IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., MSD INTERNATIONAL BUSINESS GMBH, MSD INTERNATIONAL GMBH, PFIZER INC., and PF PRISM IMB B.V., Plaintiff, v. ZENARA PHARMA PRIVATE LIMITED, Defendant.	C.A. No. 22-379-VAC

DEFENDANT ZENARA PHARMA PRIVATE LIMITED'S ANSWER TO COMPLAINT, AND ADDITIONAL DEFENSES

Defendant Zenara Pharma Private Limited ("Zenara" or "Defendant") by its counsel, hereby responds to the allegations set forth in the Plaintiffs Merck Sharp & Dohme Corp. ("Merck"), MSD International Business GmbH ("MSD International Business"), MSD International GmbH ("MSD International"), Pfizer Inc. ("Pfizer"), and PF PRISM IMB B.V.'s ("PRISM") (collectively "Plaintiffs") Complaint for patent infringement against Zenara under 35 U.S.C. § 271(e)(2). This response is based on Zenara's current knowledge as to its own activities, and on information and belief as to the activities of others. If not specifically admitted herein, the allegations of the Complaint are denied.

NATURE OF THE ACTION

1. Zenara admits that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 271(e)(2). Zenara further admits that Plaintiffs purport to seek relief from alleged infringement by Zenara of U.S. Patent No. 8,080,580 ("the '580 patent"). Zenara admits that it filed ANDA No. 216842 with the FDA for approval to sell its ANDA Product, as a generic

version of Steglatro® (ertugliflozin) in 5 and 15 mg strength tablets ("Zenara's Proposed ANDA Product") prior to the expiration of the '580 patent. Zenara denies the remaining allegations in this paragraph.

PARTIES

2. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint, and therefore denies them.

3. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint, and therefore denies them.

4. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint, and therefore denies them.

5. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 5 of the Complaint, and therefore denies them.

6. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 6 of the Complaint, and therefore denies them.

7. Admitted.

JURISDICTION AND VENUE

8. Paragraph 8 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara will not contest subject matter jurisdiction for the limited purpose of this action under 35 U.S.C. § 271(e)(2) only. Zenara denies the remaining allegations in this paragraph.

9. Paragraph 9 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Zenara in this case under 35 U.S.C. § 271(e)(2) and solely as they

apply to the proposed products described in Zenara's ANDA No. 216842.

10. Paragraph 10 of the Complaint states legal conclusions to which no response is required. Zenara will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Zenara in this case under 35 U.S.C. § 271(e)(2) and solely as they apply to the proposed products described in Zenara's ANDA No. 216842. Zenara denies the remaining allegations in this paragraph.

11. Denied.

12. Paragraph 12 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Zenara will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Zenara in this case under 35 U.S.C. § 271(e)(2) and solely as they apply to the proposed products described in Zenara's ANDA No. 216842. Zenara denies the remaining allegations in this paragraph.

13. Paragraph 13 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Zenara will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Zenara in this case under 35 U.S.C. § 271(e)(2) and solely as they apply to the proposed products described in Zenara's ANDA No. 216842. Zenara denies the remaining allegations in this paragraph.

14. Paragraph 14 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara will not contest venue for the limited purpose of this action under 35 U.S.C. § 271(e)(2) only. Zenara denies any remaining allegations in this paragraph.

BACKGROUND

STEGLATRO®(ERTUGLIFLOZIN)

15. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15 and therefore denies them.

16. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 16 and therefore denies them.

17. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17 and therefore denies them.

18. Zenara admits that the '580 patent is listed in the FDA's electronic version of the Orange Book under Steglatro® (last visited on March 31, 2022). To the extent that paragraph 18 includes any allegations as to the propriety of the '580 patent's listing in the FDA's Orange Book, Zenara denies such allegations.

19. Zenara admits that Plaintiffs purport that a copy of the '580 patent is attached to the Complaint as Exhibit A and that the '580 patent is entitled "Dioxa-bicyclo[3.2.1]octane-2,3,4-triol derivatives." Zenara denies the remaining allegations in paragraph 19.

20. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 20 and therefore denies them.

21. Zenara is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 21 and therefore denies them.

22. Paragraph 22 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara will not contest that an actual case or controversy exists between the parties in this case solely under 35 U.S.C. § 271(e)(2) with respect to Zenara's ANDA No. 216842. Zenara denies any remaining allegations in this

paragraph.

