IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. 18-cv-00090-LPS

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

Defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. (collectively, "Defendants"), by and through their counsel, hereby answer and respond to each of the allegations in the Complaint of Plaintiffs H. Lundbeck A/S, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs") (D.I. 1), and assert their separate defenses, and Lupin Ltd. asserts its separate counterclaims, as follows. Defendants deny all allegations not expressly admitted herein.

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Defendants' recent submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 211105 (hereinafter, "Defendants' ANDA"). Through Defendants' ANDA, Defendants seek approval to market generic versions of Plaintiffs' pharmaceutical product TRINTELLIX®, prior

to the expiration of United States Patent No. 8,722,684 ("the '684 Patent"); United States Patent No. 8,969,355 ("the '355 Patent"); and United States Patent No. 9,227,946 ("the '946 Patent").

ANSWER: Paragraph 1 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that the Complaint purports to state claims for infringement under the patent laws of the United States, 35 U.S.C. § 1, *et seq*. Defendants further admit that Lupin Ltd. submitted Abbreviated New Drug Application ("ANDA") No. 211105 (hereinafter, "the Lupin ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval for vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg, prior to the expiration of United States Patent No. 8,722,684 ("the '684 Patent"); United States Patent No. 8,969,355 ("the '355 Patent"); and United States Patent No. 9,227,946 ("the '946 Patent") (collectively, "Patents-in-Suit"). Defendants deny that the Complaint states a proper claim for infringement of the Patents-in-Suit and/or that such claims have any merit. Defendants deny any remaining allegations of Paragraph 1.

THE PARTIES

2. Plaintiff H. Lundbeck A/S ("Lundbeck") is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Lundbeck is the assignee and owner of the '684 Patent, the '355 Patent, and the '946 Patent.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore deny them.

3. Plaintiff Takeda Pharmaceutical Company Ltd. is a corporation organized and existing under the laws of Japan, with a place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan. Lundbeck has granted Takeda Japan an exclusive license to the '684, '355, and '946 Patents in connection with the use, importation, distribution, marketing, promotion, and sale of Trintellix® in the United States.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore deny them.

4. Plaintiff Takeda Pharmaceuticals International AG is a corporation organized and existing under the laws of Switzerland, with a place of business at Thurgauerstrasse 130, 8152

Glattpark-Opfikon, Zurich, Switzerland. Takeda International is an indirect wholly owned subsidiary of Takeda Japan. Takeda International has an exclusive sublicense to the '684, '355, and '946 Patents from Takeda Japan in connection with the commercialization of Trintellix® in the United States.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore deny them.

5. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda International and Takeda Japan own Takeda USA. Takeda USA holds the New Drug Application ("NDA") No. 204447 for TRINTELLIX® and has an exclusive sublicense to the '684, '355, and '946 Patents from Takeda International, which grants it the right to import, distribute, and sell TRINTELLIX® in the United States on behalf of Takeda.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5, and therefore deny them.

6. Plaintiff Takeda Pharmaceuticals America, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda America is a wholly owned subsidiary of Takeda USA. Takeda America distributes and markets TRINTELLIX® in the United States on behalf of Takeda USA.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 6, and therefore deny them.

7. Lundbeck and Takeda are engaged in the business of creating, researching, developing, and bringing to market revolutionary pharmaceutical products to help treat serious diseases, including major depressive disorder.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 7, and therefore deny them.

8. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

ANSWER: Defendants admit that Lupin Ltd. is an entity organized and existing under the laws of India, with a place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

9. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202.

ANSWER: Defendants admit that Lupin Pharmaceuticals, Inc. is a Delaware corporation with a place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202.

10. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Limited.

ANSWER: Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action.

11. On information and belief, Lupin Pharmaceuticals, Inc. acts at the direction, and for the benefit, of Lupin Limited, and is controlled and/or dominated by Lupin Limited.

ANSWER: Paragraph 11 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 11.

12. On further information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

ANSWER: Paragraph 12 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 12.

13. On information and belief, Lupin Pharmaceuticals, Inc. maintains a website, http://www.lupinpharmaceuticals.com, which states that "Lupin Pharmaceuticals, Inc. is the U.S. wholly owned subsidiary of Lupin Limited," and that Lupin Pharmaceuticals, Inc. is "building on [its] parent company's strengths of vertical integration in discovery research, process chemistry, active pharmaceutical ingredient production, formulation development and regulatory filings." Lupin Pharmaceuticals, Inc.'s website also reports that "Vinita Gupta, CEO of Lupin Pharmaceuticals, Inc. says 'founded on the strengths of our parent company Lupin Limited, Lupin Pharmaceuticals, Inc. intends to bring a portfolio of generics as well as branded products to the US market.'"

ANSWER: Paragraph 13 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. The website, http://www.lupinpharmaceuticals.com, and the statements therein speak for themselves. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 13.

14. On information and belief, Lupin Pharmaceuticals, Inc. acts as the U.S. agent for Lupin Limited for purposes of regulatory submissions to the U.S. Food and Drug Administration ("FDA") in seeking approval for generic drugs.

