDA approval prior to the expiration of the '235 patent would constitute an act of infringement of the '235 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the '235 patent.

ANSWER:

Anobri admits that it had knowledge of the '235 patent before the submission of Anobri's ANDA No. 218956. Otherwise denied.

62. In addition, Defendants submitted Defendants' ANDA without adequate justification for asserting the '235 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the '235 patent thus renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER:

Denied.

63. Boehringer will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '235 patent. Boehringer does not have an adequate remedy at law and, considering the balance of hardships between Boehringer and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT IV

64. Boehringer incorporates by reference paragraphs 1–63 as if fully set forth herein.

ANSWER:

Anobri repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

65. On information and belief, Defendants have submitted or caused the submission of Defendants' ANDA to FDA and continue to seek FDA approval of Defendants' ANDA.

ANSWER:

Anobri admits that it submitted ANDA No. 218956 to FDA and continues to seek FDA approval of Anobri's ANDA No. 218956. Anobri also admits that Shanghai Anovent and Nanchang Anovent were involved in the preparation of ANDA No. 218956. Otherwise denied.

66. Defendants have infringed the '3,341 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV certification and seeking FDA approval of Defendants' ANDA prior to the expiration of the '3,341 patent.

ANSWER:

Denied.

67. On information and belief, if Defendants' ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of New Jersey, directly infringing one or more claims of the '3,341 patent.

ANSWER:

Denied.

68. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the '3,341 patent. Accordingly, unless enjoined by this Court, upon FDA approval

of ANDA No. 218956, Defendants 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 '3,341 patent.

ANSWER:

Denied.

69. Defendants had actual knowledge of the '3,341 patent prior to submitting Defendants' ANDA and were aware that the submission of Defendants' ANDA with the request for FDA approval prior to the expiration of the '3,341 patent would constitute an act of infringement of the '3,341 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the '3,341 patent.

ANSWER:

Anobri admits that it had knowledge of the '3,341 patent before the submission of Anobri's ANDA No. 218956. Otherwise denied.

70. In addition, Defendants submitted Defendants' ANDA without adequate justification for asserting the '3,341 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the '3,341 patent thus renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER:

Denied.

71. Boehringer will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '3,341 patent. Boehringer does not have an adequate remedy at law and, considering the balance of hardships between Boehringer and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT V

72. Boehringer incorporates by reference paragraphs 1–71 as if fully set forth herein.

ANSWER:

Anobri repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

73. Boehringer's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Denied.

74. On information and belief, if Defendants' 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 Defendants and their affiliates.

ANSWER:

Denied.

75. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants' ANDA, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '6,341 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

ANSWER:

Denied.

76. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '6,341 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '6,341 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

ANSWER:

Denied.

77. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Boehringer and Defendants concerning liability for the infringement of the '6,341 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER:

Denied.

78. Boehringer will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Boehringer has no adequate remedy at law.

ANSWER:

Denied.

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

ANSWER:

Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT VI

80. Boehringer incorporates by reference paragraphs 1–79 as if fully set forth herein.

ANSWER:

Anobri repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

81. Boehringer's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Denied.

82. On information and belief, if Defendants' 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 Defendants and their affiliates.

ANSWER:

Denied.

83. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants' ANDA, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '967 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

ANSWER:

Denied.

84. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '967 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '967 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

ANSWER:

Denied.

85. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Boehringer and Defendants concerning liability for the infringement of the '967 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER:

Denied.

86. Boehringer will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Boehringer has no adequate remedy at law.

ANSWER:

Denied.

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

ANSWER:

Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT VII

88. Boehringer incorporates by reference paragraphs 1–87 as if fully set forth herein.

ANSWER:

Anobri repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

89. Boehringer's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Denied.

90. On information and belief, if Defendants' 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 Defendants and their affiliates.

ANSWER:

Denied.

91. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants'

ANDA, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '235 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

ANSWER:

Denied.

92. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '235 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '235 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f), and (g).

ANSWER:

Denied.

93. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Boehringer and Defendants concerning liability for the infringement of the '235 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER:

Denied.

94. Boehringer will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Boehringer has no adequate remedy at law.

ANSWER:

Denied.

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

ANSWER:

Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT VIII

96. Boehringer incorporates by reference paragraphs 1–95 as if fully set forth herein.

ANSWER:

Anobri repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

97. Boehringer's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Denied.

98. On information and belief, if Defendants' 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 Defendants and their affiliates.

ANSWER:

Denied.

99. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants' ANDA, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '3,341 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f), and (g).

ANSWER:

Denied.

100. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '3,341 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '3,341 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f), and (g).

ANSWER:

Denied.

101. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Boehringer and Defendants concerning liability for the infringement of the '3,341 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER:

Denied.

102. Boehringer will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Boehringer has no adequate remedy at law.

ANSWER:

Denied.

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

ANSWER:

Denied.

RESPONSE TO PRAYER FOR RELIEF

Anobri denies that Plaintiffs are entitled to the judgment or other relief prayed for in subparagraphs A – I under the heading "PRAYER FOR RELIEF" in the Complaint.

* * *

Any allegation in the Complaint and documents purported to be incorporated therein not specifically admitted in the paragraphs above is denied.

AFFIRMATIVE DEFENSES

Pursuant to Fed. R. Civ. P. 8(b) and (c), without assuming any burden that it would not otherwise bear, without reducing or removing Plaintiffs' burdens of proof on their affirmative claims against Anobri, and reserving its rights to assert additional defenses, Anobri asserts the following defenses to the Complaint.

