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

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

Plaintiffs,

v.

LUPIN LIMITED; LUPIN
PHARMACEUTICALS, INC.;
and LUPIN INC.,

Defendants.

Civil Action No. 20-2786

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 Lupin Limited (“Lupin Ltd.”), Lupin Pharmaceuticals, Inc. (“LPI”), and Lupin Inc. (“Lupin Inc.”) (collectively, “Lupin 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 Lupin 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 Lupin Limited (“Lupin Ltd.”) is a corporation organized and existing under the laws of India, with a place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 400051, India. On information and belief, Lupin Ltd. 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 LPI and Lupin Inc.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. (“LPI”)

is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. On information and belief, LPI 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, LPI is a wholly owned subsidiary of Lupin Ltd.

7. On information and belief, Defendant Lupin Inc. (“Lupin Inc.”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. On information and belief, Lupin Inc. 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, Lupin Inc. is a wholly owned subsidiary of Lupin Ltd.

9. On information and belief, LPI and Lupin Inc. have at least one place of business in the State of New Jersey, including but not limited to manufacturing and research operations at the following business address: 400 Campus Drive, Somerset, New Jersey 08873.

10. By a letter dated January 31, 2020 (“Lupin Notice Letter”), Lupin Ltd. notified Merck that Lupin Ltd. had submitted to the FDA ANDA No. 214338 (“Lupin’s ANDA”) for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL (“Lupin ANDA Products”), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Products in or into the United States, including New Jersey, prior to the expiration of the ’733 patent.

11. On information and belief, Lupin Ltd., LPI, and Lupin Inc. acted in concert to prepare and submit Lupin's ANDA and the Lupin Notice Letter.

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

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

JURISDICTION AND VENUE

14. Merck incorporates each of the preceding paragraphs 1–13 as if fully set forth herein.

15. 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.

16. Lupin Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Lupin Ltd. itself, and through its wholly owned subsidiaries LPI and Lupin Inc., 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, Lupin Ltd. itself, and through its wholly owned subsidiaries LPI and Lupin Inc., 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, Lupin Ltd. is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates LPI and Lupin Inc., and therefore the activities of LPI and Lupin Inc. in this jurisdiction are attributed to Lupin Ltd.

17. Lupin Ltd., in concert with LPI and Lupin Inc., has committed an act of infringement in this judicial district by filing ANDA No. 214338 with the intent to make, use, sell, offer for sale, and/or import the Lupin ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

18. Upon information and belief, Lupin Ltd., LPI, and Lupin Inc. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products in the United States. Lupin Ltd.'s website states that Lupin Ltd. is "a fully integrated pharmaceutical company with an unrivalled position in the US..." *See Our Vision, available at* <https://www.lupin.com/our-world/our-purpose/> (last visited March 6, 2020). Lupin Ltd.'s website further states that Lupin Ltd.'s "position is built on a backbone of cutting-edge research, world-class manufacturing facilities and a truly global supply chain." *Id.* It further states that Lupin Ltd. "is the 3rd largest pharmaceutical player in the US by prescriptions" and that Lupin Ltd.'s "US marketing arm, Lupin Pharmaceuticals Inc. (LPI), is dedicated to delivering superior quality branded and generic medicines." *See Key Markets, available at* <https://www.lupin.com/our-business/global-research-and-manufacturing-facilities/usa/> (last

visited March 10, 2020).

19. Lupin Ltd.'s 2019 Annual Report states that "Lupin has made great strides in building a sustainable and vibrant business in the US." *See* Lupin 2019 Annual Report at 22, *available at* <https://www.lupin.com/pdf/annual-report/2019/lupin-annual-report-2018-19.pdf> (last visited March 6, 2020) ("Lupin Annual Report"). The Lupin Annual Report further states that Lupin Ltd. "has built strong relationships in the US wholesale and retail channels with an excellent reputation as a reliable, and in many cases a preferred supplier of quality generics." *Id.*

20. This Court has personal jurisdiction over LPI because LPI is a corporation with a regular and established place of business in New Jersey.

21. LPI 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, LPI 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.

22. LPI's website states that LPI "is the U.S. wholly owned subsidiary of [Lupin Ltd.]" *See Who We Are*, *available at* <http://www.lupinpharmaceuticals.com/about.htm> (last visited March 6, 2020). The website further states that LPI is "building on our parent company's [Lupin Ltd.] strengths of vertical integration in discovery research, process chemistry, active pharmaceutical ingredient production, formulation development and regulatory filings." LPI's website also states, "founded on the strengths of our parent company Lupin Limited, Lupin Pharmaceuticals, Inc. intends to bring a portfolio of generics as well as branded products to the

US market.” *Id.*

23. On information and belief, LPI is registered as “Manufacturer and Wholesale” with the State of New Jersey’s Department of Health under Registration Nos. 5004060 and 5005159.

24. On information and belief, LPI 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 Nos. 0100953673 and 0101043376.

25. Lupin Inc. is subject to personal jurisdiction in New Jersey. On information and belief, Lupin Inc. 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.

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

27. On information and belief, Lupin 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.

28. On information and belief, if Lupin’s ANDA is approved, Lupin Defendants will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the Lupin

ANDA Products within the United States, including in New Jersey, consistent with Lupin Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Lupin 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, Lupin Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the Lupin 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 Lupin ANDA Products are approved before the '733 patent expires.

