

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ARBOR PHARMACEUTICALS, LLC and)
TAKEDA PHARMACEUTICAL COMPANY)
LIMITED,)

Plaintiffs,)

v.)

LUPIN LIMITED and LUPIN)
PHARMACEUTICALS, INC.,)

Defendants.)

C.A. No. 1:20-cv-922-MN

LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.
ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants Lupin Limited (“Lupin Ltd.”) and Lupin Pharmaceuticals, Inc. (“LPI”) (collectively, “Lupin”), through their undersigned counsel, hereby answer the Complaint of Plaintiffs Arbor Pharmaceuticals, LLC (“Arbor”) and Takeda Pharmaceutical Company Limited (“Takeda”) (collectively, “Plaintiffs”) as follows:

To the extent not specifically admitted herein, the allegations of the Complaint are denied.

THE PARTIES¹

1. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 1 of the Complaint and, therefore, denies each and every allegation contained in Paragraph 1.

¹ For the Court’s convenience, Lupin has incorporated the “Headings” that appear in the Complaint. It should be understood, however, that Lupin does not necessarily agree with the characterizations of such Headings, and does not waive any right to object to those characterizations.

2. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 2 of the Complaint and, therefore, denies each and every allegation contained in Paragraph 2.

3. Lupin admits that Lupin Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.. Lupin admits that Lupin Ltd. manufactures pharmaceutical products for the United States market. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 3 of the Complaint.

4. Lupin admits that LPI is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin admits that LPI is an indirect wholly-owned subsidiary of Lupin Ltd. Lupin admits that LPI sells and distributes pharmaceutical products throughout the United States. Lupin admits that Lupin Ltd. appointed LPI as the U.S. Agent for ANDA No. 214489 for Azilsartan Medoxomil Tablets, 40 mg and 80 mg and the Type-II DMF of Azilsartan Kamedoxomil (DMF No. 033732). Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 4 of the Complaint.

NATURE OF THE ACTION

5. Lupin admits that the Complaint filed by Plaintiffs purports to state a civil action for infringement of United States Patent Nos. 7,157,584 (the “‘584 patent”), 7,572,920 (the “‘920 patent”), and 9,066,936 (the “‘936 patent”) (collectively the “patents-in-suit”), and that Plaintiffs allege the action pled arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 5 of the Complaint.

JURISDICTION & VENUE

6. Paragraph 6 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) solely for the claims directed against Lupin Ltd. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 6 of the Complaint.

7. Paragraph 7 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 7 of the Complaint.

8. Paragraph 8 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 8 of the Complaint.

9. Paragraph 9 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin admits that at least one of Lupin Ltd. and LPI was a named defendant in each of the following actions: Merck Sharp & Dohme Corp. v. Lupin Limited and Lupin Pharmaceuticals, Inc., No. 19-347-RGA (D. Del.); Anacor Pharm., Inc. v. Lupin Ltd., No. 18-1606-RGA (D. Del.); H Lundbeck A/S v. Lupin Ltd., No. 18-777-LPS (D. Del.); Bial-Portela & CA S.A. v. Lupin Ltd., No. 18-312-CFC-CJB (D. Del.); Bayer

Intellectual Prop. GmbH v. Lupin Ltd., No. 17-1047-RGA (D. Del.); ViiV Healthcare Co. v. Lupin Ltd., 17-1576-MSG-RL (D. Del.); Astellas Pharma Inc. v. Lupin Ltd., No. 16-908-JFB-CJB (D. Del.); Arena Pharm., Inc. v. Lupin Ltd., No. 16-887-RGA (D. Del.). Lupin denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 9 of the Complaint.

10. Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court for the purposes of this civil action only. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 10 of the Complaint.

11. Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin Ltd. does not contest venue in this Court for the purposes of this civil action only. Except as expressly as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 11 of the Complaint.

THE PATENTS-IN-SUIT

12. Lupin admits that the face of the '584 patent states that the '584 patent is entitled "BENZIMIDAZOLE DERIVATIVE AND USE THEREOF" and identifies an issue date of January 2, 2007. Lupin admits that what purports to be a copy of the '584 patent is attached to the Complaint as Exhibit A. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 12 of the Complaint.