DEFENSE NO. 1

Plaintiffs fail to state a claim upon which relief can be granted.

DEFENSE NO. 2

Each asserted claim of the '6,341, '967, '235, and '3,341 patents is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability, including obviousness-type double patenting.

DEFENSE NO. 3

Anobri has not infringed, induced infringement of, or contributed to the infringement of, and Anobri will not infringe, induce infringement of, or contribute to the infringement of, either literally or under the doctrine of equivalents, any valid and enforceable asserted claim of the '6,341, '967, '235, and '3,341 patents.

DEFENSE NO. 4

Plaintiffs are not entitled to seek injunctive relief against Anobri because the alleged harm is not immediate or irreparable, and therefore Plaintiffs have an adequate remedy at law.

DEFENSE NO. 5

Plaintiffs are not entitled to attorneys' fees against Anobri because Plaintiffs have not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

DEFENSE NO. 6

35 U.S.C. § 288 prevents Plaintiffs from recovering any costs associated with this action.

DEFENSE NO. 7

Any additional legal or equitable defenses or counterclaims that discovery may reveal, including, but not limited to, defenses of unenforceability, as well as any defenses raised by another defendant in any action involving the '6,341, '967, '235, and '3,341 patents.

DEFENSE NO. 8

Anobri reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

COUNTERCLAIMS

Counterclaim Plaintiff Anobri Pharmaceuticals US, LLC ("Counterclaim Plaintiff" or "Anobri"), for its Counterclaims against Counterclaim Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH (collectively, "Counterclaim Defendants"), alleges and avers as follows:

NATURE OF THE ACTION

1. Anobri repeats and incorporates by reference each of the foregoing paragraphs 1–103 of its Answer as well as its Affirmative Defenses to the Complaint, as if fully set forth herein.

2. These counterclaims seek a declaratory judgment of non-infringement and invalidity of one or more claims of U.S. Patent Nos. 7,396,341 ("the '6,341 patent"), 9,027,967 ("the '967 patent"), 7,837,235 ("the '235 patent"), and 8,733,341 ("the '3,341 patent") (collectively, the "Asserted Patents") under 28 U.S.C. §§ 2201, 2202.

3. Pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I), these counterclaims also seek removal of the Asserted Patents from the listing for STIOLTO® Respimat® in the United States Food and Drug Administration' ("FDA's") "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book" (the "Orange Book").

4. Upon information an belief, true and correct copies of the Asserted Patents were attached as Exhibits B-E of the Complaint.

A. THE PARTIES

5. Anobri is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at One Gateway Center, Suite 2600, Newark, New Jersey 07102.

6. Upon information and belief based upon the allegations in the Complaint, Counterclaim Defendant 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.

7. Upon information and belief based upon the allegations in the Complaint,

Counterclaim Defendant 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.

B. JURISDICTION AND VENUE

8. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and 21 U.S.C. § 355(j)(5)(C)(ii)(I).

9. This is an action for a declaratory judgment, together with such further relief based thereon as may be necessary or proper, pursuant to the Federal Declaratory Judgment Act 28

U.S.C. §§ 2201 and 2202.

10. This Court has subject matter jurisdiction to hear these counterclaims under 28 U.S.C. §§ 1331, 1337(a), and 1338(a); 15 U.S.C. §§ 15 and 26; and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§ 1331 and 1338.

12. This Court has personal jurisdiction over Counterclaim Defendants because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their Complaint here.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b), and because Counterclaim Defendants commenced this lawsuit in this venue.

14. There is an actual and justiciable controversy between the parties that is of sufficient immediacy and reality to warrant the relief sought in these counterclaims. Counterclaim Defendants filed the Complaint in this Court against Anobri alleging that

the filing of Anobri's ANDA No. 218956 ("Anobri's ANDA") infringed the Asserted Patents, and that any commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Anobri's ANDA would infringe the Asserted Patents.

15. Anobri requires a declaration of their rights vis-á-vis the Counterclaim Defendants with respect to the products which are the subject of Anobri's ANDA and the Asserted Patents.

BACKGROUND

A. PATENT LISTING AND THE ORANGE BOOK

16. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA" or "Act"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States.

17. Pursuant to the FDCA, any company that wishes to sell a new drug in the United States must seek FDA approval by filing an NDA with the FDA. As part of that application, the submitter of the NDA must provide the FDA with information identifying each patent "for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug" that is the subject of the NDA, and that either (I) "claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent;" or (II) "claims a method of using such drug for which approval is sought or has been granted in the application." 21 U.S.C. § 355(b)(1)(A)(viii); *Jazz Pharms., Inc. v. Avadel CNS Pharms.*, LLC., 60 F.4th 1373, 1377 (Fed. Cir. 2023).

18. "To list a patent in the Orange Book, that patent must, among other

things, claim the drug for which the applicant submitted the application and for which the application was approved. And to claim that drug, the patent must claim at least the active ingredient." *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Amneal Pharmaceuticals of New York, LLC, et al.*, 124 F.4th 898, 919 (Fed. Cir. 2024). A patent claims the drug for which the applicant submitted the application when it particularly points out and distinctly claims the drug—not simply when the claim could somehow be interpreted to read on the drug." *Id.* at 916. A claim that does not require the presence of the particular active ingredient of the NDA product does not claim the drug for which the applicant submitted the NDA. *Id*. at 922.