ZENARA'S ANDA

23. Paragraph 23 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara admits that on February 15, 2022, it sent a Notice Letter to Merck and Pfizer pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("the Act") and 21 C.F.R. § 314.95 and filed a patent certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its ANDA No. 216842. Zenara denies any remaining allegations in this paragraph.

24. Paragraph 24 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara admits that on February 15, 2022, it sent a Notice Letter to Merck and Pfizer pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and filed a patent certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its ANDA No. 216842. Zenara denies any remaining allegations in this paragraph.

25. Denied.

26. Paragraph 26 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara admits that it filed ANDA No. 216842 with the FDA seeking regulatory approval to make and sell a generic version of Steglatro® tablets. Zenara is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

27. Denied.

28. Paragraph 28 of the Complaint states a legal conclusion to which no response is required.

CLAIM FOR RELIEF
(Infringement of the '580 Patent)

29. Zenara incorporates each of the preceding paragraphs 1-28 as if fully set forth herein.

30. Paragraph 30 of the Complaint states a legal conclusion to which no response is required.

31. Paragraph 31 of the Complaint states a legal conclusion to which no response is required.

32. Denied.

33. Paragraph 33 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara admits that on February 15, 2022, it sent a Notice Letter to Merck and Pfizer pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and filed a patent certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its ANDA No. 216842. Zenara denies any remaining allegations in this paragraph.

34. Paragraph 34 of the Complaint states a legal conclusion to which no response is required.

35. Paragraph 35 of the Complaint states a legal conclusion to which no response is required.

36. Paragraph 36 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement that does not obviate Plaintiffs' burden to prove infringement and does not carry with it any implication of willful infringement.

37. Denied.

38. Paragraph 38 of the Complaint states a legal conclusion to which no response is required. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

REQUEST FOR RELIEF

Zenara denies that Plaintiffs are entitled to any of the relief sought in their Request for Relief, including the relief sought in Paragraphs (a) – (g) on pages 9-10 of the Complaint.

ADDITIONAL DEFENSES

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

First Additional Defense – Non-Infringement of the Claims of the '580 Patent

Zenara 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 '580 patent against Zenara.

Second Additional Defense – Invalidity of the Claims of the '580 Patent

The claims of the '580 patent against Zenara 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, and/or for double patenting.

Third Additional Defense – Estoppel

Plaintiffs' claims are barred, in whole or in part, by estoppel (*e.g.*, doctrine of prosecution

history estoppel; e.g., collateral estoppel).

Fourth Additional Defense – Failure to State a Claim

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

RESERVATION OF ADDITIONAL DEFENSES

Zenara reserves the right to assert such other defenses and damages, if such defenses and/or damages are discovered during the course of this litigation.

PRAYER FOR RELIEF

WHEREFORE, Zenara respectfully prays that this Court enter judgment in Zenara's favor and grant the following relief:

A. Dismiss Plaintiffs' Complaint with prejudice and deny each and every prayer for relief applicable to Zenara contained therein;

B. A declaration that Zenara does not infringe the claims of the '580 patent against Zenara;

C. A declaration that the claims of the '580 patent against Zenara are invalid;

D. Assess the costs of this action against Plaintiffs;

E. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Zenara is entitled to recover its reasonable attorney fees and costs upon prevailing in this action;

F. That the effective date of any FDA approval of Zenara's ANDA product shall not be stayed thirty months from the date of its Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii);

G. An award to Zenara of such further and other relief as this Court deems necessary, just, and proper.

Dated: April 5, 2022

SMITH, KATZENSTEIN & JENKINS, LLP

/s/ Eve H. Ormerod

Neal C. Belgam (No. 2721)
Eve H. Ormerod (No. 5369)
1000 West Street, Suite 1501
Wilmington, DE 19801
(302) 652-8400
nbelgam@skjlaw.com
eormerod@skjlaw.com

Counsel for Defendant Zenara Pharma Private Limited

Of Counsel:
Dmitry V. Shelhoff
Kenneth S. Canfield
Edward D. Pergament
Julia S. Kim
PERGAMENT CEPEDA, LLP
25A Hanover Road, Suite 104
Florham Park, NJ 07932
(973) 998-7722

dshelhoff@pergamentcepeda.com
kcanfield@pergamentcepeda.com
epergament@pergamentcepeda.com
jkim@pergamentcepeda.com