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

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|---|---|---|
| OTSUKA PHARMACEUTICAL CO., LTD. and H. LUNDBECK A/S, | ) | |
| | ) | C.A. No. 20-1295-LPS |
| Plaintiffs, | ) | |
| v. | ) | |
| UNICHEM LABORATORIES LTD., | ) | |
| Defendant. | ) | |

## ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANT

Defendant Unichem Laboratories Ltd. ("Defendant" or "Unichem"), by and through its attorneys, responds to the numbered paragraphs of the Complaint filed by Plaintiffs Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively "Plaintiffs"), as follows:

## NATURE OF THE ACTION

1. Defendant admits that this action purports to be an action alleging infringement of the recited patents, and that Defendant seeks FDA approval to market the products that are the subject of an ANDA Defendant filed under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") before the expiration of the recited patents. However, Defendant denies the substantive allegation of patent infringement inferred by paragraph 1 of the Complaint.

## PARTIES

2. On information and belief, Defendant admits that 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.

3. On information and belief, Defendant admits that Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Defendant lacks sufficient information regarding assignment and licensing of the RE'059 patent to admit or deny this allegation, and therefore denies the same.

4. Defendant admits that Otsuka and Lundbeck are in the business of researching, developing, and bringing to market pharmaceutical products, but denies that any product covered by the claims of the patents in suit is innovative.

5. Defendant admits that it is a corporation organized under the laws of India, but denies that the listed place of business is its principal place of business.

**JURISDICTION AND VENUE**

6. Admitted.

7. Defendant does not dispute that this Court has personal jurisdiction for purposes of this action only, and otherwise denies the allegations of Paragraph 7 of the Complaint.

8. Defendant admits that the quoted statement is an accurate copy of text residing on the referenced website on the date it was alleged to have been accessed.

9. Defendant admits that the quoted statement is an accurate copy of text residing on the referenced website on the date it was alleged to have been accessed.

10. Admitted.

11. Defendant denies the allegations of Paragraph 11 of the Complaint as phrased, but does not contest personal jurisdiction in this Court solely for the purposes of this action.

12. Defendant denies the allegations of Paragraph 12 of the Complaint as phrased, but does not contest personal jurisdiction in this Court solely for the purposes of this action.

13. Defendant denies the allegations of Paragraph 13 of the Complaint as phrased, but admits that it has sought, and continues to seek, FDA approval to market the products that are the subject of ANDA No. 213710

14. Defendant denies the allegations of Paragraph 14 of the Complaint as phrased, but does not contest that venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) solely for the purposes of this action.

## FACTUAL BACKGROUND

### The NDA

15. Admitted.

16. Admitted.

17. Admitted.

### The Patent in Suit

18. Admitted.

19. Admitted.

20. Admitted.

21. Admitted.

22. Admitted.

23. Admitted.

### The ANDA

24. Admitted.

25. Admitted.

26. Admitted.

27. Admitted.

28. Admitted.

29. Admitted.

30. Admitted.

**COUNT I**

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

31. Defendant incorporate its responses to each preceding paragraph as if fully set forth herein.

32. Admitted.

33. Admitted.

34. Denied.

35. Admitted.

36. Defendant admits that filing its ANDA with a Paragraph IV certification to the '362 patent constituted a technical act of infringement of that patent under 35 U.S.C. § 271(e). Defendant denies the balance of the allegations of paragraph 36 of the Complaint.

37. Defendant states that as for all events that may or may not occur upon approval by the FDA of Unichem's ANDA, it lacks sufficient information to admit or deny said allegations, and therefore denies the same.

38. Denied.

39. Admitted.

40. Denied.

41. Denied.

## RESPONSE TO REQUEST FOR RELIEF

Unichem denies that Plaintiffs are entitled to any of the relief requested by the Complaint, or to any other relief whatsoever.

## AFFIRMATIVE DEFENSES

In further response to the Complaint, and as additional defenses thereto, Defendant asserts the following affirmative defenses without prejudice to any denial in its Answer and without admission to any allegation in the Complaint, unless otherwise explicitly admitted above. Defendant reserves the right to assert additional defenses in view of further information and/or analysis.

### FIRST SEPARATE DEFENSE
**(Non-Infringement)**

The manufacture, use, sale, offer for sale, or importation of Defendant's ANDA products have not, do not and will not infringe any valid and enforceable claim of the RE'059 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

### SECOND SEPARATE DEFENSE
**(Invalidity of the RE'059 Patent)**

For the reasons stated in the detailed statement accompanying the letter that is the subject of Paragraphs 25 and 29 of the Complaint, the claims of the RE'059 patent is invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112.

### THIRD SEPARATE DEFENSE
**(Lack of Irreparable Harm)**

Plaintiffs have planned for, and in fact anticipated, the filing of several ANDA applications with the FDA for the approval of generic forms of its REXULTI® product for many years.

Accordingly, should Defendant's ANDA products be approved and should those products further be sold in the United States market, Plaintiffs would not be irreparably harmed as a result of such anticipated competition. Further, should such sales occur, there are adequate remedies at law available, assuming such sales are found to be infringing any patent in suit, and should said patents be deemed valid. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

**FOURTH SEPARATE DEFENSE**
**(Failure To State A Claim)**

The Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

**FIFTH SEPARATE DEFENSE**
**(Other Defenses)**

Defendant reserves 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 this is an exceptional case and an award of attorney's fees under 35 U.S.C. § 285 is warranted.

**PRAYER FOR RELIEF**

**WHEREFORE**, Unichem respectfully requests the Court to enter judgment against Plaintiffs to include:

(a) Dismissing the Complaint with prejudice;

(b) Finding that Unichem's submission of ANDA No. 213710 seeking FDA approval to market its ANDA products will not directly, indirectly, contributorily, and/or by

inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the RE'059 patent under 35 U.S.C. § 271;

(c) Finding that the claims of the patents-in-suit are invalid for failure to comply with one or more provisions of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103 and/or 112 as well as any non-statutory judicially created doctrine;

(d) Finding in Unichem's favor on any or all of the affirmative defenses set forth herein; and

(e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Unichem its attorneys' fees, costs and expenses.

*/s/ Kelly E. Farnan*

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