19. Submission of information on patents that do not meet the listing criteria is prohibited by law. 21 U.S.C. § 355(c)(2) ("Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.").

20. Upon approval of an NDA, the patent information submitted to the FDA by the NDA holder under 21 U.S.C. § 355(b)(1)(A)(viii) is published by the FDA in the Orange Book, a publicly available online database. *Jazz Pharms., Inc.*, 60 F.4th at 1377. The Orange Book is located at the following web address: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm

21. "[T]he FDA does not verify that submitted patents actually meet the statutory listing criteria, nor does the FDA proactively remove improperly listed patents" from the Orange Book. *Jazz Pharms., Inc.*, 60 F.4th at 1378. Rather, the FDA's role with respect to Orange Book patent listings is "purely ministerial." *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (noting FDA arguments that (i) FDA does not have

a duty to determine "whether the patent claims the drug," (ii) "FDA has a only a ministerial role in the listing process," and (iii) "it is the responsibility of the NDA holder to determine whether a patent claims the drug or a method of using the drug that is the subject of the NDA for purposes of Orange Book listing"); *Jazz Pharmaceuticals, Inc.*, 60 F.4th at 1378.

22. The FDA has adopted a regulation, 21 C.F.R. § 314.53(f), codifying and implementing its position that its duties with respect to Orange Book listings are purely ministerial. *Apotex, Inc.*, 347 F.3d at 1347. Under this regulation, a third party may dispute an Orange Book listing, but the FDA will not modify the listing unless the NDA holder itself requests the modification. 21 C.F.R. § 314.53(f); *Apotex, Inc.*, 347 F.3d at 1347.

B. APPROVAL OF GENERIC DRUGS

23. When an ANDA is submitted to the FDA seeking permission to market a generic version of an approved NDA product, if there are no patents listed in the Orange Book for the corresponding NDA product, the ANDA must include a certification that no such patent information has been filed. 21 U.S.C. § 355 (j)(2)(A)(vii)(I). This is known as a "Paragraph I Certification."

24. If, however, there are any patents listed in the Orange Book for the corresponding NDA, for each patent listed in the Orange Book for the relevant NDA product, the ANDA must include a certification for each patent stating (a) that the patent has expired (a "Paragraph II Certification"), (b) when the patent will expire (a "Paragraph III Certification"), or (c) that the patent is invalid or will not be infringed by the manufacture, use or sale of the ANDA product (a "Paragraph IV Certification" or "PIV Certification"). 21 U.S.C. §355 (j)(2)(A)(vii)(II)-(IV).

25. If the ANDA contains only Paragraph I Certification(s) and/or Paragraph II certification(s), the FDA may approve the ANDA immediately. 21 U.S.C. § 355 (j)(5)(B)(i).

26. If the ANDA contains Paragraph III Certifications and no PIV Certification, the FDA may approve the ANDA on the patent expiration date certified in the Paragraph III certification. 21 U.S.C. § 355 (j)(5)(B)(ii).

27. If an ANDA contains one or more PIV Certifications, the ANDA applicant must provide notice of same to the NDA holder and owner(s) of the corresponding patent(s) and provide a "detailed statement of the factual and legal basis for the opinion that the patent is invalid or will not be infringed." 21 U.S.C. § 355 (j)(2)(B)(iv)(II).

28. If an ANDA containing a PIV Certification is the first such ANDA submitted, then, subject to other requirements, it can qualify for 180 days of generic exclusivity, during which the FDA will not make effective its approval of another ANDA product that is a generic version of the same NDA product as the first-to-file ANDA. 21 U.S.C. § 355 (j)(5)(B)(iv).

29. The filing of a PIV Certification is treated under the patent law as an act of technical infringement that provides the brand company with an opportunity to sue. 35 U.S.C. § 271(e)(2)(A). If the NDA holder brings a patent infringement suit within 45 days after it receives the notice of the PIV filing, the FDA's approval of the corresponding ANDA will automatically be stayed for 30 months, unless the patent litigation is resolved sooner. 21 U.S.C.§ 355 (j)(5)(B)(iii).

30. If an infringement action is brought against an ANDA applicant in

response to receiving notice of a PIV Certification, the ANDA applicant may "assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the [NDA] holder." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

C. THE STIOLTO® RESPIMAT® NDA AND NDA PRODUCT

31. STIOLTO® Respimat® (olodaterol hydrochloride; tiotropium bromide) Inhalation Spray was approved under New Drug Application ("NDA") No. 206756 (the "STIOLTO® Respimat® NDA")

32. On information and belief, Counterclaim Defendant is the owner of the STIOLTO® Respimat® NDA.

33. The FDA approved the commercial marketing of STIOLTO® Respimat® (olodaterol hydrochloride; tiotropium bromide) Inhalation Spray effective May 21, 2015. Attached as **Exhibit 1** is a copy of the original approval letter for STIOLTO® Respimat®. Attached as **Exhibit 2** is a copy of the May 21, 2015 Summary Review for NDA No. 206756 published by the FDA as part of the approval package for STIOLTO® Respimat®.

34. The original NDA submission for STIOLTO® Respimat® was submitted on May 22, 2014. Attached as **Exhibit** 3 is a copy of the Risk Assessment and Risk Mitigation Review(s) document published by the FDA as part of the approval package for STIOLTO® Respimat®.

