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.	**Document Electronically Filed** Civil Action No. 20-2909 (CCC) (MF)

DEFENDANTS' ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Dr. Reddy's Laboratories, Inc. ("DRL Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively, "DRL") hereby answer the Complaint for Patent Infringement of Plaintiffs Merck Sharp & Dohme B.V. ("Merck B.V.") and Organon USA Inc. ("Organon") (collectively, "Merck Plaintiffs" or "Plaintiffs"), as set forth below.

This pleading is based upon DRL's knowledge as to its own activities, and upon information and belief as to the activities of others. DRL denies all allegations except those specifically admitted below. *See* Fed. R. Civ. P. 8(b)(3).

NATURE OF THE ACTION

Complaint ¶ 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").

Response: Paragraph 1 states legal conclusions to which no response is required. To the extent a response is required, DRL admits that Plaintiffs purport to bring an action for patent infringement under the patent laws of the United States. DRL admits that DRL Inc. submitted Abbreviated New Drug Application ("ANDA") No. 214236 to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, or sale of sugammadex injection, 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL) ("the ANDA Products"). Otherwise denied.

PARTIES

Complaint ¶ 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.

Response: DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

Complaint ¶ 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.

Response: DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

Complaint ¶ 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.

Response: DRL Inc. admits that DRL Inc. 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. DRL Inc. admits that it is in the business of selling pharmaceutical products for markets including the United States. Otherwise denied.

Complaint ¶ 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.

Response: DRL Ltd. admits that DRL Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India. DRL Ltd. admits that it is in the business of developing, manufacturing, distributing, and selling pharmaceutical products. Otherwise denied.

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

Response: Admitted that DRL Inc. is a subsidiary of DRL Ltd. Otherwise denied.

Complaint ¶ 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.

Response: Admitted that DRL Inc. sent a letter dated February 11, 2020 to Plaintiffs ("the Notice Letter") stating that DRL Inc. had submitted ANDA No. 214236 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products. Otherwise denied.

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

Response: This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, admitted that DRL Inc. submitted ANDA No. 214236 to the FDA, and that DRL Inc. sent the Notice Letter to Plaintiffs. Otherwise denied.

Complaint ¶ 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.

Response: With respect to the allegations in the first sentence of Paragraph 9, admitted that DRL Inc. submitted ANDA No. 214236 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this sentence, and therefore denies them. The remainder of Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, DRL admits that DRL Inc. is a subsidiary of DRL Ltd., that DRL Inc. prepared and submitted ANDA No. 214236 to the FDA, and that DRL Inc. prepared the Notice Letter and sent it to Plaintiffs. Otherwise denied.

Complaint ¶ 10. On information and belief, DRLL holds Drug Master File No. 32614 for sugammadex sodium.

Response: Admitted.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

JURISDICTION AND VENUE

Complaint ¶ 12. Merck incorporates each of the preceding paragraphs 1–11 as if fully set forth herein.

Response: DRL repeats and incorporates its responses to Paragraphs 1–11 of the Complaint as if fully set forth herein.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no response is required. To the extent a response is required, DRL admits that the Complaint purports to state a cause of action for patent infringement. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no response is required. To the extent a response is required, for the purposes of this case only, DRL Inc. does not contest personal jurisdiction in this Judicial District. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no response is required. To the extent a response is required, for the purposes of this case only, DRL Inc. does not contest personal jurisdiction in this Judicial District. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no answer is required. To the extent a response is required, admitted that DRL Inc. submitted ANDA No. 214236 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no answer is required. To the extent a response is required, for the purposes of this case only, DRL Ltd. does not contest personal jurisdiction in this Judicial District. Otherwise denied.

Complaint ¶ 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.

Response: DRL Ltd.'s 2019 Annual Report speaks for itself and is the best source for its content. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no answer is required. To the extent a response is required, admitted that DRL Inc. submitted ANDA No. 214236 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no answer is required. To the extent a response is required, DRL Inc. admits that it is in the business of selling pharmaceutical products for markets including the United States, and DRL Ltd. admits that it is in the business of developing, manufacturing, distributing, and selling pharmaceutical products. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no answer is required. To the extent a response is required, DRL Inc. admits that it is in the business of selling pharmaceutical products for markets including the United States, and DRL Ltd. admits that it is in the business of developing, manufacturing, distributing, and selling pharmaceutical products. Otherwise denied.

Complaint ¶ 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.

Response: Admitted.

Complaint ¶ 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.

