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Dr. Reddy's Laboratories, Inc.

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, LLC, Plaintiff, v. DR. REDDY'S LABORATORIES LTD. and DR. REDDY'S LABORATORIES INC., Defendants.	Civil Action No. 3:24-cv-07875-SRC-LDW ELECTRONICALLY FILED

DEFENDANTS DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively, "DRL" or "Defendants") respond to the Complaint of Plaintiff Impax Laboratories, LLC ("Impax" or "Plaintiff") as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the food and drug laws and patent laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Impax's RYTARY® (Carbidopa/Levodopa) extended-release capsules prior to the expiration of United States Patent Nos. 8,557,283 ("the '283 patent"), 9,089,608 ("the '608 patent"), 9,463,246 ("the '246 patent"), 9,533,046 ("the '046 patent"), and 9,901,640 ("the '640 patent") (collectively,

the "Patents-in-Suit"), and before the expiration dates of other patents listed in the Orange Book for RYTARY®.

ANSWER:

Paragraph 1 contains legal conclusions to which no response is required. To the extent an answer is required, DRL admits that Plaintiff purports to bring an action for patent infringement under the patent laws of the United States but DRL denies that Impax is entitled to any of the relief it seeks. DRL admits that DRL submitted Abbreviated New Drug Application ("ANDA") No. 219231 ("DRL ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a carbidopa/levodopa product as described in the DRL ANDA ("DRL ANDA Product") prior to the expiration of the Patents-in-Suit. DRL denies that the Patents-in-Suit are valid and/or infringed by the DRL ANDA Product. DRL denies any remaining allegations of paragraph 1 of the Complaint.

THE PARTIES

2. Plaintiff Impax Laboratories, LLC is a limited liability company organized and existing under the laws of the State of Delaware and is wholly-owned by Amneal Pharmaceuticals LLC. Impax's registered business address is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Amneal Pharmaceuticals LLC is a limited liability company organized under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

ANSWER:

DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint and, on that basis, denies them.

3. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. ("DRL Inc.") is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

ANSWER:

DRL admits that DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 600 College Road East, 4th Floor, Princeton, New Jersey 08540.

4. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") is a corporation organized and existing under the laws of India having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India. On information and belief, DRL Ltd. conducts business in the United States and in the State of New Jersey through and using the offices of DRL Inc.

ANSWER:

DRL admits DRL Ltd. is a corporation organized and existing under the laws of India having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India. DRL admits that DRL Inc. is a subsidiary of DRL Ltd. DRL further admits that DRL Inc. conducts business in the United States and in the State of New Jersey. DRL denies any remaining allegations of paragraph 4 of the Complaint.

5. On information and belief, DRL Inc. is a wholly-owned direct or indirect subsidiary of DRL Ltd.

ANSWER:

DRL admits that DRL Inc. is a subsidiary of DRL Ltd. DRL denies any remaining allegations of paragraph 5 of the Complaint.

6. On information and belief, DRL Inc. and DRL Ltd. ("Defendants" or "DRL") are in the business of developing, preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including the State of New Jersey.

ANSWER:

DRL admits that DRL Ltd. is in the business of manufacturing pharmaceutical products and that DRL, Inc. sells pharmaceutical products in the United States. DRL denies any remaining allegations of paragraph 6 of the Complaint.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

Paragraph 7 contains legal conclusions to which no response is required. To the extent an answer is required, and for purposes of this action only, DRL does not contest that this Court has subject matter jurisdiction over this action. DRL denies any remaining allegations of paragraph 7 of the Complaint.

8. On information and belief, Defendants purposefully have conducted and continue to conduct business in this Judicial District.

ANSWER:

Paragraph 8 contains legal conclusions to which no response is required. For purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for this action and venue is proper in this Judicial District. DRL denies any remaining allegations of paragraph 8 of the Complaint.

9. On information and belief, Defendants are in the business of, among other things, manufacturing, marketing, importing, distributing, offering for sale, and/or selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER:

Paragraph 9 seeks to establish personal jurisdiction over DRL and proper venue in this Court. For purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for this action and does not contest venue in this action in this Judicial District. DRL denies any remaining allegations of paragraph 9 of the Complaint.

10. On information and belief, Defendants directly or indirectly develop, manufacture, import, market, distribute, and/or sell pharmaceutical products that are and/or will be manufactured and

sold, pursuant to ANDA filings or other regulatory filings, throughout the United States, including in this Judicial District.

ANSWER:

Paragraph 10 seeks to establish personal jurisdiction over DRL and proper venue in this Court. For purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for this action and does not contest venue in this action in this Judicial District. DRL denies any remaining allegations of paragraph 10 of the Complaint.

11. On information and belief, Defendants develop and manufacture generic pharmaceutical products, which they then sell in the United States, the locations or operations of which are in, among other places, the State of New Jersey.

ANSWER:

Paragraph 11 seeks to establish personal jurisdiction over DRL and proper venue in this Court. For purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for this action and does not contest venue in this action in this Judicial District. DRL denies any remaining allegations of paragraph 11 of the Complaint.

12. On information and belief, this Judicial District will be a destination for the generic version of Impax's RYTARY® (Carbidopa/Levodopa) extended-release capsules for which Defendants seek FDA approval to manufacture, market, import, offer to sell, and/or sell pursuant to ANDA No. 219231.

ANSWER:

Paragraph 12 seeks to establish personal jurisdiction over DRL and proper venue in this Court. For purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for this action and does not contest venue in this action in this Judicial District. DRL denies any remaining allegations of paragraph 12 of the Complaint.

13. On information and belief, if the DRL ANDA (defined below) is approved, the DRL ANDA Products (defined below) will be marketed, distributed, and/or sold, directly or indirectly, by Defendants in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, on information and

belief, if Defendants succeed in obtaining FDA approval, Defendants will, directly or indirectly, market, distribute, and/or sell the DRL ANDA Products in the State of New Jersey.

ANSWER:

Paragraph 13 seeks to establish personal jurisdiction over DRL and proper venue in this Court. For purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for this action and does not contest venue in this action in this Judicial District. DRL denies any remaining allegations of paragraph 13 of the Complaint.

14. On information and belief, DRL Inc. is a company organized and existing under the laws of the state of New Jersey, and has its principal place of business in New Jersey.

ANSWER:

DRL admits DRL Inc. is a company organized and existing under the laws of the state of New Jersey, and has its principal place of business in New Jersey.

15. On information and belief, DRL Inc. is registered with the New Jersey Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0100518911.

ANSWER:

DRL admits DRL Inc. is a company organized and existing under the laws of the state of New Jersey, and has its principal place of business in New Jersey. DRL denies any remaining allegations of paragraph 15 of the Complaint.

16. On information and belief, DRL Inc. is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under registration number 5002312.

ANSWER:

DRL admits DRL Inc. is a company organized and existing under the laws of the state of New Jersey, and has its principal place of business in New Jersey. DRL denies any remaining allegations of paragraph 16 of the Complaint.

17. On information and belief, DRL Inc. is in the business of, *inter alia*: (a) developing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States, including throughout the State of New Jersey; (b) in concert with and/or through its affiliates, including DRL Ltd., the preparation, submission, and filing of Abbreviated New Drug Applications seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (c) alone or in concert with and/or through its affiliates, including DRL Ltd., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER:

Paragraph 17 seeks to establish personal jurisdiction over DRL and proper venue in this Court. For purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for this action and does not contest venue in this action in this Judicial District. DRL denies any remaining allegations of paragraph 17 of the Complaint.