35. STIOLTO® Respimat® is a combination of two active ingredients, tiotropium bromide and olodaterol hydrochloride, for oral inhalation use.

36. STIOLTO® Respimat® is a drug-device combination product consisting of a plastic/aluminum cartridge containing sterile aqueous formulation of tiotropium bromide and olodaterol hydrochloride. Attached as **Exhibit 4** is a copy of the Cross

Discipline Team Leader Review for NDA No. 206756 published by the FDA as part of the approval package for STIOLTO® Respimat®.

37. The dosage form of STIOLTO® Respimat® is referred to as an "inhalation spray" or "oral inhalation spray."

38. STIOLTO® Respimat® is indicated for the long-term, once daily maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Attached as **Exhibit 5** is a copy of the revised prescribing information for STIOLTO® Respimat®, submitted to FDA in December of 2024.

39. At the time STIOLTO® Respimat® was approved by FDA, the Respimat device itself was approved as an integral part of three inhalation products for treatment of COPD: (a) Combivent Respimat (ipratropium bromide/albuterol) Inhalation Spray, (b) Spiriva Respimat (tiotropium bromide) Inhalation Spray, and (c) Striverdi Respimat (olodaterol) Inhalation Spray.

40. The STIOLTO® Respimat® product is an inhalation spray delivered via the Respimat® device. Attached as **Exhibit 6** is a copy of the Medical Review(s) document published by the FDA as part of the approval package for STIOLTO® Respimat®.

41. Tiotropium bromide is a drug substance.

42. Olodaterol hydrochloride is a drug substance.

43. Tiotropium bromide and olodaterol hydrochloride are each a drug substance in STIOLTO® Respimat®.

44. The formulation of the STIOLTO® Respimat® product is aqueous based, sterile, and contains tiotropium bromide, benzalkonium chloride, edetate sodium, and

hydrochloric acid. Attached as **Exhibit 7** is a copy of the Chemistry Review(s) document published by the FDA as part of the approval package for STIOLTO® Respimat®.

45. The Respimat inhaler is the device constituent part of the STIOLTO® Respimat® drug-device combination product. Attached as **Exhibit 8** is a copy of the Other Review(s) document published by the FDA as part of the approval package for STIOLTO® Respimat®.

46. The Respimat device has its own Drug Master File ("DMF") on file with the FDA.

47. STIOLTO® Respimat® is a true drug-device combination product. Attached as **Exhibit 9** is a copy of the Administrative and Correspondence Documents document published by the FDA as part of the approval package for STIOLTO® Respimat®.

48. As part of the FDA review process for the STIOLTO® Respimat® NDA, the FDA's Center for Device and Radiological Health (CDRH) was consulted regarding the device constituent part of STIOLTO® Respimat®.

49. On information and belief, Counterclaim Defendants listed and maintained a listing for the Asserted Patents in the Orange Book in connection with NDA No. 206756. Attached as **Exhibit 10** is a copy of the Orange Book entry for STIOLTO® Respimat®.

50. The Asserted Patents are currently listed in the Orange Book entry for STIOLTO® Respimat®.

51. None of the Asserted Patents are properly or lawfully listed in the Orange Book entry for STIOLTO® Respimat®.

52. None of the Asserted Patents meet the statutory requirements to qualify for listing in the Orange Book.

53. None of the Asserted Patents claims the drug for which the applicant submitted the STIOLTO® Respimat® NDA.

54. None of the Asserted Patents is a drug product patent.

55. None of the Asserted Patents claim a drug product.

56. None of the Asserted Patents is a drug substance (active ingredient) patent.

57. None of the Asserted Patents claim a drug substance (active ingredient).

58. None of the Asserted Patents claims a method of using the STIOLTO® Respimat® drug product.

59. None of the Asserted Patents claims a method of using a drug.

60. Each of the Asserted Patents is also listed in the Orange Book entries for at least three products other than STIOLTO® Respimat®, including at least Spiriva Respimat, Combivent Respimat, and Striverdi Respimat. Attached as **Exhibits 11-13** are copies of the Orange Book listings for Spiriva Respimat, Combivent Respimat, and Striverdi Respimat, respectively.

D. ANOBRI'S ANDA AND THE 30-MONTH STAY TRIGGERED BY COUNTERCLAIM DEFENDANTS

61. Anobri Pharmaceuticals US, LLC, submitted Abbreviated New Drug Application ("ANDA") No. 218956 ("Anobri's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of a generic version of STIOLTO® Respimat® Inhalation Spray, 2.5 mcg per actuation

("Anobri's ANDA Product").

62. Because the Asserted Patents were listed in the Orange Book entry for STIOLTO® Respimat® at the time Anobri submitted its ANDA to the FDA, in order for Anobri to seek approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Anobri's ANDA Product prior to the expiration of the Asserted Patents, Anobri was required to file a Paragraph IV Certification with respect to each of the Asserted Patents.

63. In accordance with 21 U.S.C. § 355 (j)(2)(B)(iv)(II), by letter dated July 30, 2024 ("Anobri Notice Letter"), Anobri notified Counterclaim Defendants that Anobri had submitted to the FDA Anobri's ANDA including Paragraph IV Certifications as to each of the Asserted Patents.

64. On information and belief, Counterclaim Defendants received the Anobri Notice Letter on August 1, 2024.

65. Counterclaim Defendants filed it Complaint in this action against Anobri on September 12, 2024, claiming that Anobri has infringed and will infringe the Asserted Patents by the filing of Anobri's ANDA with the FDA and/or by manufacturing, using, offering for sale, selling, marketing, distributing, and/or importing the products described in that ANDA.

