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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., Plaintiffs, v. BIOPHORE PHARMA INC.; BIOPHORE INDIA PHARMACEUTICALS PRIVATE LTD.; ZENARA PHARMA LTD.; and ZENARA PHARMA PRIVATE LTD., Defendants.	Civil Action No. 20-3795 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Sharp & Dohme B.V. ("Merck B.V.") and Organon USA Inc. ("Organon") (together, "Merck"), by their attorneys, bring this complaint against Defendants Biophore Pharma Inc. ("BPI"), Biophore India Pharmaceuticals Private Ltd. ("Biophore India"), Zenara Pharma Ltd. ("ZPL"), and Zenara Pharma Private Ltd. ("Zenara Pvt.") (together, "Biophore-Zenara Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*., including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Biophore-Zenara Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import all strengths of a purported generic version of Bridion® (sugammadex) Injection prior to the expiration of U.S. Patent No. RE44,733 ("the '733 patent").

PARTIES

2. Plaintiff Merck Sharp & Dohme B.V. ("Merck B.V.") is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, Haarlem, Netherlands 2031 BN. Merck B.V. is an indirect, wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

3. Plaintiff Organon USA Inc. ("Organon") is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Organon is a wholly owned subsidiary of Merck & Co., Inc.

4. On information and belief, Defendant Biophore Pharma Inc. ("BPI") is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 1 Deerpark Drive, Suite F-8, Monmouth Junction, New Jersey 08852. On information and belief, BPI is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States,

generic versions of branded pharmaceutical drugs for the U.S. market.

5. On information and belief, Defendant Biophore India Pharmaceuticals Private Ltd. ("Biophore India") is a corporation organized and existing under the laws of India, having a place of business at Plot No 92, 1-98/2/92, Kavuri Hills, Phase-II, Jubilee Hills, Hyderabad, Tekangana, 500033, India. On information and belief, Biophore India is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, through various operating agents, affiliates, and subsidiaries, including BPI, ZPL and Zenara Pvt.

6. On information and belief, Defendant Zenara Pharma Ltd. ("ZPL") is a corporation organized and existing under the laws of the United Kindom, having a place of business at Russell Bedford House, City Forum 250 City Road, London, Greater London EC1V 2QQ, United Kingdom. On information and belief, ZPL is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, through various operating agents, affiliates, and subsidiaries, including BPI, Biophore India, and Zenara Pvt.

7. On information and belief, Defendant Zenara Pharma Private Ltd. ("Zenara Pvt.") is a corporation organized and existing under the laws of India, having a place of business at Plot No. 83/B, 84, 87-96 Phase III, IDA Cherlapally, Hyderabad, 500051, India. On information and belief, Zenara Pvt. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

8. On information and belief, BPI is a wholly owned subsidiary and/or the U.S. agent of Biophore India.

9. On information and belief, Zenara Pvt. is a wholly owned subsidiary of Biophore India.

10. On information and belief, Biophore India and ZPL are related corporate entitites.

11. By a letter dated March 12, 2020 ("Biophore-Zenara Notice Letter"), BPI and ZPL notified Merck that BPI and ZPL had submitted to the FDA ANDA No. 214406 ("Biophore-Zenara's ANDA") for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL ("Biophore-Zenara ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Biophore-Zenara ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent.

12. On information and belief, BPI, Biophore India, ZPL, and Zenara Pvt. acted in concert to prepare and submit Biophore-Zenara's ANDA and the Biophore-Zenara Notice Letter.

13. On information and belief, BPI, Biophore India, ZPL, and Zenara Pvt. know and intend that upon approval of Biophore-Zenara's ANDA, BPI and/or Biophore India and/or ZPL and/or Zenara Pvt. will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Biophore-Zenara ANDA Products throughout the United States, including in New Jersey. On information and belief, BPI, Biophore India, ZPL, and Zenara Pvt. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the Biophore-Zenara ANDA Products, and enter into agreements that are nearer than

arm's length. On information and belief, BPI, Biophore India, ZPL, and Zenara Pvt. participated, assisted, and cooperated in carrying out the acts complained of herein.

14. On information and belief, Biophore India holds Drug Master File No. 34170 for sugammadex sodium.

15. On information and belief, following any FDA approval of Biophore-Zenara's ANDA, BPI, Biophore India, ZPL, and Zenara Pvt. will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Biophore-Zenara ANDA Products throughout the United States, including New Jersey.

JURISDICTION AND VENUE

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

17. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, for infringement of the asserted patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

18. This Court has personal jurisdiction over BPI because BPI is a corporation organized and existing under the laws of New Jersey and because BPI has its principal place of business in New Jersey.

