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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., *Plaintiffs,* v. FISIOPHARMA S.R.L., *Defendant.*	C.A. No. 2:20-cv-02964-CCC-MF *Electronically Filed*

DEFENDANT FISIOPHARMA S.R.L.'S ANSWER TO COMPLAINT AND AFFIRMATIVE DEFENSES

Defendant Fisiopharma S.r.l. ("Fisiopharma") responds to the Complaint by Plaintiffs Merck Sharp & Dohme B.V. and Organon USA Inc. as follows:

To the extent not specifically admitted herein, the allegations of the complaint are denied.

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 Fisiopharma's 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 one strength of a purported generic version of Bridion® (sugammadex) Injection prior to the expiration of U.S. Patent No. RE44,733 ("the '733 patent").

ANSWER: Paragraph 1 contain legal conclusions to which no answer is required. To the extent an answer is required, Fisiopharma admits that Plaintiffs' Complaint purports to be a civil action to state an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Fisiopharma further admits that it filed an Abbreviated New Drug Application ("ANDA") No. 214279 with the United States Food and Drug Administration ("FDA") seeking approval for the sugammadex sodium containing product(s) described in that ANDA prior to the expiration of U.S. Patent No. RE44,733 ("the '733 patent"), and that ANDA No. 214279 includes a certification 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 proposed product(s) described in ANDA No. 214279. Fisiopharma denies all other allegations in paragraph 1.

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.

ANSWER: Fisiopharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2, and therefore denies them.

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.

ANSWER: Fisiopharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore denies them.

4. On information and belief, Defendant Fisiopharma S.r.l. ("Fisiopharma") is a corporation organized and existing under the laws of Italy, with a place of business at 84020 Palomonte SA, Loc. Sperlonga, Zona Industriale, Italy. On information and belief, Fisiopharma 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, itself or through its U.S. agents.

ANSWER: Fisiopharma admits it is a private limited liability company organized and existing under the laws of Italy, with a place of business at 84020 Palomonte SA, Loc. Sperlonga, Zona Industriale, Italy. Fisiopharma further admits that it is in the business of manufacturing, marketing, distributing, and selling pharmaceutical drugs, including generic pharmaceutical drugs. Fisiopharma denies all other allegations in paragraph 4.

5. By a letter dated February 13, 2020 ("Fisiopharma Notice Letter"), Fisiopharma notified Merck that Fisiopharma had submitted to the FDA ANDA No. 214279 ("Fisiopharma's ANDA") for a purported generic version of sugammadex injection, 200 mg/2 mL ("Fisiopharma ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Fisiopharma ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent.

ANSWER: Fisiopharma admits that its counsel sent a letter dated February 13, 2020 notifying plaintiffs regarding the submission to the FDA of ANDA No. 214279 seeking approval to market a sugammadex sodium injection, 200 mg/2ML (100mg/ML) prior to the expiration of the '733 patent. Fisiopharma denies all other allegations in paragraph 5.

JURISDICTION AND VENUE

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

ANSWER: Fisiopharma restates and incorporates by reference its responses to Paragraphs 1-5 of this Answer as if fully set forth herein.

7. 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.

ANSWER: The allegations in paragraph 7 are legal conclusions to which no answer is required. To the extent an answer is required, Fisiopharma admits that Plaintiffs' Complaint purports to be an action arising under the patent laws of the United States, including 35 U.S.C. § 271, for alleged infringement of the '733 patent. Fisiopharma does not contest subject matter jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Fisiopharma in this case and solely as they apply to the proposed products described in ANDA No. 214279. Fisiopharma denies all other allegations in paragraph 7.

8. Fisiopharma is subject to personal jurisdiction in New Jersey because, among other things, Fisiopharma itself, and through its U.S. agents, 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, Fisiopharma itself and through its U.S. agents, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

ANSWER: The allegations in paragraph 8 are legal conclusions to which no answer is required. To the extent an answer is required, Fisiopharma denies all allegations

in paragraph 8.

9. Fisiopharma has committed an act of infringement in this judicial district by filing ANDA No. 214279 with the intent to make, use, sell, offer for sale, and/or import the Fisiopharma ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

ANSWER: The allegations in paragraph 9 are legal conclusions to which no answer is required. To the extent an answer is required, Fisiopharma admits that it submitted ANDA No. 214279 to the FDA, from outside of this judicial district, and that this ANDA was filed with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '733 patent. Fisiopharma denies all remaining allegations in paragraph 9.

