

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

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H. LUNDBECK A/S, TAKEDA	:	
PHARMACEUTICAL COMPANY LTD.,	:	
TAKEDA PHARMACEUTICALS U.S.A., INC.,	:	
TAKEDA PHARMACEUTICALS	:	
INTERNATIONAL AG, and TAKEDA	:	
PHARMACEUTICALS AMERICA, INC.,	:	
		C.A. No. 1:18-cv-00853-LPS
Plaintiffs,	:	
v.	:	
	:	
MSN LABORATORIES PRIVATE LIMITED,	:	
MSN PHARMACEUTICALS, INC., and MSN	:	
PHARMACHEM PRIVATE LIMITED,	:	
	:	
Defendants.	:	

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**ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF  
MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS, INC.,  
AND MSN PHARMACHEM PRIVATE LIMITED**

Defendants MSN Laboratories Private Limited (“MSN Laboratories”), MSN Pharmaceuticals Inc. (“MSN Pharmaceuticals”), and MSN Pharmachem Private Limited (collectively “Defendants” or “MSN”), hereby answer 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”) Complaint, and present their affirmative defenses and counterclaims, as follows:

**NATURE OF THE ACTION**

1. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants admit that Plaintiffs purport to bring this action under the patent laws of the United States, pursuant to title 35 of the United States Code. Defendants admit that they have applied for approval of their Abbreviated New Drug Application (“ANDA”) No. 211101. Defendants admit that ANDA No. 211101 contains a Paragraph IV certification with regard to United States Patent No. 9,861,630 (“the ’630 patent”). To the extent there are any remaining allegations in paragraph 1 not addressed by the foregoing, Defendants deny them.

**THE PARTIES**

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2, and therefore deny the same.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3, and therefore deny the same.

4. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4, and therefore deny the same.

5. Defendants admit that Takeda Pharmaceuticals U.S.A., Inc. is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (a Food and Drug Administration publication commonly known as the “Orange Book”) as the holder of NDA No. 204447 for TRINTELLIX®. Defendants are without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in paragraph 5, and therefore deny the same.

6. Defendants admit that the Trintellix® prescribing information contains the statement “Distributed and Marketed by: Takeda Pharmaceutical America, Inc. Deerfield, IL 60015” and “Marketed by: Lundbeck, Deerfield, IL 60015.” Defendants are without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in paragraph 6, and therefore deny the same.

7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 7, and therefore deny the same.

8. Defendants admit that MSN Laboratories Private Limited is an Indian corporation, having a principal place of business at MSN House Plot No.: C-24, Industrial Estate, Sanath Nagar, Hyderabad 500018, India.

9. Defendants admit that MSN Pharmaceuticals Inc. is a Delaware corporation, having its principal place of business at 343 Thornall Street, Suite 678, Edison, New Jersey 08837.

10. Defendants admit that MSN Pharmaceuticals Inc. is a wholly owned subsidiary of MSN Laboratories Private Limited and the U.S. agent of MSN Laboratories Private Limited.

11. Defendants admit that MSN Pharmachem Private Limited is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Plot No: 212/A/B/C/D, IDA, Phase-II, Pashamylaram (Village), Patancheru (Mandal), Sangareddy (District), 502307, Telangana, India.

12. Defendants admit the websites “<http://www.msnlabs.com/>” and “<http://www.msnlabs.com/contact.html>” exist. To the extent there are any remaining allegations in paragraph 12 not addressed by the foregoing, Defendants deny them.

13. Defendants admit MSN Laboratories Private Limited develops and manufactures pharmaceutical products, including generic drug products for sale in the United States. Defendants admit MSN Pharmachem Private Limited is an API manufacturing facility and U.S. DMF holder. Defendants admit MSN Pharmaceuticals, Inc. markets and sells pharmaceutical products, including generic drug products, in the United States. To the extent there are remaining allegations in paragraph 13 not addressed by the foregoing, Defendants deny them.

