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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and MERCK SHARP & DOHME LLC, Plaintiffs, v. USV PRIVATE LIMITED, Defendant.	Civil Action No. 25-694 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Sharp & Dohme B.V. ("Merck B.V.") and Merck Sharp & Dohme LLC ("Merck LLC") (together, "Merck"), by their attorneys, bring this complaint against Defendant USV Private Limited ("USV") based on a new "Paragraph IV" notice letter from USV dated December 11, 2024 ("USV Notice of Recertification"), and relating to Abbreviated New Drug Application 214276 ("USV's ANDA"). This is the same ANDA that is and remains subject to the Final Judgment and associated injunction entered by the Court on June 29, 2023 in connection with *In re Sugammadex*, Civil Action No. 20-2576 (CCC) (LDW) ("*In re Sugammadex*"). ECF

No. 423.[1] Merck brings this action in view of the the USV Notice of Recertification and to avoid any uncertainty, and hereby alleges 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 USV'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 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 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 126 East Lincoln Avenue, P.O. Box 2000, Rahway, New Jersey 07065.

3. Plaintiff Merck LLC, which holds approved New Drug Application No. 022225 for Bridion®, is a limited liability company formed and existing under the laws of New Jersey, having its corporate offices and principal place of business at 126 East Lincoln Avenue, P.O. Box 2000, Rahway, New Jersey 07065. Merck LLC is a direct, wholly owned subsidiary of Merck & Co., Inc.

[1] ECF No. refers to the docket number in *In re Sugammadex*, unless otherwise noted.

4. Defendant USV Private Limited ("USV") is a corporation organized and existing under the laws of India, having a place of business at Arvind Vithal Gandhi Chowk, B.S.D. Marg, Station Road, Govandi East, Mumbai, Maharashtra, 400088 India. USV 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.

5. By a letter dated February 13, 2020 ("USV Notice Letter"), USV notified Merck that USV had submitted to the FDA USV's ANDA No. 214276 ("USV's ANDA") for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL ("USV ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the USV ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent.

6. Merck timely filed suit against USV in the District of New Jersey within 45 days of receiving the USV Notice Letter (Civil Action No. 20-3072), and that case was ultimately consolidated as part of *In re Sugammadex*.

7. In *In re Sugammadex*, the consolidated defendants, including USV, admitted infringement but contested the validity of a portion of the term of the '733 patent as invalid. After trial, this Court rejected defendants' position, and found that the '733 patent does not expire until January 27, 2026, as previously determined by the PTO. ECF Nos. 418, 419, 423. The Court then entered Final Judgment, attached as Exhibit A, directing that FDA cannot approve the USV ANDA until after the '733 patent expires, and enjoining USV from infringing that patent. ECF No. 423. The consolidated defendants' appeal of that judgment to the Federal Circuit is pending in *Merck, Sharp & Dohme B. V. v. Aurobindo Pharma USA*, No. 23-2254 (Fed. Cir.).

8. By the USV Notice of Recertification, dated December 11, 2024, USV notified Merck that "FDA has received an ANDA Amendment from USV for Sugammadex Injection 200 mg/2 ml (100 mg/ml) and 500 mg/5 ml (100 mg/ml) (the 'USV ANDA Products'), containing any required bioavailability and/or bioequivalence data or information." The USV Notice of Recertification is directed to the same USV ANDA that is the subject of the Final Judgment in *In re Sugammadex*.

9. On information and belief, USV holds Drug Master File No. 34052 for sugammadex sodium.

JURISDICTION AND VENUE

10. Merck incorporates each of the preceding paragraphs 1–9 as if fully set forth herein.

11. 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.

12. USV is subject to personal jurisdiction in New Jersey because, among other things, USV 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, USV itself, and through its U.S. agents, 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.

13. USV's website states that USV's "Finished Products are marketed in [the] US." *See* usvindia.com, International Operations tab, *available at*

https://www.usvindia.com/international.php (last visited March 16, 2020).

14. USV has committed an act of infringement in this judicial district by filing ANDA No. 214276 with the intent to make, use, sell, offer for sale, and/or import the USV ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

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

16. On information and belief, USV has systematic and continuous contacts with New Jersey; has established distribution channels for drug products in New Jersey; regularly and continuously conducts business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through its US agents; has purposefully availed itself of the privilege of doing business in New Jersey; and derives substantial revenue from the sale of drug products in New Jersey.

