IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VERTEX PHARMACEUTICALS INC., Plaintiff, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 1:21-cv-01019-RGA

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

Defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively, "Defendants"), by and through their counsel, hereby answer and respond to each of the allegations in the Complaint by Vertex Pharmaceuticals Inc. ("Vertex" or "Plaintiff"), and assert their separate defenses, and Lupin Ltd. asserts its separate counterclaims, as follows.

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny all allegations in Plaintiff's Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Defendant Lupin Limited's submission of Abbreviated New Drug Application ("ANDA") No. 216074 to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Vertex's KALYDECO® (ivacaftor) tablets prior to the expiration of a patent, which covers, *inter alia*, KALYDECO® and its use.

ANSWER: The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Complaint purports to state a claim for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201. Defendants further admit that Lupin Ltd., as the sole applicant, submitted Abbreviated New Drug Application ("ANDA") No. 216074 to the U.S. Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking FDA approval of the ivacaftor tablets described in ANDA No. 216074. Defendants further admit that ANDA No. 216074 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to U.S. Patent No. 10,646,481 ("the '481 patent"). Defendants deny all other allegations in paragraph 1.

2. In ANDA No. 216074, Defendant Lupin Limited seeks approval to commercially market a generic version of Vertex's KALYDECO® tablets prior to the expiration of United States Patent No. 10,646,481 (the "'481 patent"), which is owned by Vertex.

ANSWER: Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 216074 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of the ivacaftor tablets described in ANDA No. 216074. Defendants further admit that ANDA No. 216074 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '481 patent. Defendants further admit that the '481 patent lists Vertex as the Assignee. Defendants deny all other allegations in paragraph 2.

THE PARTIES

3. Plaintiff Vertex is a corporation organized and existing under the laws of Massachusetts with its principal place of business at 50 Northern Avenue, Boston, MA 02210. Vertex is a biopharmaceutical company committed to improving the lives of patients worldwide. Vertex focuses on the pursuit of medical research to create transformative medicines for people with serious and life-threatening diseases, such as cystic fibrosis.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore deny them.

4. Upon information and belief, Defendant Lupin Limited is a company organized and existing under the laws of India, with its principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

ANSWER: Admitted.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Limited.

ANSWER: Defendants admit that Lupin Pharmaceuticals is a corporation organized and existing under the laws of Delaware, with a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, MD 21202. The allegations in the second sentence of paragraph 5 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Pharmaceuticals is an indirect, wholly owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals is a proper party to this action. Defendants deny all other allegations in paragraph 5.

6. Upon information and belief, Defendant Lupin Limited is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the United States market, alone and/or through its wholly owned subsidiaries and agents, including Defendant Lupin Pharmaceuticals, Inc.

ANSWER: Defendants admit that Lupin Ltd. manufactures pharmaceutical products, including generic pharmaceutical products. Defendants further admit that Lupin Pharmaceuticals distributes pharmaceutical products, including generic pharmaceutical products, in the United States. Defendants deny that Lupin Pharmaceuticals is a proper party to this action. Defendants deny all other allegations in paragraph 6.

THE PATENT-IN-SUIT

7. On May 12, 2020, the United States Patent and Trademark Office duly and legally issued the '481 patent, entitled "Pharmaceutical Composition and Administrations Thereof," to Vertex as assignee. A copy of the '481 patent is attached to this Complaint as Exhibit A.

ANSWER: Defendants admit that the '481 patent is titled "Pharmaceutical Composition and Administrations Thereof" and lists May 12, 2020 as the Date of Patent. Defendants further admit that the '481 patent lists Vertex as the Assignee. Defendants further admit that, on information and belief, what purports to be a copy of the '481 patent is attached to the Complaint as Exhibit A. Defendants deny all other allegations in paragraph 7.

8. Vertex is the lawful owner of and holds right, title, and interest in the patent-in-suit.

ANSWER: The allegations in paragraph 8 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '481 patent lists Vertex as the Assignee. Defendants deny all other allegations in paragraph 8.

KALYDECO®

9. Vertex holds approved New Drug Application No. 203188 for the use of ivacaftor 150 mg tablets for the treatment of cystic fibrosis in patients age six and older who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or *in vitro* assay data. Vertex sells the ivacaftor tablets under the trade name KALYDECO®.

