

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MERCK SHARP & DOHME B.V. and
ORGANON USA INC.,

Plaintiffs,

v.

ASPIRO PHARMA LIMITED,

Defendants.

C.A. No. 20-cv-3112 (CCC)(MF)

ELECTRONICALLY FILED

ASPIRO PHARMA LIMITED'S ANSWER TO COMPLAINT

Defendant Aspiro Pharma Limited (“Aspiro”) by its 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 Aspiro under 35 U.S.C. § 271(e)(2). This response is based on Aspiro’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. Aspiro admits that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 271 (e)(2). Aspiro further admits that Plaintiffs purport to seek relief from alleged infringement by Aspiro of U.S. Patent Nos. RE44,733 (“the ’733 patent”) and 6,949,527 (“the ’527 patent”) (collectively, “patents-in-suit”). Aspiro admits that it filed ANDA No. 214337 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. Aspiro denies the remaining allegations of paragraph 1.

THE PARTIES

2. Aspiro 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. Aspiro 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.

JURISDICTION AND VENUE

6. Aspiro incorporates each of the preceding paragraphs 1-5 as if fully set forth herein.

7. Paragraph 7 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aspiro will not contest subject matter jurisdiction for the limited purpose of this action only. Aspiro denies the remaining allegations in this paragraph as the specific sections of 35 U.S.C. references in paragraph 7 as “*et seq.*” are not enumerated.

8. Paragraph 8 of the Complaint states a legal conclusion to which no response is required. Aspiro will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs’ claims against Aspiro in this case and solely as they apply to the proposed products described in ANDA No. 214337. Aspiro denies any remaining allegations in this paragraph.

9. Paragraph 9 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.

10. Paragraph 10 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aspiro will not contest personal jurisdiction for the limited purpose of this action only.

11. Paragraph 11 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aspiro will not contest personal jurisdiction for the limited purpose of this action only.

12. Paragraph 12 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aspiro will not contest personal jurisdiction for the limited purpose of this action only.

13. Paragraph 13 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aspiro will not contest venue for the limited purpose of this action only. Aspiro denies any remaining allegations in this paragraph.

THE PATENTS-IN-SUIT

14. Aspiro admits that Plaintiffs purport that a true and correct copy of the '733 patent is attached to the Complaint as Exhibit **A**. Aspiro further admits that the '733 patent is entitled "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block." Aspiro denies any remaining allegations in this paragraph.

15. Denied.

16. Denied.

17. Denied.

18. Aspiro 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**. Aspiro is without knowledge or information sufficient to form a

belief as to the truth of the remaining allegations of paragraph 18 of the Complaint, and therefore denies them.

19. Aspiro admits that Plaintiffs purport that a true and correct copy of the '527 patent is attached to the Complaint as Exhibit **D**. Aspiro further admits that the '527 patent is entitled "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block." Aspiro denies any remaining allegations in this paragraph.

20. Denied.

21. Denied.

22. Admitted.

THE BRIDION® DRUG PRODUCT

23. Aspiro admits that Plaintiffs purport that a true and correct copy of the Bridion® package insert is attached to the Complaint as Exhibit **C**. Aspiro is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 23 of the Complaint, and therefore denies them.

24. Aspiro is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24 of the Complaint, and therefore denies them.

25. Aspiro is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25 of the Complaint, and therefore denies them.

26. Paragraph 26 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aspiro admits that the '733 and '527 patents are listed in the 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

27. Admitted.

28. Admitted.

29. Admitted.

30. Paragraph 30 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aspiro admits that on January 31, 2020, it sent a Notice Letter to Merck pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and filed patent certifications 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 Abbreviated New Drug Application (“ANDA”). Aspiro 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, Aspiro admits that on January 31, 2020, it sent a Notice Letter to Merck pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and filed patent certifications 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 Abbreviated New Drug Application (“ANDA”). Aspiro 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, Aspiro admits that on January 31, 2020, it sent a Notice Letter to Merck pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and filed patent certifications 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 Abbreviated New Drug Application (“ANDA”). Aspiro denies any remaining allegations in this paragraph.

33. Denied.

34. Paragraph 34 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aspiro admits that it filed ANDA No. 214337 with the FDA, seeking regulatory approval to make and sell Sugammadex intravenous solution throughout the United States. Aspiro is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

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

COUNT I – INFRINGEMENT OF THE '733 PATENT

36. Aspiro incorporates each of the preceding paragraphs 1-35 as if fully set forth herein.

37. Paragraph 37 of the Complaint states a legal conclusion to which no response is required.

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

39. Paragraph 39 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.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.
46. Denied.
47. Denied.
48. Paragraph 48 of the Complaint states a legal conclusion to which no response is required.

49. Denied.

50. Denied.

COUNT II: INFRINGEMENT OF THE '527 PATENT

51. Aspiro 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. Denied.
63. Paragraph 63 of the Complaint states a legal conclusion to which no response is required.
64. Denied.
65. Denied.

REQUESTED RELIEF

Aspiro denies that Plaintiffs are entitled to any of the relief sought in its Prayer for Relief, including the relief sought in Paragraphs (a)-(q) on pages 19-21 of the Complaint.

AFFIRMATIVE DEFENSES

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

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

Aspiro 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 Aspiro.

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

The claims of the patents-in-suit against Aspiro 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 Aspiro are so limited as not to cover the manufacture, use, offer for sale, sale or importation of the product described in Aspiro's ANDA No. 214337 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

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

PRAAYER FOR RELIEF

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

- A. Dismiss Plaintiffs' Complaint with prejudice and deny each and every prayer for relief applicable to Aspiro contained therein;
- B. A declaration that Aspiro does not infringe the claims of the patents-in-suit against Aspiro;
- C. A declaration that the claims of the patents-in-suit against Aspiro 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 Aspiro 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 Aspiro'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 Aspiro of such further and other relief as this Court deems necessary, just, and proper.

Date: May 1, 2020

Respectfully submitted,

/s/ Dmitry Shelhoff
Dmitry V. Shelhoff
Edward D. Pergament
Pergament & Cepeda LLP
89 Headquarters Plaza
North Tower, 14th Floor
Morristown, NJ 07960
973.998.7722
dshelhoff@pergamentcepeda.com

Attorney for Aspiro Pharma Limited