IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 1:20-01296-LPS
LUPIN LIMITED, Counterclaimant, v. OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Counterdefendants.	

DEFENDANTS LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin"), through their undersigned counsel, hereby answer the Complaint of Plaintiffs Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S (collectively, "Plaintiffs") as follows:

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

NATURE OF THE ACTION[1]

1. Lupin admits that the Complaint filed by Plaintiffs purports to state a civil action for patent infringement under the United States patent laws, Title 35, United States Code. Lupin admits that the Complaint purports to allege infringement of United States Patent No. RE48,059 ("the RE'059 patent"). Lupin admits that the Complaint purports to concern Lupin Ltd.'s filing of Abbreviated New Drug Application ("ANDA") No. 213512 with the United States Food and Drug Administration ("FDA"), pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval of the drug products described therein in the United States. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 1 of the Complaint.

THE PARTIES

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 in Paragraph 2.

3. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 3 of the Complaint and, therefore, denies each and every allegation in Paragraph 3.

4. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 4 of the Complaint and, therefore, denies each and every allegation in Paragraph 4.

[1] For the Court's convenience, Lupin has incorporated the section titles that appear in the Complaint. Lupin does not necessarily agree with the characterizations of such section titles and does not waive any right to object to those characterizations.

5. Lupin admits that Lupin Ltd. is a corporation organized and existing under the laws of India, with a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 5 of the Complaint.

6. Lupin admits that LPI is a corporation organized and existing under the laws of Delaware and has its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, MD 21202. Lupin admits that LPI is an indirect wholly-owned subsidiary of Lupin Ltd. Lupin denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 6 of the Complaint.

JURISDICTION AND VENUE

7. Paragraph 7 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 under 28 U.S.C. §§ 1331 and 1338(a) solely for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2). 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 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. Lupin admits that Lupin Ltd. manufactures pharmaceutical products for the United States market. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 8 of the Complaint.

9. Lupin admits that Lupin Ltd.'s Investor Presentation Q4 FY2020 11 (May 29, 2020) (accessed at https://www.lupin.com/wp-content/uploads/2020/05/lupin-q4fy20-investor-

presentation.pdf on October 15, 2020) contains text under "Major Markets" that states: "3rd Largest in the US." Lupin also admits that the same presentation contains text that states: "430 US ANDAs; 272 approved" and also states "43 pending US First to Files." Lupin further admits that https://www.lupin.com/research/generic-pharmaceutical-and-api-research/ (accessed October 15, 2020) contains text that states: "Lupin's Generic Pharmaceutical Research team has demonstrated a stellar performance with a record number of ANDA filings in the US and other advanced markets from its global R&D hub in Pune, India." Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 9 of the Complaint.

10. Lupin admits that Lupin Ltd. is the holder of Drug Master File No. 33421, whose subject is brexpiprazole. Except as expressly admitted, Lupin denies each and every 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 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. Lupin admits that LPI sells and distributes pharmaceutical products throughout the United States. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 11 of the Complaint.

12. Lupin admits that https://www.lupin.com/US/about-us (accessed Oct. 17, 2020) contains text that states: "Lupin has a strong and well-established generic presence in the United States, having entered the U.S. market in 2003 and maintaining a competitive edge in the list of top 5 generic pharmaceutical companies by prescriptions dispensed since 2010." Lupin admits that https://www.lupin.com/US/generics (accessed Oct. 17, 2020) has text that states: "Lupin entered the U.S. generic pharmaceutical market in 2003 with ANDA approval for Cefuroxime

Axetil Tablets. We have since received more than 250 FDA approvals and market a total of 180 generic products." Lupin denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 12 of the Complaint.

13. Lupin admits that LPI has an active license of the type "Pharmacy – Wholesale" with the license number A4-0002387 in the state of Delaware. Lupin also admits that LPI has an active license of the type "Distributor/Manufacturer CSR" with the license number DM-0012065 in the state of Delaware. Lupin denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 13 of the Complaint.