ANSWER: Defendants admit that the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists "IVACAFTOR" as the Active Ingredient, "150 MG" as the Strength, "VERTEX PHARMACEUTICALS INC" as the Applicant Holder, and "KALYDECO" as the Proprietary Name in connection with New Drug Application ("NDA") No. 203188. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 9 and therefore deny them.

10. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the '481 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to New Drug Application No. 203188.

ANSWER: The allegations in paragraph 10 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the FDA's Orange Book lists the '481 patent in connection with NDA No. 203188, KALYDECO® (ivacaftor) tablets, 150 mg. Defendants deny all other allegations in paragraph 10.

LUPIN'S ANDA

11. Upon information and belief, Defendant Lupin Limited acted in concert with Defendant Lupin Pharmaceuticals, Inc. to prepare and submit ANDA No. 216074 ("Lupin's ANDA") to the FDA. Defendants submitted ANDA No. 216074, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of 150 mg ivacaftor tablets ("Lupin's ANDA Product"), which are based on Vertex's KALYDECO® 150 mg tablets, before the expiration of the '481 patent.

ANSWER: The allegations in paragraph 11 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 216074 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of the ivacaftor tablets described in ANDA No. 216074. Defendants further admit that ANDA No. 216074 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '481 patent. Defendants deny all other allegations in paragraph 11.

12. Upon information and belief, Lupin's ANDA refers to and relies upon Vertex's New Drug Application No. 203188 and contains data that, according to Defendant Lupin Limited, demonstrates the bioequivalence of Lupin's ANDA Product to KALYDECO® 150 mg tablets.

ANSWER: Defendants admit that ANDA No. 216074 identifies NDA No. 203188 and KALYDECO® (ivacaftor) tablets, 150 mg, as the Reference Listed Drug. Defendants further admit that ANDA No. 216074 contains information intended to establish bioequivalence with the Reference Listed Drug. Defendants deny all other allegations in paragraph 12.

13. By letter to Vertex, dated June 1, 2021 ("Lupin's Paragraph IV Notice Letter"), Defendant Lupin Limited stated that Lupin's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid claim of the '481 patent will be infringed by the manufacture, importation, use, or sale of Lupin's ANDA Product (the "Paragraph IV Certification"). Defendant Lupin Limited attached an exhibit to its June 1, 2021 letter, in which it purported to allege the factual and legal bases for its Paragraph IV Certification.

ANSWER: Defendants admit that Lupin Ltd. transmitted a letter dated June 1, 2021 ("Notice Letter") to Plaintiff, notifying Plaintiff that Lupin Ltd., as the sole applicant, submitted ANDA No. 216074 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of the ivacaftor tablets described in ANDA No. 216074 and that ANDA No. 216074 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '481 patent. Defendants further admit that Lupin Ltd.'s Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '481 patent. Defendants deny all other allegations in paragraph 13.

14. Upon information and belief, if the FDA approves Lupin's ANDA, Defendants will manufacture, distribute, import, offer for sale and/or sell Lupin's ANDA Product throughout the United States, including within the State of Delaware.

ANSWER: Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 216074 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of the ivacaftor tablets described in ANDA No. 216074. Defendants deny all other allegations in paragraph 14.

15. This action is being filed within 45 days of Vertex's receipt of Lupin's Paragraph IV Notice Letter.

ANSWER: The allegations in paragraph 15 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiff commenced this action by filing its Complaint on July 13, 2021. Defendants deny all other allegations in paragraph 15.

JURISDICTION AND VENUE

16. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has jurisdiction over its subject matter under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: The allegations in paragraph 16 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Complaint purports to state a claim for patent infringement under the patent laws of the United States, Title 35 of the United States Code. Defendants state that Defendants do not contest subject matter jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 216074. Defendants deny all other allegations in paragraph 16.

17. This Court has personal jurisdiction over Defendant Lupin Limited because of Lupin Limited's regular transaction and/or solicitation of business in this State. Furthermore, by continuously placing its products into the stream of commerce for distribution and consumption in Delaware, and throughout the United States, Defendant Lupin Limited has engaged in the regular conduct of business within this judicial district.

ANSWER: The allegations in paragraph 17 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd. manufactures pharmaceutical products, including generic pharmaceutical products. Defendants state that Lupin Ltd. does not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Lupin Ltd. in this case and solely as they apply to the proposed product described in ANDA No. 216074. Defendants deny all other allegations in paragraph 17.