Response: DRL Inc. admits that DRL Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services under Business ID No. 0100518911. Otherwise denied.

Complaint ¶ 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.

Response: DRL Inc. admits that it is in the business of selling pharmaceutical products for markets including the United States, and DRL Ltd. admits that it is in the business of developing, manufacturing, distributing, and selling pharmaceutical products. Otherwise denied.

Complaint ¶ 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).

Response: Admitted that, in the following litigations, DRL Inc. stated in its answer to the Complaint that it did not contest personal jurisdiction of this Court for purposes of that particular litigation, and/or asserted counterclaims: *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). Otherwise denied.

Complaint ¶ 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).

Response: Admitted that, in the following litigations, DRL Ltd. stated in its answer to the Complaint that it did not contest personal jurisdiction of this Court for purposes of that particular litigation, and/or asserted counterclaims: *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). Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no response is required . To the extent a response is required, for the purposes of this case only, DRL Ltd. does not contest personal jurisdiction in this Judicial District. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no response is required. To the extent a response is required, for the purposes of this case only, DRL Inc. does not contest venue in this Judicial District. Otherwise denied.

Complaint ¶ 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).

Response: This paragraph states legal conclusions to which no response is required. To the extent a response is required, for the purposes of this case only, DRL Ltd. does not contest venue in this Judicial District.

Complaint ¶ 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.

Response: Admitted that DRL Inc. informed Plaintiffs that it will not contest personal jurisdiction or venue in the United States District Court for the District of New Jersey, for the purposes of this case only.

THE PATENT-IN-SUIT

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no response is required. To the extent a response is required, admitted that the face of U.S. Patent No. RE44,733 ("the '733 patent") lists the title as "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block" and Merck B.V. as the assignee and that Exhibit A purports to be a copy of the '733 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no response is required. To the extent a response is required, admitted that the face of the '733 patent states that the '733 patent issued on January 28, 2014 as a reissue of U.S. Patent No. 6,670,340 ("the '340 patent"), and that the '340 patent issued on December 30, 2003. Denied that the '733 patent was duly and legally issued. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph states legal conclusions to which no response is required. To the extent a response is required, the '733 patent speaks for itself and is the best source for its content. Otherwise denied.

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

Response: Admitted.

Complaint ¶ 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.

Response: Admitted that, as of June 8, 2020, the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") listed the expiration of the '733 patent as January 27, 2021. Admitted that Exhibit B purports to be a copy of the Notice of Final Determination on the patent term extension ("PTE") application for the '733 patent. Admitted that Exhibit B states that the '733 patent "is eligible for patent term extension under 35 U.S.C. § 156" and that "[t]he period of extension has been determined to be 5 years." The allegation that the expiration of the '733 patent will be January 27, 2026 after the PTE certificate is issued states a legal conclusion to which no response is required; to the extent a response is required, DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegation, and therefore denies it. Otherwise denied.

THE BRIDION® DRUG PRODUCT

Complaint ¶ 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.

Response: Admitted that Organon purports to be the holder of New Drug Application ("NDA") No. 022225 for sugammadex injections, which are sold under the trade name Bridion®. Admitted that, as of June 8, 2020, the Orange Book listed the approval date for NDA No. 022225 as December 15, 2015. Admitted that Exhibit C purports to be prescribing information for Bridion® and purports to have a revision date of December 2018. Admitted that Exhibit C contains a section titled "Dosage Forms and Strengths" which lists "200 mg/2 mL (100 mg/mL) in a single-dose vial for bolus injection" and "500 mg/5 mL (100 mg/mL) in a single-dose vial for bolus injection." Admitted that Exhibit C states that "BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery." Admitted that Exhibit C states that Bridion® is distributed by Merck Sharp and Dohme Corp., a subsidiary of Merck & Co., Inc. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies them.

Complaint ¶ 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.

Response: Admitted that Exhibit C states that "BRIDION (sugammadex) injection, for intravenous use, contains sugammadex sodium, a modified gamma cyclodextrin chemically

designated as *6^{A},6^{B},6^{C},6^{D},6^{E},6^{F},6^{G},6^{H}-Octakis-S-(2-carboxyethyl)-6^{A},6^{B},6^{C},6^{D},6^{E},6^{F},6^{G},6^{H}-octathio-γ-cyclodextrin sodium salt* (1:8) with a molecular weight of 2178.01." Admitted that Exhibit C contains a heading of "BRIDION® (sugammadex) Injection, for intravenous use." DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies them.

Complaint ¶ 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.

Response: DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies them.