ANSWER: Paragraph 14 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 14.

15. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. acted collaboratively in the preparation and submission of ANDA No. 211105.

ANSWER: Paragraph 15 states legal conclusions and allegations to which no answer is required. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 15.

16. On information and belief, Defendants caused ANDA No. 211105 to be submitted to FDA and seek FDA approval of ANDA No. 211105.

ANSWER: Defendants admit that Lupin Ltd., as a sole applicant, submitted ANDA No. 211105 to FDA seeking approval for vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants deny any remaining allegations of Paragraph 16.

17. On information and belief, Defendants intend to commercially manufacture, market, offer for sale, and sell the vortioxetine hydrobromide tablets described in Defendants' ANDA ("the ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves Defendants' ANDA.

ANSWER: Paragraph 17 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 17.

18. On information and belief, Defendants intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the ANDA Products, in the event FDA approved Defendants' ANDA.

ANSWER: Paragraph 18 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 18.

JURISDICTION AND VENUE

19. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '684, '355, and '946 Patents.

ANSWER: Paragraph 19 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that the Complaint purports to state claims for infringement under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '684, '355, and '946 Patents. Defendants deny that the Complaint states a proper claim for infringement of the Patents-in-Suit and/or that such claims have any merit. Defendants deny any remaining allegations of Paragraph 19.

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

ANSWER: Paragraph 20 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338 solely for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2). Defendants deny any remaining allegations of Paragraph 20.

21. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, *inter alia*, have continuous and systematic contacts with the State of Delaware, regularly conduct business in the State of Delaware, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, have purposefully availed themselves of the privilege of doing business in the State of Delaware, and intend to sell the ANDA Products in the State of Delaware upon approval of ANDA No. 211105.

ANSWER: Paragraph 21 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 21.

22. Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware.

ANSWER: Defendants admit that Lupin Pharmaceuticals, Inc. is a Delaware corporation.

23. On information and belief, Defendants are in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter-egos, which Defendants manufacture, distribute, market, and/or sell throughout the United States and in this judicial district.

ANSWER: Paragraph 23 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 23.

24. On information and belief, Defendants are licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos. On information and belief, Lupin Pharmaceuticals, Inc. holds a current and valid "Pharmacy-Wholesale" License in Delaware.

ANSWER: Paragraph 24 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 24.

25. On information and belief, Defendants and/or their subsidiaries actively seek employment of sales representatives to serve customers in the State of Delaware, continuously employ sales representatives in the State of Delaware, and regularly market their products in the State of Delaware.

ANSWER: Paragraph 25 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 25.

26. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture TRINTELLIX® for sale and use throughout the United States, including this judicial district. On information and belief and as indicated by a letter dated November 30, 2017 sent by Lupin Limited to H. Lundbeck and Takeda USA pursuant to 21 U.S.C. § 355(j)(2)(B) (hereinafter, the "Notice Letter"), ANDA No. 211105 was prepared and filed with the intention of seeking to market the ANDA Products nationwide, including within this judicial district.

ANSWER: Paragraph 26 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 211105 to FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants admit that Lupin Ltd. by Notice letter dated November 30, 2017 (hereinafter, the "Notice Letter")

notified Plaintiffs that Lupin Ltd., as the sole applicant, submitted the Lupin ANDA to the FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants deny any remaining allegations of Paragraph 26.

27. On information and belief, Defendants plan to sell the ANDA Products in the State of Delaware, list the ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Paragraph 27 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 211105 to FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 27.

28. On information and belief, Defendants know and intend that their proposed ANDA Products will be distributed and sold in Delaware and will thereby displace sales of TRINTELLIX®, causing injury to Lundbeck and Takeda. Defendants intend to take advantage of their established channels of distribution in Delaware for the sale of their proposed ANDA Products.

ANSWER: Paragraph 28 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 28.

29. Lupin Limited and Lupin Pharmaceuticals, Inc. regularly engage in patent litigation concerning FDA-approved drug products in this judicial district, have not contested personal jurisdiction in such litigation, in this judicial district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Omeros Corp. v. Lupin Ltd. et al*, 17-cv-00803, D.I. 9 (D. Del. Aug. 23, 2017); *Bayer Intellectual Prop. GmbH et al v. Lupin Ltd. et al*, 17-cv-01047, D.I. 9 (D. Del. Aug. 22, 2017); *Bristol-Myers Squibb Co. et al v. Lupin Ltd*., 17-cv-00378, D.I. 8 (D. Del. May 4, 2017); *ViiV Healthcare Co. et al v. Lupin Ltd. et al*, 17-cv-00315, D.I. 8 (D. Del. Apr. 17, 2017); *Astellas*

Pharma Inc. et al v. Lupin Ltd. et al, 16-cv-00908, D.I. 20 (D. Del. Jan. 17, 2017); *Arena Pharm., Inc. et al v. Lupin Ltd. et al*, 16-cv-00887, D.I. 12 (Jan. 11, 2017).