18. In addition, this Court has personal jurisdiction over Defendant Lupin Limited by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc., a wholly-owned subsidiary of Lupin Limited, is incorporated in Delaware.

ANSWER: The allegations in paragraph 18 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Pharmaceuticals is a

corporation organized and existing under the laws of Delaware. Defendants state that Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 216074. Defendants deny that Lupin Pharmaceuticals is a proper party to this action. Defendants deny all other allegations in paragraph 18.

19. Defendant Lupin Limited filed ANDA No. 216074 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product in the United States, including in Delaware. Upon information and belief, upon approval of ANDA No. 216074, Defendant Lupin Limited will market, distribute, offer for sale, and/or sell Lupin's ANDA Product in the United States, including in Delaware.

ANSWER: The allegations in paragraph 19 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 216074 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of the ivacaftor tablets described in ANDA No. 216074. Defendants deny all other allegations in paragraph 19.

20. This Court has personal jurisdiction over Defendant Lupin Pharmaceuticals, Inc. because, among other things, Lupin Pharmaceuticals, Inc. is a corporation formed under the laws of the state of Delaware and has appointed a registered agent in Delaware to accept service of process. Defendant Lupin Pharmaceuticals, Inc. has therefore purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

ANSWER: The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Pharmaceuticals is a corporation organized and existing under the laws of Delaware. Defendants further admit that Lupin Pharmaceuticals has appointed a registered agent in Delaware. Defendants state that Lupin Pharmaceuticals does not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Lupin Pharmaceuticals in this case and solely as they apply to the

proposed product described in ANDA No. 216074. Defendants deny that Lupin Pharmaceuticals is a proper party to this action. Defendants deny all other allegations in paragraph 20.

21. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc., acting as the agent of Defendant Lupin Limited, markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Defendant Lupin Limited or for which Defendant Lupin Limited is the named applicant on approved ANDAs. Upon information and belief, upon approval of ANDA No. 216074, Defendant Lupin Pharmaceuticals, Inc. will market, distribute, offer for sale, and/or sell Lupin's ANDA Product in the United States, including in Delaware.

ANSWER: The allegations in paragraph 21 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd. manufactures pharmaceutical products, including generic pharmaceutical products. Defendants further admit that Lupin Pharmaceuticals distributes pharmaceutical products, including generic pharmaceutical products, in the United States. Defendants deny that Lupin Pharmaceuticals is a proper party to this action. Defendants deny all other allegations in paragraph 21.

22. Upon information and belief, Defendants have previously consented to suit in this judicial district and have not challenged personal jurisdiction. Defendants have further availed themselves of the jurisdiction of this Court by previously asserting counterclaims in this jurisdiction. *See, e.g.*, *Bayer Pharma AG, et al., v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 21-314-RGA (D.I. 14); *Bayer Intellectual Property GmbH, et al., v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 17-1047-RGA (D.I. 9); *Genentech, Inc., et al. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 19-109-RGA (D.I. 10).

ANSWER: The allegations in paragraph 22 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 216074. Defendants deny all other allegations in paragraph 22.

23. Venue is proper in this Court for Defendant Lupin Limited under 28 U.S.C. § 1391(c)(3) because Lupin Limited, on information and belief, is not a resident of the United States and may thus be sued in any judicial district.

ANSWER: The allegations in paragraph 23 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd. is a company organized and existing under the laws of India. Defendants state that Lupin Ltd. does not contest venue in this Court solely for purposes of Plaintiff's claims against Lupin Ltd. in this case and solely as they apply to the proposed product described in ANDA No. 216074. Defendants deny all other allegations in paragraph 23.

24. Venue is proper in this Court for Defendant Lupin Pharmaceuticals, Inc. under 28 U.S.C. § 1400(b) because, *inter alia*, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

ANSWER: The allegations in paragraph 24 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Pharmaceuticals is a corporation organized and existing under the laws of Delaware. Defendants state that Lupin Pharmaceuticals does not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Lupin Pharmaceuticals in this case and solely as they apply to the proposed product described in ANDA No. 216074. Defendants deny that Lupin Pharmaceuticals is a proper party to this action. Defendants deny all other allegations in paragraph 24.