14. Defendants admit MSN Laboratories Private Limited develops and manufactures pharmaceutical products, including generic drug products for sale in the United States. Defendants admit MSN Pharmachem Private Limited is an API manufacturing facility and U.S. DMF holder. Defendants admit MSN Pharmaceuticals, Inc. markets and sells pharmaceutical products, including generic drug products, in the United States. Defendants admit that MSN Pharmaceuticals, Inc. is designated as the U.S. agent of MSN Laboratories Private Limited in relation to ANDA No. 211101. To the extent there are any remaining allegations in paragraph 14 not addressed by the foregoing, Defendants deny them.

15. Defendants admit that MSN Pharmaceuticals, Inc. is designated as the U.S. agent of MSN Laboratories Private Limited in relation to ANDA No. 211101. To the extent there are any remaining allegations in paragraph 15 not addressed by the foregoing, Defendants deny them.

16. Defendants admit MSN Laboratories Private Limited develops and manufactures pharmaceutical products, including generic drug products for sale in the United States. Defendants admit MSN Pharmachem Private Limited is an API manufacturing facility and U.S. DMF holder. Defendants admit MSN Pharmaceuticals, Inc. markets and sells pharmaceutical products, including generic drug products, in the United States. Defendants admit that MSN

Pharmaceuticals, Inc. is designated as the U.S. agent of MSN Laboratories Private Limited in relation to ANDA No. 211101. To the extent there are any remaining allegations in paragraph 16 not addressed by the foregoing, Defendants deny them.

17. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets as set forth in its ANDA. Defendants admit that ANDA No. 211101 contains a Paragraph IV certification with regards to the '630 patent. To the extent there are any remaining allegations in paragraph 17 not addressed by the foregoing, Defendants deny them.

18. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets as set forth in its ANDA. In addition, Defendants are not contesting jurisdiction or venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 18 not addressed by the foregoing, Defendants deny them.

19. This paragraph contains legal conclusions to which no response is required. Defendants admit MSN Laboratories Private Limited develops and manufactures pharmaceutical products, including generic drug products for sale in the United States. Defendants admit MSN Pharmachem Private Limited is an API manufacturing facility and U.S. DMF holder. Defendants admit MSN Pharmaceuticals, Inc. markets and sells pharmaceutical products, including generic drug products, in the United States. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets as set forth in its ANDA. Defendants admit that MSN Pharmaceuticals,

Inc. is designated as the U.S. agent of MSN Laboratories Private Limited in relation to ANDA No. 211101. To the extent there are any remaining allegations in paragraph 19 not addressed by the foregoing, Defendants deny them.

**JURISDICTION AND VENUE**

20. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants admit that Plaintiffs purport to bring this action under the patent laws of the United States, pursuant to title 35 of the United States Code. To the extent there are any remaining allegations in paragraph 20 not addressed by the foregoing, Defendants deny them.

21. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants do not contest that this Court has jurisdiction over the subject matter under 28 U.S.C. §§ 1331 and 1338. To the extent there are any remaining allegations in paragraph 21 not addressed by the foregoing, Defendants deny them.

22. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting jurisdiction or venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 22 not addressed by the foregoing, Defendants deny them.

23. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting jurisdiction or venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. Defendants admit that in *H. Lundbeck A/S et al. v. MSN Laboratories Private Limited et al.*, 18-cv-00114-LPS, D.I. 15 (D. Del. April 6, 2018) they stated that ‘Defendants are not contesting personal jurisdiction in the Unites States District Court for the District of

Delaware for the limited purposes of this civil action only." To the extent there are any remaining allegations in paragraph 23 not addressed by the foregoing, Defendants deny them.

24. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting jurisdiction or venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 24 not addressed by the foregoing, Defendants deny them.

25. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting jurisdiction or venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 25 not addressed by the foregoing, Defendants deny them.

26. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting jurisdiction or venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 26 not addressed by the foregoing, Defendants deny them.

27. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting jurisdiction or venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 27 not addressed by the foregoing, Defendants deny them.

28. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting jurisdiction or venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 28 not addressed by the foregoing, Defendants deny them.

29. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting personal jurisdiction in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 29 not addressed by the foregoing, Defendants deny them.

30. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 30 not addressed by the foregoing, Defendants deny them.

31. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 31 not addressed by the foregoing, Defendants deny them.

32. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To

the extent there are any remaining allegations in paragraph 32 not addressed by the foregoing, Defendants deny them.

33. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 33 not addressed by the foregoing, Defendants deny them.

34. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in paragraph 34 not addressed by the foregoing, Defendants deny them.

35. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants are not contesting venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. Defendants admit that in *H. Lundbeck A/S et al. v. MSN Laboratories Private Limited et al.*, 18-cv-00114-LPS, D.I. 15 (D. Del. April 6, 2018) they stated that “Defendants are not contesting venue in the Unites States District Court for the District of Delaware for the limited purposes of this civil action only.” To the extent there are any remaining allegations in paragraph 35 not addressed by the foregoing, Defendants deny them.

**PLAINTIFFS’ APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS**

36. Defendants admit that Takeda Pharmaceuticals U.S.A., Inc. is listed in FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as

FDA's "Orange Book") as the holder of NDA No. 204447 for TRINTELLIX® tablets (5 mg, 10 mg, 15 mg, and 20 mg dosage strengths). Defendants admit that FDA's Orange Book states that TRINTELLIX® tablets 15 mg has been discontinued. Defendants admit that the active ingredient in TRINTELLIX® is vortioxetine hydrobromide. Defendants admit that the FDA approved New Drug Application ("NDA") No. 204447 on September 30, 2013. To the extent there are any remaining allegations in paragraph 36 not addressed by the foregoing, Defendants deny them.

37. Defendants admit that the prescribing information for TRINTELLIX® identifies it as an oral antidepressant indicated for the treatment of Major Depressive Disorder (MDD). Defendants admit that the prescribing information for TRINTELLIX® states at section 12.1 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). It also has several other activities including 5-HT3 receptor antagonism and 5-HT1A receptor agonism. The contribution of these activities to vortioxetine's antidepressant effect has not been established." To the extent there are any remaining allegations against Defendants in paragraph 37, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 37, and therefore deny the same.

38. Defendants admit that the '630 patent is listed in the Orange Book for TRINTELLIX®. To the extent there are any remaining allegations in paragraph 38 not addressed by the foregoing, Defendants deny them.

39. Defendants admit that the '630 patent indicates on its face that it issued on January 9, 2018 and is titled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl]piperazine as a

Compound with Combined Serotonin Reuptake, 5-HT<sub>3</sub> and 5-HT<sub>1A</sub> Activity for the Treatment of Cognitive Impairment.” Defendants deny that the ’630 patent was duly and lawfully issued. To the extent there are any remaining allegations against Defendants in paragraph 39, Defendants are without knowledge or information sufficient to form a belief as to their truth, and therefore deny the same.

**DEFENDANTS’ ANDA NO. 211101**

40. This paragraph contains legal conclusions to which no response is required. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets. Defendants admit that ANDA No. 211101 contains Paragraph IV certification for the ’630 patent. To the extent there are any remaining allegations in paragraph 40 not addressed by the foregoing, Defendants deny them.

41. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets. To the extent there are any remaining allegations in paragraph 41 not addressed by the foregoing, Defendants deny them.

42. Defendants admit that MSN Laboratories Private Limited sent H. Lundbeck A/S and Takeda Pharmaceuticals U.S.A., Inc. a Notice Letter dated April 23, 2018 in accordance with Sections 505(j)(2)(B)(i), (ii), (iii), and (iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(i), (ii), (iii), and (iv)) and 21 C.F.R. § 314.95 as well as all other applicable regulations. Defendants admit that the Notice Letter represented that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets and contained a Paragraph IV certification for the ’630 patent. To the extent there are any remaining allegations in paragraph 42 not addressed by the foregoing, Defendants deny them.

43. This paragraph contains legal conclusions to which no response is required. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets. Defendants admit that ANDA No. 211101 contains Paragraph IV certifications with regard to the '630 patent. To the extent there are any remaining allegations in paragraph 43 not addressed by the foregoing, Defendants deny them.

44. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets. Defendants admit that the prescribing information for TRINTELLIX<sup>®</sup> identifies it as an oral antidepressant indicated for the treatment of Major Depressive Disorder (MDD). To the extent there are any remaining allegations in paragraph 44 not addressed by the foregoing, Defendants deny them.

45. This paragraph contains legal conclusions to which no response is required. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets. Defendants admit that ANDA No. 211101 contains Paragraph IV certifications with regard to the '630 patent. To the extent there are any remaining allegations in paragraph 45 not addressed by the foregoing, Defendants deny them.

46. Denied.

47. This paragraph contains legal conclusions to which no response is required. To the extent any response is required to the allegations in paragraph 47, Defendants deny them.

#### **CLAIM FOR RELIEF**

48. Defendants restate and reincorporate their responses to paragraphs 1-47 as if fully set forth herein.

49. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets. Defendants admit that ANDA No. 211101 contains a Paragraph IV certification for the '630 patent.

50. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets. Defendants admit that ANDA No. 211101 contains a Paragraph IV certification for the '630 patent.

51. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 49, and therefore deny the same.

52. Denied.

53. Defendants admit that MSN Laboratories Private Limited applied for approval of ANDA No. 211101 with the FDA for vortioxetine hydrobromide tablets. Defendants admit that the prescribing information for TRINTELLIX® identifies it as an oral antidepressant indicated for the treatment of Major Depressive Disorder (MDD). To the extent there are any remaining allegations in paragraph 53 not addressed by the foregoing, Defendants deny them.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. This paragraph contains legal conclusions to which no response is required. To the extent any response is required to the allegations of paragraph 58, Defendants deny them.

59. Denied.

60. Denied.

**PRAYER FOR RELIEF**

Defendants deny that Plaintiffs are entitled to any of the relief requested by the Complaint, or any other remedy or relief whatsoever.

**AFFIRMATIVE DEFENSES**

Without any admission as to burden of proof, burden of persuasion, or the truth of any of the allegations in Plaintiffs' Complaint, Defendants state the following affirmative defenses. Defendants reserve the right to assert additional defenses, as warranted by the facts learned through investigation and discovery.

**First Affirmative Defense**  
**(Invalidity of U.S. Patent No. 9,861,630)**

One or more claims of the '630 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103, and 112, and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

**Second Affirmative Defense**  
**(Non-Infringement of U.S. Patent No. 9,861,630)**

Plaintiffs have failed to aver any facts that support their allegations of infringement by the proposed ANDA Products. The proposed ANDA Products, which may be marketed if and when ANDA No. 211101 receives final approval from the FDA, will not infringe any valid and enforceable claim of the '630 patent, either literally or under the doctrine of equivalents.

**Third Affirmative Defense**  
**(Estoppel)**

Plaintiffs are estopped from arguing and have waived arguments that the claims of the '630 patent covers the products described in ANDA No. 211101 by virtue of amendments, positions, and arguments made to the USPTO when obtaining the asserted patents.

**Fourth Affirmative Defense**  
**(Failure to State a Claim)**

Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

**Fifth Affirmative Defense**  
**(Lack of Standing)**

Plaintiffs do not have standing to assert claims for patent infringement under 35 U.S.C. § 271(a), (b), and (c).

**Sixth Affirmative Defense**  
**(Additional Defenses or Counterclaims)**

Defendants reserve all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent laws and any additional defenses or counterclaims that discovery may reveal including that Plaintiffs have failed to aver any facts supporting the conclusion that they have suffered any irreparable injury or harm under 35 U.S.C. § 283, and that Plaintiffs have failed to aver any facts supporting that this is an exceptional case and/or an award of attorney's fees under 35 U.S.C. § 285.

