

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

OTSUKA PHARMACEUTICAL CO., LTD.,
AND H. LUNDBECK A/S,

Plaintiffs,

v.

OPTIMUS PHARMA PVT. LTD.,

Defendant.

C.A. No. 1:20-cv-1332-LPS

**DEFENDANT OPTIMUS PHARMA PVT. LTD.'S
ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Optimus Pharma Pvt. Ltd. ("Optimus" or "Defendant"), by and through its undersigned attorneys, respond to the Complaint filed by Plaintiffs Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S ("Plaintiffs") as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Optimus denies all allegations in Plaintiffs' Complaint, except those expressly admitted below.

NATURE OF THE ACTION

1. Optimus admits that Plaintiffs' complaint appears to raise a patent infringement action arising under Title 35 of the United States Code and concerning an Abbreviated New Drug Application ("ANDA") submitted to the United States Food and Drug Administration ("FDA") by Optimus seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic pharmaceutical products prior to the expiration of U.S. Reissue Patent No. RE48,059

(“the RE’059 patent”). Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in paragraph 1 and, therefore, denies them on this basis.

PARTIES

2. On information and belief, Optimus admits Plaintiff Otsuka Pharmaceutical Co., Ltd.’s (“Otsuka”) principal place of business. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in paragraph 2 and, therefore, denies them on this basis.

3. On information and belief, Optimus admits Plaintiff H. Lundbeck A/S’s (“Lundbeck”) principal place of business. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in paragraph 3 and, therefore, denies them on this basis.

4. Optimus is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 4 and, therefore, denies them on this basis.

5. Optimus admits that it is a corporation organized under the laws of India and does business at 2nd Floor, Sy No. 37/A & 37/P, Plot No. 6P, Signature Towers, Kothaguda, Kondapur, Hyderabad 500084, Telangana, India. Optimus denies the remaining allegations contained in this paragraph.

JURISDICTION AND VENUE

6. This paragraph contains legal conclusions to which no answer is required.
7. This paragraph contains legal conclusions to which no answer is required.

For purposes of this action only, Optimus does not contest that personal jurisdiction is

proper as to Optimus. To the extent that a response is required, Optimus denies the remaining allegations in this paragraph.

8. Optimus states that the documents cited by the Complaint speak for themselves. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in paragraph 8 and, therefore, denies them on this basis.

9. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Optimus does not contest that personal jurisdiction is proper as to Optimus. To the extent that a response is required, Optimus denies the remaining allegations in this paragraph.

10. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Optimus does not contest that personal jurisdiction is proper as to Optimus. To the extent that a response is required, Optimus denies the remaining allegations in this paragraph.

11. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Optimus does not contest that personal jurisdiction is proper as to Optimus. To the extent that a response is required, Optimus denies the remaining allegations in this paragraph.

12. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Optimus does not contest that venue is proper as to Optimus. To the extent that a response is required, Optimus denies the remaining allegations in this paragraph.

FACTUAL BACKGROUND

The NDA

13. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

14. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

15. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

The Patent In Suit

16. Optimus admits that the face of U.S. Patent No. 7,888,362 ("the '362 patent"), lists "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" as and that the '362 patent has an issue date of February 15, 2011. Optimus denies the remaining allegations in this paragraph.

17. Optimus admits that face of the RE'059 patent has a reissue date of June 23, 2020. Optimus admits that a copy of the RE'059 patent appears to be included as Exhibit A to the Complaint. Optimus denies that the RE '059 is duly and legally issued. Optimus denies the remaining allegations in this paragraph.

18. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

19. Optimus admits that a copy of the terminal disclaimer appears to be included as Exhibit B to the Complaint. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

20. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

21. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

The ANDA

22. Optimus admits that it filed ANDA No. 213758 with the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg ("Optimus's generic products"). Optimus denies the remaining allegations contained in this paragraph.

23. Optimus admits that on or about September 16, 2019, Optimus sent a letter notifying Otsuka of ANDA No. 213758 and that this letter speaks for itself.

24. Optimus admits that the action *Otsuka Pharmaceutical Co., Ltd., et al. v. Optimus Pharma Pvt. Ltd.*, C.A. No. 19-2008-LPS is pending and further states that the

action speaks for itself. Optimus denies the remaining allegations contained in this paragraph.