14. Lupin denies each and every allegation contained in Paragraph 14 of the Complaint.

15. Lupin admits that https://www.lupin.com/our-world/corporateoverview (accessed Oct. 17, 2020) contains text that refers to the United States and the number 38% and states: "Contribution to Lupin's global revenues." Lupin admits that https://www.lupin.com/our-business/global-research-and-manufacturing-facilities/usa (accessed Oct. 17, 2020) contains text that states: "Lupin is the 3rd largest pharmaceutical player in the US by prescriptions (IQVIA NPA, March 2019). Headquartered in Baltimore, Maryland, the Company's US marketing arm, Lupin Pharmaceuticals Inc. (LPI), is dedicated to delivering superior quality branded and generic medicines trusted by healthcare professionals and patients across the region." Lupin denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 15 of the Complaint.

16. Lupin admits that https://www.lupin.com/US/generics (accessed Oct. 17, 2020) contains text that states: "We are vertically integrated, from process development of the API to the submission of dossiers for finished dosages. This provides control over the supply chain and the ability to offer quality products at the right time—and the right price." Lupin admits that the same

website contains text that states: "The rapid pace of our generic growth is possible, in part, thanks to our globally integrated network of 18 manufacturing facilities. These world class facilities are built to manufacture and deliver a wide range of finished products to the U.S. market. All facilities are committed to compliance with quality, safety and environmental standards." *Id.* Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 16 of the Complaint.

17. Lupin admits that the Complaint purports to allege infringement of the RE'059 patent based on Lupin Ltd.'s submission of ANDA No. 213512 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of drug products containing brexpiprazole in the United States ("Lupin Ltd.'s ANDA Products"). Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 17 of the Complaint.

18. Lupin admits that Lupin Ltd. submitted ANDA No. 213512 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 18 of the Complaint.

19. Lupin admits that Lupin Ltd. drafted and submitted ANDA No. 213512 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 19 of the Complaint.

20. Paragraph 20 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest venue 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 20 of the Complaint.

21. Paragraph 21 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest venue 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 21 of the Complaint.

FACTUAL BACKGROUND

The NDA

22. Lupin admits that the electronic version of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies "OTSUKA PHARMACEUTICAL CO LTD" as holding New Drug Application ("NDA") No. 205422 for Rexulti® brand brexpiprazole tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms. Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 22 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 22.

23. Lupin admits that the electronic version of FDA's Orange Book indicates that the FDA approved NDA No. 205422 on July 10, 2015. Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 23 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 23.

24. Lupin admits that, pursuant to the FDA-approved label for Rexulti® brand brexpiprazole tablets, "Rexulti® is an atypical antipsychotic indicated for: • Adjunctive treatment of major depressive disorder (MDD). . . . • Treatment of schizophrenia. . . ." Lupin admits that the electronic version of FDA's Orange Book indicates that brexpiprazole is the active ingredient in

Rexulti® brand brexpiprazole tablets. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 24 of the Complaint.

The Patent In Suit

25. Lupin admits that, according to the face of U.S. Patent No. 7,888,362 ("the '362 patent"), the '362 patent is titled "PIPERAZINE-SUBSTITUTED BENZOTHIOPHENES FOR TREATMENT OF MENTAL DISORDERS" and issued on February 15, 2011. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 25 of the Complaint.

26. Lupin admits that, according to the face of the RE'059 patent, the '362 patent was reissued as the RE'059 patent on June 23, 2020. Lupin admits that what purports to be a copy of the RE'059 patent is attached to the Complaint as Exhibit A. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 26 of the Complaint.

27. Paragraph 27 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the records of the United States Patent and Trademark Office ("PTO") identify "OTSUKA PHARMACEUTICAL CO., LTD." as the purported assignee of the '362 patent. Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 27 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 27.