13. Paragraph 13 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the face of the '584 patent lists Takeda Pharmaceutical Company Limited, Osaka (JP) as the purported assignee. Lupin admits that the electronic records of the U.S. Patent and Trademark Office identify Takeda as the assignee

of the '584 patent. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 13, and therefore denies each and every remaining allegation in Paragraph 13.

14. Lupin admits that the face of the '920 patent states that the '920 patent is entitled "BENZIMIDAZOLE DERIVATIVE AND USE AS A II RECEPTOR ANTAGONIST" and identifies an issue date of August 11, 2009. Lupin admits that what purports to be a copy of the '920 patent is attached to the Complaint as Exhibit B. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 14 of the Complaint.

15. Paragraph 15 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the face of the '920 patent lists Takeda Pharmaceutical Company Limited, Osaka (JP) as the purported assignee. Lupin admits that the electronic records of the U.S. Patent and Trademark Office identify Takeda as the assignee of the '920 patent. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 15, and therefore denies each and every remaining allegation in Paragraph 15.

16. Lupin admits that the face of the '936 patent states that the '936 patent is entitled "SOLID PHARMACEUTICAL COMPOSITION COMPRISING A BENZIMIDAZOLE-7-CARBOXYLATE DERIVATIVE AND A PH CONTROL AGENT" and identifies an issue date of June 30, 2015. Lupin admits that the electronic records of the U.S. Patent and Trademark Office identify Takeda as the assignee of the '936 patent. Lupin admits that what purports to be a copy of the '936 patent is attached to the Complaint as Exhibit C. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 16 of the Complaint.

17. Paragraph 17 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the face of the '936 patent lists Takeda Pharmaceutical Company Limited, Osaka (JP) as the purported assignee. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 17, and therefore denies each and every remaining allegation in Paragraph 17.

ACTS GIVING RISE TO THIS ACTION

18. Lupin admits that the electronic version of the United States Food and Drug Administration's ("FDA") "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") identifies Arbor Pharmaceuticals LLC as the Applicant Holder in connection with New Drug Application No. 200796, lists azilsartan kamedoxomil as the Active Ingredient, lists Edarbi as the Proprietary Name, lists tablet as the dosage form, lists oral as the route of administration, and lists a strength of EQ 40MG MEDOXOMIL and EQ 80MG MEDOXOMIL. Lupin lacks sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 18, and therefore denies those allegations.

19. Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits the Orange Book lists the '584, '920, and '936 patents in connection with the name Edarbi. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 19 of the Complaint.

20. Lupin admits that Lupin Ltd. submitted and the FDA has received, an abbreviated new drug application ("ANDA"), assigned No. 214489, under FDCA Section 505(j)(2)(B)(ii) seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of 40 mg or 80 mg oral tablets of azilsartan medoxomil prior to the expiration of the '584, '920,

and '936 patents. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 20 of the Complaint.

21. Lupin admits that Lupin's proposed drug product is in the form of tablets containing azilsartan kamedoxomil as the active ingredient, in amounts equivalent to 40 mg or 80 mg of azilsartan medoxomil. Lupin admits that the labeling of Lupin's proposed drug product is based on the reference listed drug Edarbi. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 21 of the Complaint.

22. Lupin admits that Lupin's ANDA No. 214489 includes a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '584 Patent, the '920 Patent, and the '936 Patent, indicating that in the opinion of Lupin and to the best of its knowledge, no valid, enforceable claim of any of the '584 Patent, the '920 Patent, and the '936 Patent will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which ANDA No. 214489 has been submitted.

23. Lupin admits it sent via Federal Express FedEx® Priority Overnight mail, a letter dated May 23, 2020 ("Lupin Notice" or "Lupin Ltd Notice") providing written notification of Lupin's ANDA No. 214489 and its certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '584 Patent, the '920 Patent, and the '936 Patent. Lupin admits that Federal Express reported the Lupin Notice was successfully delivered to each of Takeda and Arbor, respectively. Lupin lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 23, and therefore denies those allegations.

24. Lupin admits the Lupin Notice included an Offer of Confidential Access, provided pursuant to FDCA Section 505 and 21 U.S.C. § 355(j)(5)(C)(i)(III) and that the parties exchanged markups of the Offer of Confidential Access. Lupin also admits that at the time of the filing the

Complaint, the parties had not reached an agreement on the Offer of Confidential Access. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 24 of the Complaint.