25. Optimus admits that RE'059 is listed in the Orange Book for REXULTI®. Optimus is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

26. Optimus states that ANDA 213758 speaks for itself. Optimus denies the remaining allegations contained in this paragraph.

27. Optimus admits that on or about August 17, 2020, Optimus sent a letter notifying Otsuka of ANDA No. 213758 and that this letter speaks for itself. Optimus denies the remaining allegations contained in this paragraph.

28. Optimus admits that on information and belief, this action was commenced on October 1, 2020.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

29. Optimus incorporates its responses to the preceding paragraphs as if fully stated herein.

30. Optimus admits that it filed ANDA No. 213758, and that this ANDA speaks for itself.

31. Optimus admits that it filed a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), and that this certification speaks for itself.

32. Optimus states that ANDA No. 213758 speaks for itself. Optimus denies the remaining allegations contained in this paragraph.

33. Optimus states that Optimus' Second Notice Letter speaks for itself. Optimus denies the remaining allegations contained in this paragraph.

34. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Optimus denies the allegations contained in this paragraph.

35. Optimus is without sufficient information or knowledge to admit or deny the allegations contained in this paragraph and, therefore, denies them on this basis.

36. Optimus denies the allegations contained in this paragraph.

37. Optimus denies the allegations contained in this paragraph.

38. Optimus denies the allegations contained in this paragraph.

39. Optimus denies the allegations contained in this paragraph.

REQUEST FOR RELIEF

- A. Optimus denies that Plaintiffs are entitled to any of the relief requested in this paragraph of its Request for Relief or to any relief whatsoever.
- B. Optimus denies that Plaintiffs are entitled to any of the relief requested in this paragraph of its Request for Relief or to any relief whatsoever.
- C. Optimus denies that Plaintiffs are entitled to any of the relief requested in this paragraph of its Request for Relief or to any relief whatsoever.
- D. Optimus denies that Plaintiffs are entitled to any of the relief requested in this paragraph of its Request for Relief or to any relief whatsoever.

- E. Optimus denies that Plaintiffs are entitled to any of the relief requested in this paragraph of its Request for Relief or to any relief whatsoever.
- F. Optimus denies that Plaintiffs are entitled to any of the relief requested in this paragraph of its Request for Relief or to any relief whatsoever.
- G. Optimus denies that Plaintiffs are entitled to any of the relief requested in this paragraph of its Request for Relief or to any relief whatsoever.
- H. Optimus denies that Plaintiffs are entitled to any of the relief requested in this paragraph of its Request for Relief or to any relief whatsoever.

DEFENDANT'S AFFIRMATIVE DEFENSES

Optimus asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Optimus does not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Optimus reserves the right to assert other defenses and/or to supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST AFFIRMATIVE DEFENSE

(No Direct Infringement)

Optimus does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claims of the RE'059 patent, and if the products that are the subject of ANDA No. 213758 were marketed, Optimus would not infringe, either

literally or under the doctrine of equivalents, any valid and enforceable claims of the RE'059 patent.

SECOND AFFIRMATIVE DEFENSE

(No Indirect Infringement)

Optimus has not induced or contributed to, and does not and will not induce or contribute to, the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claims of the RE'059 patent, and if the products that are the subject of ANDA No. 213758 were marketed, Optimus would not induce or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claims of the RE'059 patent.

THIRD AFFIRMATIVE DEFENSE

(Invalidity)

The claims of the RE'059 patent are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE

(Prosecution History Estoppel)

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent application leading to the RE'059 patent, Plaintiffs are estopped from maintaining that any valid or enforceable claims of the RE'059 patent are infringed by the product that is the subject of Optimus's ANDA No. 213758.

FIFTH AFFIRMATIVE DEFENSE

(Failure to State a Claim)

Plaintiffs have failed to state a claim upon which relief can be granted.

WHEREFORE, Defendant Optimus Pharma Ltd. having fully answered Plaintiffs' Complaint, respectfully prays to be dismissed with its costs expended herein, and for such other and further relief as is just and proper.

Dated: October 31 2020

Respectfully submitted,

/s/ Stamatiou Stamboulis

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