28. Paragraph 28 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that what purports to be a copy of a terminal disclaimer concerning the '362 patent is attached to the Complaint as Exhibit B. Lupin admits that Exhibit B states: "Assignee hereby disclaims, except as provided below, the terminal

part of the statutory term of U.S. Patent No. 7,888,362 that would extend beyond April 12, 2026, which is equivalent to the 317 days of patent term adjustment granted to this patent under 35 U.S.C. § 154(b)." Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 28 of the Complaint

29. Paragraph 29 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that what purports to be a copy of a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination was attached as Exhibit C to a prior complaint concerning the '362 patent. *See Otsuka Pharmaceutical Co., Ltd. et al. v. Lupin Limited, et al.*, C.A. No. 19-1988-LPS. Lupin admits that Exhibit C to that prior complaint stated: "the terminal disclaimer filed June 4, 2019 will change the original expiration date of the '362 Patent to April 12, 2026, change the period of § 156 term ex tension to 986 days, and change the expiration date of the term extension to December 23, 2028." Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 29 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 29.

30. Lupin admits that the RE'059 patent is currently listed in FDA's Orange Book in connection with NDA No. 205422 for Rexulti® brand brexpiprazole tablets.

The ANDA

31. Lupin admits that Lupin Ltd. submitted ANDA No. 213512 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Lupin Ltd.'s ANDA Products. Lupin admits that Lupin Ltd.'s ANDA Products are in the form of tablets, containing 0.25, 0.5, 1, 2, 3, and 4 mg brexpiprazole. Lupin admits that REXULTI is the reference listed drug for ANDA No. 213512.

Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 31 of the Complaint.

32. Lupin admits that Lupin Ltd. sent a letter, dated September 5, 2019, to Otsuka Pharmaceutical Co., Ltd. providing a "Notice of Paragraph IV Certification" for ANDA No. 213512 ("Lupin Ltd.'s Notice Letter") pursuant to § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act ("FDCA") and 21 C.F.R. § 314.95. Lupin admits that Lupin Ltd.'s Notice Letter notified Otsuka Pharmaceutical Co., Ltd. that Lupin Ltd. has submitted, and the FDA has received, ANDA No. 213512 under FDCA § 505(j)(2)(B)(ii) in order to obtain approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 32.

33. Lupin admits that Plaintiffs have filed a separate action in this Court against Lupin *Otsuka Pharmaceutical Co., Ltd. et al. v. Lupin Limited, et al.*, C.A. No. 19-1988-LPS. Lupin admits that this separate action purports to allege patent infringement of the '362, '840, '109, '637 and '419 patents. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 33.

34. Lupin admits that, according to the face of the RE'059 patent, the '362 patent was reissued as the RE'059 patent on June 23, 2020. Lupin admits that the RE'059 patent is currently listed in FDA's Orange Book in connection with NDA No. 205422 for Rexulti® brand brexpiprazole tablets. Except as expressly admitted, Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 34 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 34.

35. Lupin admits that ANDA No. 213512 includes a certification pursuant to the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that, in the opinion of Lupin Ltd. and to the

best of its knowledge, no valid, enforceable claim of any of the RE'059 patent will be infringed by the manufacture, use, or sale of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 35.

36. Lupin admits that Lupin Ltd. sent a letter, dated August 12, 2020, to Otsuka Pharmaceutical Co., Ltd. providing a "Notice of Paragraph IV Certification" for ANDA No. 213512 ("Lupin Ltd.'s Supplemental Notice Letter") pursuant to § 505(j)(2)(B) of the FDCA and 21 C.F.R. § 314.95. Lupin admits that Lupin Ltd.'s Supplemental Notice Letter notified Otsuka Pharmaceutical Co., Ltd. that Lupin Ltd. has submitted, and the FDA has received, ANDA No. 213512 under FDCA § 505(j)(2)(B)(ii) in order to obtain approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 36.

37. Lupin admits that Lupin Ltd. sent Otsuka Pharmaceutical Co., Ltd. a letter containing a "Notice of Paragraph IV Certification Regarding NDA 205422" on August 12, 2020 ("Lupin Ltd.'s Supplemental Notice Letter"). Lupin admits that delivery confirmations for Lupin Ltd.'s Supplemental Notice Letter indicate that it was received by Otsuka and Otsuka's counsel on August 13, 2020. Lupin admits to receiving notice of Plaintiffs' complaint for patent infringement of the RE'059 patent on September 25, 2020. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 37.