Complaint ¶ 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.

Response: Admitted that the '733 patent was listed in connection with NDA No. 022225 in the FDA's Orange Book as of June 8, 2020. The remainder of this paragraph contains legal conclusions to which no response is required. To the extent a response is required, denied.

DEFENDANTS' ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

Complaint ¶ 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.

Response: Admitted that DRL Inc. submitted ANDA No. 214236 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products. Otherwise denied.

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

Response: Admitted that the FDA had not yet approved ANDA No. 214236 as of June 8, 2020. Otherwise denied.

Complaint ¶ 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.

Response: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, the Notice Letter speaks for itself and is the best source for its content. Admitted that DRL Inc. notified Plaintiffs in the Notice Letter of DRL Inc.'s submission of ANDA No. 214236 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products. Otherwise denied.

Complaint ¶ 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.

Response: Admitted that Exhibit C states that "BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery." Otherwise denied.

Complaint ¶ 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.

Response: Admitted that DRL Inc. notified Plaintiffs in the Notice Letter that DRL Inc. filed a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '733 patent. Otherwise denied.

Complaint ¶ 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.

Response: Admitted that DRL Inc. submitted ANDA No. 214236 to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Otherwise denied.

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

Response: Admitted that DRL Inc. stated in the Notice Letter that "the active ingredient of the proposed drug product in [ANDA No. 214236] is sugammadex." Otherwise denied.

Complaint ¶ 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.

Response: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, admitted that DRL Inc. submitted ANDA No. 214236 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products. DRL lacks knowledge or information sufficient to form a belief as to the

truth of the remaining allegations of this paragraph, and therefore denies them. Otherwise denied.

Complaint ¶ 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).

Response: Admitted that Plaintiffs filed this action on March 16, 2020. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of the first sentence of this paragraph, and therefore denies them. The remainder of this paragraph states legal conclusions to which no response is required; to the extent a response is required, denied.

COUNT I – INFRINGEMENT OF THE '733 PATENT

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

Response: DRL repeats and incorporates its responses to Paragraphs 1–48 of the Complaint as if fully set forth herein.

Complaint ¶ 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.

Response: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, denied.

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

Response: The Notice Letter speaks for itself and is the best source for its content. Otherwise denied.

Complaint ¶ 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).

Response: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, admitted that DRL Inc. submitted ANDA No. 214236 to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Otherwise denied.

Complaint ¶ 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).

Response: Denied.

Complaint ¶ 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.

Response: Admitted that DRL Inc. submitted ANDA No. 214236 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

Complaint ¶ 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.

Response: Denied.

Complaint ¶ 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.

Response: Denied.

Complaint ¶ 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.

Response: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations of the first sentence in this paragraph, and therefore denies them. Otherwise denied.

Complaint ¶ 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.

Response: Denied.

Complaint ¶ 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.

Response: Denied.

Complaint ¶ 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.

Response: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, admitted that DRL Inc. submitted ANDA No. 214236 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products. Otherwise denied.

Complaint ¶ 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.

Response: Denied.

Complaint ¶ 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.

Response: Denied.

Complaint ¶ 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.

Response: Denied.

PRAYER FOR RELIEF

DRL denies that Plaintiffs are entitled to any of the relief set forth in their request for relief or to any relief whatsoever.

AFFIRMATIVE DEFENSES

Without any admissions as to burden of proof, and expressly reserving their right to assert additional defenses, DRL states the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Non-Infringement of the '733 Patent)

DRL's manufacture, sale, use, offer for sale, and/or importation of the ANDA Products would not infringe any valid and enforceable claim of the '733 patent.

THIRD AFFIRMATIVE DEFENSE
(Invalidity of the '733 Patent)

The claims of the '733 patent are invalid for failure to comply with the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting and/or the reissue-recapture rule, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

FOURTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

FIFTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

Plaintiffs may not seek injunctive relief against DRL because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

SIXTH AFFIRMATIVE DEFENSE
(No Willful Infringement)

DRL has not, does not, and/or will not willfully infringe any valid or enforceable claim of the '733 patent, and Plaintiffs are not entitled to enhanced damages.

SEVENTH AFFIRMATIVE DEFENSE
(Exceptional Case)

DRL is entitled to an award of its reasonable attorneys' fees to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable, including without limitation, Fed. R. Civ. P. 11.

