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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, INC. and SUN PHARMACEUTICAL INDUSTRIES LIMITED, Defendants.	Civil Action No. 20-3007 *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 Sun Pharmaceutical Industries, Inc. ("Sun Inc.") and Sun Pharmaceutical Industries Limited ("Sun Ltd.") (together, "Sun 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 Sun 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 Sun Pharmaceutical Industries, Inc. ("Sun Inc.") is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business in New Jersey at the following business address: 1 Commerce Drive, Cranbury, New Jersey 08512. On information and belief, Sun 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.

5. On information and belief, Sun Inc. has several places of business in the

State of New Jersey, including but not limited to at the following business address: 2 Independence Way, Princeton, New Jersey 08540.

6. On information and belief, Defendant Sun Pharmaceutical Industries Limited ("Sun Ltd.") is a corporation organized and existing under the laws of India, having a place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, 400063 India. On information and belief, Sun 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 Sun Inc.

7. On information and belief, Sun Inc. is a wholly owned subsidiary of Sun Ltd.

8. By a letter dated February 14, 2020 ("Sun Notice Letter"), Sun Inc. notified Merck that Sun Inc. had submitted to the FDA ANDA No. 214319 ("Sun's ANDA") for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL ("Sun ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Sun ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent.

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

10. On information and belief, Sun Inc. and Sun Ltd. know and intend that upon approval of Sun's ANDA, Sun Inc. and/or Sun Ltd. will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Sun ANDA Products throughout the United States, including in New Jersey. On information and belief, Sun Inc. and Sun Ltd. are agents of each

other and/or operate in concert as integrated parts of the same business group, including with respect to the Sun ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, Sun Inc. and Sun Ltd. participated, assisted, and cooperated in carrying out the acts complained of herein.

11. On information and belief, following any FDA approval of Sun's ANDA, Sun Inc. and Sun Ltd. will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Sun 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 patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. This Court has personal jurisdiction over Sun Inc. because Sun Inc. is a corporation having a principal place of business in New Jersey, and it has at least one other regular and established place of business in New Jersey.

15. Sun Inc. is also subject to personal jurisdiction in New Jersey because, among other things, Sun Inc. 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, Sun 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.

16. Sun Inc., in concert with Sun Ltd., has committed an act of infringement in this judicial district by filing ANDA No. 214319 with the intent to make, use, sell, offer for sale, and/or import the Sun ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

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

18. Sun Ltd.'s website states that the "world's largest pharmaceuticals market is also the biggest market for Sun Pharma…. Being a vertically integrated company with a global presence, we have the flexibility to develop and manufacture products in the US as well as at other locations across the world." *See* SunPharma.com, USA tab, *available at* https://www.sunpharma.com/usa (last visited March 16, 2020). Sun Ltd.'s website also states that Sun Ltd.'s "US headquarters are in Cranbury, New Jersey," and that "Sun Pharma's latest acquisition of a majority interest in Ranbaxy Laboratories Limited (Ranbaxy) and its Ohm

Laboratories facilities in the [*sic*] New Jersey makes it the largest Indian pharma company in the US market, with a significantly expanded portfolio of life-saving and enhancing medicines." *Id.*

19. Sun Ltd.'s 2018-19 Annual Report states that "[r]evenues in the US increased 22% to ₹107 Billion and accounted for 37% of [Sun Ltd.'s] consolidated revenues for FY19." *See* Sun Pharmaceutical Industries Ltd. Annual Report 2018-19 at 4, *available at* https://www.sunpharma.com/sites/default/files/annual/Complete%20Annual%20Report.pdf (last visited March 16, 2020) ("Sun Ltd. Annual Report"). The Sun Ltd. Annual Report also states that "Sun Pharmaceutical Industries Limited including its subsidiaries and associates…is the largest Indian pharmaceutical company in the US…." *Id.* at 14. The Sun Ltd. Annual Report further states that Sun Ltd. is the "8th largest generics company in the US with a strong pipeline (118 ANDAs and 8 NDAs awaiting approval)." *Id.* at 16.

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

21. On information and belief, Sun 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.

22. On information and belief, if Sun's ANDA is approved, Sun Defendants will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the Sun ANDA Products within the United States, including in New Jersey, consistent with Sun Defendants'

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

23. On information and belief, Sun Inc. is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5003437.

24. On information and belief, Sun Inc. 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. 0100954087 and 0100970132.

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

26. On information and belief, Sun 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.,*; *Celgene Corp. v. Sun Pharm. Indus., Inc. et al.*, No. 2:18-cv-11630-SDW-LDW (D.N.J. July 13, 2018).

27. On information and belief, Sun 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.*, *Celgene Corp. v. Sun Pharm. Indus., Inc. et al.*, No. 2:18-cv-11630-SDW-LDW (D.N.J. July 13, 2018).

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

29. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b) as to Sun Inc. because, on information and belief, Sun Inc. has a regular and established place of business in New Jersey, and because, on information and belief, Sun Inc. has 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 Sun's ANDA in New Jersey and/or with the intention of seeking to market the Sun ANDA Products nationwide, including within New Jersey.

30. Venue is proper in this Court as to Sun Ltd. because Sun 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).

31. Sun Inc. has informed Merck that it will not contest personal jurisdiction or venue in the United States District Court for the District of New Jersey for purposes of this action.

THE PATENT-IN-SUIT

32. 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.

33. 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.

34. 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.

35. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

36. 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

37. 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.

38. 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.

39. 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.

40. 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

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

42. On information and belief, the FDA has not yet approved Sun's ANDA.

43. In the Sun Notice Letter, Sun Inc. notified Merck of the submission of Sun'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 Sun ANDA Products prior to the expiration of the '733 patent.

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

45. In the Sun Notice Letter, Sun Inc. also notified Merck that, as part of its ANDA, Sun Inc. 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.

46. On information and belief, Sun Inc. 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 Sun ANDA Products.

47. In the Sun Notice Letter, Sun Inc. stated that the Sun ANDA Products contain sugammadex as an active ingredient.

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

49. Merck brings this action within forty-five days of receipt of the Sun 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

50. Merck incorporates each of the preceding paragraphs 1–49 as if fully set forth herein.

51. The Sun ANDA Products, and the use of the Sun 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 Sun ANDA

Products.

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

53. Sun Defendants' submission of Sun'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 Sun 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).

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

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

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

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

58. On information and belief, upon FDA approval of Sun's ANDA, Sun Defendants will, through their own actions or through the actions of their agents, affiliates, and

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

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

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

61. Notwithstanding Sun Defendants' knowledge of the claims of the '733 patent, Sun Defendants have continued to assert their intent to manufacture, use, offer for sale,

sell, distribute, and/or import the Sun ANDA Products with its product labeling in or into the United States following FDA approval of Sun's ANDA prior to the expiration of the '733 patent.

62. The foregoing actions by Sun 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.

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

64. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless Sun 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 Sun 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 Sun Defendants' submission to the FDA of Sun'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 Sun 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 Sun Defendants, and all persons acting in concert with Sun Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Sun 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 Sun 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 Sun Defendants' commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Sun ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of

the ’733 Patent by Sun 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 Sun Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Sun 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 Sun 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 18, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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