66. Counterclaim Defendants filed this lawsuit within 45 days of receiving the Anobri Notice Letter. By doing so, Counterclaim Defendants triggered a 30-month stay of final FDA approval of Anobri's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). This 30-month stay is not set to expire until February 1, 2027.

67. But for Counterclaim Defendants' listing of the Asserted Patents in the

Orange Book and Counterclaim Defendants' choice to bring litigation within 45 days of receipt of the Anobri Notice Letter, there would be no 30-month stay imposed under 21 U.S.C. § 355(j)(5)(B)(iii).

68. Anobri's ANDA does not seek FDA approval prior to January 19, 2027, the expiration date of U.S. Patent No. 7,727,984, which is listed in the Orange Book entry for Stiolto Respimat.

69. During the time after January 19, 2027 and between the time Anobri obtains tentative approval of its ANDA and February 1, 2027, due to the 30-month stay, Anobri will be deprived of the ability to launch its generic product.

70. But for Counterclaim Defendants' listing of the Asserted Patents in the Orange Book and Counterclaim Defendants' choice to bring litigation within 45 days of receipt of the Anobri Notice Letter, the remedy of an automatic injunction prohibiting FDA from granting final approval of Anobri's ANDA product until expiration of the corresponding patent would not be available to Counterclaim Defendants against Anobri.

FIRST COUNTERCLAIM

71. Counterclaim Plaintiff repeats and realleges the allegations contained in the preceding paragraphs of the Counterclaims as if fully set forth herein.

72. Each and every asserted claim of the '6,341 patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability.

73. Counterclaim Plaintiff is entitled to a judicial declaration that the claims

of the ’6,341 patent are invalid.

SECOND COUNTERCLAIM

74. Counterclaim Plaintiff repeats and realleges the allegations contained in the preceding paragraphs of the Counterclaims as if fully set forth herein.

75. Counterclaim Plaintiff has not infringed, induced infringement, or contributed to the infringement, and Anobri will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of the ’6,341 patent.

76. Counterclaim Plaintiff is entitled to a judicial declaration that manufacture, use, sale, offer for sale, or importation of the product that is the subject of Anobri’s ANDA No. 218956 has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the ’6,341 patent.

THIRD COUNTERCLAIM

77. Counterclaim Plaintiff repeats and realleges the allegations contained in the preceding paragraphs of the Counterclaims as if fully set forth herein.

78. Each and every asserted claim of the ’967 patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability.

79. Counterclaim Plaintiff is entitled to a judicial declaration that the claims of the ’967 patent are invalid.

FOURTH COUNTERCLAIM

80. Counterclaim Plaintiff repeats and realleges the allegations contained in the preceding paragraphs of the Counterclaims as if fully set forth herein.

81. Counterclaim Plaintiff has not infringed, induced infringement, or contributed to the infringement, and Anobri will not infringe, induce infringement, or contribute to the

infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of the '967 patent.

82. Counterclaim Plaintiff is entitled to a judicial declaration that manufacture, use, sale, offer for sale, or importation of the product that is the subject of Anobri's ANDA No. 218956 has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '967 patent.

FIFTH COUNTERCLAIM

83. Counterclaim Plaintiff repeats and realleges the allegations contained in the preceding paragraphs of the Counterclaims as if fully set forth herein.

84. Each and every asserted claim of the '235 patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability.

85. Counterclaim Plaintiff is entitled to a judicial declaration that the claims of the '235 patent are invalid.

SIXTH COUNTERCLAIM

86. Counterclaim Plaintiff repeats and realleges the allegations contained in the preceding paragraphs of the Counterclaims as if fully set forth herein.

87. Counterclaim Plaintiff has not infringed, induced infringement, or contributed to the infringement, and Anobri will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of the '235 patent.

88. Counterclaim Plaintiff is entitled to a judicial declaration that manufacture, use, sale, offer for sale, or importation of the product that is the subject of Anobri's ANDA No. 218956 has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '235 patent.

SEVENTH COUNTERCLAIM

89. Counterclaim Plaintiff repeats and realleges the allegations contained in the preceding paragraphs of the Counterclaims as if fully set forth herein.

90. Each and every asserted claim of the '3341 patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability.

91. Counterclaim Plaintiff is entitled to a judicial declaration that the claims of the '3,341 patent are invalid.

EIGHTH COUNTERCLAIM

92. Counterclaim Plaintiff repeats and realleges the allegations contained in

the preceding paragraphs of the Counterclaims as if fully set forth herein.

93. Counterclaim Plaintiff has not infringed, induced infringement, or contributed to the infringement, and Anobri will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of the '3,341 patent.

94. Counterclaim Plaintiff is entitled to a judicial declaration that manufacture, use, sale, offer for sale, or importation of the product that is the subject of Anobri's ANDA No. 218956 has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '3,341 patent.

NINTH COUNTERCLAIM: REQUIRING DELISTING OF U.S. PATENT NO. 8,733,341

95. Anobri incorporates and re-alleges each of the foregoing paragraphs of these Counterclaims, as if fully set forth herein.

96. The '3341 patent is listed in the Orange Book entry for STIOLTO® Respimat®.

97. Counterclaim Defendants have caused the '3341 patent to be and remain listed in the Orange Book entry for STIOLTO® Respimat®.