10. Fisiopharma has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Fisiopharma ANDA Products, that will be purposefully directed at New Jersey and elsewhere in the United States.

ANSWER: Fisiopharma admits that it submitted ANDA No. 214279 to the FDA, seeking approval to market sugammadex sodium injection product(s). Fisiopharma denies all remaining allegations in paragraph 10.

11. On information and belief, if Fisiopharma's ANDA is approved, Fisiopharma will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the Fisiopharma ANDA Products within the United States, including in New Jersey. On information and belief, the Fisiopharma 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 Fisiopharma ANDA Products are approved before the '733 patent expires.

ANSWER: The allegations in paragraph 11 contain legal conclusions to which no answer is required. To the extent an answer is required, Fisiopharma admits that it submitted ANDA No. 214279 to the FDA seeking approval to market sugammadex sodium

injection product(s), and that Fisiopharma is in the business of manufacturing, marketing, distributing, and selling pharmaceutical drugs, including generic pharmaceutical drugs. Fisiopharma lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 11, and therefore denies them.

12. Additionally, this Court has personal jurisdiction over Fisiopharma 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) Fisiopharma is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Fisiopharma has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Fisiopharma's ANDA, and/or Fisiopharma's future manufacturing and/or selling of the Fisiopharma ANDA Products throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Fisiopharma satisfies due process.

ANSWER: The allegations in paragraph 12 contain legal conclusions to which no answer is required. To the extent an answer is required, Fisiopharma admits that plaintiffs' claims arise under federal law, and that Fisiopharma is a foreign defendant not subject to general personal jurisdiction in the courts of any state. Fisiopharma denies the remaining allegations in paragraph 12.

13. Venue is proper in this Court as to Fisiopharma because Fisiopharma is a foreign entity 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).

ANSWER: The allegations in paragraph 13 contain legal conclusions to which no answer is required. To the extent an answer is required, for the purposes of this case only, Fisiopharma does not contest venue in this judicial district. Fisiopharma denies the remaining allegations in paragraph 13.

THE PATENT-IN-SUIT

14. 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.

ANSWER: The allegations in paragraph 14 contain legal conclusions to which no answer is required. To the extent an answer is required, Fisiopharma admits that the face of U.S. Patent No. RE44,733 ("the '733 patent") lists the title as "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block" and Merck B.V. as the assignee and that Exhibit A purports to be a copy of the '733 patent. Fisiopharma lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 14, and therefore denies them.

15. 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.

ANSWER: The allegations in paragraph 15 contain legal conclusions to which no answer is required. To the extent an answer is required, Fisiopharma admits that the face of the '733 patent states that the '733 patent issued on January 28, 2014 as a reissue of U.S. Patent No. 6,670,340 ("the '340 patent"), and that the '340 patent issued on December 30, 2003. Fisiopharma denies the remaining allegations in paragraph 15, including that the '733 patent was legally issued.

16. 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.

ANSWER: The allegations in paragraph 16 contain legal conclusions to which no answer is required. To the extent an answer is required, Fisiopharma admits that certain claims within the '733 patent contain the term: "6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin." Fisiopharma otherwise states that the '733 patent speaks for itself and is the best source for its content, and denies the remaining allegations in paragraph 16.

17. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

ANSWER: Fisiopharma admits that 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin can be a chemical name for sugammadex. Fisiopharma otherwise denies the allegations in Paragraph 17.

18. 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.

ANSWER: Fisiopharma admits that, as of July 8, 2020, the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") listed the expiration of the '733 patent as January 27, 2021, and that Exhibit B to plaintiffs' complaint purports to be a copy of the Notice of Final Determination on the patent term extension ("PTE") application for the '733 patent, which, in turn, states that the '733 patent "is eligible for patent term extension under 35 U.S.C. § 156" and that "[t]he period of extension has been determined to be 5 years." The allegation that the expiration of the '733 patent

will be January 27, 2026 after the PTE certificate is issued states a legal conclusion to which no response is required. To the extent a response is required, Fisiopharma lacks knowledge or information sufficient to form a belief as to the truth of the allegation, and therefore denies it, and any other remaining allegations from paragraph 18.

THE BRIDION® DRUG PRODUCT

19. 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.