18. On information and belief, DRL Ltd. is in the business of, *inter alia*: (a) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (b) in concert with and/or through its various affiliates, including DRL Inc., the preparation, submission, and filing of Abbreviated New Drug Applications seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (c) in concert with and/or through its various affiliates, including DRL Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER:

Paragraph 18 seeks to establish personal jurisdiction over DRL and proper venue in this Court. For purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for this action and does not contest venue in this action in this Judicial District. DRL denies any remaining allegations of paragraph 18 of the Complaint.

19. On information and belief, Defendants intend to benefit directly if the DRL ANDA is approved by participating in the manufacture, importation, distribution, offer to sell, and/or sale of the generic drug products throughout the United States, including in the State of New Jersey, that are the subject of the DRL ANDA.

ANSWER:

Paragraph 19 seeks to establish personal jurisdiction over DRL and proper venue in this Court. For purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for this action and does not contest venue in this action in this Judicial District. DRL denies any remaining allegations of paragraph 19 of the Complaint.

20. On information and belief, Defendants have previously submitted to the jurisdiction of this Court and/or have further previously availed themselves of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Dr. Reddy's Labs. Inc. v. Amarin Pharma, Inc.*, No. 21-10309 (D.N.J. Apr. 27, 2021); *Celgene Corp. v. Dr. Reddy's Labs., Ltd. et al.*, No. 21-2111 (D.N.J. Feb. 8, 2021); *Merck Sharp & Dohme BV, et al. v. Dr. Reddy's Laboratories, Inc., et al.*, C.A. No. 20-02909 (D.N.J. Mar. 16, 2020); *AstraZeneca LP, et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 19-15739 (D.N.J. July 23, 2019); *Bristol-Myers Squibb Co. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 19-18686 (D.N.J. Oct. 3, 2019); *Horizon Pharma, Inc. v. Dr. Reddy's Labs., Ltd. et al.*, No. 15-3324 (D.N.J. May 13, 2016) (collectively, "Prior Actions").

ANSWER:

Paragraph 20 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest that this Court has personal jurisdiction over DRL for purposes of this action. DRL denies any remaining allegations of paragraph 20 of the Complaint.

21. For at least the foregoing reasons set forth above, this Court has personal jurisdiction over Defendants because, on information and belief, Defendants: (a) have substantial, continuous, and systematic contacts with the State of New Jersey; (b) have in the past and intend in the future to manufacture, market, import, offer to sell, sell, and/or distribute Defendants' pharmaceutical products to residents of the State of New Jersey; (c) maintain a distributorship network within the State of New Jersey; (d) enjoy income from sales of their generic pharmaceutical products in the State of New Jersey; (e) are located in and/or have consented to and/or not contested personal jurisdiction in the Prior Actions; and (f) have availed themselves of the jurisdiction of this Court by asserting counterclaims in at least one of the Prior Actions.

ANSWER:

Paragraph 21 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest that this Court has

personal jurisdiction over DRL in this action. DRL denies any remaining allegations of paragraph 21 of the Complaint.

22. For at least the foregoing reasons set forth above, venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and/or 1400(b). Among other reasons, venue is proper in this Judicial District because: (a) on information and belief, DRL Inc. is incorporated in and has a principal place of business in New Jersey and has and will continue to engage in infringement activities in New Jersey; (b) on information and belief, DRL Ltd. is incorporated in India and may be sued in any judicial district in which the DRL Ltd. is subject to the court's personal jurisdiction, and further operates in the United States, upon information and belief, through or in concert with DRL Inc.; and (c) Defendants have previously consented to and/or not contested venue in this Judicial District in at least one of the Prior Actions.

ANSWER:

Paragraph 22 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest that venue in this action in this Judicial District is proper. DRL denies any remaining allegations of paragraph 22 of the Complaint.

BACKGROUND

U.S. Patent No. 8,557,283

23. On October 15, 2013, the United States Patent & Trademark Office ("PTO"), duly and legally issued United States Patent No. 8,557,283 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. The '283 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '283 patent is attached as **Exhibit 1**.

ANSWER:

DRL admits that the cover page of United States Patent No. 8,557,283 ("the '283 patent") indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" and issued on October 15, 2013. DRL further admits that the cover page of the '283 patent lists Ann Hsu, Jim H. Kou, and Laman Lynn Alani as Inventors. DRL further admits that as of the date of this Answer, the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange

Book") lists December 26, 2028 as the expiration date of the '283 patent. DRL further admits that what purports to be a copy of the '283 patent is attached to the Complaint as Exhibit 1. DRL denies that the '253 patent was duly and legally issued and denies that the '283 patent is valid and/or not infringed by the DRL ANDA Product. DRL is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 23 and therefore denies the remaining allegations contained in paragraph 23 of the Complaint.

U.S. Patent No. 9,089,608

24. On July 28, 2015, the PTO duly and legally issued United States Patent No. 9,089,608 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. The '608 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '608 patent is attached as **Exhibit 2**.

ANSWER:

DRL admits that the cover page of United States Patent No. 9,089,608 ("the '608 patent") indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" and issued on July 28, 2015. DRL further admits that the cover page of the '608 patent lists Ann Hsu, Jim H. Kou, and Laman Lynn Alani as Inventors. DRL further admits, based on information and belief, that the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists December 26, 2028 as the expiration date of the '608 patent. DRL further admits that what purports to be a copy of the '608 patent is attached to the Complaint as Exhibit 2. DRL denies that the '608 patent was duly and legally issued and denies that the '608 patent is valid and/or not infringed by the DRL ANDA Product. DRL is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 24 and therefore denies the remaining allegations contained in paragraph 24 of the Complaint.

U.S. Patent No. 9,463,246

25. On October 11, 2016, the PTO duly and legally issued United States Patent No. 9,463,246 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. The '246 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '246 patent is attached as **Exhibit 3**.

ANSWER:

DRL admits that the cover page of United States Patent No. 9,463,246 ("the '246 patent") indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" and issued on October 11, 2016. DRL further admits that the cover page of the '246 patent lists Ann Hsu, Jim H. Kou, and Laman Lynn Alani as Inventors. DRL further admits, based on information and belief, that the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists December 26, 2028 as the expiration date of the '246 patent. DRL further admits that what purports to be a copy of the '246 patent is attached to the Complaint as Exhibit 3. DRL denies that the '246 patent was duly and legally issued and denies that the '246 patent is valid and/or not infringed by the DRL ANDA Product. DRL is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 25 and therefore denies the remaining allegations contained in paragraph 25 of the Complaint.

U.S. Patent No. 9,533,046

26. On January 3, 2017, the PTO duly and legally issued United States Patent No. 9,533,046 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim Kou and Laman Alani. The '046 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '046 patent is attached as **Exhibit 4**.

ANSWER:

DRL admits that the cover page of United States Patent No. 9,533,046 ("the '046 patent") indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" and issued on January 3, 2017. DRL further admits that the cover page of the '046 patent lists Ann

Hsu, Jim H. Kou, and Laman Lynn Alani as Inventors. DRL further admits, based on information and belief, that the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists December 26, 2028 as the expiration date of the '046 patent. DRL further admits that what purports to be a copy of the '046 patent is attached to the Complaint as Exhibit 4. DRL denies that the '046 patent was duly and legally issued and denies that the '046 patent is valid and/or not infringed by the DRL ANDA Product. DRL is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 26 and therefore denies the remaining allegations contained in paragraph 26 of the Complaint.

U.S. Patent No. 9,901,640

27. On February 27, 2018, the PTO duly and legally issued United States Patent No. 9,901,640 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim Kou and Laman Alani. The '640 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '640 patent is attached as **Exhibit 5**.

