UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., Plaintiffs, v. BIOPHORE PHARMA INC., BIOPHORE INDIA PHARMACETICALS PRIVATE LTD., ZENARA PHARMA LTD., ZENARA PHARMA PRIVATE LTD. Defendants.	C.A. No. 20-cv-3795 (CCC)(MF) ELECTRONICALLY FILED

DEFENDANTS' ANSWER TO COMPLAINT

Defendants Biophore Pharma Inc., Biophore India Pharmaceuticals Private Ltd., Zenara Pharma Ltd. and Zenara Pharma Private Ltd. (collectively, "Biophore") by their counsel, hereby respond to the allegations set forth in the Plaintiffs Merck Sharp & Dohme B.V. and Organon USA Inc.'s (collectively, "Merck," or "Plaintiffs"), Complaint for patent infringement against Biophore under 35 U.S.C. § 271(e)(2). This response is based on Biophore's current knowledge as to their 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. Biophore admits that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 271 (e)(2). Biophore further admits that Plaintiffs purport to seek relief from alleged infringement by Biophore of U.S. Patent Nos. RE44,733 ("the '733 patent" or "patent-in-suit"). Biophore admits that it filed ANDA No. 214306 with the FDA for approval

to sell its ANDA product, as a generic version of Plaintiff's Bridion® drug product prior to the expiration of the patents-in-suit. Biophore denies the remaining allegations of paragraph 1.

THE PARTIES

2. Biophore 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. Biophore 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. Admitted.

5. Admitted.

6. Admitted.

7. Admitted.

8. Denied.

9. Admitted.

10. Denied.

11. Denied.

12. Denied.

13. Denied.

14. Admitted.

15. Denied.

JURISDICTION AND VENUE

16. Biophore incorporates each of the preceding paragraphs 1-15 as if fully set forth herein.

17. Paragraph 17 of the Complaint states a legal conclusion to which no response is

required. To the extent a response is required, Biophore will not contest subject matter jurisdiction for the limited purpose of this action only. Biophore denies the remaining allegations in this paragraph as the specific sections of 35 U.S.C. references in paragraph 17 as "*et seq.*" are not enumerated.

18. Paragraph 18 of the Complaint states a legal conclusion to which no response is required. Defendant Biophore Pharma Inc. will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Defendant Biophore Pharma Inc. in this case and solely as they apply to the proposed products described in ANDA No. 214306.

19. Paragraph 19 of the Complaint states a legal conclusion to which no response is required. Defendant Biophore Pharma Inc. will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Biophore Pharma Inc. in this case and solely as they apply to the proposed products described in ANDA No. 214306. Biophore Pharma Inc. denies any remaining allegations in this paragraph.

20. Paragraph 20 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.

21. Paragraph 21 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore will not contest personal jurisdiction for the limited purpose of this action only.

22. Admitted.

23. Denied.

24. Denied.

25. Paragraph 25 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara Pharma Private Ltd. will not contest personal jurisdiction for the limited purpose of this action only.

26. Denied.

27. Denied.

28. Paragraph 28 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore Pharma Inc. will not contest personal jurisdiction for the limited purpose of this action only.

29. Denied.

30. Paragraph 30 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara Pharma Private Ltd. will not contest personal jurisdiction for the limited purpose of this action only. Biophore denies any remaining allegations in this paragraph.

31. Paragraph 31 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore Pharma Inc. will not contest venue for the limited purpose of this action only. Biophore denies any remaining allegations in this paragraph.

32. Paragraph 32 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore Pharma Inc. and Zenara Pharma Private Ltd. will not contest venue for the limited purpose of this action only. Biophore denies any remaining allegations in this paragraph.

THE PATENT-IN-SUIT

33. Biophore admits that Plaintiffs purport that a true and correct copy of the ’733

patent is attached to the Complaint as Exhibit **A**. Biophore further admits that the '733 patent is entitled "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block." Biophore denies any remaining allegations in this paragraph.

34. Denied.

35. Denied.

36. Denied.

37. Biophore admits that Plaintiffs purport that a true and correct copy of the Notice of Final Determination on the patent term extension application for the '733 patent is attached to the Complaint as Exhibit **B**. Biophore is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 33 of the Complaint, and therefore denies them.

THE BRIDION® DRUG PRODUCT

38. Biophore admits that Plaintiffs purport that a true and correct copy of the Bridion® package insert is attached to the Complaint as Exhibit **C**. Biophore is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 38 of the Complaint, and therefore denies them.

39. Biophore is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 39 of the Complaint, and therefore denies them.

40. Biophore is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 40 of the Complaint, and therefore denies them.

41. Paragraph 41 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore admits that the '733 is listed in the FDA's electronic version of Approved Drug Products with Therapeutic Equivalence Evaluations

under Bridion®. (last visited on April 20, 2020).

DEFENDANTS' ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

42. Admitted.

43. Admitted.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Paragraph 49 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore admits that it filed ANDA No. 214306 with the FDA, seeking regulatory approval to make and sell Sugammadex intravenous solution throughout the United States. Biophore is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

50. Paragraph 50 of the Complaint states a legal conclusion to which no response is required.

COUNT I – INFRINGEMENT OF THE '733 PATENT

51. Biophore incorporates each of the preceding paragraphs 1-50 as if fully set forth herein.

52. Paragraph 52 of the Complaint states a legal conclusion to which no response is required.

53. Paragraph 53 of the Complaint states a legal conclusion to which no response is required.

54. Paragraph 54 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.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Paragraph 62 of the Complaint states a legal conclusion to which no response is required.

63. Paragraph 63 of the Complaint states a legal conclusion to which no response is required.

64. Denied.

65. Denied.

REQUESTED RELIEF

Biophore denies that Plaintiffs are entitled to any of the relief sought in its Prayer for Relief, including the relief sought in Paragraphs (a)-(j) on pages 16-18 of the Complaint.

AFFIRMATIVE DEFENSES

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

First Affirmative Defense – Non-Infringement of the Claims of Patents-In-Suit

Biophore 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 patents-in-suit against Biophore.

Second Affirmative Defense – Invalidity of the Claims of Patents-In-Suit

The claims of the patents-in-suit against Biophore 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 Affirmative Defense – Prosecution History Estoppel

Merck's claims are barred, in whole or in part, by the doctrine of prosecution history estoppel. The claims of the patents-in-suit against Biophore are so limited as not to cover the manufacture, use, offer for sale, sale or importation of the product described in Biophore's ANDA No. 214306 due to the arguments, statements, representations and/or amendments made by Plaintiffs to the United States Patent and Trademark Office during the prosecution of the applications leading to issuance of the patents-in-suit.

Fourth Affirmative Defense – Failure to State a Claim

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

RESERVATION OF ADDITIONAL DEFENSES

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

PRAYER FOR RELIEF

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

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

B. A declaration that Biophore does not infringe the claims of the patents-in-suit against Biophore;

C. A declaration that the claims of the patents-in-suit against Biophore 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 Biophore 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 Biophore'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 Biophore of such further and other relief as this Court deems necessary, just, and proper.

Date: May 13, 2020

Respectfully submitted,

/s/ Dmitry Shelhoff
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