ANSWER: Fisiopharma admits that as of July 8, 2020, the Orange book lists Organon as the holder of New Drug Application ("NDA") No. 022225 for sugammadex injections, which are sold under the proprietary name Bridion®, and lists December 15, 2015 as an approval date for NDA No. 022225. Fisiopharma admits that Exhibit C to the Complaint purports to be the prescribing information for Bridion® and purports to have a revision date of December 2018. Fisiopharma admits that Exhibit C contains a section titled "Dosage Forms and Strengths" which lists "200 mg/2 mL (100 mg/mL)" and "500 mg/5 mL (100 mg/mL)," "in a single dose vial for bolus injection." Fisiopharma further admits that Exhibit C states that "BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery." Fisiopharma admits that the end of the final page of Exhibit C states: "Distributed by Merck Sharp and Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station,

NJ 08889, USA." Fisiopharma lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 19 and therefore denies them.

20. 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.

ANSWER: Fisiopharma admits that Exhibit C to plaintiffs' complaint states: "BRIDION (sugammadex) injection, for intravenous use, contains sugammadex sodium, a modified gamma cyclodextrin chemically designated as *6A,6B,6C,6D,6E,6F,6G,6H-Octakis-S-(2-carboxyethyl)-6A,6B,6C,6D,6E,6F,6G,6Hoctathio-γ-cyclodextrin sodium salt* (1:8) with a molecular weight of 2178.01." Fisiopharma admits that Exhibit C contains a heading of "BRIDION® (sugammadex) Injection, for intravenous use." Fisiopharma lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 20, and therefore denies them.

21. 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.

ANSWER: Fisiopharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21, and therefore denies them.

22. 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.

ANSWER: Fisiopharma admits that the '733 patent was listed in connection with NDA No. 022225 in the FDA's Orange Book as of July 3, 2020. The remainder of paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Fisiopharma denies the remaining allegations in paragraph 22.

DEFENDANT'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

23. On information and belief, Fisiopharma has submitted or caused the submission of Fisiopharma'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 Fisiopharma ANDA Products, as a purported generic version of Bridion®, prior to the expiration of the '733 patent.

ANSWER: Fisiopharma admits that it submitted ANDA No. 214279 to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of at least sugammadex sodium injection 200 mg/2 mL (100 mg/mL). Fisiopharma admits that ANDA No. 214279 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '733 patent. Fisiopharma denies the remaining allegations set forth in paragraph 23.

24. On information and belief, the FDA has not yet approved Fisiopharma's ANDA.

ANSWER: Fisiopharma admits that the FDA has not yet provided final approval of Fisiopharma's ANDA No. 214279.

25. In the Fisiopharma Notice Letter, Fisiopharma notified Merck of the submission of Fisiopharma'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 Fisiopharma ANDA Products prior to the expiration of the '733 patent.

ANSWER: Fisiopharma admits that its Notice letter dated February 13, 2020, notified Plaintiffs that Fisiopharma had submitted ANDA No. 214279 to the FDA under 21 U.S.C. § 355(j), "which seeks approval to engage in the commercial manufacture, use, or sale of sugammadex sodium injection, 200 mg/2ML (100mg/ML) prior to the expiration of U.S. Patent No. RE44,733 (the "'733 patent")." Fisiopharma further admits that its Notice Letter contains a detailed statement of the factual and legal bases for Fisiopharma's Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '733 patent. Fisiopharma denies all other allegations in paragraph 25.

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

ANSWER: Fisiopharma admits that Exhibit C to the complaint states that "BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery." Fisiopharma denies all other allegations in paragraph 26.

27. In the Fisiopharma Notice Letter, Fisiopharma also notified Merck that, as part of its ANDA, Fisiopharma 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.

ANSWER: Fisiopharma admits that with respect to the '733 patent, its February 13, 2020 letter provided notice to Merck of all identified information required by and set

forth with the FDC Act § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), including that "Fisiopharma has received the paragraph IV acknowledgement letter for ANDA 214279." Fisiopharma denies all other allegations in paragraph 27.

28. On information and belief, Fisiopharma 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 Fisiopharma ANDA Products.

ANSWER: Fisiopharma admits that its ANDA No. 214279 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '733 patent. Fisiopharma denies all other allegations in paragraph 28.

29. In the Fisiopharma Notice Letter, Fisiopharma stated that the Fisiopharma ANDA Products contain sugammadex as an active ingredient.

ANSWER: Fisiopharma admits that its February 13, 2020 Notice letter states: "the active ingredient, strength and dosage form of the proposed drug product are sugammadex sodium injection, 200 mg/2mL (100mg/mL)." Fisiopharma denies all other allegations in paragraph 29.