ANSWER: Paragraph 29 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 29.

30. Venue is proper in this district for Lupin Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Lupin Limited is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 30 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest venue over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 30.

31. Venue is proper in this district for Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 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: Paragraph 31 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 31.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

32. Takeda USA is the holder of New Drug Application ("NDA") No. 204447 for TRINTELLIX® tablets (5 mg, 10 mg, 15 mg, and 20 mg dosage strengths).[1] The active ingredient in TRINTELLIX® is vortioxetine hydrobromide. FDA approved NDA No. 204447 on September 30, 2013.

[1] Plaintiffs do not sell 15 mg TRINTELLIX® tablets in the United States.

ANSWER: Defendants admit that according to the United States Food and Drugs Administration (FDA) publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") Takeda USA is identified as the holder of NDA No. 204447 for TRINTELLIX® tablets (5 mg, 10 mg, 15 mg, and 20 mg dosage strengths) and the products that are the subject of NDA No. 204447 were approved by FDA on September 30, 2013. Defendants further admit that as per the Orange Book, the active ingredient in TRINTELLIX® is vortioxetine hydrobromide. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 32, and therefore deny them.

33. TRINTELLIX® is an oral antidepressant indicated for the treatment of Major Depressive Disorder (MDD). It is an inhibitor of serotonin (5-HT) reuptake, an agonist at 5-HT1A receptors, a partial agonist at 5-HT1B receptors, and an antagonist at 5-HT3, 5-HT1D and 5-HT7 receptors. It is considered to be the first and only drug with this combination of pharmacodynamic activity. It represents a major advancement in the treatment of depression.

ANSWER: Defendants admit that the labeling included with TRINTELLIX® states that it is indicted for the treatment of Major Depressive Disorder (MDD). Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 33, and therefore deny them.

34. The '684, '355, and '946 Patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for TRINTELLIX®.

ANSWER: Upon information and belief, Defendants admit that the '684, '355, and '946 Patents are listed in the Orange Book as purportedly associated with TRINTELLIX®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 34, and therefore deny them.

35. The '684 Patent, entitled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment

of Cognitive Impairment," was duly and lawfully issued by the USPTO on May 13, 2014. A true and correct copy of the '684 Patent is attached hereto as Exhibit A.

ANSWER: Defendants admit that Plaintiffs purport to attach a copy of the '684 Patent to the Complaint as Exhibit A. Defendants further admit that the face of the '684 patent indicates that it issued on May 13, 2014, and that the '684 Patent is titled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment." Defendants deny any remaining allegations of Paragraph 35, including any suggestion or implication that the '684 patent was duly and legally issued or is valid or enforceable.

36. The '355 Patent, entitled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment," was duly and lawfully issued by the USPTO on March 3, 2015. A true and correct copy of the '355 Patent is attached hereto as Exhibit B.

ANSWER: Defendants admit that Plaintiffs purport to attach a copy of the '355 Patent to the Complaint as Exhibit B. Defendants further admit that the face of the '335 patent indicates that it issued on March 3, 2015, and that the '335 Patent is titled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment." Defendants deny any remaining allegations of Paragraph 36, including any suggestion or implication that the '335 patent was duly and legally issued or is valid or enforceable.

37. The '946 Patent, entitled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment," was duly and lawfully issued by the USPTO on January 5, 2016. A true and correct copy of the '946 Patent is attached hereto as Exhibit C.

ANSWER: Defendants admit that Plaintiffs purport to attach a copy of the '946 Patent to the Complaint as Exhibit C. Defendants further admit that the face of the '946 patent indicates that it issued on January 5, 2016, and that the '946 Patent is titled "1-[2-(2,4-

dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment." Defendants deny any remaining allegations of Paragraph 37, including any suggestion or implication that the '946 patent was duly and legally issued or is valid or enforceable.

38. On information and belief, Defendants have submitted ANDA No. 211105 to FDA, or caused ANDA No. 211105 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of vortioxetine hydrobromide tablets as purported generic versions of TRINTELLIX® tablets prior to the expiration of the '684, '355, and '946 Patents.

ANSWER: Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 211105 to FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg, prior to the expiration of the Patents-in-Suit. Defendants deny any remaining allegations of Paragraph 38.

39. On information and belief, FDA has not approved Defendants' ANDA.

ANSWER: Defendants admit that FDA has not approved ANDA No. 211105.

40. On information and belief, Lupin Limited sent Lundbeck and Takeda USA a Notice Letter dated November 30, 2017. The Notice Letter represented that Lupin Limited had submitted to FDA ANDA No. 211105 and a purported Paragraph IV certification for the '684, '355, and '946 Patents. Plaintiffs reserve all rights to challenge the sufficiency of Defendants' ANDA and Notice Letter.

