

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

OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 20-1428-LPS
)	
MSN LABORATORIES PVT. LTD., MSN)	
PHARMACEUTICALS INC. AND MSN)	
LIFE SCIENCES PVT. LTD.,)	
)	
Defendants.)	

MSN'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants MSN Laboratories Pvt. Ltd. (“MSN Labs”) and MSN Pharmaceuticals Inc. (“MSN Inc.”) (collectively, “MSN”) by their undersigned attorneys, hereby answer the Complaint filed by Otsuka Pharmaceutical Co., Ltd. (“Otsuka”) and H. Lundbeck A/S (“Lundbeck”) (collectively, “Plaintiffs”).¹

ANSWER TO COMPLAINT

For ease of reference, MSN incorporates the outline headings used in the Complaint. To the extent that such headings make factual allegations, characterizations of fact, or legal conclusions, MSN does not adopt or admit such statements and instead denies them. Pursuant to Fed. R. Civ. P. 8(b)(3), MSN denies all allegations in Plaintiffs’ Complaint except those expressly

¹ The Parties have agreed in principle to dismiss MSN Life Sciences Pvt. Ltd. (“MSN Life”) from this action and MSN Life has not been formally served with the Complaint in this action. Accordingly, MSN Life is not a party to this Answer. MSN Life reserves all rights with respect to all affirmative defenses and counterclaims it may raise upon proper service in the event the Parties are not able to stipulate to dismiss MSN Life.

admitted below. MSN denies that Plaintiffs are entitled to the relief requested or any other relief. With respect to the allegations in the Complaint, MSN states as follows:

NATURE OF THE ACTION

1. **Answer:** Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that this action purports to be an action for patent infringement against MSN in relation to an Abbreviated New Drug Application (“ANDA”), which seeks approval to engage in the commercial manufacture, use, sale, offer to sell and/or importation in the United States of generic pharmaceutical products, prior to the expiration of U.S. Reissue Patent No. RE48,059. MSN denies the remaining allegations of paragraph 1.

THE PARTIES

2. **Answer:** MSN is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies them.

3. **Answer:** MSN is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies them. This paragraph also contains conclusions of law to which no response is required and MSN therefore denies them on this basis too.

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

5. **Answer:** MSN admits the allegations in Paragraph 5.

6. **Answer:** MSN admits the allegations in Paragraph 6.

7. **Answer:** No response is required from MSN because the allegations of paragraph 7 are directed solely to MSN Life Sci. Pvt. Ltd (“MSN Life”), which the parties have agreed they would stipulate to dismiss from the case.

JURISDICTION AND VENUE

8. **Answer:** Paragraph 8 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, MSN does not contest subject matter jurisdiction for purposes of this civil action only. MSN denies any remaining allegations in paragraph 8.

9. **Answer:** Paragraph 9 of the Complaint contains legal conclusions to which no response is required.

10. **Answer:** MSN admits that the cited website speaks for itself. MSN denies any remaining allegations in paragraph 10.

11. **Answer:** MSN admits that the cited websites speak for themselves. MSN admits that it has applied for International Publication No. WO 2018/087775 and U.S. Publication No. 2019/0359606. MSN denies any remaining allegations in paragraph 11.

12. **Answer:** MSN Inc. admits that it is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products in the United States. MSN Inc. will not contest personal jurisdiction in this Court for purposes of this civil action only and only for claims that are properly before this Court. MSN Inc. denies any other allegations contained in Paragraph 12.

13. **Answer:** MSN admits that the cited website speaks for itself. MSN denies any remaining allegations in paragraph 13.

14. **Answer:** No response is required from MSN because the allegations of paragraph 14 are directed solely to MSN Life, which the parties have agreed they would stipulate to dismiss from the case.

15. **Answer:** No response is required from MSN because the allegations of paragraph 15 are directed solely to MSN Life, which the parties have agreed they would stipulate to dismiss from the case.