25. Admitted.

26. Paragraph 26 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies each and every allegation contained in paragraph 26 of the Complaint.

27. Lupin admits that the Complaint was filed on July 8, 2020, and that the Lupin Notice was sent May 23, 2020. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 27 of the Complaint.

COUNT 1

INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 7,157,584

28. Lupin incorporates its responses in paragraphs 1-27 as if fully set forth herein.

29. Lupin denies each and every allegation contained in paragraph 29 of the Complaint.

30. Lupin denies each and every allegation contained in paragraph 30 of the Complaint.

31. Lupin admits that Lupin's ANDA product does not infringe any valid claim of the '584 patent. Lupin denies each and every remaining allegation contained in paragraph 31 of the Complaint.

32. Lupin denies each and every allegation contained in paragraph 32 of the Complaint.

33. Lupin denies each and every allegation contained in paragraph 33 of the Complaint.

34. Lupin denies each and every allegation contained in paragraph 34 of the Complaint.

COUNT II

INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 7,572,920

- 35. Lupin incorporates its responses in paragraphs 1-34 as if fully set forth herein.
- 36. Lupin denies each and every allegation contained in paragraph 36 of the Complaint.
- 37. Lupin denies each and every allegation contained in paragraph 37 of the Complaint.
- 38. Lupin admits that Lupin's ANDA product does not infringe any valid claim of the '920 patent. Lupin denies each and every allegation contained in paragraph 38 of the Complaint.
- 39. Lupin denies each and every allegation contained in paragraph 39 of the Complaint.
- 40. Lupin denies each and every allegation contained in paragraph 40 of the Complaint.
- 41. Lupin denies each and every allegation contained in paragraph 41 of the Complaint.

COUNT III

INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 9,066,936

- 42. Lupin incorporates its responses in paragraphs 1-41 as if fully set forth herein.
- 43. Lupin denies each and every allegation contained in paragraph 43 of the Complaint.
- 44. Lupin denies each and every allegation contained in paragraph 44 of the Complaint.
- 45. Lupin denies each and every allegation contained in paragraph 45 of the Complaint.
- 46. Lupin denies each and every allegation contained in paragraph 46 of the Complaint.
- 47. Lupin denies each and every allegation contained in paragraph 47 of the Complaint.

RESPONSE TO PRAYER FOR RELIEF

Lupin denies all allegations not specifically admitted herein, and further denies that Plaintiffs are entitled to the judgment and relief requested in the Complaint or to any other relief. Lupin respectfully requests that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of Lupin; (c) award Lupin the reasonable attorneys' fees and costs of defending

this action pursuant to 35 U.S.C. § 285; and (d) award Lupin such further relief as the Court deems just and appropriate.

DEFENSES

Without prejudice to the denials set forth in its responses to Paragraphs 1 through 47 of the Complaint, and without undertaking any of the burdens imposed by law on the Plaintiffs, Lupin avers and asserts the following separate defenses to the Complaint. Lupin expressly reserves the right to allege additional defenses as they become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

Plaintiffs have failed to state a claim for which relief can be granted because, *inter alia*, LPI has not committed an act of infringement as prescribed in 35 U.S.C. § 271(e)(2).

SECOND AFFIRMATIVE DEFENSE

(Lack of Subject Matter Jurisdiction)

This Court lacks subject matter jurisdiction over any and all claims asserted against LPI.

THIRD AFFIRMATIVE DEFENSE

(Non-Infringement)

The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '584, '920, and '936 patents.

FOURTH AFFIRMATIVE DEFENSE

(Invalidity)

One or more claims of the '584, '920, and '936 patents are invalid for failure to comply with one or more of the conditions set forth in Title 35 of the United States Code, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or the defenses recognized in 35 U.S.C. § 282.

FIFTH AFFIRMATIVE DEFENSE

(Failure to State a Claim for Exceptional Case)

To the extent the Complaint purports to seek an “exceptional case” determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Lupin’s actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

SIXTH AFFIRMATIVE DEFENSE

(Improper Party)

LPI is not a proper party to this action.