WHEREFORE, Defendants request that Plaintiffs' Complaint be dismissed with prejudice and that Defendants be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

## **COUNTERCLAIMS**

For their counterclaims against 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 “Counterclaim-Defendants” or “Lundbeck”), Counterclaim-Plaintiffs MSN Laboratories Private Limited (“MSN Laboratories”), MSN Pharmaceuticals, Inc. (“MSN Pharmaceuticals”), and MSN Pharmachem Private Limited (collectively “Counterclaim-Plaintiffs” or “MSN”), state as follows:

## **PARTIES**

1. Counterclaim-Plaintiff MSN Pharmaceuticals Inc. is a Delaware corporation, having its principal place of business at 343 Thornall Street, Suite 678, Edison, New Jersey 08837.

2. Counterclaim-Plaintiff MSN Laboratories Private Limited is an Indian corporation, having a principal place of business at MSN House Plot No.: C-24, Industrial Estate, Sanath Nagar, Hyderabad 500018, India.

3. Counterclaim-Plaintiff MSN Pharmachem Private Limited is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Plot No: 212/A/B/C/D, IDA, Phase-II, Pashamylaram (Village), Patancheru (Mandal), Sangareddy (District), 502307, Telangana, India.

4. On information from the Complaint, Counterclaim-Defendant H. Lundbeck A/S (“Lundbeck A/S”) is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. The assignment document records of the USPTO list Lundbeck A/S as the assignee of the ’630 patent.

5. On information from the Complaint, Counterclaim-Defendant 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.

6. On information from the Complaint, Counterclaim-Defendant 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.

7. On information from the Complaint, Counterclaim-Defendant 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.

8. On information from the Complaint, Counterclaim-Defendant 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.

#### **JURISDICTION AND VENUE**

9. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. This Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges of this forum by bringing this civil action in this judicial district and because, upon information and belief, Counterclaim-Defendants conduct substantial business in, and have regular and systematic contact with, this judicial district.

12. Venue for these counterclaims is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

### **FACTUAL BACKGROUND**

#### **A. FDA Approval of Brand Name Pharmaceuticals**

13. The Federal Food, Drug, and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the FDA follows when considering whether to approve the marketing of both brand-name and generic drugs.

14. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a NDA for consideration by the FDA. *See* 21 U.S.C. § 355.

15. Upon approval of the NDA, the FDA publishes patent information for the approved drug in the Orange Book. *See* 21 C.F.R. § 314.53(e).

16. The FDA’s duties with respect to the Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or “reference listed drug”), but instead relies on the NDA holder to properly list the patent.

## **B. FDA Approval of Generic Pharmaceuticals**

17. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

18. Under the Hatch Waxman Amendments, Congress provided for an Abbreviated New Drug Application (“ANDA”) as a submission for the approval of certain generic drugs. An ANDA must include, among other things, the number of any patent that allegedly claims the “drug” or a “method of using [the] drug” for which the NDA was submitted and for which a claim of patent infringement could reasonable be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1),-(c)(2); 21 C.F.R. § 314.53(b)(1),-(c)(2).

19. Among other things, an ANDA must also contain a “certification” as to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

20. A “Paragraph IV” certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4)

21. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

22. Patent holders have significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

23. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

### **C. NDA No. 204447 And The Patents-In-Suit**

24. On information and belief, the Orange Book identifies Takeda Pharmaceuticals U.S.A., Inc. is the applicant holder of NDA No. 204447.

25. NDA No. 204447 is associated with vortioxetine hydrobromide immediate-release tablets, having the proprietary name TRINTELLIX®.

26. On information and belief, Takeda Pharmaceuticals U.S.A., Inc. has listed U.S. Patent No. 7,144,884 ("the '884 patent"), U.S. Patent No. 8,476,279 ("the '279 patent"), U.S. Patent No. 8,722,684 ("the '684 patent"), U.S. Patent No. 8,969,355 ("the '355 patent"), U.S. Patent No. 9,125,908 ("the '908 patent"), U.S. Patent No. 9,125,909 ("the '909 patent"), U.S.

Patent No. 9,125,910 (“the ’910 patent”), U.S. Patent No. 9,227,946 (“the ’946 patent”), and U.S. Patent No. 9,861,630 (“the ’630 patent”) in the Orange Book as allegedly covering the TRINTELLIX® drug product, the compound vortioxetine hydrobromide, pharmaceutical compositions containing vortioxetine hydrobromide, and methods of using vortioxetine hydrobromide.