EIGHTH AFFIRMATIVE DEFENSE
(Reservation of Rights)

DRL reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

* * *

COUNTERCLAIMS

Without admitting any of the Plaintiffs' allegations other than those expressly admitted herein, and without prejudice of the rights of Defendants to plead additional Counterclaims as the facts of the matter warrant, Defendants Dr. Reddy's Laboratories, Inc. ("DRL Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively, "DRL" or "Counterclaim-Plaintiffs") hereby assert the following Counterclaims against Merck Sharp & Dohme B.V. ("Merck B.V.") and Organon USA Inc. ("Organon") (collectively, "Counterclaim-Defendants").

THE PARTIES

1. DRL Inc. 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.

2. DRL Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

3. On information and belief, 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.

4. On information and belief, 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.

5. On information and belief, 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.

6. On information and belief, Organon is a wholly owned subsidiary of Merck & Co., Inc.

JURISDICTION AND VENUE

7. These Counterclaims seek declaratory relief arising under the patent laws of the United States, Title 35, United States Code.

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. The Court has personal jurisdiction over Merck B.V. because, *inter alia*, Merck B.V. subjected itself to the jurisdiction of this Court by filing this action, and because, on information and belief, Merck B.V. researches, manufactures, and markets branded drug products, and continuously and systematically conducts business throughout the United States,

including in New Jersey, and because, either directly or through agents, it transacts business in, and derives substantial revenue from, New Jersey.

11. The Court has personal jurisdiction over Organon because, *inter alia*, on information and belief, 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.

12. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400 and by virtue of the Counterclaim-Defendants' filing of this action in this Court.

FACTUAL BACKGROUND

13. According to the United States Food and Drug Administration ("FDA") publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), Organon is the holder of New Drug Application ("NDA") No. 022225 for Bridion®, sugammadex sodium EQ 200 mg base/2 mL (EQ 100 mg base/mL) and EQ 500 mg base/5 mL (EQ 100 mg base/mL) solution for intravenous administration, approved on December 15, 2015.

14. According to Exhibit C of the Complaint, "BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery."

15. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

16. The Orange Book entry for Bridion® lists in relevant part U.S. Patent No. RE44,733 ("the '733 patent").

17. The ’733 patent lists the title as “6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block,” the issue date for the reissued patent as January 28, 2014, and the assignee as Merck B.V. The ’733 patent states that the ’733 patent is a reissue of U.S. Patent No. 6,670,340 (“the ’340 patent”) and that the ’340 patent issued on December 30, 2003.

18. Merck B.V. purports and claims to own, and to have the right to enforce, the ’733 patent.

19. DRL Inc. submitted Abbreviated New Drug Application (“ANDA”) No. 214236 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, or sale of sugammadex injection, 200 mg/2 mL (100 mg/mL) and 500 mg/5mL (100 mg/mL) (“the ANDA Products”). DRL Inc. submitted ANDA No. 214236 to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’733 patent.

20. DRL Inc. sent notice of this certification to Counterclaim-Defendants on or about February 11, 2020 (“the Notice Letter”). On information and belief, and as Counterclaim-Defendants allege in their Complaint, Counterclaim-Defendants received the Notice Letter.

21. On March 16, 2020, Counterclaim-Defendants filed suit in this Judicial District against DRL in connection with ANDA No. 214236. (D.I. 1.)

22. A justiciable controversy exists as to infringement of the ’733 patent and the validity of the ’733 patent because Counterclaim-Defendants brought an action alleging that the manufacture, use, offer for sale, sale, or importation of the ANDA Products would infringe the ’733 patent, and Counterclaim-Plaintiffs have denied the alleged infringement and further allege that the claims of the ’733 patent are invalid. This controversy is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

FIRST COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the '733 Patent

23. DRL restates and incorporates by reference the allegations in Paragraphs 1–22 of DRL's Counterclaims as if fully set forth herein.

24. DRL has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid and enforceable claims of the '733 patent.

25. For example, DRL will not infringe one or more claims of the '733 patent because DRL will not treat patients, DRL will not encourage another party to practice the claimed methods, the ANDA Products will not be in the form of a kit comprising a neuromuscular blocking agent, and the claims of the '733 patent are invalid.

26. The Court should declare that DRL has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid and enforceable claims of the '733 patent.

SECOND COUNTERCLAIM
Declaratory Judgment of Invalidity or Unenforceability of the '733 Patent

27. DRL repeats and incorporates the allegations in Paragraphs 1–26 of DRL's Counterclaims as if fully set forth herein.

28. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '733 patent are invalid.