16. **Answer:** No response is required from MSN because the allegations of paragraph 16 are directed solely to MSN Life, which the parties have agreed they would stipulate to dismiss from the case.

17. **Answer:** Paragraph 17 of the Complaint contains legal conclusions to which no response is required.

18. **Answer:** MSN admits that the cited website speaks for itself. MSN denies any remaining allegations in paragraph 18,

19. **Answer:** MSN admits that the cited website speaks for itself. MSN denies any remaining allegations in paragraph 19.

20. **Answer:** To the extent the allegations of paragraph 20 are directed to MSN Life, no response is required from MSN because the parties have agreed they would stipulate to dismiss MSN Life from the case. To the extent the allegations of paragraph 20 are directed to MSN Labs, MSN Labs states that the cited website speaks for itself. MSN denies any remaining allegations in paragraph 20.

21. **Answer:** Paragraph 21 contains legal conclusions to which no response is required and MSN therefore denies them. To the extent a response is required, MSN is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 21 because they relate to speculative future events, and therefore, denies them on this basis too.

22. **Answer:** Paragraph 22 contains legal conclusions to which no response is required and MSN therefore denies them. To the extent a response is required, MSN admits that it submitted ANDA No. 213740 to FDA. MSN denies the remainder of the allegations in paragraph 22.

23. **Answer:** MSN admits that it submitted ANDA No. 213740 to FDA. MSN denies the remainder of the allegations in paragraph 22.

24. **Answer:** To the extent the allegations of paragraph 24 are directed to MSN Life, no response is required from MSN because the parties have agreed they would stipulate to dismiss MSN Life from the case. To the extent the allegations of paragraph 20 are directed to MSN Labs, for purposes of this case only, MSN Labs does not contest venue in this Court.

25. **Answer:** Paragraph 25 contains conclusions of law to which no response is required and MSN therefore denies them. For purposes of this case only, MSN Inc. does not contest venue in this Court.

FACTUAL BACKGROUND

The NDA

26. **Answer:** MSN admits only that the electronic version of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") currently lists "Otsuka Pharm Co Ltd" as the apparent holder of New Drug Application ("NDA") No. 205422 for REXULTI® tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms ("REXULTI® Tablets"). MSN is without knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 26, and therefore denies them.

27. **Answer:** MSN admits that the electronic version of the Orange Book currently lists the approval date of NDA No. 205422 as July 10, 2015. MSN denies all other allegations in Paragraph 27.

28. **Answer:** Paragraph 28 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, MSN admits that the “Indications and Usage” section for the labeling for REXULTI® Tablets approved February 9, 2018, states that REXULTI® is indicated for “Adjunctive treatment of major depressive disorder (MDD)” and “Treatment of schizophrenia.” MSN also admits that the Orange Book lists the brexpiprazole as the active ingredient of REXULTI®. MSN denies all other allegations in Paragraph 28.

The Patent In Suit

29. **Answer:** MSN admits that the face of the ’362 patent lists its title as “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders” and that the face of the patent includes an issue date of February 15, 2011.

30. **Answer:** MSN admits that the face of the RE’059 patent lists an issue date of June 23, 2020. MSN also admits that the file history on record at the United States Patent and Trademark Office (“USPTO”) for RE’059 indicates the ’362 patent was reissued as the RE’059 patent. MSN further admits that Exhibit A to the Complaint purports to be a copy of the RE’059 patent.

31. **Answer:** MSN admits that the file history of the RE’059 patent identifies Otsuka as the purported assignee. MSN lacks sufficient knowledge or information sufficient to form a belief as to the truth of the remaining allegations and therefore denies them.

32. **Answer:** Paragraph 32 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, MSN admits that Exhibit B of the Complaint purports to be a copy of a document entitled “Terminal Disclaimer.” MSN further states that the document speaks for itself. MSN denies all other allegations in Paragraph 32.

33. **Answer:** MSN is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 33, and therefore denies them.