ANSWER: Defendants admit that Lupin Ltd. sent a Notice Letter dated November 30, 2017 to Takeda Pharmaceuticals U.S.A. Inc., Takeda Pharmaceuticals America, Inc., H. Lundbeck A/S, and Lundbeck that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 211105 to the FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg, prior to the expiration of the Patents-in-Suit, which contained a Paragraph IV certification as to the Patents-in-Suit. Defendants state that the Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 40 to the extent they deviate from or otherwise do not accurately reflect or describe the Notice Letter or Lupin Ltd.'s proposed vortioxetine

hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants deny the remaining allegations of Paragraph 40.

41. On information and belief, the purpose of an ANDA and Paragraph IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products before expiration of the '684, '355, and '946 Patents. Hence, Defendants' purpose in submitting ANDA No. 211105 is to market the products described therein before the expiration of the '684, '355, and '946 Patents.

ANSWER: Paragraph 41 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. as the sole applicant, submitted ANDA No. 211105 to FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg, prior to the expiration of the Patents-in-Suit. Defendants deny any remaining allegations of Paragraph 41.

42. In the Lupin Limited's Notice Letter, Lupin Limited purported to offer confidential access to portions of its ANDA No. 211105 on terms and conditions set forth in the Notice Letter ("the Lupin Offer"). Lupin Limited requested that Lundbeck and Takeda accept the Lupin Offer before receiving access to ANDA No. 211105. The Lupin Offer contained unreasonable restrictions on who could view the ANDA, well beyond those that would apply under a protective order. The Lupin Offer did not permit outside expert access to ANDA No. 211105. Nor did it permit any of Plaintiffs' in-house attorneys to access ANDA No. 211105. Additionally, the Lupin Offer contained provisions that unreasonably restricted the ability of counsel receiving access to ANDA No. 211105 to engage in any patent prosecution or other proceedings before patent offices or work relating to the FDA and/or regulatory advising. The restrictions Lupin placed on access to ANDA No. 211105 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, *as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information*" (emphasis added).

ANSWER: Paragraph 42 states legal conclusions and allegations to which no answer is required. Defendants admit that the Notice Letter included an offer of confidential access to portions of ANDA No. 211105. Defendants state that the Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 42 to the extent they deviate from or otherwise do not accurately reflect or describe the Notice Letter. Defendants deny any remaining allegations of Paragraph 42.

43. On December 11, 2017, outside counsel for Plaintiffs contacted counsel for Lupin Limited—who was designated as Lupin's agent for service in the Notice Letter—via email in an effort to negotiate reasonable terms of confidential access to the ANDA. Plaintiffs' correspondence included proposed modifications to Lupin's unduly restrictive Offer. Receiving no response from Lupin's counsel, Plaintiffs' outside counsel once again contacted Lupin's counsel via email on January 3, 2018. To date, Lupin's counsel has not responded to any of Plaintiffs' correspondence regarding confidential access to Lupin's ANDA.

ANSWER: Paragraph 43 contains unverified allegations which do not go to the merits of the case. On that basis, denied.

44. On information and belief, if approved, the ANDA Products will have the same indication as TRINTELLIX®. On further information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 211105 for the ANDA Products is the treatment of major depressive disorder (MDD).

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that ANDA No. 211105 speaks for itself. Defendants deny the remaining allegations of Paragraph 44.

45. On information and belief, if FDA approves Defendants' ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Products, within the United States, including within the State of Delaware, or will import the ANDA Products into the United States, including the State of Delaware.

ANSWER: Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 211105 to FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants deny any remaining allegations of Paragraph 45.

46. On information and belief, if FDA approves Defendants' ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products in a manner that infringes the '684, '355, and '946 Patents.

ANSWER: Paragraph 46 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 211105 to FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants deny any remaining allegations of Paragraph 46.

47. This action is being brought within forty-five days of Plaintiffs' receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

ANSWER: Paragraph 47 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, upon information and belief, Defendants admit that the Complaint was filed within forty-five days of Plaintiffs' receipt of the Notice Letter. Defendants deny any remaining allegations of Paragraph 47.

COUNT I
ALLEGED INFRINGEMENT OF THE '684 PATENT

48. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–47 as if fully set forth herein.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–47 in full herein.

49. On information and belief, Defendants submitted or caused the submission of ANDA No. 211105 to FDA, and thereby seek FDA approval of Defendants' ANDA.

ANSWER: Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 211105 to FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants deny any remaining allegations of Paragraph 49.

50. Plaintiffs own all rights, title, and interest in and to the '684 Patent.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 50, and therefore deny them.

51. The ANDA Products fall within one or more claims of the '684 patent.

ANSWER: Defendants deny the allegations of Paragraph 51.

52. Defendants have infringed at least one claim of the '684 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '684 Patent.

ANSWER: Defendants deny the allegations of Paragraph 52.

53. If approved, the importation, manufacture, sale, offer for sale, or use of the ANDA Products will infringe one or more claims of the ’684 Patent under 35 U.S.C. § 271(a).

ANSWER: Defendants deny the allegations of Paragraph 53.

54. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the ’684 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants’ ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce infringement of one or more claims of the ’684 Patent. On information and belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the ’684 Patent and knowledge that their acts are encouraging infringement.

ANSWER: Defendants deny the allegations of Paragraph 54.

55. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the ’684 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants’ ANDA, Defendants will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the ’684 Patent. On information and belief, Defendants have had and continue to have knowledge of the ’684 Patent and knowledge that their acts will lead to infringement of the patent. On information and belief, Defendants have had and continue to have knowledge that the ANDA Products are especially made or especially adapted for a use that infringes the ’684 Patent and that there are no substantial non-infringing uses for the ANDA Products.

ANSWER: Defendants deny the allegations of Paragraph 55.

56. Defendants had actual and constructive notice of the ’684 Patent prior to filing Defendants’ ANDA, and were aware that the filing of Defendants’ ANDA with the request for FDA approval prior to the expiration of the ’684 Patent would constitute an act of infringement of the ’684 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the ’684 Patent.

ANSWER: Paragraph 56 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 56.

57. Defendants filed Defendants’ ANDA without adequate justification for asserting the ’684 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’684 Patent renders this case

"exceptional" as that term is set forth in 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

ANSWER: Paragraph 57 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 57.

58. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '684 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendants deny the allegations of Paragraph 58.

COUNT II
ALLEGED INFRINGEMENT OF THE '355 PATENT

59. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–58 as if fully set forth herein.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–58 in full herein.

60. On information and belief, Defendants submitted or caused the submission of ANDA No. 211105 to FDA, and thereby seek FDA approval of Defendants' ANDA.

ANSWER: Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 211105 to FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants deny any remaining allegations of Paragraph 60.

61. Plaintiffs own all rights, title, and interest in and to the '355 Patent.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 61, and therefore deny them.

62. The ANDA Products fall within one or more claims of the '355 patent.

ANSWER: Defendants deny the allegations of Paragraph 62.

63. On information and belief, the ANDA Products will be indicated for the treatment of major depressive disorder.

ANSWER: Defendants state that ANDA No. 211105 speaks for itself. Defendants deny the remaining allegations of Paragraph 63.

64. Defendants have infringed at least one claim of the '355 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '355 Patent.

ANSWER: Defendants deny the allegations of Paragraph 64.

65. If approved, use of the ANDA Products in accordance with the proposed labeling will directly infringe one or more claims of the '355 Patent.

ANSWER: Defendants deny the allegations of Paragraph 65.

66. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '355 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce infringement of one or more claims of the '355 Patent. On information and belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the '355 Patent and knowledge that their acts are encouraging infringement.

ANSWER: Defendants deny the allegations of Paragraph 66.

67. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '355 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendants will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the '355 Patent. On information and belief, Defendants have had and continue to have knowledge of the '355 Patent and knowledge that their acts will lead to infringement of the patent. On information and belief, Defendants have had and continue to have knowledge that the ANDA Products are especially made or especially adapted for a use that infringes the '355 Patent and that there are no substantial non-infringing uses for the ANDA Products.

ANSWER: Defendants deny the allegations of Paragraph 67.

68. Defendants had actual and constructive notice of the '355 Patent prior to filing Defendants' ANDA, and were aware that the filing of Defendants' ANDA with the request for FDA approval prior to the expiration of the '355 Patent would constitute an act of infringement of the '355 Patent. Defendants have no reasonable basis for asserting that the commercial

manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the '355 Patent.

ANSWER: Paragraph 68 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 68.

69. Defendants filed Defendants' ANDA without adequate justification for asserting the '355 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '355 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

ANSWER: Paragraph 69 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 69.

70. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '355 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendants deny the allegations of Paragraph 70.

COUNT III
ALLEGED INFRINGEMENT OF THE '946 PATENT

71. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–70 as if fully set forth herein.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–70 in full herein.

72. On information and belief, Defendants have submitted or caused the submission of ANDA No. 211105 to FDA, and thereby seek FDA approval of Defendants' ANDA.

ANSWER: Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 211105 to FDA seeking approval for its proposed vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Defendants deny any remaining allegations of Paragraph 72.

73. Plaintiffs own all rights, title, and interest in and to the '946 Patent.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 73, and therefore deny them.

74. The ANDA Products fall within one or more claims of the '946 Patent.

ANSWER: Defendants deny the allegations of Paragraph 74.

75. On information and belief, the ANDA Products will be indicated for the treatment of major depressive disorder.

ANSWER: Defendants state that ANDA No. 211105 speaks for itself. Defendants deny the remaining allegations of Paragraph 75.

76. Defendants have infringed at least one claim of the '946 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '946 Patent.

ANSWER: Defendants deny the allegations of Paragraph 76.

77. If approved, use of the ANDA Products in accordance with the proposed labeling will directly infringe one or more claims of the '946 Patent.

ANSWER: Defendants deny the allegations of Paragraph 77.

78. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '946 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce infringement of one or more claims of the '946 Patent. On information and belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the '946 Patent and knowledge that their acts are encouraging infringement.

ANSWER: Defendants deny the allegations of Paragraph 78.

79. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '946 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendants will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the '946 Patent. On information and belief, Defendants have had and continue to have knowledge of the '946 Patent and knowledge that their acts will lead to infringement of the patent. Upon information and belief, Defendants have had and continue to have knowledge that the ANDA Products are especially made or especially adapted for a use that infringes the '946 Patent and that there are no substantial non-infringing uses for the ANDA Products.

ANSWER: Defendants deny the allegations of Paragraph 79.

80. Defendants had actual and constructive notice of the '946 Patent prior to filing Defendants' ANDA, and were aware that the filing of Defendants' ANDA with the request for FDA approval prior to the expiration of the '946 Patent would constitute an act of infringement of the '946 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the '946 Patent.

ANSWER: Paragraph 80 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 80.

81. In addition, Defendants filed Defendants' ANDA without adequate justification for asserting the '946 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '946 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

ANSWER: Paragraph 81 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 81.

82. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '946 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendants deny the allegations of Paragraph 82.

RESPONSE TO REQUEST FOR RELIEF

All remaining allegations not specifically admitted herein are denied. Defendants further deny that Plaintiffs are entitled to any judgment or relief against Defendants and, therefore, specifically deny paragraphs A through I of Plaintiffs' Request for Relief.

GENERAL DENIAL

Defendants deny all remaining allegations not specifically admitted herein. Defendants further deny that Plaintiffs are 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.

DEFENDANTS' AFFIRMATIVE DEFENSES

Without prejudice to the responses and denials set forth in Defendants' Answer, without admitting any allegations of the Complaint not expressly admitted, and without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs, Defendants assert the following separate defenses to the Complaint:

First Affirmative Defense

(Failure to State a Claim)

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Second Affirmative Defense

(Invalidity of the Patents-in-Suit)

The claims of the Patents-in-Suit are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States

Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120, and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

Third Affirmative Defense

(Noninfringement of the Patents-in-Suit)

Defendants do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the Patents-in-Suit, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of Lupin Ltd.'s ANDA No. 211105 do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the Patents-in-Suit, either directly, indirectly, contributorily, by inducement, or in any other manner.

Fourth Affirmative Defense

(Prosecution History Estoppel)

Plaintiff's cause of action is barred, in whole or in part, by the doctrine of prosecution history estoppel.

Fifth Affirmative Defense

(Limitation of Remedies)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit. The remedy of an injunction or other equitable relief sought by Plaintiffs in the Complaint is unavailable to Plaintiffs in this action.

Sixth Affirmative Defense

(Improper Party)

Lupin Pharmaceuticals, Inc. is not a proper party to this action.

Seventh Affirmative Defense

(Lack of Subject Matter Jurisdiction)

This Court lacks subject matter jurisdiction over any and all claims asserted against Lupin Pharmaceuticals, Inc. and any and all claims asserted under 35 U.S.C. § 271(a), (b) or (c).

Eighth Affirmative Defense

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

The Complaint fails to state a claim for exceptional case and/or willful infringement under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4).

Reservation of Rights

Defendants expressly reserve the right to supplement and/or amend their Answer to Plaintiffs' 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.

COUNTERCLAIMS BY LUPIN LTD.

Counterclaim-Plaintiff Lupin Ltd., for its Counterclaims against Plaintiffs/Counterclaim Defendants H. Lundbeck A/S, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc. (collectively, "Lundbeck/Takeda"), alleges as follows:

1. This is a counterclaim action for declaratory judgment of noninfringement and/or invalidity of one or more claims of U.S. Patent Nos. 8,722,684 ("the '684 patent"), 8,969,355 ("the '355 patent") and 9,227,946 ("the '946 patent").

THE PARTIES

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

3. On information and belief, and based on the allegations in the Complaint, H. Lundbeck A/S ("Lundbeck") is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark, and is the assignee and owner of the '684 Patent, the '355 Patent, and the '946 Patent.

4. On information and belief, and based on the allegations in the Complaint, Takeda Pharmaceutical Company Ltd. is a corporation organized and existing under the laws of Japan, with a place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

5. On information and belief, and based on the allegations in the Complaint, Takeda Pharmaceuticals International AG is a corporation organized and existing under the laws of Switzerland, with a place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland.

6. On information and belief, and based on the allegations in the Complaint, Takeda Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

7. On information and belief, and based on the allegations in the Complaint, Takeda Pharmaceuticals America, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

JURISDICTION AND VENUE

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

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

10. This is an action based on an actual controversy between Lupin Ltd. and Lundbeck/Takeda concerning the noninfringement and/or invalidity of the '684, '355, and '946 patents arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*., and Lupin Ltd.'s right to continue to seek approval by the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 211105, and upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg, that are the subject of Lupin Ltd.'s ANDA No. 211105 ("Lupin Ltd.'s ANDA Products").

11. The Court has personal jurisdiction over Lundbeck/Takeda because, on information and belief, Lundbeck/Takeda transact business within the State of Delaware and/or have engaged in systematic and continuous business contacts within the State of Delaware. Further, Lundbeck/Takeda have subjected themselves to the jurisdiction of this Court by virtue of filing their Complaint.

12. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Lundbeck/Takeda's choice of forum.

