

**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.

TORRENT PHARMACEUTICALS LIMITED,
and TORRENT PHARMA INC.

Defendants.

C. A. No. 18-672-LPS

**DEFENDANTS/COUNTERCLAIM-PLAINTIFFS TORRENT PHARMACEUTICALS
LIMITED'S AND TORRENT PHARMA INC.'S ANSWER, DEFENSES, AND
COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Torrent Pharmaceuticals Limited (“Torrent Ltd.”) and Torrent Pharma Inc. (“Torrent Pharma”) (collectively “Torrent”) for their Answer, Defenses, and Counterclaims to the Complaint of Plaintiffs H. Lundbeck A/S (“Lundbeck”), Takeda Pharmaceutical Company Ltd. (“Takeda Japan”), Takeda Pharmaceuticals U.S.A., Inc. (“Takeda USA”), Takeda Pharmaceuticals International AG (“Takeda International”), and Takeda Pharmaceuticals America, Inc. (“Takeda America”) (collectively, “Plaintiffs”), respond as follows:

NATURE OF THE ACTION

1. Paragraph 1 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent denies those allegations and legal conclusions. Torrent admits that the Complaint purports to be a civil action alleging infringement of United States Patent No. 9,861,630 (“the ’630 patent”) in connection with Torrent’s submission

of Abbreviated New Drug Application (“ANDA”) No. 211108 to the United States Food and Drug Administration (“FDA”) seeking approval to market vortioxetine tablets, 5 mg, 10 mg, and 20 mg as described in ANDA No. 211108 (“Torrent ANDA Products”) prior to the expiration of the ’630 patent. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 1.

THE PARTIES

2. Paragraph 2 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that H. Lundbeck A/S was identified as the assignee on the face of the ’630 patent. Torrent is without knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 2, and therefore denies them.

3. Torrent is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies them.

4. Torrent is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 4, and therefore denies them.

5. Paragraph 5 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that the electronic version of the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) currently lists “Takeda USA” as the apparent holder of New Drug Application (“NDA”) No. 204447 for TRINTELLIX®. Torrent is without knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 5, and therefore denies them.

6. Torrent is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 6, and therefore denies them.

7. Torrent is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 7, and therefore denies them.

8. Torrent admits only that Torrent Ltd. is a corporation organized and existing under the laws of the Republic of India, with a place of business at Off. Ashram Road, Ahmedabad – 380 009, Gujarat, India. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 8.

9. Torrent admits only that Torrent Pharma is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey, 07920. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 9.

10. Admitted.

11. Denied.

12. Paragraph 12 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that the website, <http://www.torrentpharma.com/>, is related to Torrent Ltd. The content of the website identified in Paragraph 12 of the Complaint speaks for itself, and Torrent denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such content. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 12.

13. Paragraph 13 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that Torrent Pharma is a wholly-owned subsidiary of Torrent Ltd. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 13.

14. Paragraph 14 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that Torrent Pharma has been designated as the U.S. agent for Torrent Ltd. for acceptance of service of process with respect to

certain of its ANDA filings. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 14.

15. Paragraph 15 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that Torrent Ltd. participated in the preparation and filing of ANDA No. 211108 with the FDA. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 15.

16. Paragraph 16 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that Torrent Ltd. submitted ANDA No. 211108 with the FDA requesting approval to engage in the commercial manufacture, use, or sale of Torrent ANDA Products. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 16.

17. Paragraph 17 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that Torrent Ltd. is seeking FDA approval to engage in the commercial manufacture, use, or sale of Torrent ANDA Products. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 17.

18. Denied.

JURISDICTION AND VENUE

19. Paragraph 19 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits that the Complaint purports to be a civil action that arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '630 patent. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 19.

20. Paragraph 20 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that this Court has subject

matter jurisdiction over the claims asserted against Torrent Ltd. under 28 U.S.C. §§ 1331 and 1338(a). Torrent denies any remaining allegations or legal conclusions contained in Paragraph 20.