29. Upon information and belief, the claims of the '733 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting and/or the

reissue-recapture rule, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

30. By way of non-limiting example, one or more claims of the '733 patent are invalid pursuant to 35 U.S.C. § 103 as obvious in view of prior art disclosing the limitations of one or more claims of the '733 patent. Non-limiting examples of such art include Cserháti, Tibor & Forgács, Esther, *Charge-Transfer Chromatographic Study of the Complex Formation of Some Steroidal Drugs with Carboxymethyl-γ-cyclodextrin*, 246 ANALYTICAL BIOCHEMISTRY 205 (1997); Frédérique Guillo et al., *Synthesis of Symmetrical Cyclodextrin Derivatives Bearing Multiple Charges*, 132 BULL. SOC. CHIM. FR. 857 (1995); Chang-Chung Ling & Raphael Darcy, *6-s-Hydroxylated 6-Thiocyclodextrins: Expandable Host Molecules*, J. CHEM. SOC., CHEM. COMMUN. 203 (1993); J. Szejtli, *Medicinal Applications of Cyclodextrins*, 14 MED. RES. REV. 353 (1994); Leo H. D. J. Booij, *Neuromuscular Transmission and its Pharmacological Blockade Part 3: Continuous Infusion of Relaxants and Reversal and Monitoring of Relaxation*, 19 PHARM WORLD SCI. 35 (1997); J. M. Hunter, *New Neuromuscular Blocking Drugs*, 332 DRUG THERAPY 1691 (1995); Thomas O. Carpenter et al., *Severe Hypervitaminosis A in Siblings: Evidence of Variable Tolerance to Retinol Intake*, 111 J. OF PEDIATRICS 507 (1987); H. W. FRIJLINK, *The Effect of Parenterally Administered Cyclodextrins on Cholesterol Levels in the Rat, in* BIOPHARMACEUTICAL ASPECTS OF CYCLODEXTRINS 139 (1990); U.S. Patent No. 5,840,881; Thorsteinn Loftsson & Marcus E. Brewster, *Pharmaceutical Applications of Cyclodextrins. 1. Drug Solubilization and Stabilization*, 85 J. PHARM. SCI. 1017 (1996); Nina Sadlej-Sosnowska, *Influence of the Structure of Steroid Hormones on Their Association with Cyclodextrins: A High-Performance Liquid Chromatography Study*, 27 J. OF INCLUSION PHENOMENA AND MOLECULAR RECOGNITION IN CHEMISTRY 31 (1997); Frédérique Leroy-Lechat et al., *Evaluation of the*

Cytotoxicity of Cyclodextrins and Hydroxypropylated Derivatives, 101 INT. J. PHARM. 97 (1994); and P. A. Keicher & J. C. McAllister, *Comprehensive Pharmaceutical Services in the Surgical Suite and Recovery Room*, 42 AM. J. HOSP. PHARM. 2454 (1985), in addition to the knowledge of a person of ordinary skill in the art ("POSA") and the state of the art.

31. The claims of the '733 patent are invalid for obviousness-type double patenting in view of at least U.S. Patent No. 7,265,099.

32. The claims of the '733 patent are invalid, in whole or in part, for failure to comply with one or more of the requirements of 35 U.S.C. § 251, including but not limited to failing to qualify as a correctable error and violating the original patent requirement.

33. The claims of the '733 patent are invalid, in whole or in part, for violating the reissue-recapture rule.

34. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '733 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

35. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

36. The Court should declare that one or more claims of the '733 patent are invalid and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, DRL respectfully prays for judgment in its favor and against Merck B.V. and Organon:

a. Declaring that the filing of ANDA No. 214236 did not infringe one or more valid and enforceable claims of the ’733 patent;

b. Declaring that the manufacture, use, sale, offer for sale, importation, distribution, and/or marketing of the ANDA Products has not infringed, does not infringe, and would not—if manufactured, used, sold, offered for sale, imported, distributed, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the ’733 patent, either literally or under the doctrine of equivalents;

c. Declaring that the claims of the ’733 patent are invalid and/or unenforceable;

d. Ordering that Plaintiffs’ Complaint be dismissed with prejudice and judgment entered in favor of DRL;

e. Denying Plaintiffs any of the relief they request in their Complaint;

f. Declaring this case exceptional and awarding DRL its reasonable attorneys’ fees and costs of defending this action and prosecuting its counterclaims under 35 U.S.C. § 285; and

g. Awarding DRL such other and further relief as the Court may deem just and proper.

Dated: June 8, 2020

Respectfully submitted,

/s/ Eric I. Abraham

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