CLAIM FOR RELIEF
INFRINGEMENT OF U.S. PATENT NO. 10,646,481

25. Defendants have infringed one or more claims of the '481 patent, pursuant to 35 U.S.C.§ 271(e)(2)(A), by submitting to the FDA and maintaining Lupin's ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Lupin's ANDA Product prior to the expiration of the '481 patent.

ANSWER: Denied.

26. Defendants' commercial manufacture, sale, offer for sale, or use of Lupin's ANDA Product within the United States, or importation of Lupin's ANDA Product into the United States, during the term of the '481 patent would infringe, induce the infringement, and/or contribute to the infringement of one or more claims of the '481 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

27. Upon information and belief, Defendants have acted with full knowledge of the '481 patent and without a reasonable basis for believing that they would not be liable for infringement of the '481 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Lupin's ANDA Product with its proposed labeling immediately and imminently upon approval of Lupin's ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '481 patent.

ANSWER: Defendants admit they are aware the FDA's Orange Book lists the '481 patent in connection with NDA No. 203188. Defendants deny all other allegations in paragraph 27.

28. Upon information and belief, if the FDA approves Lupin's ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '481 patent, and will do so immediately and imminently upon approval.

ANSWER: Denied.

29. Upon information and belief, Defendants know that Lupin's ANDA Product is especially made or adapted for use in infringing the '481 patent, and that Lupin's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '481 patent immediately and imminently upon approval of Lupin's ANDA.

ANSWER: Denied.

30. Vertex will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '481 patent.

ANSWER: Denied.

31. Vertex has no adequate remedy at law.

ANSWER: Denied.

32. Vertex is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

PRAYER FOR RELIEF

Defendants deny all remaining allegations not specifically admitted herein. Defendants further deny that Plaintiff is entitled to any judgment or relief requested in the Complaint, or to any relief whatsoever. Defendants respectfully request that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of Defendants; (c) award Defendants the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Defendants such further relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiff's Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,646,481)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed ivacaftor tablets described in ANDA No. 216074 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '481 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,646,481)

Upon information and belief, the claims of the '481 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

RESERVATION OF DEFENSES

Defendants expressly reserve the right to supplement and/or amend their Answer to Plaintiff's Complaint, including, but not limited to, supplementation and/or amendment of their defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery hereby reserve any and all defenses.

COUNTERCLAIMS

Lupin Limited ("Lupin Ltd." or "Counterclaimant"), by its attorneys, alleges the following counterclaims against Vertex Pharmaceuticals Inc. ("Vertex" or "Counterclaim Defendant").

THE PARTIES

1. Counterclaimant Lupin Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at 3rd Floor, Kalpataru Inspire, Off Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

2. Upon information and belief, Counterclaim Defendant Vertex is a corporation organized and existing under the laws of Massachusetts with its principal place of business at 50 Northern Avenue, Boston, MA 02210.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 *et seq.*, and 35 U.S.C. § 271(e)(5).

4. This Court has personal jurisdiction over Counterclaim Defendant because Counterclaim Defendant commenced and continues to maintain this action against Counterclaimant in this district.

5. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II), and because Counterclaim Defendant commenced and continues to maintain this action against Counterclaimant in this district.

REGULATORY FRAMEWORK

6. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference listed drug ("RLD").

7. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] … and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA lists the patent number(s) and expiration date(s) in its publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

8. The Hatch-Waxman Act codified a process for the approval of generic drugs by allowing a generic applicant to seek approval by filing an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j).

9. An ANDA must contain a certification with respect to any patent or patents listed in the Orange Book in connection with the RLD. *See id.* at § 355(j)(2)(A)(vii). ANDA filers may make one of four certifications with respect to each listed patent. Pertinent here is the so-called Paragraph IV certification, which asserts that the listed patent is invalid or will not be infringed by the proposed generic drug product. *See id.* at § 355(j)(2)(A)(vii)(IV).

ORANGE BOOK-LISTED PATENTS FOR KALYDECO®

10. Upon information and belief, Counterclaim Defendant is the holder of NDA No. 203188 on KALYDECO® (ivacaftor) tablets, 150 mg.

11. Upon information and belief, on May 12, 2020, U.S. Patent No. 10,646,481 ("the '481 patent"), titled "Pharmaceutical Composition and Administrations Thereof"—a copy of which Counterclaim Defendant purported to attach to its Complaint as Exhibit A—was issued to Vertex Pharmaceuticals Incorporated as Assignee. The FDA's Orange Book lists the expiration date of the '481 patent as August 13, 2029.