98. The Orange Book entry for STIOLTO® Respimat® identifies the '3341 patent as a drug product ("DP") patent. Counterclaim Defendants have represented to the FDA that the '3341 patent is a drug product patent.

99. Anobri hereby seeks a declaration and order pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim Defendants to request that FDA remove the '3341 patent from the Orange Book listing for STIOLTO® Respimat®.

100. An actual controversy exists between Counterclaim Defendants and Anobri over the continued listing of the '3341 patent in the Orange Book.

101. The '3341 patent is not properly or lawfully listed in the Orange Book entry for STIOLTO® Respimat®.

102. The '3341 patent does not satisfy any of the statutory requirements for being listed in the Orange Book entry for STIOLTO® Respimat®.

103. The '3341 patent is not a patent that "claims the drug for which the applicant submitted the application" within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

104. The '3341 patent does not claim the drug for which the applicant submitted the STIOLTO® Respimat® NDA.

105. The '3341 patent does not claim the drugs for which the applicant submitted the STIOLTO® Respimat® NDA.

106. The '3341 patent does not claim any drug for which the applicant submitted the STIOLTO® Respimat® NDA.

107. The '3341 patent does not claim the active ingredient in STIOLTO® Respimat®.

108. The '3341 patent does not claim the active ingredients in STIOLTO® Respimat®.

109. The '3341 patent does not claim any of the active ingredients in STIOLTO® Respimat®.

110. The '3341 patent does not claim the specific combination of active ingredients in STIOLTO® Respimat®.

111. The ’3341 patent does not claim tiotropium bromide.

112. The ’3341 patent does not claim olodaterol hydrochloride.

113. The ’3341 patent does not claim tiotropium bromide and olodaterol hydrochloride.

114. The ’3341 patent does not claim the combination of tiotropium bromide and olodaterol hydrochloride.

115. The ’3341 patent is not “a drug substance (active ingredient) patent” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

116. The ’3341 patent does not claim a drug substance.

117. The ’3341 patent does not claim an active ingredient.

118. The ’3341 patent is not “a drug product (formulation or composition) patent” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

119. The ’3341 patent does not claim a drug product.

120. The ’3341 patent does not claim a drug formulation.

121. The ’3341 patent does not claim a drug composition.

122. The ’3341 patent does not claim “a method of using such drug for which approval is sought or has been granted in the application” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

123. The ’3341 patent does not claim an approved method of using STIOLTO® Respimat®.

124. The ’3341 patent does not refer expressly to olodaterol.

125. The ’3341 patent does not refer expressly to olodaterol hydrochloride.

TENTH COUNTERCLAIM: REQUIRING DELISTING OF U.S. PATENT NO. 7,837,235

126. Anobri incorporates and re-alleges each of the foregoing paragraphs of these Counterclaims as if fully set forth herein.

127. The '235 patent is listed in the Orange Book entry for STIOLTO® Respimat®.

128. Counterclaim Defendants have caused the '235 patent to be and remain listed in the Orange Book entry for STIOLTO® Respimat®.

129. The Orange Book entry for STIOLTO® Respimat® identifies the '235 patent as a drug product ("DP") patent. Counterclaim Defendants have represented to the FDA that the '235 patent is a drug product patent.

130. Anobri hereby seeks a declaration and order pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim Defendants to request that FDA remove the '235 patent from the Orange Book listing for STIOLTO® Respimat®.

131. An actual controversy exists between Counterclaim Defendants and Anobri over the continued listing of the '235 patent in the Orange Book.

132. The '235 patent is not properly or lawfully listed in the Orange Book entry for STIOLTO® Respimat®.

133. The '235 patent does not satisfy any of the statutory requirements for being listed in the Orange Book entry for STIOLTO® Respimat®.

134. The '235 patent is not a patent that "claims the drug for which the applicant submitted the application" within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

135. The '235 patent does not claim the drug for which the applicant submitted

the application for approval of STIOLTO® Respimat®.

136. The ’235 patent does not claim the drugs for which the applicant submitted the application for approval of STIOLTO® Respimat®.

137. The ’235 patent does not claim any drug for which the applicant submitted the application for approval of STIOLTO® Respimat®.

138. The ’235 patent does not claim the active ingredient in STIOLTO® Respimat®.

139. The ’235 patent does not claim the active ingredients in STIOLTO® Respimat®.

140. The ’235 patent does not claim any of the active ingredients in STIOLTO® Respimat®.

141. The ’235 patent does not claim the specific combination of active ingredients in STIOLTO® Respimat®.

142. The ’235 patent does not claim tiotropium bromide.

143. The ’235 patent does not claim olodaterol hydrochloride.

144. The ’235 patent does not claim tiotropium bromide and olodaterol hydrochloride.

145. The ’235 patent does not claim the combination of tiotropium bromide and olodaterol hydrochloride.

146. The ’235 patent is not “a drug substance (active ingredient) patent” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

147. The ’235 patent does not claim a drug substance.

148. The ’235 patent does not claim an active ingredient.

149. The ’235 patent is not “a drug product (formulation or composition) patent” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

150. The ’235 patent does not claim a drug product.

151. The ’235 patent does not claim a drug formulation.

152. The ’235 patent does not claim a drug composition.

153. The ’235 patent does not claim “a method of using such drug for which approval is sought or has been granted in the application” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

154. The ’235 patent does not claim an approved method of using STIOLTO® Respimat®.

155. The ‘235 patent does not claim any method of using anything.

156. The ’235 patent does not mention olodaterol.

157. The ’235 patent does not mention olodaterol hydrochloride.

158. The claims of the ’235 patent are directed to “an apparatus” having recited structural features with recited configurations, shapes, orientations, and spatial relationships.

