William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545

Attorneys for Plaintiffs
Merck Sharp & Dohme B.V.
and Organon USA Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., Plaintiffs, v. MANKIND PHARMA LIMITED and LIFESTAR PHARMA LLC, Defendants.	Civil Action No. 20-2787 *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 Mankind Pharma Limited ("MPL") and LifeStar Pharma LLC ("LifeStar") (together, "Mankind 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 Mankind 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 Nos. RE44,733 ("the '733 patent") and 6,949,527 ("the '527 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 Mankind Pharma Limited ("MPL") is a corporation organized and existing under the laws of India, with a place of business at 208 Okhla Industrial Estate Phase III, New Delhi, 110020 India. On information and belief, MPL 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 subsidiaries, including LifeStar.

5. On information and belief, Defendant LifeStar Pharma LLC ("LifeStar") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1200 MacArthur Blvd., Mahwah, New Jersey 07430. On information and belief, LifeStar 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.

6. On information and belief, LifeStar is a wholly owned subsidiary of MPL.

7. By a letter dated January 31, 2020 ("Mankind Notice Letter"), MPL notified Merck that MPL had submitted to the FDA ANDA No. 214230 ("Mankind's ANDA") for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL ("Mankind ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Mankind ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 and '527 patents.

8. On information and belief, MPL and LifeStar acted in concert to prepare and submit Mankind's ANDA and the Mankind Notice Letter.

9. On information and belief, MPL and LifeStar know and intend that upon approval of Mankind's ANDA, MPL and/or LifeStar will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Mankind ANDA Products throughout the United States, including in New Jersey. On information and belief, MPL and LifeStar are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the Mankind ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, MPL and LifeStar participated, assisted, and cooperated in carrying out the acts complained of herein.

10. On information and belief, MPL holds Drug Master File No. 33864 for sugammadex sodium.

11. On information and belief, following any FDA approval of Mankind's ANDA, MPL and LifeStar will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Mankind ANDA Products throughout the United States, including New Jersey.

JURISDICTION AND VENUE

12. Merck incorporates each of the preceding paragraphs 1–11 as if fully set forth herein.

13. 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 patents. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. MPL is subject to personal jurisdiction in New Jersey because, among other things, MPL itself, and through its wholly owned subsidiary LifeStar, 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, MPL itself, and through its wholly owned subsidiary LifeStar, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic 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. In addition, MPL is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates LifeStar, and therefore the activities of LifeStar in this jurisdiction are attributed to MPL.

15. MPL, in concert with LifeStar, has committed an act of infringement in this judicial district by filing ANDA No. 214230 with the intent to make, use, sell, offer for sale, and/or import the Mankind ANDA Products in or into this judicial district, prior to the expiration of the '733 and '527 patents.

16. This Court has personal jurisdiction over LifeStar because LifeStar is a corporation with its principal place of business in New Jersey.

17. LifeStar is also 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, LifeStar develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic 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.

18. LifeStar's website states that LifeStar "is a subsidiary of Mankind Pharma Limited" and a "pharmaceutical supply chain partner that focuses on developing and marketing affordable, high quality, multi-source specialty pharmaceuticals for the US market." *See* Who We Are, *available at* https://www.lifestarpharma.com/aboutus/ (last visited March 6, 2020).

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

20. On information and belief, Mankind Defendants have systematic and continuous contacts with New Jersey; have established distribution channels for drug products in New Jersey; regularly and continuously conduct business in New Jersey, including by selling drug

products in New Jersey, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in New Jersey; and derive substantial revenue from the sale of drug products in New Jersey.

21. On information and belief, if Mankind's ANDA is approved, Mankind Defendants will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the Mankind ANDA Products within the United States, including in New Jersey, consistent with Mankind Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Mankind 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, Mankind Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the Mankind 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 and '527 patents in the event that the Mankind ANDA Products are approved before the '733 and '527 patents expire.

22. On information and belief, LifeStar is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5005074.

23. On information and belief, LifeStar 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. 0450064472.

24. On information and belief, Mankind Defendants derive substantial revenue

from generic pharmaceutical products that are used and/or consumed within New Jersey, and that are manufactured by Mankind Defendants and/or for which MPL and/or LifeStar is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which MPL and/or Lifestar is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in New Jersey.

25. On information and belief, MPL has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g.*, *Celgene Corp. v. Mankind Pharma Ltd. et al*., No. 3:18-cv-11081-MAS-DEA (D.N.J. June 26, 2018).

26. Additionally, this Court has personal jurisdiction over MPL 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) MPL is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) MPL has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Mankind's ANDA, participating in the preparation and submission of DMF No. 33864 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 MPL satisfies due process.