34. **Answer:** MSN admits that the RE'059 patent is currently listed in the Orange Book in connection with NDA No. 205422 for REXULTI® Tablets.

The ANDA

35. **Answer:** MSN admits that it filed ANDA No. 213740 with FDA under 21 U.S.C. § 355(j). To the extent there are any remaining factual allegations in paragraph 35, MSN denies them.

36. **Answer:** Paragraph 36 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, MSN admits that it sent Otsuka a “Notice of Paragraph IV Certification” for ANDA No. 213740 (“MSN’s First Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95 dated September 5, 2019 and that the letter speaks for itself. Upon information and belief, and as Plaintiffs allege in their Complaint, Otsuka received MSN’s September 5, 2019 Notice Letter. MSN denies all other allegations in Paragraph 36.

37. **Answer:** MSN admits that Plaintiffs filed a separate action in this court against MSN for infringement of U.S. Patent No. 7,888,362 (“the ’362 patent”), and U.S. Patent Nos. 8,349,840 (“the ’840 patent”), 8,618,109 (“the ’109 patent”), 9,839,637 (“the ’637 patent”) and 10,307,419 (“the ’419 patent”). MSN is without knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 37, and therefore denies them.

38. **Answer:** MSN admits that the file history for RE'059 states that the ’362 patent was issued as the RE'059 patent and that the face of the RE'059 patent includes an issue date of June 23, 2020 and that it is listed in the Orange Book for REXULTI®. MSN is without knowledge

or information to form a belief as to the truth of the remaining allegations of Paragraph 38, and therefore denies them.

39. **Answer:** MSN admits that ANDA No. 213740 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certification”) that the claims of the RE’059 patent are invalid, unenforceable and/or would not be infringed by MSN’s ANDA Products. MSN denies any remaining allegations of this paragraph.

40. **Answer:** MSN admits that it sent a letter, dated September 9, 2020, to Otsuka providing a “Notice of Certification” for ANDA No. 213740 (“MSN’s September 9, 2020, Second Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. MSN states that its September 9, 2020 letter speaks for itself. MSN denies any remaining allegations of this paragraph.

41. **Answer:** MSN is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 41, and therefore denies them.

COUNT I
(INFRINGEMENT OF THE RE’059 PATENT)

42. **Answer:** MSN incorporates its answers to Paragraph 1-41, as if fully set forth herein.

43. **Answer:** MSN admits that it filed ANDA No. 213740 seeking approval to market its ANDA Products in the United States. MSN denies the remaining allegations in Paragraph 43.

44. **Answer:** MSN admits that it filed certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the RE’059 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or importation of MSN’s ANDA product. MSN denies the remaining allegations in Paragraph 44.

45. **Answer:** MSN admits that it filed ANDA No. 213740 seeking approval to market its ANDA Products in the United States. MSN denies the remaining allegations in Paragraph 45.

46. **Answer:** Paragraph 46 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, MSN's September 9, 2020, Second Notice Letter speaks for itself. MSN denies all other allegations in Paragraph 46.

47. **Answer:** Paragraph 47 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, denied.

48. **Answer:** MSN is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 48 because they relate to speculative future events, and therefore, denies them.

49. **Answer:** Paragraph 49 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, denied.

50. **Answer:** MSN admits that it filed ANDA No. 213740 seeking approval to market its ANDA Products in the United States. MSN denies the remaining allegations in Paragraph 50.

51. **Answer:** Paragraph 51 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, denied.

52. **Answer:** Paragraph 52 of the Complaint contains allegations and/or legal conclusions to which no response is required. To the extent a response is required, denied.

GENERAL DENIAL AND RESPONSE TO REQUEST FOR RELIEF

Any allegations in the Complaint not expressly admitted by MSN are denied. MSN denies that Plaintiffs are entitled to any judgment or relief requested in Paragraphs (A) through (H) of their "Request for Relief."