159. None of the claims of the ’235 patent claim or require the presence of any drug, drug product, active ingredient, or drug substance.

160. In addition to being listed in the Orange Book entry for STIOLTO® Respimat®, the ’235 patent is listed in the Orange Book entry for SPIRIVA® Respimat® and COMBIVENT® Respimat®.

161. The FTC has already determined that the ’235 patent is not properly listed in the Orange Book for STIOLTO® Respimat®.

162. On or about April 30, 2024, the FTC sent a letter to Boehringer bearing that date and informing Boehringer that the FTC believes that the '235 patent is "improperly or inaccurately listed in the Orange Book" for STIOLTO® Respimat®. A copy of the FTC Delisting Letter to Boehringer is attached to this Answer, Affirmative Defenses, and Counterclaims as **Exhibit 14**.

163. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding the '235 patent, among other patents.

ELEVENTH COUNTERCLAIM: REQUIRING DELISTING OF U.S. PATENT NO. 9,027,967

164. Anobri incorporates and re-alleges each of the foregoing paragraphs of its Counterclaims as if fully set forth herein.

165. The '967 patent is listed in the Orange Book entry for STIOLTO® Respimat®.

166. Counterclaim Defendants have caused the '967 patent to be and remain listed in the Orange Book entry for STIOLTO® Respimat®.

167. The Orange Book entry for STIOLTO® Respimat® identifies the '967 patent as a drug product ("DP") patent. Counterclaim Defendants have represented to the FDA that the '967 patent is a drug product patent.

168. Anobri hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim Defendants to delete or withdraw the '967 patent from the Orange Book listing for STIOLTO® Respimat®.

169. An actual controversy exists between Counterclaim Defendants and Anobri over the continued listing of the '967 patent in the Orange Book.

170. The ’967 patent is not properly or lawfully listed in the Orange Book for STIOLTO® Respimat®.

171. The ’967 patent does not satisfy any of the statutory requirements for being listed in the Orange Book for STIOLTO® Respimat®.

172. The ’967 patent is not a patent that “claims the drug for which the applicant submitted the application” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

173. The ’967 patent does not claim the drug for which the applicant submitted the application for approval of STIOLTO® Respimat®.

174. The ’967 patent does not claim the drugs for which the applicant submitted the application for approval of STIOLTO® Respimat®.

175. The ’967 patent does not claim any drug for which the applicant submitted the application for approval of STIOLTO® Respimat®.

176. The ’967 patent does not claim the active ingredient in STIOLTO® Respimat®.

177. The ’967 patent does not claim the active ingredients in STIOLTO® Respimat®.

178. The ’967 patent does not claim any of the active ingredients in STIOLTO® Respimat®.

179. The ’967 patent does not claim the specific combination of active ingredients in STIOLTO® Respimat®.

180. The ’967 patent does not claim tiotropium bromide.

181. The ’967 patent does not claim olodaterol hydrochloride.

182. The ’967 patent does not claim tiotropium bromide and olodaterol hydrochloride.

183. The ’967 patent does not claim the combination of tiotropium bromide and olodaterol hydrochloride.The ’967 patent is not “a drug substance (active ingredient) patent” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

184. The ’967 patent does not claim a drug substance.

185. The ’967 patent does not claim an active ingredient.

186. The ’967 patent is not “a drug product (formulation or composition) patent” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

187. The ’967 patent does not claim a drug product.

188. The ’967 patent does not claim a drug formulation.

189. The ’967 patent does not claim a drug composition.

190. The ’967 patent does not claim “a method of using such drug for which approval is sought or has been granted in the application” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

191. The ’967 patent does not claim an approved method of using STIOLTO® Respimat®.

192. The ‘967 patent does not claim any method of using anything.

193. The ’967 patent does not mention olodaterol.

194. The ’967 patent does not mention olodaterol hydrochloride.

195. The claims of the ’967 patent are directed to “an apparatus” having recited structural features with recited configurations, shapes, orientations, and spatial relationships.

196. None of the claims of the ’967 patent claim or require the presence of any drug, drug product, active ingredient, or drug substance.

197. In addition to being listed in the Orange Book entry for STIOLTO® Respimat®, the ’967 patent is listed in the Orange Book entry for SPIRIVA® Respimat® and COMBIVENT® Respimat®.

198. The FTC has already determined that the ’967 patent is not properly listed in the Orange Book for STIOLTO® Respimat®.

199. On or about April 30, 2024, the FTC sent a letter to Boehringer bearing that date and informing Boehringer that the FTC believes that the ’967 patent is “improperly or inaccurately listed in the Orange Book” for STIOLTO® Respimat®. A copy of the FTC Delisting Letter to Boehringer is attached to this Answer, Affirmative Defenses, and Counterclaims as **Exhibit 14**.

200. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding the ’967 patent, among other patents.

TWELFTH COUNTERCLAIM: REQUIRING DELISTING OF U.S. PATENT NO. 7,396,341

201. Anobri incorporates and re-alleges each of the foregoing paragraphs of its Counterclaims as if fully set forth herein.

202. The ’6,341 patent is listed in the Orange Book entry for STIOLTO® Respimat®.

203. Counterclaim Defendants have caused the ’6,341 patent to be and remain listed in the Orange Book entry for STIOLTO® Respimat®.