21. Paragraph 21 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent does not contest this Court's personal jurisdiction for the limited purposes of this action only. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 21.

22. Paragraph 22 contains allegations and/or conclusions of law to which no response is required. The documents filed in the civil action identified in Paragraph 22 of the Complaint speak for themselves, and Torrent denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 22.

23. Admitted.

24. Paragraph 24 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. admits only that it manufactures, markets, distributes, offers for sale, and sells certain generic drug products. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 24.

25. Paragraph 25 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. admits only that it sells certain generic pharmaceutical products. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 25.

26. Denied.

27. Paragraph 27 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. admits only that it sent a letter dated

December 13, 2017 (“First Notice Letter”) and a letter dated March 23, 2018 (“Second Notice Letter”) to notify Lundbeck and Takeda USA that Torrent Ltd. had submitted ANDA No. 211108 to the FDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act seeking approval to engage in the commercial manufacture, use, or sale of Torrent ANDA Products. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 27.

28. Denied.

29. Denied.

30. Paragraph 30 contains allegations and/or conclusions of law to which no response is required. The documents filed in the civil action identified in Paragraph 30 of the Complaint speak for themselves, and Torrent denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 30.

31. Paragraph 31 contains allegations and/or conclusions of law to which no response is required. The documents filed in the civil actions identified in Paragraph 31 of the Complaint speak for themselves, and Torrent denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 31.

32. Paragraph 32 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. does not contest that venue in this judicial district is proper for the limited purposes of this action only. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 32.

33. Paragraph 33 contains allegations and/or conclusions of law to which no response is required. The documents filed in the civil action identified in Paragraph 33 of the Complaint

speak for themselves, and Torrent denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 33.

34. Paragraph 34 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Pharma does not contest that venue in this judicial district is proper for the limited purposes of this action only. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 34.

35. Paragraph 35 contains allegations and/or conclusions of law to which no response is required. The documents filed in the civil action identified in Paragraph 35 of the Complaint speak for themselves, and Torrent denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 35.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

36. Paragraph 36 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits that the electronic version of the Orange Book currently lists “Takeda USA” as the apparent holder of NDA No. 204447 for TRINTELLIX® (vortioxetine hydrobromide) tablets, 5 mg, 10 mg, 15 mg, and 20 mg. Torrent also admits that the electronic version of the Orange Book lists September 30, 2013 as the approval date of NDA No. 204447. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 36.

37. Paragraph 37 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits that the “Indications and Usage” section for the labeling for TRINTELLIX® tablets (for oral use), approved April 11, 2017, states that TRINTELLIX® is “indicated for the treatment of major depressive disorder (MDD).” Torrent

also admits that the “Clinical Pharmacology” section of the labeling for TRINTELLIX®, approved April 11, 2017, states that “[t]he mechanism of the antidepressant effect of vortioxetine is not fully understood, but is thought to be related to its enhancement of serotonergic activity in the CNS through inhibition of the reuptake of serotonin (5-HT)” and that “[v]ortioxetine binds to 5-HT3 ($K_i=3.7$ nM), 5-HT1A ($K_i=15$ nM), 5-HT7 ($K_i=19$ nM), 5-HT1D ($K_i=54$ nM), and 5-HT1B ($K_i=33$ nM), receptors and is a 5-HT3, 5-HT1D, and 5-HT7 receptor antagonist, 5-HT1B receptor partial agonist, and 5-HT1A receptor agonist.” Torrent denies that TRINTELLIX® represents a major advancement in the treatment of depression. Torrent is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 37, and on that basis denies those allegations.

38. Paragraph 38 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that the electronic version of the Orange Book currently lists, *inter alia*, the ’630 patent in association with TRINTELLIX®. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 38.

39. Paragraph 39 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits that Exhibit A of the Complaint purports to be a copy of the ’630 patent. Torrent further admits that the face of Exhibit A states that the ’630 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,” and issued on January 9, 2018. Torrent specifically denies that the ’630 patent was “duly and lawfully” issued by the USPTO. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 39.