COUNT I

(INFRINGEMENT OF THE '059 PATENT

38. Lupin realleges, and incorporates fully herein, each preceding paragraph.

39. Lupin admits that Lupin Ltd. filed ANDA No. 213512, seeking approval of Lupin Ltd.'s ANDA Products in the United States prior to the expiration of the RE'059 patent. Except

as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 39 of the Complaint.

40. Lupin admits that ANDA No. 213512 includes a certification pursuant to the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) indicating that, in the opinion of Lupin Ltd. and to the best of its knowledge, the claims of the RE'059 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Lupin Ltd.'s ANDA products. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 40 of the Complaint.

41. Lupin admits that Lupin Ltd. submitted ANDA No. 213512 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 41 of the Complaint.

42. Lupin admits that it is presently aware of the RE'059 patent. Lupin admits that Lupin Ltd.'s Supplemental Notice Letter referred to the RE'059 patent. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 42.

43. Lupin denies each and every allegation contained in Paragraph 43 of the Complaint.

44. Lupin admits that Lupin Ltd. submitted ANDA No. 213512 to the FDA, seeking approval of the drug products described therein in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 44 of the Complaint.

45. Lupin denies each and every allegation contained in Paragraph 45 of the Complaint.

46. The allegations of Paragraph 46 are vague as to which "actions" are referred to and which "Lupin" entity is being referenced. Accordingly, 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.

48. Lupin denies each and every allegation contained in Paragraph 48 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 Paragraphs A–H of the Complaint or to any other relief.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its responses to Paragraphs 1 through 48 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)

Lupin does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the RE'059 patent by the manufacture, use, sale, offer for sale, or importation of Lupin Ltd.'s ANDA Products.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity)

One or more claims of the RE'059 patent are invalid for failure to comply with one or more of the conditions set forth in 35 U.S.C. §§ 101 *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 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.") brings the following Counterclaims against Plaintiffs/Counterdefendants Otsuka Pharmaceuticals Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs" of "Counterdefendants") for a declaratory judgment that U.S. Patent No. RE48,059 ("the RE'059 patent") is invalid and/or not

infringed by the manufacture, use, sale, offer for sale, or importation of the brexpiprazole tablets that are the subject of Lupin Ltd.'s ANDA No. 213512 ("Lupin Ltd.'s ANDA Products").

PARTIES

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

2. On information and belief, and based on Counterdefendant's allegations, Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. On information and belief, and based on Counterdefendant's allegations, Lundbeck is a corporation organized and existing under the laws of Denmark, with place of business at Ottiliavej 9, DK-2500 Valby, Denmark.

JURISDICTION AND VENUE

4. Lupin Ltd. 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 Counterdefendants' 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 RE'059 patent and Lupin Ltd.'s right to continue to seek approval of Lupin Ltd.'s ANDA No. 213512 for Lupin Ltd.'s ANDA Products.

8. Lupin Ltd. has been and presently is engaged in the submission of documents to the Food & Drug Administration ("FDA") in connection with ANDA No. 213512, and those

documents seek approval of Lupin Ltd.'s ANDA Products. Counterdefendants have alleged that the submission of Lupin Ltd.'s ANDA No. 213512 infringes, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the RE'059 patent.

9. Counterdefendants have filed in this Court an infringement action to enforce the RE'059 patent against Lupin Ltd.

10. On information and belief, and according to Counterdefendants' allegations, Otsuka is the assignee of the RE'059 patent.

11. On information and belief, and according to Counterdefendants' allegations, Otsuka is the holder of New Drug Application ("NDA") No. 205422 for Rexulti® (brexpiprazole) tablets.

12. Lupin Ltd. has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of, any valid and/or enforceable claim of the RE'059 patent.

13. Lupin Ltd. has further asserted that one or more claims of the RE'059 patent is invalid for failure to comply with one or more of the conditions set forth in 35 U.S.C. §§ 101 *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 patents and/or the defenses recognized in 35 U.S.C. § 282.

14. The RE'059 patent is listed in the electronic version of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Rexulti®.