30. On information and belief, Fisiopharma prepared and submitted Fisiopharma's ANDA, and intends to further prosecute Fisiopharma's ANDA. On information and belief, if the FDA approves Fisiopharma's ANDA, Fisiopharma will manufacture, distribute, promote, market, offer for sale, or sell the Fisiopharma ANDA Products within the United States, or will import the Fisiopharma ANDA Products into the United States. On information and belief, if the FDA approves Fisiopharma's ANDA, Fisiopharma will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Fisiopharma ANDA Products in or into the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Fisiopharma admits that it owns ANDA

214279, which seeks approval from the FDA to market the ANDA products described therein within the United States. Fisiopharma otherwise denies the remaining allegations in Paragraph 30.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Fisiopharma admits that Plaintiffs' complaint, filed on March 17, 2020, was filed within forty-five days of receipt of Fisiopharma's February 13, 2020 Notice letter. Fisiopharma otherwise denies the remaining allegations in Paragraph 31.

COUNT 1 – INFRINGMENT OF THE ´733 PATENT

32. Merck incorporates each of the preceding paragraphs 1–31 as if fully set forth herein.

ANSWER: Fisiopharma restates and incorporates by reference its responses to Paragraphs 1-31 of this Answer as if fully set forth herein.

33. The Fisiopharma ANDA Products, and the use of the Fisiopharma 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 Fisiopharma ANDA Products.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Fisiopharma denies the allegations in Paragraph 33.

34. In the Fisiopharma Notice Letter, Fisiopharma did not contest infringement of claims 1-5 and 11-14 of the '733 patent.

ANSWER: Fisiopharma denies that the allegations in paragraph 34 accurately and completely recite Fisiopharma's February 13, 2020 Notice Letter and therefore denies them. Fisiopharma does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '733 patent in this or any other litigation or other proceeding. *See Abbott Labs., Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 728 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV [notice] letter"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 WL 257125, at *1 (S.D.N.Y. Mar. 8, 2000) ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counter-claims not noticed in [its] ANDA."). Fisiopharma denies all other allegations in paragraph 34.

35. Fisiopharma's submission of Fisiopharma'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 Fisiopharma 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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Fisiopharma admits that its ANDA 214279 was submitted to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Fisiopharma denies all other allegations in Paragraph 35.

36. If approved by the FDA, Fisiopharma's commercial manufacture, use, importation, sale, and/or offer for sale of the Fisiopharma 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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Fisiopharma denies the allegations in Paragraph 36.

37. On information and belief, Fisiopharma will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Fisiopharma ANDA Products in or into the United States immediately and imminently upon approval of Fisiopharma's ANDA.

ANSWER: Fisiopharma admits that its ANDA 214279 was submitted to the FDA to seek approval for the commercial manufacture, use, or sale of certain sugammadex sodium injection products within the United States. Fisiopharma otherwise denies the allegations of Paragraph 37.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Fisiopharma denies the allegations in Paragraph 38.

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

ANSWER: This paragraph contains legal conclusions to which no answer is

required. To the extent a response is required, Fisiopharma denies the allegations in Paragraph 39.

40. On information and belief, upon FDA approval of Fisiopharma's ANDA, Fisiopharma will, through its own actions or through the actions of its agents, market and/or distribute the Fisiopharma ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Fisiopharma will knowingly and intentionally accompany the Fisiopharma ANDA Products with a product label or product insert that will include instructions for using or administering the Fisiopharma 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, Fisiopharma will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Fisiopharma ANDA Products to directly infringe the '733 patent. On information and belief, Fisiopharma will encourage acts of direct infringement with knowledge of the '733 patent and knowledge that Fisiopharma is encouraging infringement.

ANSWER: This paragraph contains legal conclusions as to which no answer is required. To the extent an answer is required, Fisiopharma admits that its proposed products that are the subject of ANDA 214279 will be accompanied by a product label or product insert that will include instructions for using or administering those products. Fisiopharma denies the remaining allegations set forth in paragraph 40.

41. On information and belief, Fisiopharma plans and intends to, and will, actively induce infringement of the '733 patent when Fisiopharma's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Fisiopharma's activities will be done with knowledge of the '733 patent and specific intent to infringe that patent.

ANSWER: This paragraph contains legal conclusions as to which no answer is required. To the extent an answer is required, Fisiopharma denies the allegations set forth in paragraph 41.

42. On information and belief, Fisiopharma knows that the Fisiopharma ANDA Products and proposed labeling are especially made or adapted for use in

infringing the '733 patent, that the Fisiopharma ANDA Products are not a staple article or commodity of commerce, and that the Fisiopharma ANDA Products and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, Fisiopharma plans and intends to, and will, contribute to infringement of the '733 patent immediately and imminently upon approval of Fisiopharma's ANDA.