DEFENDANTS' ANDA NO. 211108

40. Paragraph 40 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. admits that it had submitted ANDA No. 211108 to the FDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, or sale of Torrent ANDA Products prior to the expiration of the '630 patent. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 40.

41. Admitted.

42. Paragraph 42 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. admits that it sent a Notice Letter dated March 23, 2018 notifying Lundbeck and Takeda USA that in connection with Torrent Ltd.'s submission of ANDA No. 211108, it had submitted certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '630 patent. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 42.

43. Paragraph 43 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. admits only that it prepared and submitted ANDA No. 211108 with FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act seeking approval to engage in the commercial manufacture, use, or sale of Torrent ANDA Products before the expiration of the '630 patent. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 43.

44. Paragraph 44 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that ANDA No. 211108 includes an FDA-required proposed labeling for Torrent ANDA Products and that proposed labeling speaks for itself, and Torrent denies any allegations to the extent they paraphrase, misstate,

or are inconsistent with such labeling. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 44.

45. Paragraph 45 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent specifically denies that the manufacture, use, offer for sale, sale, or importation of its ANDA Products would directly infringe the '630 Patent. Torrent is also presently without knowledge or information sufficient to form a belief as to the truth of any of the remaining allegations of Paragraph 45, and therefore denies them.

46. Denied.

47. Paragraph 47 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. admits that it sent Lundbeck and Takeda USA the Notice Letter. The requirements for 21 U.S.C. §§ 355(c)(3)(C), 355(j)(5)(B)(iii) and 355(j)(5)(F)(ii) speak for themselves. Torrent is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 47, and on that basis denies those allegations.

CLAIM FOR RELIEF

48. Insofar as Plaintiffs repeat and reallege the allegations of Paragraphs 1–47 of the Complaint, Torrent repeats and incorporates its responses thereto as if fully set forth herein.

49. Paragraph 49 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. admits that it submitted ANDA No. 211108 to the FDA requesting approval to engage in the commercial manufacture, use, or sale of Torrent ANDA Products. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 49.

50. Paragraph 50 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent Ltd. admits that it submitted a certification

under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) with respect to the ’630 patent for ANDA No. 211108. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 50.

51. Torrent is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 51.

52. Denied.

53. Paragraph 53 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that ANDA No. 211108 includes an FDA-required proposed labeling for Torrent ANDA Products and that the proposed labeling speaks for itself, and Torrent denies any allegations to the extent they paraphrase, misstate, or are inconsistent with such labeling. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 53.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Paragraph 58 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Torrent admits only that Torrent Ltd. was aware of the ’630 patent prior to filing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) with respect to the ’630 patent for ANDA No. 211108. Torrent denies any remaining allegations or legal conclusions contained in Paragraph 58.

59. Denied.

60. Denied.

GENERAL DENIAL AND RESPONSE TO REQUEST FOR RELIEF

Any allegations in Plaintiffs' Complaint not expressly admitted by Torrent are hereby denied. Having answered Plaintiffs' Complaint, Torrent denies that Plaintiffs are entitled to any judgment or relief requested in Paragraphs (A) through (I) of their "Request for Relief" or to any relief whatsoever.

TORRENT'S SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Torrent asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defenses that would otherwise rest on the Plaintiffs:

First Separate Defense – Non-Infringement of the '630 Patent

The manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Torrent Ltd.'s ANDA No. 211108 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported infringe directly and/or indirectly (whether contributorily or through inducement) any valid or enforceable claim of the '630 patent, either literally or under the doctrine of equivalents.

Second Separate Defense – Invalidity of the '630 Patent

One or more claims of the '630 patent are invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially-created bases for invalidation.

Third Separate Defense – Failure to State a Claim

Plaintiffs' Complaint, in whole or in part, fails to state a claim upon which relief may be granted.

Fourth Separate Defense – Not An Exceptional Case

Neither the filing of ANDA No. 211108 nor the defense of this action gives rise to or constitutes an exceptional case under 35 U.S.C. § 285.