204. The Orange Book entry for STIOLTO® Respimat® identifies the ’6,341

patent as a drug product ("DP") patent. Counterclaim Defendants have represented to the FDA that the '6,341 patent is a drug product patent.

205. Anobri hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim Defendants to delete or withdraw the '6,341 patent from the Orange Book listing for STIOLTO® Respimat®.

206. An actual controversy exists between Counterclaim Defendants and Anobri over the continued listing of the '6,341 patent in the Orange Book.

207. The '6,341 patent is not properly or lawfully listed in the Orange Book for STIOLTO® Respimat®.

208. The '6,341 patent does not satisfy any of the statutory requirements for being listed in the Orange Book for STIOLTO® Respimat®.

209. The '6,341 patent is not a patent that "claims the drug for which the applicant submitted the application" within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

210. The '6,341 patent does not claim the drug for which the applicant submitted the application for approval of STIOLTO® Respimat®.

211. The '6,341 patent does not claim the drugs for which the applicant submitted the application for approval of STIOLTO® Respimat®.

212. The '6,341 patent does not claim any drug for which the applicant submitted the application for approval of STIOLTO® Respimat®.

213. The '6,341 patent does not claim the active ingredient in STIOLTO® Respimat®.

214. The '6,341 patent does not claim the active ingredients in STIOLTO®

Respimat®.

215. The ’6,341 patent does not claim any of the active ingredients in STIOLTO® Respimat®.

216. The ’6,341 patent does not claim the specific combination of active ingredients in STIOLTO® Respimat®.

217. The ’6,341 patent does not claim tiotropium bromide.

218. The ’6,341 patent does not claim olodaterol hydrochloride.

219. The ’6,341 patent does not claim tiotropium bromide and olodaterol hydrochloride.

220. The ’6,341 patent does not claim the combination of tiotropium bromide and olodaterol hydrochloride.

221. The ’6,341 patent is not “a drug substance (active ingredient) patent” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

222. The ’6,341 patent does not claim a drug substance.

223. The ’6,341 patent does not claim an active ingredient.

224. The ’6,341 patent is not “a drug product (formulation or composition) patent” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

225. The ’6,341 patent does not claim a drug product.

226. The ’6,341 patent does not claim a drug formulation.

227. The ’6,341 patent does not claim a drug composition.

228. The ’6,341 patent does not claim “a method of using such drug for which approval is sought or has been granted in the application” within the meaning of 21 U.S.C. § 355(b)(1)(A)(viii).

229. The ’6,341 patent does not claim an approved method of using STIOLTO® Respimat®.

230. The ’6,341 patent does not mention olodaterol.

231. The ’6,341 patent does not mention olodaterol hydrochloride.

232. The claims of the ’6,341 patent are directed to “an apparatus” having recited structural features with recited configurations, shapes, orientations, and spatial relationships.

233. None of the claims of the ’6,341 patent claim or require the presence of any specific drug or drugs, or any specific drug product or drug products, any specific active ingredient or active ingredients, or any specific drug substance or drug substances.

234. In addition to being listed in the Orange Book entry for STIOLTO® Respimat®, the ’6,341 patent is listed in the Orange Book entry for SPIRIVA® Respimat® and COMBIVENT® Respimat®.

235. The FTC has already determined that the ’6,341 patent is not properly listed in the Orange Book for STIOLTO® Respimat®.

236. On or about April 30, 2024, the FTC sent a letter to Boehringer bearing that date and informing Boehringer that the FTC believes that the ’6,341 patent is “improperly or inaccurately listed in the Orange Book” for STIOLTO® Respimat®. A copy of the FTC Delisting Letter to Boehringer is attached to this Answer, Affirmative Defenses, and Counterclaims as **Exhibit 14**.

237. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding the ’6,341 patent, among other patents.

REQUEST FOR RELIEF

WHEREFORE, Counterclaim Plaintiff Anobri respectfully requests that this Court:

a. Enter judgment declaring that the commercial manufacture, use, offer to sell, sale or import of Anobri's ANDA Products do not and will not infringe any valid asserted claim of the '6,341, '967, '235, and '3,341 patents;

b. Enter judgment declaring each claim of each of the Asserted Patents are invalid;

c. Dismiss the complaint against Anobri with prejudice and declare that Counterclaim Defendants take nothing thereby;

d. Enter judgment declaring that each of the Asserted Patents were not and are not properly listed in the Orange Book for STIOLTO® Respimat®.

e. Order Counterclaim Defendant to submit a request to FDA to withdraw all the Asserted Patents from the Orange Book listing for the STIOLTO® Respimat®, in compliance with 21 C.F.R.§ 314.53(f)(2)(i).

f. Enter an order deeming this an exceptional case within the meaning of 35 U.S.C. § 285 and awarding Anobri its costs, expenses, and reasonable attorneys' fees.

g. Award Anobri such other and further relief as this Court may deem necessary, just, and proper.

Dated: February 7, 2025

Respectfully submitted,

s/Eric Abraham

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(*pro hac vices* to be filed)

Attorneys for Defendant
Anobri Pharmaceuticals US, LLC

CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2025, I caused a true and correct copy of the foregoing document to be served via electronic mail on counsel of record in this matter.

Dated: February 7, 2025

Respectfully submitted,

By: *s/Eric I. Abraham*
Eric I. Abraham