AFFIRMATIVE DEFENSES

An allegation of any defense below is not an admission that Hetero bears the burden of proof or persuasion on any claim or issue.

First Affirmative Defense – Non-Infringement of the Claims of the RE'059 Patent

MSN has not infringed, is not infringing, will not infringe, will not induce to infringe, and will not contribute to infringement of, literally or under the doctrine of equivalents, any valid and enforceable claims of the RE'059 patent.

Second Affirmative Defense – Invalidity of the Claims of the RE'059 Patent

The claims of the RE'059 patent are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 251 and/or for obviousness-type double patenting.

Third Affirmative Defense – Failure to State a Claim

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

Fourth Affirmative Defense – No Injunctive Relief

Plaintiffs may not seek injunctive relief under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 against MSN because Plaintiff's alleged damages are not irreparable and Plaintiffs have an adequate remedy at law.

Sixth Affirmative Defense – Collateral Estoppel

Plaintiffs' claims are barred, in whole or in part, by the doctrine of collateral estoppel.

Seventh Affirmative Defense – No Exceptional Case

MSN's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Seventh Affirmative Defense – No Costs

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

COUNTERCLAIMS

In further response to the Complaint, Defendants MSN Laboratories Pvt. Ltd. (“MSN Labs”) and MSN Pharmaceuticals Inc. (“MSN Inc.”) (collectively, “MSN”), without admitting any of the allegations of Plaintiffs other than those expressly admitted herein, and without prejudice of the rights of MSN to plead additional Counterclaims as the facts of the matter warrant, alleges as follows:

THE PARTIES

1. MSN Laboratories Pvt. Ltd. (“MSN Labs”) is a corporation
2. MSN Pharmaceuticals Inc. (“MSN Inc.”) is a corporation
3. On information and belief, Counterclaim Defendant Otsuka Pharmaceutical Co. Ltd. (“Otsuka”) is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535 Japan.
4. Upon information and believe, Counterclaim Defendant 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.

JURISDICTION AND VENUE

5. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Otsuka and Lundbeck (collectively, “Counterclaim Defendants”) because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their Complaint here.

7. Venue is proper in this District pursuant to §§ 1391 and 1400(b).

8. There is an actual justiciable controversy between the parties as to the infringement and validity of U.S. Reissue Patent No. RE48,059 (the “RE’059 patent”).

FACTUAL BACKGROUND

9. The United States Food & Drug Administration (“FDA”) publication titled Approved Drug Products and Therapeutic Equivalence Evaluations (the “Orange Book”) lists Otsuka as the holder of approved New Drug Application (“NDA”) No. 205422.

10. The FDA granted approval for brexpiprazole tablets in 0.25, 0.5, 1, 2, 3 and 4 mg dosage forms marketed in the United States under the trade name REXULTI® (“REXULTI® Tablets”).

11. Pursuant to FDA requirements, the Orange Book maintained by the FDA lists patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The Orange Book lists the RE’059 patent in association with NDA No. 205422, for REXULTI® Tablets. Upon information and belief, Otsuka caused the RE’059 patent to be listed in the Orange Book in connection with NDA No. 205422.

12. Upon information and belief, the RE’059 patent was issued on or about June 23, 2020, and states on its face that it was assigned to Otsuka.

13. MSN filed ANDA No. 213740 with FDA under 21 U.S.C. § 355(j), seeking approval for brexpiprazole tablets 0.25, 0.5, 1, 2, 3, and 4 mg (“MSN’s ANDA Products”).

14. MSN sent Otsuka a “Notice of Paragraph IV Certification” for ANDA No. 213740 pursuant to 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95 stating that the RE’059 patent is invalid, unenforceable, or not infringed by MSN’s ANDA Products. MSN sent this letter on September 9, 2020 (“MSN’s September 9, 2020, Second Notice Letter”) providing a detailed statement of the factual and legal bases as to why the claims of the RE’059 patent are invalid or not infringed, directly or indirectly, either literally or under the

doctrine of equivalents, by commercial manufacture, use, offer for sale, and/or sale of MSN's ANDA Products.