Reservation of Additional Separate Defenses

Torrent reserves the right to assert any and all additional such other defenses and counterclaims that are appropriate or as discovery may reveal.

WHEREFORE, Torrent hereby demands judgment dismissing Plaintiffs' Complaint with prejudice, judgment for costs and fees of suit and for such other relief as the Court may deem just and proper.

COUNTERCLAIMS

Without admitting any of the allegations in Plaintiffs H. Lundbeck A/S (“Lundbeck”), Takeda Pharmaceutical Company Ltd. (“Takeda Japan”), Takeda Pharmaceuticals U.S.A., Inc. (“Takeda USA”), Takeda Pharmaceuticals International AG (“Takeda International”), and Takeda Pharmaceuticals America, Inc.’s (“Takeda America”) (collectively, “Lundbeck and Takeda” or “Plaintiffs”) Complaint, other than those allegations expressly admitted herein, and without prejudice to Defendants/Counterclaim-Plaintiffs Torrent Pharmaceuticals Limited (“Torrent Ltd.”) and Torrent Pharma Inc.’s (“Torrent Pharma”) (collectively “Torrent”) right to plead additional Counterclaims as the facts of the matter warrant, Torrent brings the following counterclaims against Lundbeck and Takeda:

THE PARTIES

1. Torrent Ltd. is a corporation organized and existing under the laws of India, having a place of business at Torrent House, Off Ashram Road, Ahmedabad, 380 009, Gujarat, India.

2. Torrent Pharma is a corporation organized and existing under the laws of Delaware, having a place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey.

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

4. On information and belief, Takeda Japan is a corporation organized and existing under the laws of Japan, with a place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka 540-8645, Japan.

5. On information and belief, Takeda International 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, Takeda USA 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, Takeda America 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.

NATURE OF ACTION

8. These counterclaims arise under at least under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

9. Torrent seeks a declaration that United States Patent No. 9,861,630 ("the '630 patent") is (1) not infringed by the products described in ANDA No. 211108 ("Torrent's ANDA")

either literally or under the doctrine of equivalents, and/or (2) invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially-created bases for unpatentability.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and (b), and 2202 based on an actual controversy among the parties as demonstrated by, *inter alia*, Plaintiffs' filing of the Complaint arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Personal jurisdiction is proper in this Court as to Plaintiffs, because, *inter alia*, Plaintiffs have submitted to the jurisdiction of this Court by virtue of filing their Complaint against Torrent in this District. On information and belief, Plaintiffs sell products here, including the pharmaceutical product TRINTELLIX® that Plaintiffs have caused the '630 patent to be listed in connection with in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluation* (commonly known as the "Orange Book"), conduct substantial business in, and have regular and systemic contacts with this District.

12. Because Plaintiffs have filed suit in this District alleging ANDA No. 211108 infringes the '630 patent, a substantial portion of the events giving rise to these counterclaims arose in this District for purposes of 28 U.S.C. § 1391(b)(2).

13. Venue for these Counterclaims is proper in this judicial district because Plaintiffs have filed suit in this judicial district alleging ANDA No. 211108 infringes the '630 patent, a substantial portion of the events giving rise to these counterclaims arose in this District for purposes of 28 U.S.C. § 1391(b)(2).

BACKGROUND

14. The face of the '630 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," indicates that it issued on January 9, 2018.

15. On information and belief, and based on Plaintiffs' allegations, Lundbeck purports to be the assignee and owner of the '630 patent.

16. On information and belief, and based on Plaintiffs' allegations, Takeda Japan purports to have an exclusive license to the '630 patent in connection with the use, importation, distribution, marketing, promotion, and sale of TRINTELLIX® in the United States.

17. On information and belief, and based on Plaintiffs' allegations, Takeda International purports to have an exclusive sublicense to the '630 patent.