BACKGROUND

13. On information and belief, on or about May 13, 2014, the United States Patent and Trademark Office ("USPTO") issued the '684 patent, titled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A

Activity for the Treatment of Cognitive Impairment." The '684 patent is attached as Exhibit A to the Complaint.

14. On information and belief, on or about March 3, 2015, the USPTO issued the '355 patent, titled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment." The '355 patent is attached as Exhibit B to the Complaint.

15. On information and belief, on or about January 5, 2016, the USPTO issued the '946 patent, titled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment." The '946 patent is attached as Exhibit C to the Complaint.

16. On information and believe, and based on the allegations in the Complaint, the '684, '355, and '946 patents are assigned to and owned by H. Lundbeck A/S.

17. On information and belief, and based on the allegations in the Complaint, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals U.S.A. are exclusive licensees and/or sublicensees under the '684, '355, and '946 patents, in connection with the use, importation, distribution, marketing, promotion, and/or sale of TRINTELLIX® in the United States. Takeda Pharmaceuticals America, Inc. distributes and markets TRINTELLIX® in the United States on behalf of Takeda Pharmaceuticals U.S.A.

18. On information and belief, and according to the United States Food and Drugs Administration (FDA) publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"), Takeda Pharmaceuticals U.S.A. is the holder of New Drug Application ("NDA") No. 204447 for vortioxetine hydrobromide tablets, with the proprietary name TRINTELLIX®.

19. On information and belief, Lundbeck/Takeda caused the FDA to list the ’684, ’355, and ’946 patents in the Orange Book in connection with NDA No. 204447.

20. By maintaining the listing of the ’684, ’355, and ’946 patents in the Orange Book, Lundbeck/Takeda represent that a claim of infringement of the ’684, ’355, and ’946 patents “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)(G).

21. On information and belief, Lundbeck/Takeda have not caused the FDA to remove the ’684, ’355, and ’946 patents from the Orange Book in connection with NDA Nos. 204447.

22. By Notice Letter dated November 30, 2017 (hereinafter, “Lupin Ltd.’s Notice Letter”), Lupin Ltd. timely notified Lundbeck/Takeda that it had submitted ANDA No. 211105 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’684, ’355, and ’946 patents. Lupin Ltd.’s Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Lupin Ltd.’s opinion that the claims of the ’684, ’355, and ’946 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Products. Lupin Ltd. incorporates by reference its Notice Letter.

23. Lupin Ltd.’s Notice Letter contained an Offer of Confidential Access that offered to provide Lundbeck/Takeda with confidential access to information from ANDA No. 211105 for the purpose of Lundbeck/Takeda making a determination of whether an infringement action could be brought with respect to the ’684, ’355, and ’946 patents.

24. On January 12, 2018, Lundbeck/Takeda filed an infringement action against Lupin Ltd. alleging infringement of the ’684, ’355, and ’946 patents.

25. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Lupin Ltd. and Lundbeck/Takeda having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the ’684, ’355, and ’946 patents, and as to Lupin Ltd.’s right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Products.

COUNT I
Declaratory Judgment of Noninfringement of the ’684 Patent

26. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1–25 of its Counterclaims.

27. Lundbeck/Takeda have accused Lupin Ltd. of infringing claims of the ’684 patent in connection with ANDA No. 211105.

28. Lupin Ltd. denies infringement of any valid, enforceable, properly construed claim of the ’684 patent and alleges that Lupin Ltd. has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the ’684 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

29. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.’s ANDA Products will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the ’684 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

30. Lupin Ltd.’s ANDA Products will not infringe any valid and/or enforceable claim of the ’684 patent, at least because Lupin Ltd.’s ANDA Products do not satisfy the claims of the

'684 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

31. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products does not, and would not if marketed, infringe any valid and/or enforceable claim of the '684 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

COUNT II
Declaratory Judgment of Invalidity of the '684 Patent

32. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1–31 of its Counterclaims.

33. The claims of the '684 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, and including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

34. The '684 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

35. The alleged invention of the '684 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '684 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to

combine the teachings of the prior art to achieve the alleged invention of the ’684 patent and would have had a reasonable expectation of success in doing so, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

36. The claims of the ’684 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including, but not limited to: PCT International Publication No. WO 03/029232 to Thomas Ruhland et al.; Center for Drug Evaluation and Research, *Guideline for Submitting Support Documentation in Drug Applications for the Manufacture of Drug Substances* (Feb. 1987); Stephen Bryn et al., *Pharmaceutical Solids: A* Strategic *Approach to Regulatory Considerations*, 12 Pharmaceutical Research, Vol. 12 No. 7, pp. 945-954 (1995); Remington, *The Science and Practice of Pharmacy* Volume 1, 20th Ed., Maryland USA: Lippincott Williams &Wilkins (2000). The differences between the subject matter claimed in the ’684 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

37. Lupin Ltd. is entitled to a judicial declaration that the claims of the ’684 patent are invalid.

COUNT III
Declaratory Judgment of Noninfringement of the ’355 Patent

38. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1–37 of its Counterclaims.

