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Impax Laboratories, LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, LLC,

Plaintiff,

v.

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.,

Defendants.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

(Filed Electronically)

L. CIV. R. 10.1 STATEMENT

The address for Plaintiff Impax Laboratories, LLC is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Impax is represented by Stephanie L. Jonaitis of Troutman Pepper Hamilton Sanders LLP, Suite 400, 301 Carnegie Center, Princeton, NJ 08540. Impax is also represented by Andrew P. Zappia (*pro hac vice* application to be filed) of Troutman Pepper Hamilton Sanders LLP, 70 Linden Oaks, Suite 210, Rochester, NY 14625 and Maia H. Harris (*pro hac vice* application to be filed) and L. Andrew Tseng (*pro hac vice* application to be filed) of Troutman Pepper Hamilton Sanders LLP, 125 High Street, 19th Floor, Boston, MA 02110.

The listed address for Defendant Dr. Reddy's Laboratories, Ltd. is 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 5000034, India. The address for Defendant Dr. Reddy's Laboratories, Inc. is 107 College Road East, Princeton, New Jersey 08540.

COMPLAINT

Plaintiff Impax Laboratories, LLC ("Impax"), by its undersigned attorneys, for its Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL" or "Defendants"), hereby alleges 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®.

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.

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.

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.

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

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.

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).

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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”).

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.

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.

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**.

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**.

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.

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.

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.

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.

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®.

ACTS GIVING RISE TO THIS ACTION

30. Impax realleges all 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").

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.

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”).

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”).

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®.

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).

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.

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.

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.

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.

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

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").

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.

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).

COUNT I - INFRINGEMENT OF THE '283 PATENT BY DRL

45. Impax realleges all 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).
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).
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.
49. A justiciable controversy exists regarding Defendants' infringement of the '283 patent.
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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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

COUNT II - INFRINGEMENT OF THE '608 PATENT BY DRL

61. Impax realleges all 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).

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).

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.

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

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.

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.

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.

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.

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.

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

COUNT III - INFRINGEMENT OF THE '246 PATENT BY DRL

72. Impax realleges all 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).

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).

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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

COUNT IV - INFRINGEMENT OF THE '046 PATENT BY DRL

88. Impax realleges all 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).

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).

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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

COUNT V - INFRINGEMENT OF THE '640 PATENT BY DRL

104. Impax realleges all 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).

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).

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.

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

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.

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.

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.

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.

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).

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

PRAYER FOR RELIEF

WHEREFORE, Impax respectfully requests that the Court enter judgment against Defendants and for the following relief:

- a. A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the Patents-in-Suit through Defendants' submission of the DRL ANDA and the DRL Paragraph IV Certifications to the FDA seeking approval to commercially manufacture, use, offer to sell, sell, and/or import in or into the United States the DRL ANDA Products before the expiration of the Patents-in-Suit;
- b. A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer to sell, sale, and/or importation in or into the United States of the DRL ANDA Products prior to the expiration of the Patents-in-Suit will infringe, actively induce infringement, and/or contribute to the infringement, literally or under the doctrine of equivalents, of at least one claim of the Patents-in-Suit;
- c. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the DRL ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, including any extensions thereof;
- d. The entry of a preliminary and/or permanent injunction enjoining Defendants, and their affiliates and subsidiaries, and each of their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them, from (i) engaging in the

commercial manufacture, use, offer to sell, or sale within the United States, and/or importation in or into the United States, of drugs or methods of administering drugs claimed in the Patents-in-Suit, and (ii) seeking, obtaining, or maintaining approval of the DRL ANDA until the expiration of the Patents-in-Suit or such other later time as the Court may determine;

e. Damages or other monetary relief to Impax if Defendants commercially manufacture, use, offer to sell, sell, and/or import in or into the United States the DRL ANDA Products prior to the expiration of the Patents-in-Suit, including any extensions, and that any such monetary relief be awarded to Impax with prejudgment interest;

f. A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Impax its attorney's fees incurred in this action;

g. A judgment awarding Impax its costs and expenses incurred in this action; and

h. Such further and other relief as this Court may deem just and proper.

Dated: July 18, 2024

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L. Civ. R. 11.2 and L. Civ. R. 40.1 CERTIFICATIONS

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy involves the same plaintiff, same drug product (RYTARY®), and same patents that are at issue in *Impax Laboratories, LLC v. Ascent Pharmaceuticals Inc.*, Civil Action No. 1:24-cv-05299-KMW-EAP (D.N.J.) (filed Apr. 18, 2024).

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration or administrative proceeding, nor are there any non-parties known to Impax that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Pursuant to Local Civil Rule 40.1(c), I hereby certify that *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, Civil Action No. 2:18-cv-09347-SRC-CLW (D.N.J.) (terminated July 26, 2018) was previously pending in this Court and involved one (1) of the same patents as the matter in controversy, including U.S. Patent No. 9,901,640.

Pursuant to Local Civil Rule 40.1(c), I hereby certify that the matter captioned *Impax Laboratories, Inc. v. Zydus Pharmaceuticals USA, Inc. et al.*, Civil Action No. 2:17-cv-13476-SRC-CLW (D.N.J.) (terminated May 19, 2020) was previously pending in this Court and involved the infringement of two (2) of the same patents as the matter in controversy, including U.S. Patent Nos. 8,557,283 and 9,089,608.

Pursuant to Local Civil Rule 40.1(c), I hereby certify that *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, Civil Action No. 2:17-cv-03295-SRC-CLW (D.N.J.) (terminated July 2, 2018) was previously pending in this Court and involved one (1) of the same patents as the matter in controversy, including U.S. Patent No. 9,533,046.

Pursuant to Local Civil Rule 40.1(c), I hereby certify that the matter captioned *Impax Laboratories, Inc. v. Sandoz, Inc.*, Civil Action No. 2:17-cv-02227-SRC-CLW (D.N.J.) (terminated December 18, 2018) was previously pending in this Court and involved the infringement of four (4) of the same patents as the matter in controversy, including U.S. Patent Nos. 8,557,283; 9,089,608; 9,463,246; and 9,533,046.

Pursuant to Local Civil Rule 40.1(c), I hereby certify that *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, Civil Action No. 2:16-cv-09416-SRC-CLW (D.N.J.) (terminated December 28, 2016) was previously pending in this Court, was consolidated with Civil Action No. 2:15-cv-06934-SRC-CLW (D.N.J.) and involved one (1) of the same patents as the matter in controversy, including U.S. Patent No. 9,463,246.

Pursuant to Local Civil Rule 40.1(c), I hereby certify that the matter captioned *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, Civil Action No. 2:15-cv-06934-SRC-CLW (D.N.J.) (terminated June 25, 2018) was previously pending in this Court and involved the infringement of four (4) of the same patents as the matter in controversy, including U.S. Patent Nos. 8,557,283; 9,089,608; 9,463,246; and 9,533,046.

Dated: July 18, 2024

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RULE 201.1 CERTIFICATION

Pursuant to Local Civil Rule 201.1(d), I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that Impax seeks, *inter alia*, injunctive relief.

Dated: July 18, 2024

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