ANSWER: This paragraph contains legal conclusions as to which no answer is required. To the extent an answer is required, Fisiopharma denies the allegations set forth in paragraph 42.

43. Notwithstanding Fisiopharma's knowledge of the claims of the '733 patent, Fisiopharma has continued to assert its intent to manufacture, use, offer for sale, sell, distribute, and/or import the Fisiopharma ANDA Products with its product labeling in or into the United States following FDA approval of Fisiopharma's ANDA prior to the expiration of the '733 patent.

ANSWER: Fisiopharma admits that its ANDA No. 214279 includes a Paragraph IV Certification 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 proposed products described in ANDA No. 214279. Fisiopharma denies all other allegations in paragraph 43.

44. The foregoing actions by Fisiopharma 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.

ANSWER: This paragraph contains legal conclusions as to which no answer is required. To the extent an answer is required, Fisiopharma denies the allegations set forth in paragraph 44.

45. On information and belief, Fisiopharma filed Fisiopharma'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 Fisiopharma ANDA Products. On information and belief, Fisiopharma has acted with full knowledge of the '733 patent and without a reasonable basis for believing that it 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 Fisiopharma of the '733 patent was and is willful. Fisiopharma's conduct renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Fisiopharma denies the allegations set forth in paragraph 45.

46. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless Fisiopharma is 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 Fisiopharma, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

ANSWER: Fisiopharma denies the allegations set forth in paragraph 46.

RESPONSE TO PRAYER FOR RELIEF

Fisiopharma denies that Plaintiff is entitled to any relief described in the section of the Complaint entitled "Prayer for Relief," and denies that Plaintiff is entitled to any relief whatsoever. Fisiopharma further denies any allegation in the Complaint and documents purported to be incorporated therein not specifically admitted above. Fisiopharma respectfully requests that the Court: (i) dismiss the Complaint with prejudice; (ii) enter judgment in favor of Fisiopharma; (iii) award Fisiopharma reasonable attorneys' fees and costs for defending this action pursuant to 35 U.S.C. § 285; and (iv) award Fisiopharma such further relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Noninfringement)

The manufacture, use, sale, offer for sale, or importation of Fisiopharma's ANDA Product has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe, either directly or indirectly, any valid and enforceable claim of the '733 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(Invalidity)

Upon information and belief, the claims of the '733 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting, the reissue-recapture rule, and/or any other judicially created requirements for patentability and enforceability of patents and/or defenses recognized in 35 U.S.C. § 282.

THIRD AFFIRMATIVE DEFENSE
(No Exceptional Case)

Plaintiffs have failed to allege facts supporting a conclusion that this case is exceptional, involves willful infringement, or that Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285 or otherwise. Fisiopharma's actions in defending this case do not render it exceptional under 35 U.S.C. § 285.

FOURTH AFFIRMATIVE DEFENSE
(No Irreparable Injury or Injunctive Relief)

Plaintiffs are not entitled to any injunction under 35 U.S.C. §§ 271(e)(4)(B) and 283, and/or Fed. R. Civ. P. 65, because Plaintiffs' alleged damages or harm are not immediate or irreparable, and Plaintiffs have an adequate remedy at law.

FIFTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this litigation.

RESERVATION OF DEFENSES

Fisiopharma reserves the right to assert any and all additional defenses available under the Federal Rules of Civil Procedure and the U.S. patent laws and any additional defenses, at law or in equity, that may now exist or become available later as a result of discovery and/or further factual investigation during this litigation.

Dated: July 8, 2020

Of Counsel:

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Defendant Fisiopharma S.r.l. hereby certifies that, to its knowledge, and other than as set forth on the annexed **Schedule A – List of Related Litigations**, this matter is not the subject of any other action asserted by the parties herein in any court, or of any pending arbitration or administrative proceeding.

Dated: July 8, 2020

FEIN, SUCH, KAHN & SHEPARD, PC
Attorneys for Defendant Fisiopharma S.r.l.

By: */s/ Alan S. Golub*

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CERTIFICATE OF SERVICE

I hereby certify that on July 8, 2020, the foregoing document was filed electronically through the Court's Electronic Case Filing System. Service of this document is being made upon all counsel of record in this case by the Notice of Electronic Filing issued through the Court's Electronic Case Filing System on this date.

/s/ Alan S. Golub
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