39. Lundbeck/Takeda have accused Lupin Ltd. of infringing claims of the ’355 patent in connection with ANDA No. 211105.

40. Lupin Ltd. denies infringement of any valid, enforceable, properly construed claim of the ’355 patent and alleges that Lupin Ltd. has not, and does not, infringe (either literally or

under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the ’355 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

41. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.’s ANDA Products will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the ’355 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

42. Lupin Ltd.’s ANDA Products will not infringe any valid and/or enforceable claim of the ’355 patent, at least because Lupin Ltd.’s ANDA Products do not satisfy the claims of the ’355 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

43. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Products does not, and would not if marketed, infringe any valid and/or enforceable claim of the ’355 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

COUNT IV
Declaratory Judgment of Invalidity of the ’355 Patent

44. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1–43 of its Counterclaims.

45. The claims of the ’355 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other

judicially-created bases for invalidation, and including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

46. The '355 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

47. The alleged invention of the '355 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '355 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '355 patent and would have had a reasonable expectation of success in doing so, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

48. The claims of the '355 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including, but not limited to: PCT International Publication No. WO 03/029232 to Thomas Ruhland et al.; Center for Drug Evaluation and Research, *Guideline for Submitting Support Documentation in Drug Applications for the Manufacture of Drug Substances* (Feb. 1987); Stephen Bryn et al., *Pharmaceutical Solids: A* Strategic *Approach to Regulatory Considerations*, 12 Pharmaceutical Research, Vol. 12 No. 7, pp. 945-954 (1995). The differences between the subject matter claimed in the '355 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the

time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

49. Lupin Ltd. is entitled to a judicial declaration that the claims of the ’355 patent are invalid.

COUNT V
Declaratory Judgment of Noninfringement of the ’946 Patent

50. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1–49 of its Counterclaims.

51. Lundbeck/Takeda have accused Lupin Ltd. of infringing claims of the ’946 patent in connection with ANDA No. 211105.

52. Lupin Ltd. denies infringement of any valid, enforceable, properly construed claim of the ’946 patent and alleges that Lupin Ltd. has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the ’946 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

53. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.’s ANDA Products will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the ’946 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

54. Lupin Ltd.’s ANDA Products will not infringe any valid and/or enforceable claim of the ’946 patent, at least because Lupin Ltd.’s ANDA Products do not satisfy the claims of the ’946 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Notice Letter.

55. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products does not, and would not if marketed, infringe any valid and/or enforceable claim of the '946 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

COUNT VI
Declaratory Judgment of Invalidity of the '946 Patent

56. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1–55 of its Counterclaims.

57. The claims of the '946 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, and including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

58. The '946 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

59. The alleged invention of the '946 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '946 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '946 patent and would

have had a reasonable expectation of success in doing so, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

60. The claims of the '946 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including, but not limited to: PCT International Publication No. WO 03/029232 to Thomas Ruhland et al.; Center for Drug Evaluation and Research, *Guideline for Submitting Support Documentation in Drug Applications for the Manufacture of Drug Substances* (Feb. 1987); Stephen Bryn et al., *Pharmaceutical Solids: A* Strategic *Approach to Regulatory Considerations*, 12 Pharmaceutical Research, Vol. 12 No. 7, pp. 945-954 (1995). The differences between the subject matter claimed in the '946 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

61. Lupin Ltd. is entitled to a judicial declaration that the claims of the '946 patent are invalid.

EXCEPTIONAL CASE

This case is an exceptional one, and Lupin Ltd. is entitled to an award of its reasonable attorneys' fees, costs and expenses under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Lupin Ltd. prays that the Court enter judgment in its favor and against Lundbeck/Takeda as follows:

a) Dismissing the Complaint with prejudice and denying each request for relief made by Lundbeck/Takeda therein;

b) Declaring that the claims of the '684, '355, and '946 patents are invalid;

c) Declaring that the submission of Lupin Ltd.'s ANDA seeking FDA approval to market the vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg, that are the subject of ANDA No. 211105 prior to the expiration of the '684, '355, and '946 patents has not infringed and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '684, '355, and '946 patents;

d) Declaring that the manufacture, use, sale, offer for sale, and/or importation of the vortioxetine hydrobromide tablets, 5 mg, 10 mg, 15 mg, and 20 mg, that are the subject of Lupin Ltd.'s ANDA No. 211105 will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '684, '355, and '946 patents;

e) A declaration that Plaintiffs/Counterclaim Defendants are not entitled to injunctive relief;

f) Granting Lupin Ltd. judgment in its favor on Lundbeck/Takeda's claims;

g) Granting Lupin Ltd. judgment in its favor on its own Counterclaims;

h) Declaring that this is an exceptional case in favor of Lupin Ltd. pursuant to 35 U.S.C. § 285;

i) Declaring that Lupin Ltd. is the prevailing party and awarding costs, attorneys' fees, and expenses to Lupin Ltd.; and

(c) Awarding Lupin Ltd. such other and further relief to which it may be entitled.

Date: March 22, 2018

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