17. On information and belief, if USV's ANDA is approved, USV will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the USV ANDA Products within the United States, including in New Jersey, consistent with USV's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, USV, either directly or indirectly through its U.S. agents, regularly does business in New Jersey, and its 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, USV's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the USV 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 USV ANDA Products are approved before the '733 patent expires.

18. On information and belief, USV derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and that are manufactured by USV and/or for which USV is the named applicant on approved ANDAs. On information and belief, various products for which USV is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

19. Additionally, this Court has personal jurisdiction over USV 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) USV is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) USV has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of USV's ANDA, participating in the preparation and submission of Drug Master File No. 34052 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 USV satisfies due process.

20. Venue is proper in this Court as to USV because USV 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).

21. USV did not contest personal jurisdiction or venue in *In re Sugammadex* involving the same ANDA. Civil Action No. 20-3072, ECF No. 9 ¶¶ 9, 10, 16, 17.[2]

[2] USV filed its Answer, Defense and Counterclaims in Civil Action No. 20-3072, ECF No. 9, prior to consolidation.

THE PATENT-IN-SUIT

22. 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 B). Merck B.V. has the right to enforce the ’733 patent.

23. 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.

24. 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.

25. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

26. 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 C). The PTE certificate issued, and the expiration of the ’733 patent is January 27, 2026 (attached as Exhibit D). The FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) currently lists the expiration of the ’733 patent as January 27, 2026.

THE BRIDION® DRUG PRODUCT

27. Merck LLC 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 E.

28. 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.

29. 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.

30. 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.

DEFENDANT'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

31. USV has submitted or caused the submission of USV'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 USV ANDA Products, as a purported generic version of Bridion®, prior to the expiration of the '733 patent.

32. The FDA has not yet approved USV's ANDA, and is in fact enjoined by this Court from doing so until after the expiration of the '733 patent. ECF No. 423.

33. In the USV Notice of Recertification, USV notified Merck of a renewed Paragraph IV recertification regarding the '733 patent. In USV's Notice of Recertification, USV stated "FDA has received an ANDA Amendment from USV for Sugammadex Injection 200 mg/2 ml (100 mg/ml) and 500 mg/5 ml (100 mg/ml) (the 'USV ANDA Products'), containing any required bioavailability and/or bioequivalence data or information. The ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), with a Paragraph IV recertification to obtain FDA approval of the USV ANDA Products before the expiration of the '733 patent . . . ." The ANDA number remains 214276, and USV's ANDA is the same USV ANDA that is subject of this Court's Final Judgment.

34. On information and belief, USV prepared and submitted USV's ANDA Amendment, and intends to further prosecute USV's ANDA.

35. On information and belief, if the FDA approves USV's ANDA, USV will manufacture, distribute, promote, market, offer for sale, or sell the USV ANDA Products within the United States, or will import the USV ANDA Products into the United States.

36. On information and belief, if the FDA approves USV's ANDA, USV will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the USV ANDA Products in or into the United States.

37. Merck brings this action within forty-five days of receipt of the USV Notice of Recertification.

COUNT I – INFRINGEMENT OF THE '733 PATENT

38. Merck incorporates each of the preceding paragraphs 1–37 as if fully set forth herein.

39. The USV ANDA Products, and the use of the USV 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 USV ANDA Products.

40. In the USV Notice of Recertification, USV did not contest infringement of claims 1-5, 9, 11-14, 20 and 21 of the '733 patent, and USV has previously admitted that the product described in the USV ANDA infringes these claims. ECF No. 252.

41. USV's submission of USV'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 USV 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).

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

43. On information and belief, USV will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the USV ANDA Products in or

into the United States immediately and imminently upon approval of USV's ANDA.

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

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

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

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

48. On information and belief, USV knows that the USV ANDA Products and proposed labeling are especially made or adapted for use in infringing the '733 patent, that the USV ANDA

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

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

50. The foregoing actions by USV 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.

51. On information and belief, USV filed USV'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 USV ANDA Products. On information and belief, USV 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 USV of the '733 patent was and is willful. USV's conduct renders this case "exceptional" under 35 U.S.C. § 285.

52. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless USV 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 USV, 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 USV's submission to the FDA of USV'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 USV 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 permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining USV, and all persons acting in concert with USV, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the USV 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 USV 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 USV's commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the USV ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '733 patent by USV 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 USV engages in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the USV 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 USV 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: January 23, 2025
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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