15. Counterclaim Defendants initiated the present litigation by filing a complaint against MSN on October 23, 2020. In this complaint, Counterclaim Defendants alleged that MSN has infringed and will infringe the RE'059 patent by filing MSN's ANDA with the FDA and/or by manufacturing, using, or selling the product described in MSN's ANDA.

16. As a consequence of the foregoing, there is an actual and justiciable controversy between MSN and Counterclaim Defendants as to whether the claims of the RE'059 patent are invalid, and whether those claims are being infringed or will be infringed by MSN's ANDA or by the manufacture, use, or sale of MSN's ANDA Products.

COUNT I
Declaratory Judgment of Non-Infringement of the RE'059 Patent

17. MSN realleges and incorporates by reference the allegations of paragraphs 1-16 as though fully set forth herein.

18. A present, genuine, and justiciable controversy exists between MSN and Counterclaim Defendants regarding, inter alia, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of MSN's ANDA Products would infringe any valid or enforceable claim of the RE'059 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

19. The manufacture, use, offer for sale, sale, importation, and/or marketing of MSN's ANDA Products would not infringe any valid or enforceable claim of the RE'059 patent, either directly or indirectly.

20. MSN is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the RE'059 patent.

COUNT II
Declaratory Judgment of Invalidity of the RE'059 Patent

21. MSN realleges and incorporates by reference the allegations of paragraphs 1-20 as though fully set forth herein.

22. A present, genuine, and justiciable controversy exists between MSN and Counterclaim Defendants regarding, inter alia, the invalidity of the RE'059 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

23. In accordance with 21 U.S.C. § 355(j)(2)(B), MSN's September 9, 2020 Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the RE'059 patent are invalid.

24. Upon information and belief, the claims of the RE'059 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., the doctrine of obviousness-type double-patenting, and/or judicially created doctrines of invalidity or unenforceability.

25. Non-limiting examples are set forth in the September 9, 2020 notice letter, explaining that one or more claims of the RE'059 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the RE'059 patent.

26. MSN is entitled to a judicial declaration that the claims of the RE'059 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

PRAYER FOR RELIEF

WHEREFORE, MSN respectfully prays for judgment in its favor and against Counterclaim Defendants:

- (a) Declaring that the filing of MSN's ANDA did not infringe one or more valid and enforceable claims of the RE'059 patent;
- (b) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of MSN's ANDA Products described in MSN' ANDA has not infringed, does not infringe, and would not – if made used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of the RE'059 patent either literally or under the doctrine of equivalents;
- (c) Declaring that the claims of the RE'059 patent is invalid;
- (d) Ordering that the Complaint be dismissed with prejudice and judgment entered in favor of MSN;
- (e) Denying Plaintiffs/Counterclaim Defendants any of the relief they request in the Complaint;
- (f) Declaring this case exceptional in favor of MSN pursuant to 35 U.S.C. § 285;
- (g) Awarding costs and attorneys' fees to MSN; and
- (h) Awarding MSN such other and further relief as the Court may deem just and proper.

Respectfully submitted,

/s/ John M. Seaman

OF COUNSEL:

Neal Seth
Teresa M. Summers
WILEY
1776 K Street, NW
Washington, DC 20036
(202) 719-7000 phone
(202) 719-7049 facsimile
nseth@wiley.law
tsummers@wiley.law

John M. Seaman (#3868)
April M. Kirby (#6152)
ABRAMS & BAYLISS LLP
20 Montchanin Road, Suite 200
Wilmington, Delaware 19807
(302) 778-1000 phone
(302) 778-1001 facsimile
seaman@abramsbayliss.com
akirby@abramsbayliss.com

*Attorneys for Defendants MSN Laboratories
PVT. LTD. and MSN Pharmaceuticals Inc.*

Dated: February 9, 2021