19. BPI is also subject to personal jurisdiction in New Jersey because, among other things, BPI has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, BPI develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs.

20. BPI, in concert with Biophore India, ZPL, and Zenara Pvt., has committed an act of infringement in this judicial district by filing ANDA No. 214306 with the intent to make, use, sell, offer for sale, and/or import the Biophore-Zenara ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

21. Biophore India is subject to personal jurisdiction in New Jersey because, among other things, Biophore India itself, and through its agents, affiliates, and/or subsidiaries BPI, ZPL, and Zenara Pvt., purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Biophore India itself, and through its agents, affiliates, and/or subsidiaries BPI, ZPL, and Zenara Pvt., develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs. In addition, Biophore India is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates BPI and Zenara Pvt., and therefore the activities of BPI and Zenara Pvt. in this jurisdiction are attributed to Biophore India.

22. Biophore India's website states that Biophore India "has emerged as a trusted partner in the generic industry across [the] US." *See* biophore.com, About Us tab, *available at* http://www.biophore.com/ (last visited on March 24, 2020). Biophore India's website states that Biophore India has "70 DMF's Filed in EU, US & Canada" with "20 Products in [the] DMF Pipeline" and "2 US-FDA Approved API Facilites." *Id.* Biophore India's website also states that Biophore India is "Trusted by global pharmaceutical giants Services from Blue print to commercial production in US FDA certified facilities." *Id.* at Infrastructure tab.

23. ZPL is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, ZPL itself,

and through its agents, affiliates, and/or subsidiaries BPI, Biophore India and Zenara Pvt., develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs.

24. ZPL, in concert with BPI, Biophore India, and Zenara Pvt., has committed an act of infringement in this judicial district by filing ANDA No. 214306 with the intent to make, use, sell, offer for sale, and/or import the Biophore-Zenara ANDA Products in or into this judicial district, prior to the expiration of the ’733 patent.

25. Zenara Pvt. is subject to personal jurisdiction in New Jersey because, among other things, Zenara Pvt. has purposely availed itself of the benefits and protections of New Jersey’s laws such that it should reasonably anticipate being sued in this Court. On information and belief, Zenara Pvt. develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs.

26. Biophore-Zenara Defendants have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Biophore-Zenara ANDA Products, that will be purposefully directed at New Jersey and elsewhere in the United States.

27. On information and belief, if Biophore-Zenara’s ANDA is approved, Biophore-Zenara Defendants will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the Biophore-Zenara ANDA Products within the United States, including in New Jersey. On information and belief, Biophore-Zenara Defendants regularly do business in New Jersey, and their practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, the Biophore-Zenara ANDA Products will be prescribed

by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the '733 patent in the event that the Biophore-Zenara ANDA Products are approved before the '733 patent expires.

28. On information and belief, BPI is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400378257.

29. This Court has personal jurisdiction over Biophore India because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Merck's claims arise under federal law; (b) Biophore India is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Biophore India has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Biophore-Zenara's ANDA, participating in the preparation and submission of Drug Master File No. 34170 to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Biophore India satisfies due process.

30. This Court has personal jurisdiction over ZPL and Zenara Pvt. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Merck's claims arise under federal law; (b) ZPL and Zenara Pvt. are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) ZPL and Zenara Pvt. have sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Biophore-Zenara's ANDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this

Court's exercise of jurisdiction over ZPL and Zenara Pvt. satisfies due process.

31. Venue is proper in this Court as to BPI pursuant to 28 U.S.C. § 1400(b) because BPI is incorporated in the State of New Jersey and therefore resides in this judicial district.

32. Venue is proper in this Court as to Biophore India, ZPL, and Zenara Pvt. because Biophore India, ZPL, and Zenara Pvt. are foreign entities who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

THE PATENT-IN-SUIT

33. Merck B.V. is the owner and assignee of the '733 patent, entitled "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block" (attached as Exhibit A). Merck B.V. has the right to enforce the '733 patent.

34. The '733 patent was duly and legally issued on January 28, 2014. The '733 patent was a reissue of U.S. Patent No. 6,670,340, which was duly and legally issued on December 30, 2003.

35. The '733 patent includes claims that recite 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, compositions containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, methods of using 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, and kits containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin.

36. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

37. The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") currently lists the expiration of the '733 patent as January 27, 2021. On February 4, 2020, the United States Patent and Trademark Office ("PTO") issued a Notice Of Final Determination on the patent term extension ("PTE") application for the '733 patent, wherein

the PTO determined that the '733 patent is eligible for 5 years of PTE (attached as Exhibit B). Therefore, after the PTE certificate is issued, the expiration of the '733 patent will be January 27, 2026.