SEVENTH AFFIRMATIVE DEFENSE

(Additional Defenses)

Lupin reserves the right to present any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaimant Lupin Limited (“Lupin Ltd.” or “Lupin”) brings the following Counterclaims against Plaintiffs/Counter-defendants Arbor Pharmaceuticals, LLC (“Arbor”) and

Takeda Pharmaceutical Company Limited (“Takeda”) (collectively, “Plaintiffs”) for a declaratory judgment that United States Patent Nos. 7,157,584 (the “’584 patent”), 7,572,920 (the “’920 patent”), and 9,066,936 (the “’936 patent”) are invalid and/or not infringed by the manufacture, use, sale, offer for sale, or importation of Lupin Ltd.’s ANDA Product, ANDA No. 214489.

PARTIES

1. Lupin Ltd. is a corporation organized and existing under the laws of India having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

2. On information and belief, and according to Counter-defendants’ allegations, Plaintiff/Counter-defendant Arbor is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.

3. On information and belief, and according to Counter-defendants’ allegations, Plaintiff/Counter-defendant Takeda is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

JURISDICTION AND VENUE

4. Lupin seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

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

6. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Counter-defendants’ choice of forum.

7. This is an action based upon an actual controversy between the parties concerning the invalidity and/or non-infringement of the ’584, ’920, and ’936 patents and Lupin Ltd.’s right

to continue to seek approval of ANDA No. 214489 (“Lupin Ltd.’s ANDA”) for tablets containing azilsartan kamedoxomil as the active ingredient, in amounts equivalent to 40 mg or 80 mg of azilsartan medoxomil (collectively, “Lupin’s Ltd.’s ANDA Products”).

8. Lupin has been and presently is engaged in the submission of documents to the FDA, and those documents seek approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of Lupin’s Ltd.’s ANDA Products. Counter-defendants have alleged that the submission of Lupin Ltd.’s ANDA infringes, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the ’584, ’920, and ’936 patents.

9. On information and belief, and according to Counter-defendants’ allegations, Takeda owns the ’584, ’920, and ’936 patents, and Arbor holds an exclusive license in the United States to the ’584, ’920, and ’936 patents.

10. On information and belief, and according to Counter-defendants’ allegations, Arbor holds New Drug Application (“NDA”) No. 200796 for oral tablets containing azilsartan kamedoxomil as the active ingredient, in amounts equivalent to 40 mg or 80 mg of azilsartan medoxomil. According to Counter-defendants’ allegations, Arbor markets and sells these oral tablets in the United States under the brand name EDARBI®.

11. Lupin has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of, any valid and enforceable claim of the ’584, ’920, and ’936 patents.

12. Lupin has further asserted that the ’584, ’920, and ’936 patents are invalid for failure to satisfy one or more of the provisions of Title 35 of the United States Code, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type

double patenting and/or any other judicially created requirements for patentability and enforceability of patent, and the defenses recognized in 35 U.S.C. § 282.

13. The '584, '920, and '936 patents are listed in the electronic Orange Book with respect to EDARBI®.

14. Lupin Ltd.'s ANDA includes a certification under FDCA § 505(j)(2)(A)(vii)(IV), with respect to the '584, '920, and '936 patents, that no valid, enforceable claim of the patent will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which Lupin Ltd.'s ANDA has been submitted. On May 23, 2020, pursuant to Section 505(j)(2)(B) of the FDCA, Lupin provided via FedEx® Priority Overnight delivery written notification to Counter-defendants that Lupin Ltd. filed ANDA No. 214489 with the FDA containing certifications pursuant to FDCA § 505(j)(2)(A)(vii)(IV) that the '584, '920, and '936 patents are invalid and/or will not be infringed by Lupin Ltd.'s ANDA product. Lupin's Notice Letter was accompanied by an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). On information and belief, and according to Counter-defendants' allegations, Counter-defendants received Lupin's Notice Letter dated May 23, 2020.

15. On July 8, 2020, Counter-defendants filed in this Court an infringement action against Lupin alleging infringement of the '584, '920, and '936 patents.

16. More than forty-five days have passed since Lupin delivered, and Counter-defendants received, Lupin's Notice Letter.

17. In view of the foregoing, a conflict of asserted rights has arisen between Lupin Ltd. and Counter-defendants with respect to the non-infringement and invalidity of the relevant claims of the '584, '920, and '936 patents, and as to Lupin Ltd.'s right to obtain FDA approval to engage

in the commercial manufacture, importation, use, offer for sale, or sale of Lupin Ltd.'s ANDA Products. An actual controversy therefore exists between Counter-defendants and Lupin Ltd.