27. Venue is proper in this Court as to MPL because MPL 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).

28. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to LifeStar because, on information and belief, LifeStar has a regular and established place of

business in New Jersey, and because, on information and belief, LifeStar has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patents that will lead to foreseeable harm and injury to Merck by preparing or assisting in preparing Mankind's ANDA in New Jersey and/or with the intention of seeking to market the Mankind ANDA Products nationwide, including within New Jersey.

THE PATENTS-IN-SUIT

29. 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.

30. 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.

31. 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.

32. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

33. 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.

34. Merck B.V. is the owner and assignee of the '527 patent, entitled "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block" (attached as Exhibit D). Merck B.V. has the right to enforce the '527 patent.

35. The '527 patent was duly and legally issued on September 27, 2005.

36. The '527 patent includes claims that recite 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.

37. The FDA's Orange Book currently lists the expiration of the '527 patent as January 27, 2021.

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 and '527 patents. The '733 and '527 patents have 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, Mankind Defendants have submitted or caused the submission of Mankind'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 Mankind ANDA Products, as a purported generic version of Bridion®, prior to the expiration of the '733 and '527 patents.

43. On information and belief, the FDA has not yet approved Mankind's

ANDA.

44. In the Mankind Notice Letter, MPL notified Merck of the submission of Mankind'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 Mankind ANDA Products prior to the expiration of the '733 and '527 patents.

45. In the Mankind Notice Letter, MPL acknowledged that the Reference Listed Drug for Mankind'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 Mankind Notice Letter, MPL also notified Merck that, as part of its ANDA, Mankind had filed a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '733 and '527 patents.

47. On information and belief, MPL submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '733 and '527 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the Mankind ANDA Products.

48. In the Mankind Notice Letter, MPL stated that the Mankind ANDA Products contain sugammadex as an active ingredient.

49. On information and belief, Mankind Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted Mankind's ANDA, and intend to further prosecute Mankind's ANDA. On information and belief, if the FDA approves Mankind's ANDA, Mankind Defendants will manufacture, offer for sale, or sell the Mankind ANDA Products within the United States, or will import the Mankind ANDA Products into the United States. On information and belief, if the FDA approves Mankind's

ANDA, Mankind 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 Mankind ANDA Products in or into the United States.

50. Merck brings this action within forty-five days of receipt of the Mankind 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 Mankind ANDA Products, and the use of the Mankind 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 Mankind ANDA Products.

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

54. Mankind Defendants' submission of Mankind'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 Mankind 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, Mankind Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the Mankind 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, Mankind Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Products in or into the United States immediately and imminently upon approval of Mankind's ANDA.

57. The commercial manufacture, use, sale, offer for sale, or importation of the Mankind 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 Mankind 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 Mankind's ANDA, Mankind Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the Mankind ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Mankind Defendants will knowingly and intentionally accompany the Mankind ANDA Products with a product label or product insert that will include instructions for using or administering the Mankind 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, Mankind Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Mankind ANDA Products to directly infringe the '733 patent. On information and belief, Mankind Defendants will encourage acts of direct infringement with knowledge of the '733 patent and knowledge that Mankind Defendants are encouraging infringement.

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

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

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

63. The foregoing actions by Mankind 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, MPL, in concert with its agents, affiliates, and subsidiaries, including LifeStar, filed Mankind'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 Mankind ANDA Products. On information and belief, Mankind 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 Mankind Defendants of the '733 patent was and is willful. Mankind 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 Mankind 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 Mankind Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT II – INFRINGEMENT OF THE '527 PATENT

66. Merck incorporates each of the preceding paragraphs 1–65 as if fully set forth herein.

67. The Mankind ANDA Products, and the use of the Mankind ANDA Products, are covered by one or more claims of the '527 patent, including at least claim 4 of the '527 patent, because claim 4 of the '527 patent recites a method of treatment with the sugammadex utilized in the Mankind ANDA Products.

68. In the Mankind Notice Letter, MPL did not contest infringement of claims 4 and 5 of the '527 patent.

69. Mankind Defendants' submission of Mankind'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 Mankind ANDA Products in or into the United States before the expiration of the '527 patent is an act of infringement of the '527 patent under 35 U.S.C. § 271(e)(2)(A).

70. If approved by the FDA, Mankind Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the Mankind 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 '527 patent under 35 U.S.C. § 271(a)-(c).

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

72. The commercial manufacture, use, sale, offer for sale, or importation of the Mankind ANDA Products in or into the United States would infringe one or more claims of the '527 patent.

73. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the Mankind ANDA Products in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '527 patent.

74. On information and belief, upon FDA approval of Mankind's ANDA, Mankind Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the Mankind ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Mankind Defendants will knowingly and intentionally accompany the Mankind ANDA

Products with a product label or product insert that will include instructions for using or administering the Mankind 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 '527 patent. Accordingly, Mankind Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Mankind ANDA Products to directly infringe the '527 patent. On information and belief, Mankind Defendants will encourage acts of direct infringement with knowledge of the '527 patent and knowledge that Mankind Defendants are encouraging infringement.