THE BRIDION® DRUG PRODUCT

38. Organon is the holder of New Drug Application ("NDA") No. 022225, under which the FDA approved the commercial marketing of Bridion® (sugammadex) Injection ("Bridion®") on December 15, 2015, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a). Bridion® is approved for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery. Bridion® is distributed in the United States by Merck Sharp and Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., in 200 mg/2 mL and 500 mg/5 mL strengths in a single-dose vial for bolus injection. A true and correct copy of the current prescribing information for Bridion® is attached as Exhibit C.

39. Bridion® is a first-in-class drug that works differently than prior agents used for the reversal of neuromuscular blockade. The active ingredient in Bridion®, sugammadex, is a modified cyclodextrin that acts by directly encapsulating, binding, and inactivating agents used by healthcare providers to induce neuromuscular blockade in patients undergoing surgery, e.g., rocuronium or vecuronium, to reverse their effects. After intravenous injection, Bridion® distributes through plasma and binds to such neuromuscular blocking agents ("NMBAs") to form a complex. This process reduces the amount of NMBA available to bind to nicotinic cholinergic receptors in the neuromuscular junction, resulting in the reversal of neuromuscular blockade.

40. By this mechanism, Bridion® also avoids several of the side effects associated with prior reversal agents, such as acetylcholinesterase inhibitors. Traditional reversal agents are co-administered with other agents to manage these side effects, but the co-administered

agents can cause a number of additional side effects. Moreover, Bridion® is capable of reversing the complete and prolonged block of neuromuscular function (known as "profound block") that can occur with the administration of NMBAs. Further, intravenous administration of sugammadex results in more rapid recovery from moderate or deep neuromuscular blockade in patients undergoing surgery who received rocuronium or vecuronium, as compared to neostigmine or succinylcholine. Because of at least these unique features, Bridion® has been viewed as a significant advance in the field of anesthesiology.

41. Bridion®, as well as methods of using Bridion®, are covered by one or more claims of the '733 patent. The '733 patent has been listed in connection with NDA No. 022225 in the FDA's Orange Book.

DEFENDANTS' ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

42. On information and belief, Biophore-Zenara Defendants have submitted or caused the submission of Biophore-Zenara's ANDA to the FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Biophore-Zenara ANDA Products, as a purported generic version of Bridion®, prior to the expiration of the '733 patent.

43. On information and belief, the FDA has not yet approved Biophore-Zenara's ANDA.

44. In the Biophore-Zenara Notice Letter, BPI and ZPL notified Merck of the submission of Biophore-Zenara's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biophore-Zenara ANDA Products prior to the expiration of the '733 patent.

45. In the Biophore-Zenara Notice Letter, BPI and ZPL acknowledged that the Reference Listed Drug for Biophore-Zenara's ANDA is Bridion®. Bridion® is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

46. In the Biophore-Zenara Notice Letter, BPI and ZPL also notified Merck that, as part of its ANDA, BPI and ZPL had filed a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '733 patent.

47. On information and belief, BPI and ZPL submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '733 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the Biophore-Zenara ANDA Products.

48. In the Biophore-Zenara Notice Letter, BPI and ZPL stated that the Biophore-Zenara ANDA Products contain sugammadex as an active ingredient.

49. On information and belief, Biophore-Zenara Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted Biophore-Zenara's ANDA, and intend to further prosecute Biophore-Zenara's ANDA. On information and belief, if the FDA approves Biophore-Zenara's ANDA, Biophore-Zenara Defendants will manufacture, distribute, promote, market, offer for sale, or sell the Biophore-Zenara ANDA Products within the United States, or will import the Biophore-Zenara ANDA Products into the United States. On information and belief, if the FDA approves Biophore-Zenara's ANDA, Biophore-Zenara Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Biophore-Zenara ANDA Products in or into the

United States.

50. Merck brings this action within forty-five days of receipt of the Biophore-Zenara Notice Letter. Accordingly, Merck is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I – INFRINGEMENT OF THE '733 PATENT

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

52. The Biophore-Zenara ANDA Products, and the use of the Biophore-Zenara ANDA Products, are covered by one or more claims of the '733 patent, including at least claim 1 of the '733 patent, because claim 1 of the '733 patent encompasses the sugammadex utilized in the Biophore-Zenara ANDA Products.

53. In the Biophore-Zenara Notice Letter, BPI and ZPL did not specifically contest infringement of claims 1-5, 9, 11-14, and 20-21 of the '733 patent.

54. Biophore-Zenara Defendants' submission of Biophore-Zenara's ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biophore-Zenara ANDA Products in or into the United States before the expiration of the '733 patent is an act of infringement of the '733 patent under 35 U.S.C. § 271(e)(2)(A).