ANSWER:

DRL admits that the cover page of United States Patent No. 9,901,640 ("the '640 patent") indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" and issued on February 27, 2018. DRL further admits that the cover page of the '640 patent lists Ann Hsu, Jim H. Kou, and Laman Lynn Alani as Inventors. DRL further admits, based on information and belief, that the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists December 26, 2028 as the expiration date of the '640 patent. DRL further admits that what purports to be a copy of the '640 patent is attached to the Complaint as Exhibit 5. DRL denies that the '640 patent was duly and legally issued and denies that the '640 patent is valid and/or not infringed by the DRL ANDA Product. DRL is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 27 and therefore denies the remaining allegations contained in paragraph 27 of the Complaint.

RYTARY®

28. Impax Laboratories, LLC is the holder of New Drug Application ("NDA") No. 203312 ("the NDA") for carbidopa and levodopa extended-release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages, which is sold under the Proprietary Name RYTARY®. On August 3, 2018, Impax filed a new assignment document with the PTO that included the Patents-in-Suit, which include the Orange Book patents listed for RYTARY®, and informed the PTO that Impax Laboratories, Inc. had been converted to Impax Laboratories, LLC and that Impax Laboratories, LLC was now the assignee. By letter dated November 14, 2018, the FDA was informed that Impax Laboratories, Inc. was now Impax Laboratories, LLC and that the holder of the NDA should be listed as Impax Laboratories, LLC. To date, the FDA has not updated its public databases to reflect this entity name change regarding the holder of the NDA.

ANSWER:

DRL admits, on information and belief, that the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists Impax Laboratories, LLC as the holder of New Drug Application (NDA) No. 203312 for carbidopa and levodopa extended-release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages, which is sold under the Proprietary Name RYTARY®. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 28 of the Complaint and, on that basis, denies them.

29. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '283, '608, '246, '046, and '640 patents, among others, are listed in the FDA "Orange Book" with respect to RYTARY®.

ANSWER:

Paragraph 29 contains legal conclusions to which no response is required. DRL admits, on information and belief, that the '283, '608, '246, '046, and '640 patents, among others, are listed in the FDA "Orange Book" with respect to RYTARY®. DRL denies any remaining allegations of paragraph 29 of the Complaint.

ACTS GIVING RISE TO THIS ACTION

30. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER:

DRL realleges and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

31. On information and belief, Defendants submitted ANDA No. 219231 (the "DRL ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of carbidopa/levodopa extended-release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages (the "DRL ANDA Products").

ANSWER:

Paragraph 31 contains legal conclusions to which no response is required. DRL admits it filed the DRL ANDA seeking approval of the DRL ANDA Product as described therein. DRL denies any remaining allegations of paragraph 31 of the Complaint.

32. On information and belief, following FDA approval of the DRL ANDA, Defendants intend to make, use, sell, or offer to sell the DRL ANDA Products throughout the United States, including in the State of New Jersey, and/or import that generic product into the United States, including into the State of New Jersey.

ANSWER:

Paragraph 32 contains legal conclusions to which no response is required. DRL admits it filed the DRL ANDA seeking approval of the DRL ANDA Product as described therein. DRL denies any remaining allegations of paragraph 32 of the Complaint.

33. On information and belief, in connection with the submission of the DRL ANDA, Defendants provided written certification to the FDA, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of the DRL ANDA Products (the "DRL Paragraph IV Certifications").

ANSWER:

Paragraph 33 contains legal conclusions to which no response is necessary. DRL admits that the DRL ANDA included certifications to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the Patents-In-Suit (and others) are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale or importation of the DRL ANDA Product ("PIV Certifications"). DRL responds that the PIV Certifications are legal documents that speak for themselves, and DRL therefore denies any remaining allegations of paragraph 33 of the Complaint and refers to the PIV Certifications for their contents.

34. No earlier than June 6, 2024, Impax received written notice of the DRL ANDA and the DRL Paragraph IV Certifications from Defendants ("Notice Letter"). The Notice Letter included a Detailed Statement of the Factual and Legal Basis for Paragraph IV Certification(s), alleging that, *inter alia*, certain claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the DRL ANDA Products ("Detailed Statement").

ANSWER:

DRL admits that by letter dated June 5, 2024 (DRL's "Notice Letter"), DRL notified Plaintiff of its PIV Certifications that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the DRL ANDA Product. DRL responds that DRL's Notice Letter is a legal document that speaks for itself. DRL lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 34 of the Complaint and, on that basis, denies them.

35. By filing the DRL ANDA, Defendants represented to the FDA that the DRL ANDA Products have the same active ingredients as RYTARY®, have the same method of administration, dosage forms, and strengths, and are bioequivalent to RYTARY®, and would be sold under a label substantively the same as the label for RYTARY®.

ANSWER:

Paragraph 35 contains legal conclusions to which no response is required. To the extent an answer is required, DRL admits that it filed the DRL ANDA seeking approval of the DRL ANDA Product described therein, and that ANDA speaks for itself. DRL denies any remaining allegations of paragraph 35 of the Complaint.

36. Pursuant to the Notice Letter, Defendants offered confidential access to portions of the DRL ANDA for the sole purpose of permitting Impax to determine whether to file an infringement action under 35 U.S.C. § 271(e)(2).

ANSWER:

.Paragraph 36 contains legal conclusions to which no response is necessary. To the extent that an answer is required, DRL admits that the DRL Notice Letter contained an Offer of Confidential Access. DRL further states that the DRL Notice Letter is a legal document that speaks for itself, and therefore DRL denies any remaining allegations of paragraph 36 of the Complaint.

37. The Offer of Confidential Access ("OCA") permitted attorneys from one outside law firm and their in-firm professional staff access to certain information from the produced portions of the DRL ANDA. The specific information disclosed to Impax was chosen by Defendants.

ANSWER:

Paragraph 37 contains legal conclusions to which no response is necessary. To the extent that an answer is required, DRL admits that the DRL Notice Letter provided an Offer of Confidential Access as set forth therein pursuant to which relevant portions of the DRL ANDA were provided to Impax. DRL further states that the DRL Notice Letter and Offer for Confidential Access are a written document that speaks for itself, and therefore DRL denies any remaining allegations of paragraph 37 of the Complaint.

38. Pursuant to the OCA, Impax's outside counsel are prohibited from sharing the selected portions of the DRL ANDA with any other person or entity, including without limitation, any expert or scientific consultant.

ANSWER:

Paragraph 38 contains legal conclusions to which no response is necessary. To the extent that an answer is required, DRL admits that the DRL Notice Letter provided an Offer of Confidential Access as set forth therein. DRL further states that the DRL Notice Letter and Offer for Confidential Access are a written document that speaks for itself, and therefore DRL denies any remaining allegations of paragraph 38 of the Complaint.

39. The OCA further requires Impax's outside counsel to destroy, with notice to Defendants' outside counsel, the provided excerpts from the DRL ANDA within forty-five (45) days of receipt or upon filing of this action against Defendants, whichever is earlier.

ANSWER:

Paragraph 39 contains legal conclusions to which no response is necessary. To the extent that an answer is required, DRL admits that the DRL Notice Letter provided an Offer of Confidential Access as set forth therein. DRL further states that the DRL Notice Letter and Offer for Confidential Access are a written document that speaks for itself, and therefore DRL denies any remaining allegations of paragraph 39 of the Complaint.

