

IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE

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

Plaintiffs,

v.

AJANTA PHARMA LTD.,

Defendant.

C.A. No. 1:20-cv-01335-UNA

**DEFENDANT AJANTA PHARMA LTD.'S  
ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Ajanta Pharma Ltd. ("Ajanta" 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), Ajanta denies all allegations in Plaintiffs' Complaint, except those expressly admitted below.

**NATURE OF THE ACTION**

1. Ajanta admits that Plaintiffs' complaint appears to raise a patent infringement action arising under Title 35 of the United States Code and concerning Abbreviated New Drug Applications ("ANDAs") submitted to the United States Food and Drug Administration ("FDA") by Ajanta 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”). Ajanta 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, Ajanta admits Plaintiff Otsuka Pharmaceutical Co., Ltd.’s (“Otsuka”) principal place of business. Ajanta 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, Ajanta admits Plaintiff H. Lundbeck A/S’s (“Lundbeck”) principal place of business. Ajanta 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. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 4 and, therefore, denies them on this basis.

5. Ajanta admits that it is a corporation organized under the laws of India and does business at 98, Ajanta House, Government Industrial Area, Charkop, Kandivali (West), Mumbai, Maharashtra 400067 India. Ajanta denies the remaining allegations contained in this paragraph.

**JURISDICTION AND VENUE**

6. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Ajanta does not contest that subject matter jurisdiction is proper.

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

For purposes of this action only, Ajanta does not contest that personal jurisdiction is proper as to Ajanta. To the extent that a response is required, Ajanta denies the remaining allegations in this paragraph.

8. Ajanta states that the webpage cited by Plaintiffs speaks for itself. To the extent that a response is required, Ajanta denies the remaining allegations in this paragraph.

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

For purposes of this action only, Ajanta does not contest that personal jurisdiction is proper as to Ajanta. To the extent that a response is required, Ajanta 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, Ajanta does not contest that personal jurisdiction is proper as to Ajanta. To the extent that a response is required, Ajanta 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, Ajanta does not contest that personal jurisdiction is proper as to Ajanta. To the extent that a response is required, Ajanta 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, Ajanta does not contest that venue is proper as to

Ajanta. To the extent that a response is required, Ajanta denies the remaining allegations in this paragraph.

### **FACTUAL BACKGROUND**

#### **The NDA**

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

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

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

#### **The Patent In Suit**

16. Ajanta 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 its title and further states that the '362 patent has an issue date of February 15, 2011. Ajanta denies the remaining allegations in this paragraph.

17. Ajanta admits the faces of the RE'059 patent has a reissue date of June 23, 2020. Ajanta admits that a copy of the RE'059 patent appears to be included as Exhibit A to the Complaint. Ajanta denies the remaining allegations in this paragraph.

18. Ajanta 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. Ajanta admits that a copy of the terminal disclaimer appears to be included as Exhibit B to the Complaint. Ajanta 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. Ajanta 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. Ajanta admits that the RE'059 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

**The ANDA**

22. Ajanta admits that it filed ANDA No. 213718 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 ("Ajanta's generic products"). Ajanta denies the remaining allegations contained in this paragraph.

23. Ajanta admits that on or about August 30, 2019, Ajanta sent a letter notifying Otsuka of ANDA No. 213718 and that this letter speaks for itself.

24. Ajanta admits that the action *Otsuka Pharmaceutical Co., Ltd., et al. v. Ajanta Pharma Ltd.*, C.A. No. 19-1939-LPS is pending and states that that action speaks for itself. Ajanta denies the remaining allegations contained in this paragraph.

25. Ajanta admits that RE'059 is listed in the Orange Book for REXULTI®.

Ajanta 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. Ajanta states that ANDA 213718 speaks for itself.

27. Ajanta admits that on or about August 17, 2020, Ajanta sent a letter and that this letter speaks for itself. Ajanta denies the remaining allegations contained in this paragraph.

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

**COUNT I**

**(INFRINGEMENT OF THE RE'059 PATENT)**

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

30. Ajanta admits that it filed ANDA No. 213718, and that this ANDA speaks for itself.

31. Ajanta 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. Ajanta admits that ANDA No. 213718 speaks for itself. Ajanta denies the remaining allegations contained in this paragraph.

33. Ajanta states that its August 17, 2020 letter speaks for itself. Ajanta denies the remaining allegations contained in this paragraph.

34. Ajanta denies the allegations contained in this paragraph.
35. Ajanta denies the allegations contained in this paragraph.
36. Ajanta denies the allegations contained in this paragraph.
37. Ajanta denies the allegations contained in this paragraph.
38. Ajanta denies the allegations contained in this paragraph.
39. Ajanta denies the allegations contained in this paragraph.

**REQUEST FOR RELIEF**

- A. Ajanta 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. Ajanta 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. Ajanta 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. Ajanta 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. Ajanta 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. Ajanta 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. Ajanta 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. Ajanta 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**

Ajanta asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Ajanta 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. Ajanta 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)**

Ajanta 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. 213718 were marketed, Ajanta 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)**

Ajanta 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. 213718 were marketed, Ajanta 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 Ajanta's ANDA No. 213718.

**FIFTH AFFIRMATIVE DEFENSE**

**(Failure to State a Claim)**

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

WHEREFORE, Defendant Ajanta 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: November 2, 2020

Respectfully submitted,

/s/ Stamatios Stamoulis

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