FIRST COUNTERCLAIM—DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 7,157,584)

18. Lupin realleges paragraphs 1-17 as though fully set forth herein.

19. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '584 patent.

20. Lupin is entitled to judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid, enforceable claim of the '584 patent.

SECOND COUNTERCLAIM— DECLARATION OF INVALIDITY

(U.S. PATENT NO. 7,157,584)

21. Lupin realleges paragraphs 1-20 as though fully set forth herein.

22. The claims of the '584 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For at least the reasons explained in Lupin Ltd.'s Notice Letter, each of the claims of the '584 patent is invalid in view of the cited prior art.

23. Lupin is entitled to a judicial declaration that one or more claims of the '584 patent are invalid.

THIRD COUNTERCLAIM—DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 7,572,920)

24. Lupin realleges paragraphs 1-23 as though fully set forth herein.

25. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '920 patent.

26. Lupin is entitled to judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid, enforceable claim of the '920 patent.

FOURTH COUNTERCLAIM—DECLARATION OF INVALIDITY

(U.S. PATENT NO. 7,572,920)

27. Lupin realleges paragraphs 1-26 as though fully set forth herein.

28. The claims of the '920 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For at least the reasons explained in Lupin Ltd.'s Notice Letter, at least claims 1-4, 7, and 8 of the '920 patent are invalid in view of the cited prior art.

29. Lupin is entitled to a judicial declaration that one or more claims of the '920 patent are invalid.

FIFTH COUNTERCLAIM— DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. 9,066,936)

30. Lupin realleges paragraphs 1-29 as though fully set forth herein.

31. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '936 patent.

32. Lupin is entitled to judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid, enforceable claim of the '936 patent.

SIXTH COUNTERCLAIM—DECLARATION OF INVALIDITY

(U.S. PATENT NO. 9,066,936)

33. Lupin realleges paragraphs 1-32 as though fully set forth herein.

34. The claims of the '936 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For at least the reasons explained in Lupin Ltd.'s Notice Letter, each of the claims of the '936 patent is invalid in view of the cited prior art.

35. Lupin is entitled to a judicial declaration that one or more claims of the '936 patent are invalid.

DEMAND FOR JUDGMENT

WHEREFORE, Lupin prays for the following relief:

A. That the Court order the Complaint dismissed with prejudice and judgment entered in favor of Lupin;

B. That a judgment be entered declaring that the manufacture, import, use, sale, and/or offer to sell Lupin's ANDA Product, has not infringed, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid, enforceable claim of U.S. Patent Nos. 7,157,584, 7,572,920, and 9,066,936;

C. That a judgment be entered declaring the claims of U.S. Patent Nos. 7,157,584, 7,572,920, and 9,066,936 invalid;

D. That the Court declare that Lupin has the lawful right to manufacture, import, use, sell, and/or offer to sell Lupin ANDA Product in the United States once the product is approved by the FDA;

E. That Counter-defendants and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Lupin or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Lupin, or charging any of them either orally or in writing with infringement of U.S. Patent Nos. 7,157,584, 7,572,920, and 9,066,936;

F. That a judgment be entered, declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Lupin is therefore entitled to recover its reasonable attorneys' fees upon prevailing in this action;

G. That Lupin be awarded costs, attorney's fees, and other relief, both legal and equitable, to which it may be justly entitled; and

H. That Lupin be awarded such other and further relief as is just and proper.

Dated: August 7, 2020

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)

David A. Bilson (#4986)

PHILLIPS, MCLAUGHLIN & HALL, P.A.

1200 North Broom Street

Wilmington, DE 19806

(302) 655-4200

jcp@pmhdelaw.com

dab@pmhdelaw.com

OF COUNSEL:

William R. Zimmerman

(*Pro Hac Vice* pending)

Jonathan E. Bachand

(*Pro Hac Vice* pending)

Jeremiah S. Helm

(*Pro Hac Vice* pending)

KNOBBE MARTENS OLSON & BEAR LLP

1717 Pennsylvania Ave. N.W., Suite 900

Washington, D.C. 20006

(202) 640-6400

bill.zimmerman@knobbe.com

jonathan.bachand@knobbe.com

jeremiah.helm@knobbe.com

*Attorneys for Defendants Lupin Limited and
Lupin Pharmaceuticals, Inc.*