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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., Plaintiffs, v. SANDOZ INC. and LEK PHARMACEUTICALS D.D., Defendants.	Civil Action No. 20-3117 *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 Sandoz Inc. ("Sandoz Inc.") and Lek Pharmaceuticals d.d. ("Lek") (together, "Sandoz 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 Sandoz 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 Sandoz Inc. ("Sandoz Inc.") is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540. On information and belief, Sandoz 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. Upon information and belief, Sandoz Inc. has several places of business in the State of New Jersey, including but not limited to at the following business address: One Health

Plaza, Bldg. 435, East Hanover, New Jersey 07936.

6. On information and belief, Defendant Lek Pharmaceuticals d.d. ("Lek") is a corporation organized and existing under the laws Slovenia, having a place of business at Verovškova 57, 1526 Ljubljana, Slovenia. On information and belief, Lek 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 affiliates, including Sandoz Inc.

7. On information and belief, Sandoz Inc. and Lek are related corporate entities.

8. By a letter dated February 19, 2020 ("Sandoz Notice Letter"), Sandoz Inc. notified Merck that Sandoz Inc. had submitted to the FDA ANDA No. 214311 ("Sandoz's ANDA") for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL ("Sandoz ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Sandoz ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent.

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

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

On information and belief, Sandoz Inc. and Lek participated, assisted, and cooperated in carrying out the acts complained of herein.

11. On information and belief, Lek holds Drug Master File No. 33817 for sugammadex sodium.

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

JURISDICTION AND VENUE

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

14. 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.

15. This Court has personal jurisdiction over Sandoz Inc. because Sandoz Inc. is a corporation having a principle place of business and at least one other regular and established place of business in New Jersey.

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

17. Sandoz Inc., in concert with Lek, has committed an act of infringement in this judicial district by filing ANDA No. 214311 with the intent to make, use, sell, offer for sale, and/or import the Sandoz ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

18. Lek is subject to personal jurisdiction in New Jersey because, among other things, Lek itself, and through its affiliate Sandoz 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, Lek itself, and through its affiliate Sandoz 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. Additionally, this Court has personal jurisdiction over Lek because on information and belief Lek assisted in the preparation and submission of Drug Master File No. 33817 to the FDA.

19. Lek's website states that it is "a Sandoz company" and that in "2017, the [Lek] Development Center Slovenia completed the development of, and filed 17 drug products dossiers for the markets in the USA." *See* lek.si, About us tab, *available* at https://www.lek.si/en/about-us/company-presentation/#locations (last visited March 17, 2020). Further, Lek's 2017 Sustainability Report states that "Sandoz successfully launched 18 medicines, developed in the Development Center Slovenia in the USA." *See* Lek d.d. 2017 Sustainability Report at 9, *available* at https://www.lek.si/media/dropbox/porocila/Lek_Sustainability%20report_2017.pdf (last visited March 17, 2020) ("Lek Report"). The Lek Report further states, "the

majority of [Lek's] products, 95%, are sold directly to foreign markets (the USA, Russia and Western Europe), and the remaining 5% to Slovenia." *Id.* at 16.

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

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

23. On information and belief, Sandoz Inc. is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5003732.

24. On information and belief, Sandoz 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 No. 010097265.

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

26. On information and belief, Sandoz Inc. has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or have filed counterclaims in such cases. *See, e.g.*, *Vifor (Int'l) AG et al. v. Sandoz, Inc.*, No. 3:19-cv-16305-FLW-DEA (D.N.J. Aug. 2, 2019); *Adamas Pharma, LLC v. Sandoz Inc.*, No. 3:18-cv-09032-BRM-TJB (D.N.J. May 10, 2018); *Par Pharm., Inc. et al. v. Sandoz Inc.*, No. 3:18-cv-14895-BRM-DEA (D.N.J. Oct. 11, 2018).

27. Additionally, this Court has personal jurisdiction over Lek 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) Lek is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lek has sufficient contacts in the United States as a whole, including,

but not limited to, by participating in the preparation and submission of Sandoz's ANDA, participating in the preparation and submission of Drug Master File No. 33817 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 Lek satisfies due process.

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

29. Venue is proper in this Court as to Lek because Lek 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).

30. Sandoz 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

31. 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.

32. 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.

33. 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.

34. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

35. 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

36. 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.

37. 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.

38. 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.

39. 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

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

41. On information and belief, the FDA has not yet approved Sandoz's ANDA.

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

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

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

45. On information and belief, Sandoz 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 Sandoz ANDA Products.

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

47. On information and belief, Sandoz Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted

Sandoz's ANDA, and intend to further prosecute Sandoz's ANDA. On information and belief, if the FDA approves Sandoz's ANDA, Sandoz Defendants will manufacture, distribute, promote, market, offer for sale, or sell the Sandoz ANDA Products within the United States, or will import the Sandoz ANDA Products into the United States. On information and belief, if the FDA approves Sandoz's ANDA, Sandoz 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 Sandoz ANDA Products in or into the United States.

48. Merck brings this action within forty-five days of receipt of the Sandoz 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

49. Merck incorporates each of the preceding paragraphs 1–48 as if fully set forth herein.

50. The Sandoz ANDA Products, and the use of the Sandoz 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 Sandoz ANDA Products.

51. In the Sandoz Notice Letter, Sandoz Inc. did not specifically contest infringement of claims 1-5 and 11-14 of the '733 patent.

52. Sandoz Defendants' submission of Sandoz'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 Sandoz 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).

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

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

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

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

57. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the Sandoz ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Sandoz Defendants will knowingly and intentionally accompany the Sandoz ANDA Products with a product label or product insert that will include instructions for using or administering the Sandoz 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, Sandoz Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare

professionals, and other end users of the Sandoz ANDA Products to directly infringe the '733 patent. On information and belief, Sandoz Defendants will encourage acts of direct infringement with knowledge of the '733 patent and knowledge that Sandoz Defendants are encouraging infringement.

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

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

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

61. The foregoing actions by Sandoz 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.

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

63. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless Sandoz 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 Sandoz 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 Sandoz Defendants' submission to the FDA of Sandoz'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 Sandoz 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 Sandoz Defendants, and all persons acting in concert with Sandoz Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Sandoz 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 Sandoz 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 Sandoz Defendants' commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Sandoz ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '733 Patent by Sandoz 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 Sandoz Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Sandoz 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 Sandoz 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 20, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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