27. There is an actual and justiciable controversy between MSN and Counterclaim-Defendants as to whether the claims of the ’630 patent is infringed or will be infringed by Counterclaim-Plaintiffs’ submission of ANDA No. 211101 or by the making, using, offering to sell, importing and/or selling of the ANDA Products. *See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (“A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.”)

### **The ’630 Patent**

28. Upon information and belief, on or about May 13, 2014, the USPTO issued the ’630 patent, entitled “1-[2-(2,4-dimethylphenylsulfanyl)-phenyl]piperazine as a Compound with Combined Serotonin Reuptake, 5-HT<sub>3</sub> and 5-HT<sub>1A</sub> Activity for the Treatment of Cognitive Impairment.”

29. Upon information and belief, a copy of the '630 patent is attached as Exhibit A to the Complaint. The assignment document records of the USPTO, at Reel 043528, Frame 0434, indicate that the '630 patent is assigned to H. Lundbeck A/S.

**COUNT I**  
**(Declaratory Judgment of Invalidity of the '630 Patent)**

30. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-29 of the Counterclaims as if fully set forth herein.

31. Counterclaim-Defendants allege that the '630 patent is assigned to H. Lundbeck A/S.

32. Counterclaim-Defendants allege that Counterclaim-Plaintiffs' filing of ANDA No. 211101 infringes the '630 patent and that the manufacture, use, offer for sale, sale, or importation of the proposed ANDA Products would infringe the '630 patent.

33. As evidenced by Counterclaim-Defendants' Complaint and Counterclaim-Plaintiffs' Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the claims of the '630 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

34. Based at least upon the facts and the reasons set forth in the Detailed Statement accompanying the Notice Letter, the claims of the '630 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

35. Counterclaim-Plaintiffs are entitled to a judicial determination that the claims of the '630 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

**COUNT II**  
**(Declaratory Judgment of Non-infringement of the '630 Patent)**

36. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-35 of the Counterclaims as if fully set forth herein.

37. Counterclaim-Defendants allege that Counterclaim-Plaintiffs' filing of ANDA No. 211101 infringes the '630 patent and that the manufacture, use, offer for sale, sale, or importation of the proposed ANDA Products would infringe the '630 patent.

38. As evidenced by Counterclaim-Defendants' Complaint and Counterclaim-Plaintiffs' Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the claims of the '630 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

39. Based at least upon the facts and the reasons set forth in the Detailed Statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by Counterclaim-Plaintiffs of their proposed ANDA Products pursuant to ANDA No. 211101 will not infringe, directly or indirectly, any valid claim of the '630 patent under any provision of 35 U.S.C. § 271.

40. The proposed ANDA Products, which may be marketed upon approval of ANDA No. 211101, would not infringe any valid claim of the '630 patent, either literally or under the doctrine of equivalents.

41. Counterclaim-Plaintiffs are entitled to a judicial determination that the proposed ANDA Products which are the subject of ANDA No. 211101 have not infringed, do not infringe, and would not, if marketed, infringe any valid claim of the '630 patent.

**PRAYER FOR RELIEF**

WHEREFORE, Counterclaim-Plaintiffs respectfully request that this Court enter a judgment in its favor and against Counterclaim-Defendants as follows:

- a. Dismissing the Complaint with prejudice and entering judgment for Counterclaim-Plaintiffs;
- b. Declaring that MSN has not infringed any valid and enforceable claim of the '630 patent;
- c. Declaring that the manufacture, use, sale, offer for sale and/or importation of Counterclaim-Plaintiffs' ANDA Products pursuant to ANDA No. 211101 would not infringe any valid or enforceable claim of the '630 patent;
- d. Declaring that the claims of the '630 patent are invalid;
- e. Declaring that this case is an exceptional one pursuant to 35 U.S.C. § 285;
- f. Awarding Counterclaim-Plaintiffs their reasonable attorney's fees, costs and expenses incurred in this action; and
- g. Awarding any such other and further relief as this Court may deem proper.

**BUCHANAN INGERSOLL & ROONEY PC**

Dated: June 29, 2018

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