40. Pursuant to the terms of the OCA, Impax's outside counsel is also prohibited from publicly disclosing any information in the produced portions of the DRL ANDA. This prohibition therefore prohibits Impax from including or referencing in this Complaint any information in the limited excerpts from the DRL ANDA that were provided to Impax's outside counsel under the OCA, beyond general statements as to whether the DRL ANDA Products meet patent claim limitations.

ANSWER:

Paragraph 40 contains legal conclusions to which no response is necessary. To the extent that an answer is required, DRL admits that DRL's Notice Letter provided an Offer of Confidential Access as set forth therein. DRL further states that the DRL Notice Letter and Offer for Confidential Access are a written document that speaks for itself, and therefore DRL denies any remaining allegations of paragraph 40 of the Complaint.

41. Impax's outside counsel executed the OCA on June 17, 2024.

ANSWER:

DRL admits it received a signed OCA from Impax's outside counsel dated June 17, 2024. DRL denies any remaining allegations of paragraph 41 of the Complaint.

42. On June 27, 2024, Defendants provided a limited, fifty-six (56) page production of documents to Impax's outside counsel under the OCA (the "OCA Production").

ANSWER:

DRL admits it produced to Plaintiff relevant documents bearing Bates-numbers DRLRYT-OCA-000001 to DRLRYT-OCA-000056, and marked "Confidential – Subject to Offer of Confidential Access – Outside Counsel Eyes Only" on June 27, 2024. DRL denies any remaining allegations of paragraph 42 of the Complaint.

43. Defendants' decision to withhold from the OCA Production the vast majority of the DRL ANDA has severely limited Impax's ability to assess Defendants' non-infringement assertions in the Notice Letter and Detailed Statement. Once Defendants produce the full DRL ANDA, Impax will be able to assess whether it has a basis to assert additional claims of patent infringement.

ANSWER:

DRL denies the allegations contained in paragraph 43 of the Complaint, and denies that the DRL ANDA Product will infringe the Patents-In-Suit.

44. This action is being commenced before the expiration of forty-five (45) days from the date Impax received the Notice Letter under 21 U.S.C. § 355(j)(5)(B)(iii) and thus triggers the thirty (30) month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER:

Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that the Complaint was filed July 18, 2024, and that the DRL Notice Letter was dated June 5, 2024. DRL denies any remaining allegations of paragraph 44 of the Complaint.

COUNT I - INFRINGEMENT OF THE '283 PATENT BY DRL

45. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER:

DRL realleges and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

46. By submission of the DRL ANDA with the DRL Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '283 patent, in the event that the FDA approves the DRL ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '283 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Paragraph 46 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this infringement action regarding the '283 patent. DRL admits that the DRL ANDA included a PIV Certification with respect to the '283 patent, and admits that the DRL Notice Letter advised Impax of that PIV Certification. DRL further states that the DRL Notice Letter and PIV Certification are legal documents that speak for themselves, and therefore DRL denies any remaining allegations of paragraph 46 of the Complaint.

47. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '283 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

48. In the Notice Letter and Detailed Statement, Defendants set forth no grounds for invalidity of any claim of the '283 patent. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe is a claim construction argument.

ANSWER:

DRL responds that the DRL Notice Letter is a legal document that speaks for itself, and therefore DRL denies the allegations of paragraph 48 of the Complaint.

49. A justiciable controversy exists regarding Defendants' infringement of the '283 patent.

ANSWER:

Paragraph 49 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this infringement action regarding the '283 patent. DRL denies that the '283 patent is valid, denies that it infringes the '283 patent and denies that Impax is entitled to the relief it seeks. DRL denies any remaining allegations of paragraph 49 of the Complaint.

50. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will infringe, for example at least under the doctrine of equivalents, one or more claims of the '283 patent, including at least claim 1, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the DRL ANDA Products. Further, in addition to the act of infringement stemming from the filing of the DRL ANDA, Defendants may also be literally infringing this patent, directly or indirectly, which issue can be further assessed upon production by Defendants of the full DRL ANDA.

ANSWER:

Denied.

51. For example, in addition to the act of infringement stemming from the filing of the DRL ANDA and the DRL Paragraph IV Certifications, based on a review of the full DRL ANDA (as opposed to the small portion of the DRL ANDA provided as part of the OCA Production), Impax believes that it can show after discovery and analysis that the DRL ANDA Products in combination with at least the label for those products proposed by Defendants in their ANDA submission, practice all the limitations of at least claim 1 of the '283 patent either literally or under the doctrine of equivalents. For example, based on a review of the OCA Production, the DRL ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '283 patent, Defendants will also indirectly infringe the methods claimed in the '283 patent, including without limitation claim 1, by inducing at least healthcare professionals and patients to directly infringe that claim.

ANSWER:

Denied.

52. On information and belief, the DRL ANDA Products, if approved by FDA, will be prescribed and administered to human patients to reduce motor fluctuations in a patient suffering from Parkinson's disease, which uses will constitute direct infringement of one or more claims of the '283 patent.

ANSWER:

Denied.

53. On information and belief, these directly infringing uses will occur with Defendants' specific intent and encouragement and will be uses that Defendants know or should know will occur.

ANSWER:

Denied.

54. On information and belief, Defendants will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Impax's rights under the '283 patent and will constitute infringement.

ANSWER:

Denied.

55. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will induce others to infringe of one or more claims of the '283 patent, including at least claim 1, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the DRL ANDA Products to reduce motor fluctuations in a patient suffering from Parkinson's disease in a manner that meets the limitations of claims in the '283 patent, including at least claim 1.

ANSWER:

Denied.

56. On information and belief, upon FDA approval of the DRL ANDA, Defendants will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '283 patent, by at least their promotional activities and package inserts for the DRL ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

57. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will contributorily infringe one or more claims of the '283 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the DRL ANDA, Defendants will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and have had and continue to have knowledge that the DRL ANDA Products constitute a material part of at least one of the claims of the '283 patent; are especially made or adapted for use in infringing the '283 patent; and that the DRL ANDA Products are not suitable for substantial non-infringing use.

ANSWER:

Denied.

58. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the DRL ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the DRL ANDA to be a date that is not earlier than the expiration date of the '283 patent, or any later expiration of exclusivity for the '283 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER:

Denied.

59. Defendants have had knowledge of the '283 patent since at least the date Defendants submitted the DRL ANDA and the DRL Paragraph IV Certifications and were aware that submission of the DRL ANDA and the DRL Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 59 contains legal conclusions to which no response is required. To the extent an answer is required, DRL admits that the DRL ANDA contained a PIV Certification to the '283 patent. DRL denies that the DRL ANDA Product will infringe the '283 patent. DRL responds that the DRL PIV Certification to the '283 patent is a legal document which speaks for itself, and therefore DRL denies any remaining allegations of paragraph 59 of the Complaint.

60. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER:

Denied.

COUNT II - INFRINGEMENT OF THE '608 PATENT BY DRL

61. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER:

DRL realleges and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

62. By submission of the DRL ANDA with the DRL Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '608 patent, in the event that the FDA approves the DRL ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '608 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Paragraph 62 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this infringement action regarding the '608 patent. DRL admits that the DRL ANDA included a PIV Certification with respect to the '608 patent, and admits that the DRL Notice Letter advised Impax of that PIV Certification. DRL further states that the DRL Notice Letter and PIV Certification are legal documents that speak for themselves, and therefore DRL denies any remaining allegations of paragraph 62 of the Complaint.

63. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '608 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

64. In the Notice Letter and Detailed Statement, Defendants set forth no grounds for non-infringement of claim 21 of the '608 patent by the DRL ANDA Products. Defendants set forth no grounds for invalidity of claims 1-20 of the '608 patent. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe claims 1-20 is a claim construction argument.