75. On information and belief, Mankind Defendants plan and intend to, and will, actively induce infringement of the '527 patent when Mankind's ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval. Mankind Defendants' activities will be done with knowledge of the '527 patent and specific intent to infringe that patent.

76. On information and belief, Mankind Defendants know that the Mankind ANDA Products and proposed labeling are especially made or adapted for use in infringing the '527 patent, that the Mankind ANDA Products are not a staple article or commodity of commerce, and that the Mankind ANDA Products and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, Mankind Defendants plan and intend to, and will, contribute to infringement of the '527 patent immediately and imminently upon approval of Mankind's ANDA.

77. Notwithstanding Mankind Defendants' knowledge of the claims of the '527 patent, Mankind Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the Mankind ANDA Products with its product labeling in or

into the United States following FDA approval of Mankind's ANDA prior to the expiration of the '527 patent.

78. The foregoing actions by Mankind Defendants constitute and/or will constitute direct infringement of the '527 patent; active inducement of infringement by others of the '527 patent; and contribution to the infringement by others of the '527 patent.

79. On information and belief, MPL, in concert with its agents, affiliates, and subsidiaries, including LifeStar, filed Mankind's ANDA with a Paragraph IV Certification without adequate justification for asserting that the '527 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 Mankind ANDA Products. On information and belief, Mankind Defendants have acted with full knowledge of the '527 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '527 patent; active inducement of infringement by others of the '527 patent; and/or contribution to the infringement by others of the '527 patent. On information and belief, the direct and indirect infringement by Mankind Defendants of the '527 patent was and is willful. Mankind Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

80. Merck will be substantially and irreparably damaged by infringement of the '527 patent. Unless Mankind Defendants are enjoined from directly infringing the '527 patent, actively inducing infringement of the '527 patent, and contributing to the infringement of the '527 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law, and considering the balance of hardships between Merck and Mankind 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 Mankind Defendants' submission to the FDA of Mankind'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 Mankind 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 Mankind Defendants, and all persons acting in concert with Mankind Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Mankind 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 Mankind 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 Mankind Defendants' commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Mankind ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or

more claims of the ’733 Patent by Mankind 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 Mankind Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Mankind 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 Mankind Defendants willfully and deliberately infringed the ’733 patent;

(h) A judgment that the ’527 patent has been infringed under 35 U.S.C. § 271(e)(2) by Mankind Defendants’ submission to the FDA of Mankind’s ANDA.

(i) 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 Mankind ANDA Products, or any other drug product that infringes or the use of which infringes the ’527 patent, be not earlier than the latest of the expiration date of the ’527 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(j) 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 Mankind Defendants and all persons acting in concert with Mankind Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Mankind ANDA Products, or any other drug product covered by or whose use is covered by the ’527 patent, prior to the expiration of the ’527 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(k) 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 Mankind ANDA Products, or any other drug product that is covered by or whose use is covered by the '527 patent, prior to the expiration of the '527 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '527 patent;

(l) A declaration that Mankind Defendants' commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Mankind ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '527 Patent by Mankind Defendants under one or more of 35 U.S.C. § 271(a), (b), and (c);

(m) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Mankind Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Mankind ANDA Products, or any product that infringes the '527 patent, or induces or contributes to such conduct, prior to the expiration of the '527 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(n) A judgment that Mankind Defendants willfully and deliberately infringed the '527 patent.

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

(p) Costs and expenses in this action; and

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

Dated: March 13, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com
cchevalier@gibbonslaw.com
jlower@gibbonslaw.com

Attorneys for Plaintiff
Merck Sharp & Dohme B.V.
and Organon USA Inc.

Of Counsel:

John J. Normile (*pro hac vice* to be submitted)
Sarah A. Geers
Lisamarie LoGiudice (*pro hac vice* to be submitted)
JONES DAY
250 Vesey Street
New York, NY 10281
(212) 326-3939

Andrea Weiss Jeffries (*pro hac vice* to be submitted)
JONES DAY
555 S. Flower Street
Los Angeles, CA 90071
(213) 243-2176

Anthony M. Insogna
JONES DAY
4655 Executive Drive, Suite 1500
San Diego, CA 92121-3134
(858) 314-1130

Jihong Lou (*pro hac vice* to be submitted)
JONES DAY
51 Louisiana Avenue, NW
Washington, DC 20001-2113
(202) 879-3631

Shayna Cook (*pro hac vice* to be submitted)
Alan Littmann (*pro hac vice* to be submitted)
Doug Winnard (*pro hac vice* to be submitted)
Lauren Abendshien (*pro hac vice* to be submitted)
GOLDMAN ISMAIL TOMASELLI
BRENNAN & BAUM LLP
200 S. Wacker Drive, 22nd Floor
Chicago, IL 60606
(312) 681-6000