29. On information and belief, Lupin Defendants derive substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and that are manufactured by Lupin Defendants and/or for which Lupin Ltd., LPI and/or Lupin Inc. is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Lupin Ltd., LPI and/or Lupin Inc. is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in New Jersey.

30. On information and belief, Lupin Ltd. and LPI availed themselves of the rights, benefits, and privileges of this Court by filing a complaint in the District of New Jersey in at least the following action: *Lupin Ltd. v. Merck, Sharp & Dohme Corp.*, Civil Action No. 10-cv-00683.

31. On information and belief, Lupin Ltd. 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., Mitsubishi Tanabe Pharma Corp. et al. v. Lupin Ltd. et al.*, No. 1:19-cv-07165-RMB-JS (D.N.J. Feb. 27, 2019); *Valeant Pharm. N. Am. LLC et al. v. Lupin Ltd. et al.*, No. 3:18-cv-13700-PGS-LHG (D.N.J. Sept. 9, 2018).

32. On information and belief, LPI 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., Mitsubishi Tanabe Pharma Corp. et al. v. Lupin Ltd. et al.*, No. 1:19-cv-07165-RMB-JS (D.N.J. Feb. 27, 2019); *Valeant Pharm. N. Am. LLC et al. v. Lupin Ltd. et al.*, No. 3:18-cv-13700-PGS-LHG (D.N.J. Sept. 9, 2018).

33. On information and belief, Lupin Inc. 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., Bausch Health Ir. Ltd. et al. v. Lupin Inc.*, No. 1:19-cv-09178-RMB-KMW (D.N.J. Apr. 1, 2019).

34. Additionally, this Court has personal jurisdiction over Lupin Ltd. 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) Lupin Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Lupin'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 Lupin Ltd. satisfies due process.

35. Venue is proper in this Court as to Lupin Ltd. because Lupin Ltd. 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).

36. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to LPI and Lupin Inc. because, on information and belief, LPI and Lupin Inc. have a regular and established place of business in New Jersey, and because, on information and belief, LPI and Lupin Inc. have committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patent that will lead to foreseeable harm and injury to Merck by preparing or assisting in preparing Lupin's ANDA in New Jersey and/or with the intention of seeking to market the Lupin ANDA Products nationwide, including within New Jersey.

THE PATENT-IN-SUIT

37. 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.

38. 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.

39. 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.

40. 6-Per-deoxy-6-per-(2-carboxyethyl)thio- γ -cyclodextrin is also referred to as sugammadex.

41. 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

42. 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.

43. 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.

44. 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.

45. 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

46. On information and belief, Lupin Defendants have submitted or caused the submission of Lupin'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 Lupin ANDA Products, as a purported generic version of Bridion[®], prior to the expiration of the '733 patent.

47. On information and belief, the FDA has not yet approved Lupin's ANDA.

48. In the Lupin Notice Letter, Lupin Ltd. notified Merck of the submission of Lupin'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 Lupin ANDA Products prior to the expiration of the '733 patent.

49. In the Lupin Notice Letter, Lupin Ltd. acknowledged that the Reference Listed Drug for Lupin's ANDA is Bridion[®]. Bridion[®] is indicated for the reversal of

neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

50. In the Lupin Notice Letter, Lupin Ltd. also notified Merck that, as part of its ANDA, Lupin 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.

51. On information and belief, Lupin Ltd. 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 Lupin ANDA Products.

52. In the Lupin Notice Letter, Lupin Ltd. stated that the Lupin ANDA Products contain sugammadex as an active ingredient.

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

54. Merck brings this action within forty-five days of receipt of the Lupin 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

55. Merck incorporates each of the preceding paragraphs 1–54 as if fully set forth herein.

56. The Lupin ANDA Products, and the use of the Lupin 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 Lupin ANDA Products.

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

58. Lupin Defendants' submission of Lupin'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 Lupin 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).

59. If approved by the FDA, Lupin Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the Lupin 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).

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

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

patent.

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

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

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

65. On information and belief, Lupin Defendants know that the Lupin ANDA Products and proposed labeling are especially made or adapted for use in infringing the '733 patent, that the Lupin ANDA Products are not a staple article or commodity of commerce, and that the

Lupin ANDA Products and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, Lupin Defendants plan and intend to, and will, contribute to infringement of the '733 patent immediately and imminently upon approval of Lupin's ANDA.

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

67. The foregoing actions by Lupin 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.

68. On information and belief, Lupin Ltd., in concert with its agents, affiliates, and subsidiaries, including LPI and Lupin Inc., filed Lupin'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 Lupin ANDA Products. On information and belief, Lupin 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 Lupin Defendants of the '733 patent was and is willful. Lupin Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

69. Merck will be substantially and irreparably damaged by infringement of the

'733 patent. Unless Lupin 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 Lupin 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 Lupin Defendants' submission to the FDA of Lupin'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 Lupin 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 Lupin Defendants, and all persons acting in concert with Lupin Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Lupin 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 Lupin 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 Lupin Defendants' commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Lupin ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '733 Patent by Lupin 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 Lupin Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Lupin 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 Lupin 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: March 13, 2020
Newark, New Jersey

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Respectfully submitted,

s/ William P. Deni, Jr.

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