12. Upon information and belief, Counterclaim Defendant submitted the '481 patent to the FDA for listing in the FDA's Orange Book.

13. Upon information and belief, the '481 patent is owned by Counterclaim Defendant.

LUPIN'S ANDA

14. In April 2021, Lupin Ltd. filed ANDA No. 216074 with the FDA seeking FDA approval to engage in the commercial manufacture, use or sale of ivacaftor tablets, 150 mg ("Proposed ANDA Product").

15. Because Lupin Ltd. seeks FDA approval to engage in the commercial manufacture, use or sale of Lupin Ltd.'s Proposed ANDA Product before expiration of the '481 patent, Lupin Ltd.'s ANDA includes a Paragraph IV certification to that patent.

16. Lupin Ltd. transmitted a letter dated June 1, 2021 to Counterclaim Defendant, notifying Counterclaim Defendant that ANDA No. 216074 had been submitted to the FDA under 21 U.S.C. § 355(j), which included a Paragraph IV certification that no valid claim of the '481 patent would be infringed by the proposed ivacaftor tablets, 150 mg, that are the subject of ANDA No. 216074 ("Lupin Ltd.'s Notice Letter"). In its Notice Letter, Lupin Ltd. included a detailed statement of the factual and legal bases upon which it based its Paragraph IV certification and extended to Counterclaim Defendant an Offer of Confidential Access to Lupin Ltd.'s ANDA No. 216074.

17. On July 13, 2021, Counterclaim Defendant filed a patent infringement lawsuit against Lupin Ltd., alleging that Lupin Ltd.'s Proposed ANDA Product would infringe the '481 patent.

18. As a consequence of Counterclaim Defendant's Complaint against Lupin Ltd., there is now an existing and continuing actual controversy between Counterclaim Defendant and Lupin Ltd. concerning the alleged infringement and validity of the '481 patent.

19. By listing and maintaining the '481 patent in the Orange Book, Counterclaim Defendant represents that the patents "claim[] the drug for which the applicant submitted the application [KALYDECO®] … and with respect to which a claim for patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1).

20. Accordingly, by virtue of listing and maintaining the '481 patent in the Orange Book, Counterclaim Defendant represents that an infringement suit based on the '481 patent could be asserted against Lupin Ltd. because Lupin Ltd. is seeking approval to market its Proposed ANDA Product before the expiration of the '481 patent.

21. Until and unless Lupin Ltd. obtains a court decision of noninfringement and/or invalidity on the ’481 patent, Lupin Ltd. potentially faces infringement liability if it commences marketing before the ’481 patent expires.

22. Accordingly, there is an actual, substantial and continuing justiciable controversy between Lupin Ltd. and Counterclaim Defendant regarding the ’481 patent over which the Court can and should exercise jurisdiction and declare the rights of the parties.

COUNT I
(Declaratory Judgment of Noninfringement of the ’481 Patent)

23. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 22 above as though fully set forth herein.

24. The proposed ivacaftor tablets, 150 mg, that are the subject of ANDA No. 216074 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’481 patent.

COUNT II
(Declaratory Judgment of Invalidity of the ’481 Patent)

25. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 24 above as though fully set forth herein.

26. The claims of the ’481 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

27. For the reasons explained in Lupin Ltd.’s Notice Letter dated June 1, 2021, transmitted to Counterclaim Defendant, which is incorporated fully by reference herein, the claims of the ’481 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 and/or the judicial doctrine of obviousness-type double patenting, in view of the prior art cited therein.

28. Counterclaimant reserves the right to provide additional and/or modified bases for invalidity of the '481 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

PRAYER FOR RELIEF

WHEREFORE, Counterclaimant respectfully requests the Court to enter judgment against Counterclaim Defendant Vertex as follows:

A. A declaration that Counterclaimant has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '481 patent;

B. A declaration that the claims of the '481 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting;

C. A declaration that Counterclaim Defendant Vertex takes nothing by its Complaint;

D. A dismissal of Counterclaim Defendant Vertex's Complaint with prejudice;

E. An award to Counterclaimant of its reasonable costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

F. An award of any other and further relief that this Court may deem just and proper.

DATED: August 20, 2021

By: /s/ Francis J. Murphy

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