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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. 20-2909 *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 Dr. Reddy's Laboratories, Inc. ("DRLI") and Dr. Reddy's Laboratories, Ltd. ("DRLL") (together, "DRL 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 DRL 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 Dr. Reddy's Laboratories, Inc. ("DRLI") is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, DRLI 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, Defendant Dr. Reddy's Laboratories Ltd. ("DRLL") is a corporation organized and existing under the laws of India, having a place of

business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, 500034 India. On information and belief, DRLL 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 DRLI.

6. On information and belief, DRLI is a wholly owned subsidiary of DRLL.

7. By a letter dated February 11, 2020 ("DRL Notice Letter"), DRLI notified Merck that DRLI had submitted to the FDA ANDA No. 214236 ("DRL's ANDA") for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL ("DRL ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the DRL ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent.

8. On information and belief, DRLI and DRLL acted in concert to prepare and submit DRL's ANDA and the DRL Notice Letter.

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

10. On information and belief, DRLL holds Drug Master File No. 32614 for

sugammadex sodium.

11. On information and belief, following any FDA approval of DRL's ANDA, DRLI and DRLL will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the DRL 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 DRLI because DRLI is a corporation organized and existing under the laws of New Jersey and because DRLI has its principal place of business in New Jersey.

15. DRLI is also subject to personal jurisdiction in New Jersey because, among other things, DRLI 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, DRLI 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. DRLI, in concert with DRLL, has committed an act of infringement in this judicial district by filing ANDA No. 214236 with the intent to make, use, sell, offer for sale, and/or

import the DRL ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

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

18. DRLL's 2019 Annual Report states that DRLL has a "pipeline" that "ensures that [DRLL] succeed[s] in delivering [] products, molecule by molecule, to the US…." *See* Dr. Reddy's Annual Report 2018-19 at 3, *available at* https://www.drreddys.com/media/904463/annualreport2019forwebsite.pdf (last visited March 6, 2020) ("DRLL Annual Report"). On information and belief, through its own actions and through the actions of its agents, affiliates, and subsidiaries, "in FY2019, [DRLL] filed 20 new [ANDAs] with the USFDA," and that a goal for 2020 is to "strengthen [DRLL's] presence in [DRLL's] six chosen spaces (United States, India, Russia, China, Global Hospitals including Biosimilars, and the Global API business)." *Id.* at 45. Further, the DRLL Annual Report states that DRLL's "principal markets" include the United States. *Id.* at 117.

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

20. On information and belief, DRL Defendants have systematic and continuous contacts with New Jersey; have established distribution channels for drug products in New Jersey; regularly and continuously conduct business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in New Jersey; and derive substantial revenue from the sale of drug products in New Jersey.

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

22. On information and belief, DRLI is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5002312.

23. On information and belief, DRLI 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. 0100518911.

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

25. On information and belief, DRLI 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.*, *AstraZeneca LP et al. v. Dr. Reddy's Labs., Ltd. et al.*, No. 2:19-cv-15739-CCC-MF (D.N.J. July 23, 2019); *Celgene Corp. v. Dr. Reddy's Labs., Ltd. et al.*, No. 2:19-cv-15343-ES-MAH (D.N.J. July 12, 2019); *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, No. 2:18-cv-02620-SRC-CLW (D.N.J. Feb. 23, 2018).

26. On information and belief, DRLL 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.*, *AstraZeneca LP et al. v. Dr. Reddy's Labs., Ltd. et al.*, No. 2:19-cv-15739-CCC-MF (D.N.J. July 23, 2019); *Celgene Corp. v. Dr. Reddy's Labs., Ltd. et al.*, No. 2:19-cv-15343-ES-MAH (D.N.J. July 12, 2019); *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, No. 2:18-cv-02620-SRC-CLW (D.N.J. Feb. 23, 2018).

27. Additionally, this Court has personal jurisdiction over DRLL 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) DRLL is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) DRLL has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of DRL's ANDA, participating in the preparation and submission of Drug Master File No. 32614 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 DRLL satisfies due process.

28. Venue is proper in this Court as to DRLI pursuant to 28 U.S.C. § 1400(b) because DRLI is incorporated in the State of New Jersey and therefore resides in this judicial district.

29. Venue is proper in this Court as to DRLL because DRLL 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. DRLI 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, DRL Defendants have submitted or caused the submission of DRL'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 DRL 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 DRL's ANDA.

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

43. In the DRL Notice Letter, DRLI acknowledged that the Reference Listed Drug for DRL'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 DRL Notice Letter, DRLI also notified Merck that, as part of its ANDA, DRL 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, DRLI 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 DRL ANDA Products.

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

47. On information and belief, DRL Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted DRL's ANDA, and intend to further prosecute DRL's ANDA. On information and belief, if the FDA approves DRL's ANDA, DRL Defendants will manufacture, distribute, promote, market, offer for

sale, or sell the DRL ANDA Products within the United States, or will import the DRL ANDA Products into the United States. On information and belief, if the FDA approves DRL's ANDA, DRL 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 DRL ANDA Products in or into the United States.

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

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

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

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

patent and knowledge that DRL Defendants are encouraging infringement.

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

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

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

61. The foregoing actions by DRL 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, DRLI, in concert with its agents, affiliates, and subsidiaries, including DRLL, filed DRL'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 DRL ANDA Products. On information and belief, DRL 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 DRL Defendants of the '733 patent was and is willful. DRL 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 DRL 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 DRL 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 DRL Defendants' submission to the FDA of DRL'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 DRL 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 DRL Defendants, and all persons acting in concert

with DRL Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the DRL 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 DRL 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 DRL Defendants' commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the DRL ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '733 Patent by DRL 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 DRL Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the DRL 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 DRL 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 16, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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