18. On information and belief, and based on Plaintiffs' allegations, Takeda USA is the apparent holder of New Drug Application ("NDA") No. 204447 for TRINTELLIX® (vortioxetine hydrobromide) tablets, 5 mg, 10 mg, 15 mg, and 20 mg.

19. Torrent Ltd. submitted its ANDA No. 211108 to the United States Food and Drug Administration ("FDA") seeking approval to market vortioxetine tablets, 5 mg, 10 mg, and 20 mg as described in ANDA No. 211108 ("Torrent ANDA Products") prior to the expiration of the '630 patent.

20. The '630 patent is currently listed in the Orange Book with respect to NDA No. 204447 for TRINTELLIX®.

21. Torrent Ltd. has certified under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the '630 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Torrent's ANDA Products.

22. On March 23, 2018, Torrent Ltd. sent a letter to Lundbeck and Takeda USA that Torrent's ANDA included a Paragraph IV Certification regarding the '630 patent.

23. On May 3, 2018, Plaintiffs filed their Complaint in this Court alleging that Torrent's submission of its ANDA to the FDA infringes the '630 patent.

24. Torrent denies that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of ANDA No. 211108 infringes any valid and enforceable claim of the '630 patent.

25. This suit by Plaintiffs impairs Torrent's ability to obtain approval of its ANDA No. 211108 to commercially market Torrent's ANDA Products.

FIRST COUNT
Declaratory Judgment of Invalidity of the '630 Patent

26. Torrent realleges paragraphs 1–25 as if fully set forth herein.

27. One or more claims of the '630 patent is invalid for failure to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code §§ 101, *et seq.*, including 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially-created bases for invalidation.

28. A present, definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Torrent and Plaintiffs concerning the validity of the '630 patent.

29. Torrent is entitled to a judicial declaration that one or more claims of the '630 patent is invalid.

SECOND COUNT
Declaratory Judgment of Non-Infringement of the '630 Patent

30. Torrent realleges paragraphs 1–29 as if fully set forth herein.

31. Torrent's manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of Torrent's ANDA has not infringed, does not infringe, and would not, if

marketed, manufactured, used, sold, offered for sale, or imported, infringe, either directly and/or indirectly (whether contributorily or through inducement) any valid or enforceable claim of the '630 patent, either literally or under the doctrine of equivalents.

32. A present, definite and concrete, real and substantial, justiciable, and continuing controversy exists between Torrent and Plaintiffs concerning whether the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Torrent's ANDA will infringe any valid or enforceable claim of the '630 patent.

33. Torrent is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of Torrent's ANDA has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe, either directly and/or indirectly (whether contributorily or through inducement) any valid or enforceable claim of the '884 patent, either literally or under the doctrine of equivalents.

THIRD COUNT
(Exceptional Case)

34. Torrent realleges Paragraphs 1–33 as if fully set forth herein.

35. This case is exceptional under 35 U.S.C. § 285 and Torrent is entitled to receive its reasonable costs and attorneys' fees incurred in connection with this action.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim-Plaintiff Torrent respectfully requests that this Court enter judgment in its favor and against Plaintiffs/Counterclaim-Defendants Lundbeck and Takeda, and grant the following relief:

A. Dismissing Plaintiffs' Complaint with prejudice and enter judgment in favor of Torrent denying each and every prayer for relief contained in the Complaint;

B. Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 211108 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '630 patent, either literally or under the doctrine of equivalents;

C. Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 211108 has not induced, does not and will not induce infringement of any valid or enforceable claim of the '630 patent, either literally or under the doctrine of equivalents;

D. Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 211108 has not contributorily infringed, does not and will not contributorily infringe any valid or enforceable claim of the '630 patent, either literally or under the doctrine of equivalents;

E. Declaring that the claims of the '630 patent are invalid;

F. Declaring that this is an exceptional case pursuant to 35 U.S.C. § 285, and that Torrent be awarded its attorney fees and costs;

G. Awarding Torrent such other and further relief as this Court may deem just and proper.

Dated: May 29, 2018

CONNOLLY GALLAGHER LLP

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