15. Lupin Ltd.'s ANDA No. 213512 includes a certification pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the

RE'059 patent, indicating that in the opinion of Lupin Ltd. and to the best of its knowledge, no valid, enforceable claim of any of the RE'059 patent will be infringed by the manufacture, use, or sale of Lupin Ltd.'s ANDA Products.

16. In view of the foregoing, a conflict of asserted rights has arisen between Lupin Ltd. and Counterdefendants with respect to the non-infringement and invalidity of the relevant claims of the RE'059 patent, and as to Lupin Ltd.'s right to obtain FDA approval of Lupin Ltd.'s ANDA Products. An actual controversy therefore exists between Counterdefendants and Lupin Ltd.

FIRST COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. PATENT NO. RE48,059)

17. Lupin Ltd. realleges Paragraphs 1–16 as though fully set forth herein.

18. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the RE'059 patent.

19. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Products do not, and would not if marketed, infringe any valid and/or enforceable claim of the RE'059 patent.

SECOND COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. PATENT NO. RE48,059)

20. Lupin Ltd. realleges Paragraphs 1–19 as though fully set forth herein.

21. The claims of the RE'059 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 Supplemental Notice Letter, each of the claims of the RE'059 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to the ABILIFY® Label; WO 2004/105682 to Kikuchi; Inoue et al., "Strategy for Modulation of Central Dopamine Transmission based on the Partial Agonist Concept in Schizophrenia Therapy," 86 JPN. J. PHARMACOL. 376–80, 380 (2001); U.S. Publication No. 2005/0043309 to Clark et al.; U.S. Patent No. 5,006,528 to Oshiro et al.; Kuipers et al., *N^4-Unsubstituted N^1-Arylpiperazines as High-Affinity 5-HT_{1A} Receptor Ligands*, 38 J. MED. CHEM. 1942–54 (1995); Rocco et al., *Advances toward new antidepressants beyond SSRIs: 1-aryloxy-3-piperidinylpropan-2-ols with dual 5-HT1A receptor antagonism/SSRI activities. Part 4*, 14 BIOORGANIC & MED. CHEM. LETT. 2653–56 (2004); U.S. Patent No. 5,436,246 to Bernotas et al.; Oshiro, Y., et al., "Novel Antipsychotic Agents with Dopamine Agonist Properties: Synthesis and Pharmacology of 7-[4-(4-Phenyl-1-piperazinyl)butoxy]-3,4-dihydro-2(1H)-quinolinone Derivatives," 41 J. MED. CHEM. 658–67 (1998); Millan, M.J., "Improving the Treatment of Schizophrenia: Focus on Serotonin $(5\text{-HT})_{1A}$ Receptors," J. Pharmacol. Exp. Ther., 295(3), 853–861 (2000); Bantick, R.A, et al., *The 5-HT_{1A} receptor in schizophrenia: a promising target for novel atypical neuroleptics?*, 15(1) JOURNAL OF PSYCHOPHARMACOLOGY 37–46 (2001); Stahl, S.M., *Dopamine System Stabilizers, Aripiprazole, and the Next Generation of Antipsychotics, Part 2*, 62(12) J. CLIN. PSYCHIATRY 923–24 (2001); Hicks, P., *The Effect of Serotonergic Agents on Haloperidol-Induced Catalepsy*, 47 LIFE SCIENCES 1609–15 (1990); and/or U.S. Publication No 2002/0173513 to Jordan et al.

22. Lupin Ltd. is entitled to a judicial determination that the claims of the RE'059 patent are invalid.

DEMAND FOR JUDGMENT

WHEREFORE, Lupin Ltd. prays for the following relief:

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

B. That a judgment be entered declaring that the manufacture, import, use, sale, and/or offer to sell Lupin Ltd.'s ANDA Products, 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 and/or enforceable claim of the RE'059 patent;

C. That a judgment be entered declaring the claims of the RE'059 patent invalid;

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

E. That Counterdefendants 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 Ltd. or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Lupin Ltd., or charging any of them either orally or in writing with infringement of the RE'059 patent;

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 Ltd. is therefore entitled to recover its reasonable attorneys' fees upon prevailing in this action;

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

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

Dated: October 28, 2020

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