ANSWER:

DRL responds that the DRL Notice Letter, is a legal document that speaks for itself, and therefore DRL denies the allegations of paragraph 64 of the Complaint.

65. A justiciable controversy exists regarding Defendants' infringement of the '608 patent.

ANSWER:

Paragraph 65 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this infringement action regarding the '608 patent. DRL denies that the '608 patent is valid, denies that it infringes the '608 patent, and denies that Impax is entitled to the relief it seeks. DRL denies any remaining allegations of paragraph 65 of the Complaint.

66. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will infringe, literally or under the doctrine of equivalents, one or more claims of the '608 patent, including at least claim 1 and/or 21, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the DRL ANDA Products. For example, in addition to the act of infringement stemming from the filing of the DRL ANDA and the DRL Paragraph IV Certifications, based on a review of the full DRL ANDA (as opposed to the small portion of the DRL ANDA provided as part of the OCA Production), Impax believes that it can show after discovery and analysis that the DRL ANDA Products practice all the limitations of at least claims 1 and/or 21 of the '608 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim. For example, with regard to the doctrine of equivalents, based on a review of the OCA Production, in addition to literal infringement, the DRL ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial.

ANSWER:

Denied.

67. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will also induce others to infringe of one or more claims of the '608 patent, including at least claims 1 and/or 21, under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of the DRL ANDA, Defendants will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the '608 patent, by at least their promotional activities and package inserts for the DRL ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

68. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will contributorily infringe one or more claims of the '608 patent, including at least claim 1 and/or 21, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the DRL ANDA, Defendants will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and have had and continue to have knowledge that the DRL ANDA Products constitute a material part of at least one of the claims of the '608 patent; are especially made or adapted for use in infringing the '608 patent; and that the DRL ANDA Products are not suitable for substantial non-infringing use.

ANSWER:

Denied.

69. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the DRL ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the DRL ANDA to be a date that is not earlier than the expiration date of the '608 patent, or any later expiration of exclusivity for the '608 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER:

Denied.

70. Defendants have had knowledge of the '608 patent since at least the date Defendants submitted the DRL ANDA and the DRL Paragraph IV Certifications and were aware that submission of the DRL ANDA and the DRL Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A), as evidenced by the fact that the Notice Letter and Detailed Statement offer no basis for non-infringement of claim 21 in the '608 patent.

ANSWER:

Paragraph 70 contains legal conclusions to which no response is required. To the extent an answer is required, DRL admits that the DRL ANDA contained a PIV Certification to the '608 patent. DRL denies that the DRL ANDA Product will infringe the '608 patent. DRL responds that the DRL PIV Certification to the '608 patent is a legal document which speaks for itself, and therefore DRL denies any remaining allegations of paragraph 70 of the Complaint.

71. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER:

Denied.

COUNT III - INFRINGEMENT OF THE '246 PATENT BY DRL

72. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER:

DRL realleges and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

73. By submission of the DRL ANDA with the DRL Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '246 patent, in the event that the FDA approves the DRL ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '246 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Paragraph 73 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this infringement action regarding the '246 patent. DRL admits that the DRL ANDA included a PIV Certification with respect to the '246 patent and admits that the DRL Notice Letter advised Impax of that PIV Certification. DRL further states that the DRL Notice Letter and PIV Certification are

legal documents that speak for themselves, and therefore DRL denies any remaining allegations of paragraph 73 of the Complaint.

74. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '246 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

75. In the Notice Letter and Detailed Statement, Defendants set forth no grounds for invalidity of any claim of the '246 patent. Defendants' basis for asserting that they do not literally infringe includes a claim construction argument.

ANSWER:

DRL responds that the DRL Notice Letter, is a legal document that speaks for itself, and therefore DRL denies the allegations of paragraph 75 of the Complaint.

76. A justiciable controversy exists regarding Defendants' infringement of the '246 patent.

ANSWER:

Paragraph 76 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this infringement action regarding the '246 patent. DRL denies that the '246 patent is valid, denies that it infringes the '246 patent and denies that Impax is entitled to the relief it seeks. DRL denies any remaining allegations of paragraph 76 of the Complaint.

77. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will infringe, for example at least under the doctrine of equivalents, one or more claims of the '246 patent, including at least claim 26, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the DRL ANDA Products. Further, in addition to the act of infringement stemming from the filing of the DRL ANDA, Defendants may also be literally infringing this patent, directly or indirectly, which issue can be further assessed upon production by Defendants of the full DRL ANDA.

ANSWER:

Denied.

78. For example, in addition to the act of infringement stemming from the filing of the DRL ANDA and the DRL Paragraph IV Certifications, based on a review of the full DRL ANDA (as opposed to the small portion of the DRL ANDA provided as part of the OCA Production), Impax believes that it can show after discovery and analysis that the DRL ANDA Products in combination with at least the label for those products proposed by Defendants in their ANDA submission, practice all the limitations of at least claim 26 of the '246 patent either literally or under the doctrine of equivalents. For example, based on review of the OCA Production, the DRL ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '246 patent, Defendants will also indirectly infringe the methods claimed in the '246 patent, including without limitation claim 26, by inducing at least healthcare professionals and patients to directly infringe that claim.

ANSWER:

Denied.

79. On information and belief, the DRL ANDA Products, if approved by FDA, will be prescribed and administered to human patients to treat Parkinson's disease, which uses will constitute direct infringement of one or more claims of the '246 patent.

ANSWER:

Denied.

80. On information and belief, these directly infringing uses will occur with Defendants' specific intent and encouragement and will be uses that Defendants know or should know will occur.

ANSWER:

Denied.

81. On information and belief, Defendants will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Impax's rights under the '246 patent and will constitute infringement.

ANSWER:

Denied.

82. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will induce others to infringe of one or more claims of the '246 patent, including at least claim 26, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the DRL ANDA Products to treat aspects of Parkinson's disease in a manner that meets the limitations of claims in the '246 patent, including at least claim 26.

ANSWER:

Denied.

83. On information and belief, upon FDA approval of the DRL ANDA, Defendants will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '246 patent, by at least their promotional activities and package inserts for the DRL ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

84. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will contributorily infringe one or more claims of the '246 patent, including at least claim 26, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the DRL ANDA, Defendants will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and have had and continue to have knowledge that the DRL ANDA Products constitute a material part of at least one of the claims of the '246 patent; are especially made or adapted for use in infringing the '246 patent; and that the DRL ANDA Products are not suitable for substantial non-infringing use.

ANSWER:

Denied.

85. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the DRL ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the DRL ANDA to be a date that is not earlier than the expiration date of the '246 patent, or any later expiration of exclusivity for the '246 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER:

Denied.

86. Defendants have had knowledge of the '246 patent since at least the date Defendants submitted the DRL ANDA and the DRL Paragraph IV Certifications and were aware that submission of the DRL ANDA and the DRL Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 86 contains legal conclusions to which no response is required. To the extent an answer is required, DRL admits that the DRL ANDA contained a PIV Certification to the '246 patent. DRL denies that the DRL ANDA Product will infringe the '246 patent. DRL responds that the DRL PIV Certification to the '246 patent is a legal document which speaks for itself, and therefore DRL denies any remaining allegations of paragraph 86 of the Complaint.

87. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER:

Denied.

COUNT IV - INFRINGEMENT OF THE '046 PATENT BY DRL

88. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER:

DRL realleges and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

89. By submission of the DRL ANDA with the DRL Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '046 patent, in the event that the FDA approves the DRL ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '046 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Paragraph 89 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this

infringement action regarding the '046 patent. DRL admits that the DRL ANDA included a PIV Certification with respect to the '046 patent, and admits that the DRL Notice Letter advised Impax of that PIV Certification. DRL further states that the DRL Notice Letter and PIV Certification are legal documents that speak for themselves, and therefore DRL denies any remaining allegations of paragraph 89 of the Complaint.

90. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '046 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

91. In the Notice Letter and Detailed Statement, Defendants set forth no grounds for invalidity of any claim of the '046 patent. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe includes a claim construction argument.

ANSWER:

DRL responds that the DRL Notice Letter is a legal document that speaks for itself, and therefore DRL denies the allegations of paragraph 91 of the Complaint.

92. A justiciable controversy exists regarding Defendants' infringement of the '046 patent.

ANSWER:

Paragraph 92 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this infringement action regarding the '046 patent. DRL denies that the '046 patent is valid, denies that it infringes the '046 patent and denies that Impax is entitled to the relief it seeks. DRL denies any remaining allegations of paragraph 92 of the Complaint.

93. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will infringe, for example at least under the doctrine of equivalents, one or more claims of the '046 patent, including at least claim 1, under 35 U.S.C. § 271(a) by making, using, offering to sell,

selling, and/or importing the DRL ANDA Products. Further, in addition to the act of infringement stemming from the filing of the DRL ANDA, Defendants may also be literally infringing this patent, directly or indirectly, which issue can be further assessed upon production by Defendants of the full DRL ANDA.

ANSWER:

Denied.

94. For example, in addition to the act of infringement stemming from the filing of the DRL ANDA and the DRL Paragraph IV Certifications, based on a review of the full DRL ANDA (as opposed to the small portion of the DRL ANDA provided as part of the OCA Production), Impax believes that it can show after discovery and analysis that the DRL ANDA Products in combination with at least the label for those products proposed by Defendants in their ANDA submission, practice all the limitations of at least claim 1 of the '046 patent either literally or under the doctrine of equivalents. For example, based on a review of the OCA Production, the DRL ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '046 patent, Defendants will also indirectly infringe the methods claimed in the '046 patent, including without limitation claim 1, by inducing at least healthcare professionals and patients to directly infringe that claim.

ANSWER:

Denied.

95. On information and belief, the DRL ANDA Products, if approved by FDA, will be prescribed and administered to human patients to treat Parkinson's disease, which uses will constitute direct infringement of one or more claims of the '046 patent.

ANSWER:

Denied.

96. On information and belief, these directly infringing uses will occur with Defendants' specific intent and encouragement and will be uses that Defendants know or should know will occur.

ANSWER:

Denied.

97. On information and belief, Defendants will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Impax's rights under the '046 patent and will constitute infringement.

ANSWER:

Denied.

98. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will induce others to infringe of one or more claims of the '046 patent, including at least claim 1, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the DRL ANDA Products to treat aspects of Parkinson's disease in a manner that meets the limitations of claims in the '046 patent, including at least claim 1.

ANSWER:

Denied.

99. On information and belief, upon FDA approval of the DRL ANDA, Defendants will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '046 patent, by at least their promotional activities and package inserts for the DRL ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

100. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will contributorily infringe one or more claims of the '046 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the DRL ANDA, Defendants will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and have had and continue to have knowledge that the DRL ANDA Products constitute a material part of at least one of the claims of the '046 patent; are especially made or adapted for use in infringing the '046 patent; and that the DRL ANDA Products are not suitable for substantial non-infringing use.

ANSWER:

Denied.

101. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the DRL ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the DRL ANDA to be a date that is not earlier than the expiration date of the '046 patent, or any later expiration of exclusivity for the '046 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER:

Denied.

102. Defendants have had knowledge of the '046 patent since at least the date Defendants submitted the DRL ANDA and the DRL Paragraph IV Certifications and were aware that submission of the DRL ANDA and the DRL Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 102 contains legal conclusions to which no response is required. To the extent an answer is required, DRL admits that the DRL ANDA contained a PIV Certification to the '046 patent. DRL denies that the DRL ANDA Product will infringe the '046 patent. DRL responds that the DRL PIV Certification to the '046 patent is a legal document which speaks for itself, and therefore DRL denies any remaining allegations of paragraph 102 of the Complaint.

103. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER:

Denied.

COUNT V - INFRINGEMENT OF THE '640 PATENT BY DRL

104. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER:

DRL realleges and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

105. By submission of the DRL ANDA with the DRL Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '640 patent, in the event that the FDA approves the DRL ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '640 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Paragraph 105 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this infringement action regarding the '640 patent. DRL admits that the DRL ANDA included a PIV Certification with respect to the '640 patent, and admits that the DRL Notice Letter advised Impax of that PIV Certification. DRL further states that the DRL Notice Letter and PIV Certification are legal documents that speak for themselves, and therefore DRL denies any remaining allegations of paragraph 105 of the Complaint.

106. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the DRL ANDA Products prior to the expiration of the '640 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

107. In the Notice Letter and Detailed Statement, Defendants set forth no grounds for non-infringement of any claim of the '640 patent by the DRL ANDA Products.

ANSWER:

DRL responds that the DRL Notice Letter, is a legal document that speaks for itself, and therefore DRL denies the allegations of paragraph 107 of the Complaint.

108. A justiciable controversy exists regarding Defendants' infringement of the '640 patent.

ANSWER:

Paragraph 108 contains legal conclusions to which no response is required. To the extent an answer is required, DRL does not contest that this Court has subject matter jurisdiction over this infringement action regarding the '640 patent. DRL denies that the '640 patent is valid, denies

that it infringes the '640 patent and denies that Impax is entitled to the relief it seeks. DRL denies any remaining allegations of paragraph 108 of the Complaint.

109. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will infringe, literally or under the doctrine of equivalents, one or more claims of the '640 patent, including at least claim 15, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the DRL ANDA Products. For example, in addition to the act of infringement stemming from the filing of the DRL ANDA and the DRL Paragraph IV Certifications, based on a review of the full DRL ANDA (as opposed to the small portion of the DRL ANDA provided as part of the OCA Production), Impax believes that it can show after discovery and analysis that the DRL ANDA Products practice all the limitations of at least claim 15 of the '640 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim. For example, with regard to the doctrine of equivalents, based on a review of the OCA Production, in addition to literal infringement, the DRL ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial.

ANSWER:

Denied.

110. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will also induce others to infringe of one or more claims of the '640 patent, including at least claim 15, under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of the DRL ANDA, Defendants will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the '640 patent, by at least their promotional activities and package inserts for the DRL ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

111. Unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will contributorily infringe one or more claims of the '640 patent, including at least claim 15, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the DRL ANDA, Defendants will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and have had and continue to have knowledge that the DRL ANDA Products constitute a material part of at least one of the claims of the '640 patent; are especially made or adapted for use in infringing the '640 patent; and that the DRL ANDA Products are not suitable for substantial non-infringing use.

ANSWER:

Denied.

112. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the DRL ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the DRL ANDA to be a date that is not earlier than the expiration date of the '640 patent, or any later expiration of exclusivity for the '640 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER:

Denied.

113. Defendants have had knowledge of the '640 patent since at least the date Defendants submitted the DRL ANDA and the DRL Paragraph IV Certifications and were aware that submission of the DRL ANDA and the DRL Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 113 contains legal conclusions to which no response is required. To the extent an answer is required, DRL admits that the DRL ANDA contained a PIV Certification to the '640 patent. DRL denies that the DRL ANDA Product will infringe the '640 patent. DRL responds that the DRL PIV Certification to the '640 patent is a legal document which speaks for itself, and therefore DRL denies any remaining allegations of paragraph 113 of the Complaint.

114. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER:

Denied.

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), any allegation in the Complaint not expressly admitted by DRL is hereby denied.

RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

This section of Plaintiff's Complaint constitutes Prayers for Relief that do not require a response. To the extent directed to DRL, DRL denies that Plaintiff is entitled to any judgment or

relief against DRL, and, therefore, specifically denies paragraphs a through h of Plaintiff's Prayer for Relief.

SEPARATE DEFENSES

DRL asserts the following affirmative defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. DRL does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. DRL reserves the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

First Separate Defense
(Non-infringement of the '283 Patent)

DRL has not infringed and will not infringe, directly or indirectly, and will not induce the infringement of, or contribute to the infringement of, any valid or enforceable claim of the '283 patent.

Second Separate Defense
(Invalidity of the '283 Patent)

Each and every claim of the '283 patent is invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation.

Third Separate Defense
(Non-infringement of the '608 Patent)

DRL has not infringed and will not infringe, directly or indirectly, and will not induce the infringement of, or contribute to the infringement of, any valid or enforceable claim of the '608 patent.

Fourth Separate Defense
(Invalidity of the ’608 Patent)

Each and every claim of the ’608 patent is invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation.

Fifth Separate Defense
(Non-infringement of the ’246 Patent)

DRL has not infringed and will not infringe, directly or indirectly, and will not induce the infringement of, or contribute to the infringement of, any valid or enforceable claim of the ’246 patent.

Sixth Separate Defense
(Invalidity of the ’246 Patent)

Each and every claim of the ’246 patent is invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation.

Seventh Separate Defense
(Non-infringement of the ’046 Patent)

DRL has not infringed and will not infringe, directly or indirectly, and will not induce the infringement of, or contribute to the infringement of, any valid or enforceable claim of the ’046 patent.

Eighth Separate Defense
(Invalidity of the ’046 Patent)

Each and every claim of the ’046 patent is invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not

limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation.

Ninth Separate Defense
(Non-infringement of the '640 Patent)

DRL has not infringed and will not infringe, directly or indirectly, and will not induce the infringement of, or contribute to the infringement of, any valid or enforceable claim of the '640 patent.

Tenth Separate Defense
(Invalidity of the '640 Patent)

Each and every claim of the '640 Patent is invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation.

Eleventh Separate Defense
(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

Twelfth Separate Defense
(No Entitlement to Injunctive Relief)

To the extent the Complaint purports to seek injunctive relief against DRL, the Complaint fails to state a claim for injunctive relief because Plaintiff's alleged damages are not immediate or irreparable, and Plaintiff therefore has an adequate remedy at law.

Thirteenth Separate Defense
(No Exceptional Damages)

To the extent the Complaint purports to seek an "exceptional case" determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or 35 U.S.C. §

271(e)(4). Moreover, DRL's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

RESERVATION OF DEFENSES

DRL reserves the right to assert additional defenses pending further investigation and discovery.

COUNTERCLAIMS

For their Counterclaims against Plaintiff/Counterclaim Defendant Impax Laboratories, LLC ("Impax"), Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL" or), DRL states as follows:

NATURE OF THE ACTION

1. DRL brings, and is entitled by statute to maintain, this action for declaratory judgment of patent non-infringement under, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, 35 U.S.C. § 100, *et seq.* (including 35 U.S.C. §271(e)(5)), and/or 21 U.S.C. § 355(j)(5)(C).

2. DRL seeks a declaratory judgment that no valid or enforceable claim of U.S. Patent Nos. 8,557,283 ("the '283 patent"), 9,463,246 ("the '246 patent"), 9,533,046 ("the '046 patent"), 9,089,608 ("the '608 patent") and 9,901,640 ("the '640 patent") is not, has not been, or will not be, infringed by the manufacture, use, sale, offer for sale, or importation of the generic carbidopa and levodopa extended-release capsules, 23.75mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg, that are the subject of ANDA No. 219231 ("DRL ANDA Product").

3. DRL seeks a declaratory judgment that one or more claims of U.S. Patent Nos. 8,557,283 ("the '283 patent"), 9,463,246 ("the '246 patent"), 9,533,046 ("the '046 patent"), 9,089,608 ("the '608 patent") and 9,901,640 ("the '640 patent") are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States,

including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation.

THE PARTIES

4. Counterclaim Plaintiff Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of India, with a place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

5. Counterclaim Plaintiff Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 600 College Road East, 4th Floor, Princeton, New Jersey 08540.

6. On information and belief, Counterclaim Defendant Impax Laboratories, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its registered business address at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. (*See* D.E. 1 ¶ 2.)

7. On information and belief, Counterclaim Defendant Impax Laboratories, LLC is wholly-owned by Amneal Pharmaceuticals LLC, a limited liability company organized under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. (*See* D.E. 1 ¶ 2.)

JURISDICTION AND VENUE

8. DRL repeats and realleges the allegations contained in paragraphs 1-7 as if fully set forth here.

9. These Counterclaims arise under, *inter alia*, the patent laws of the United States and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, 35 U.S.C. § 100, *et seq.* (including 35 U.S.C. §271(e)(5)), and/or 21 U.S.C. § 355(j)(5)(C).

10. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j)(5)(C)(ii)(I).

11. This Court has personal jurisdiction over Impax on the bases of, *inter alia*, its contacts with the State of New Jersey relating to the subject matter of this action, including having voluntarily filed suit in this Court. (*See* D.E. 1.)

12. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) and/or 1400(b), and because Counterclaim Defendant has commenced and continues to prosecute this action in this Court. (*See* D.E. 1.)

BACKGROUND

13. On information and belief, Impax is the holder of New Drug Application ("NDA") No. 203312 ("the NDA") for carbidopa and levodopa extended-release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages, which is sold under the Proprietary Name RYTARY®. (*See* D.E. 1 ¶ 28.)

14. Upon information and belief, pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists the '283, '608, '246, '046, and '640 patents, with respect to RYTARY®. (*See* D.E. 1 ¶ 29.)

15. Upon information and belief, Counterclaim Defendant caused each of the Patents-in-Suit to be listed in the Orange Book in connection with NDA No. 203312, with respect to RYTARY®. (*See* D.E. 1 ¶¶ 28-29.)

16. DRL filed Abbreviated New Drug Application ("ANDA") No. 219231 ("DRL ANDA") to obtain FDA approval for the carbidopa and levodopa extended-release capsules described therein ("DRL ANDA Product").

17. By letter dated June 5, 2024 ("DRL Notice Letter"), DRL notified Impax of its Paragraph IV ANDA certifications that the'283,'608, '246, '046, and '640, Patents-in-Suit, as well as U.S Patent Nos. 8,377,474, 8,454,998, and 9,089,607, are invalid, unenforceable, and/or will not be infringed by the DRL ANDA product.

18. On July 18, 2024, Counterclaim Defendant filed this instant lawsuit alleging infringement of the Patents-in-Suit. (*See* D.E. 1 ¶ 1.)

U.S. Patent No. 8,557,283

19. Upon information and belief, the cover page of the '283 patent indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" issued on October 15, 2013. (*See* D.E. 1 ¶ 23.)

20. Upon information and belief, Impax is the current owner by assignment of the '283 patent. (*See* D.E. 1 ¶ 23.)

21. Upon information and belief, the '283 patent is currently listed in the Orange Book with respect to RYTARY®. (*See* D.E. 1 ¶ 23.)

U.S. Patent No. 9,089,608

22. Upon information and belief, the cover page of the '608 patent indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" issued on July 28, 2015. (*See* D.E. 1 ¶ 24.)