55. If approved by the FDA, Biophore-Zenara Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the Biophore-Zenara ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '733 patent under 35 U.S.C. § 271(a)-(c).

56. On information and belief, Biophore-Zenara Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of

the Biophore-Zenara ANDA Products in or into the United States immediately and imminently upon approval of Biophore-Zenara's ANDA.

57. The commercial manufacture, use, sale, offer for sale, or importation of the Biophore-Zenara ANDA Products in or into the United States would infringe one or more claims of the '733 patent.

58. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the Biophore-Zenara ANDA Products in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '733 patent.

59. On information and belief, upon FDA approval of Biophore-Zenara's ANDA, Biophore-Zenara Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the Biophore-Zenara ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Biophore-Zenara Defendants will knowingly and intentionally accompany the Biophore-Zenara ANDA Products with a product label or product insert that will include instructions for using or administering the Biophore-Zenara ANDA Products, which are substantially similar to the instructions in the prescribing information for Bridion®, attached as Exhibit C, and which, if followed, will infringe the '733 patent. Accordingly, Biophore-Zenara Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Biophore-Zenara ANDA Products to directly infringe the '733 patent. On information and belief, Biophore-Zenara Defendants will encourage acts of direct infringement with knowledge of the '733 patent and knowledge that Biophore-Zenara Defendants are encouraging infringement.

60. On information and belief, Biophore-Zenara Defendants plan and intend to, and will, actively induce infringement of the ’733 patent when Biophore-Zenara’s ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval. Biophore-Zenara Defendants’ activities will be done with knowledge of the ’733 patent and specific intent to infringe that patent.

61. On information and belief, Biophore-Zenara Defendants know that the Biophore-Zenara ANDA Products and proposed labeling are especially made or adapted for use in infringing the ’733 patent, that the Biophore-Zenara ANDA Products are not a staple article or commodity of commerce, and that the Biophore-Zenara ANDA Products and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, Biophore-Zenara Defendants plan and intend to, and will, contribute to infringement of the ’733 patent immediately and imminently upon approval of Biophore-Zenara’s ANDA.

62. Notwithstanding Biophore-Zenara Defendants’ knowledge of the claims of the ’733 patent, Biophore-Zenara Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the Biophore-Zenara ANDA Products with its product labeling in or into the United States following FDA approval of Biophore-Zenara’s ANDA prior to the expiration of the ’733 patent.

63. The foregoing actions by Biophore-Zenara Defendants constitute and/or will constitute direct infringement of the ’733 patent; active inducement of infringement by others of the ’733 patent; and contribution to the infringement by others of the ’733 patent.

64. On information and belief, BPI and ZPL, in concert with their agents, affiliates, and subsidiaries, including Biophore India and Zenara Pvt., filed Biophore-Zenara’s ANDA with a Paragraph IV Certification without adequate justification for asserting that the ’733

patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Biophore-Zenara ANDA Products. On information and belief, Biophore-Zenara Defendants have acted with full knowledge of the '733 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and/or contribution to the infringement by others of the '733 patent. On information and belief, the direct and indirect infringement by Biophore-Zenara Defendants of the '733 patent was and is willful. Biophore-Zenara Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

65. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless Biophore-Zenara Defendants are enjoined from directly infringing the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement of the '733 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law, and considering the balance of hardships between Merck and Biophore-Zenara Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the '733 patent has been infringed under 35 U.S.C. § 271(e)(2) by Biophore-Zenara Defendants' submission to the FDA of Biophore-Zenara's ANDA;

(b) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of the Biophore-Zenara ANDA Products, or any other drug product that infringes or the use of which infringes the '733 patent, be not earlier than the expiration date of the '733 patent, inclusive of any extension(s) and additional

period(s) of exclusivity;

(c) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Biophore-Zenara Defendants, and all persons acting in concert with Biophore-Zenara Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Biophore-Zenara ANDA Products, or any other drug product covered by or whose use is covered by the '733 patent, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Biophore-Zenara ANDA Products, or any other drug product that is covered by or whose use is covered by the '733 patent, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity, will infringe, induce the infringement of, and contribute to the infringement by others of the '733 patent;

(e) A declaration that Biophore-Zenara Defendants' commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Biophore-Zenara ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '733 Patent by Biophore-Zenara Defendants under one or more of 35 U.S.C. § 271(a), (b), and (c);

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Biophore-Zenara Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Biophore-Zenara ANDA Products, or any product that infringes the '733 patent, or induces or contributes to such conduct, prior to

the expiration of the ’733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment that Biophore-Zenara Defendants willfully and deliberately infringed the ’733 patent;

(h) A declaration that this is an exceptional case and an award of attorney’s fees pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Dated: April 8, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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