23. Upon information and belief, Impax is the current owner by assignment of the '608 patent. (*See* D.E. 1 ¶ 24.)

24. Upon information and belief, the '608 patent is currently listed in the Orange Book with respect to RYTARY®. (*See* D.E. 1 ¶ 24.)

U.S. Patent No. 9,463,246

25. Upon information and belief, the cover page of the '246 patent indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" issued on October 11, 2016. (*See* D.E. 1 ¶ 25.)

26. Upon information and belief, Impax is the current owner by assignment of the '246 patent. (*See* D.E. 1 ¶ 25.)

27. Upon information and belief, the '246 patent is currently listed in the Orange Book with respect to RYTARY®. (*See* D.E. 1 ¶ 25.)

U.S. Patent No. 9,533,046

28. Upon information and belief, the cover page of the '046 patent indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" issued on January 3, 2017. (*See* D.E. 1 ¶ 26.)

29. Upon information and belief, Impax is the current owner by assignment of the '046 patent. (*See* D.E. 1 ¶ 26.)

30. Upon information and belief, the '046 patent is currently listed in the Orange Book with respect to RYTARY®. (*See* D.E. 1 ¶ 26.)

U.S. Patent No. 9,901,640

31. Upon information and belief, the cover page of the '640 patent indicates it is entitled "Controlled Release Formulations of Levodopa and Uses Thereof" issued on February 27, 2018. (*See* D.E. 1 ¶ 27.)

32. Upon information and belief, Impax is the current owner by assignment of the '640 patent. (*See* D.E. 1 ¶ 27.)

33. Upon information and belief, the ’640 patent is currently listed in the Orange Book with respect to RYTARY®. (*See* D.E. 1 ¶ 27.)

First Counterclaim
(Declaratory Judgment of Non-Infringement of the ’283 Patent)

34. DRL repeats and realleges the allegations contained in paragraphs 1-33 as if fully set forth herein.

35. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL’s ANDA and/or the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DRL’s ANDA Product infringes, has infringed, and/or will infringe any valid and enforceable claim of the ’283 patent.

36. The DRL ANDA Product does not and will not infringe, directly or indirectly, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the ’283 patent.

37. DRL is entitled to a declaration that the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the DRL ANDA Product would not infringe any valid or enforceable claim of the ’283 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of the ’283 Patent)

38. DRL repeats and realleges the allegations contained in paragraphs 1-37 as if fully set forth herein.

39. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the validity of the ’283 patent.

40. The ’283 patent is invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

41. DRL is entitled to a declaration that the '283 patent is invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or other judicially created bases for invalidation.

Third Counterclaim
(Declaratory Judgment of Non-Infringement of the '608 Patent)

42. DRL repeats and realleges the allegations contained in paragraphs 1-41 as if fully set forth herein.

43. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA and/or the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid and enforceable claim of the '608 patent.

44. The DRL ANDA Product has not or will not infringe, directly or indirectly, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '608 patent.

45. DRL is entitled to a declaration that the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DRL's ANDA Product would not infringe any valid or enforceable claim of the '608 patent.

Fourth Counterclaim
(Declaratory Judgment of Invalidity of the '608 Patent)

46. DRL repeats and realleges the allegations contained in paragraphs 1-45 as if fully set forth herein.

47. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the validity of the '608 patent.

48. The '608 patent is invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

49. DRL is entitled to a declaration that the '608 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or other judicially created bases for invalidation.

Fifth Counterclaim
(Declaratory Judgment of Non-Infringement of the '246 Patent)

50. DRL repeats and realleges the allegations contained in paragraphs 1-49 as if fully set forth here.

51. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA and/or the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid and enforceable claim of the '246 patent.

52. The DRL ANDA Product has not and will not infringe, directly or indirectly, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '246 patent.

53. DRL is entitled to a declaration that the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DRL's ANDA Product would not infringe any valid or enforceable claim of the '246 patent.

Sixth Counterclaim
(Declaratory Judgment of Invalidity of the '246 Patent)

54. DRL repeats and realleges the allegations contained in paragraphs 1-53 as if fully set forth here.

55. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the validity of the '246 patent.

56. The '246 patent is invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

57. DRL is entitled to a declaration that the '246 patent is invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or other judicially created bases for invalidation.

Seventh Counterclaim
(Declaratory Judgment of Non-Infringement of the '046 Patent)

58. DRL repeats and realleges the allegations contained in paragraphs 1-57 as if fully set forth here.

59. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA and/or the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the DRL ANDA Product infringes, has infringed, and/or will infringe any valid and enforceable claim of the '046 patent.

60. The DRL ANDA Product has not and will not infringe, directly or indirectly, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '046 patent.

61. DRL is entitled to a declaration that the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the DRL ANDA Product would not infringe any valid or enforceable claim of the '046 patent.

Eighth Counterclaim
(Declaratory Judgment of Invalidity of the '046 Patent)

62. DRL repeats and realleges the allegations contained in paragraphs 1-61 as if fully set forth herein.

63. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the validity of the '046 patent.

64. One or more claims of the '046 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

DRL is entitled to a declaration that one or more of the claims of the '046 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or other judicially created bases for invalidation.

Ninth Counterclaim
(Declaratory Judgment of Non-Infringement of the '640 Patent)

65. DRL repeats and realleges the allegations contained in paragraphs 1-64 as if fully set forth here.

66. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA and/or the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid and enforceable claim of the '640 patent.

67. The DRL ANDA Product has not and will not infringe, directly or indirectly, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '640 patent.

68. DRL is entitled to a declaration that the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the DRL ANDA Product would not infringe any valid or enforceable claim of the '640 patent.

Tenth Counterclaim
(Declaratory Judgment of Invalidity of the '640 Patent)

69. DRL repeats and realleges the allegations contained in paragraphs 1-68 as if fully set forth here.

70. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the validity of the '640 patent.

71. One or more claims of the '640 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

72. DRL is entitled to a declaration that one or more of the claims of the '640 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or other judicially created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, DRL prays for relief as follows:

(a) That the Complaint against DRL be dismissed in its entirety and with prejudice, and that Plaintiff takes nothing thereby;

(b) That the Court permanently enjoins Plaintiff from asserting the '283, '608, '246, '046, and '640 patents against DRL or any purchasers of any of DRL's ANDA Products;

(c) That the Court issue a declaration that Impax is not entitled to damages, interest, costs or any other monetary relief from DRL;

(d) That the Court issue a declaration that Impax is not entitled to any injunctive relief;

(e) That the Court issue a declaration preliminarily and permanently enjoining Impax, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with them, from taking any action to unlawfully prevent the FDA approval of the DRL ANDA and the product described there;

(f) That DRL be awarded its attorney fees and costs and expenses of the suit; and

(g) That the Court award other and further relief as it deems just and proper.

Dated: November 18, 2024

Respectfully submitted,

By: */s/ Frank D. Rodriguez*
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Attorneys for Defendants
Dr. Reddy's Laboratories, Ltd. and
Dr. Reddy's Laboratories, Inc.

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a true and accurate copy of the foregoing, DEFENDANTS DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT, was caused to be filed with the Court's electronic filing system, and served on all counsel of record for Plaintiff via the Court's electronic filing system and electronic mail on November 18, 2024.

Dated: November 18, 2024

Respectfully submitted,

By: */s/ Frank D. Rodriguez*
Frank D. Rodriguez
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Attorney for Defendants
Dr. Reddy's Laboratories, Ltd. and
Dr. Reddy's Laboratories, Inc.