Stephanie L. Jonaitis
TROUTMAN PEPPER
HAMILTON SANDERS LLP
301 Carnegie Center, Suite 400
Princeton, NJ 08540
Tel.: (609) 951-4212
Fax: (609) 452-1147
Email: Stephanie.Jonaitis@troutman.com

Attorney for Plaintiff
Impax Laboratories, LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, LLC,

Plaintiff,

vs.

ASCENT PHARMACEUTICALS INC.,

Defendant.

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 address for Defendant Ascent Pharmaceuticals Inc. is 400 South Technology Drive, Central Islip, New York 11722.

COMPLAINT

Plaintiff Impax Laboratories, LLC ("Impax"), by its undersigned attorneys, for its Complaint against Defendant Ascent Pharmaceuticals Inc. ("Ascent" or "Defendant"), 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 Defendant's 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. 8,377,474 ("the '474 patent"), 8,454,998 ("the '998 patent"), 8,557,283 ("the '283 patent"), 9,089,607 ("the '607 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").

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 Ascent is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 400 South Technology Drive, Central Islip, New York 11722.

4. On information and belief, Ascent is in the business of developing, preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including the State of New Jersey.

JURISDICTION AND VENUE

5. 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).

6. On information and belief, Ascent purposefully has conducted and continues to conduct business in this Judicial District.

7. On information and belief, Ascent is 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.

8. On information and belief, Ascent directly or indirectly develops, manufactures, imports, markets, distributes, and/or sells pharmaceutical products, including at least thirty-two generic drug 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.

9. On information and belief, Ascent develops and manufactures generic pharmaceutical products, which then are sold in the United States by independent marketing groups, the locations or operations of which are in, among other places, the State of New Jersey.

10. 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 Ascent seeks FDA approval to manufacture, market, import, offer to sell, and/or sell pursuant to ANDA No. 219307.

11. On information and belief, if the Ascent ANDA (defined below) is approved, the Ascent ANDA Products (defined below) will be marketed, distributed, and/or sold, directly or indirectly, by Ascent 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 Ascent succeeds in obtaining FDA approval, Ascent will, directly or indirectly, market, distribute, and/or sell the Ascent ANDA Products in the State of New Jersey.

12. On information and belief, Ascent has registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5005459.

13. On information and belief, Ascent intends to benefit directly if the Ascent 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 Ascent ANDA.

14. On information and belief, Ascent and/or Ascent's employees have used or have the ability to use and/or operate out of offices located in the State of New Jersey listed under the name of an affiliated company, Camber Pharmaceuticals, Inc., with offices at 800 Centennial Avenue, Suite 1, Piscataway, New Jersey 08854; 1035 Centennial Avenue, Piscataway, New Jersey 08854; and 1031 Centennial Avenue, Piscataway, New Jersey 08854 which company is under common ownership with Ascent.

15. Ascent has consented to and/or agreed not to contest personal jurisdiction and venue in this Judicial District in recent actions arising out of its ANDA filings and has availed itself of the jurisdiction of this Court including through the assertion of counterclaims. *See, e.g.*, *Tris Pharma, Inc. v. Ascent Pharms., Inc.*, No. 21-cv-12867 (D.N.J.); *GW Rsch., Ltd. v. Teva Pharms., Inc. et al.*, No. 23-cv-00018 (D.N.J.); *GW Rsch., Ltd. v. Teva Pharms., Inc. et al.*, No. 23-cv-03914 (D.N.J.); *Supernus Pharms., Inc. v. Ascent Pharms., Inc.*, No. 23-cv-04015 (D.N.J.) (collectively, the "Prior Actions").

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

17. Ascent has confirmed that it does not contest that Ascent is subject to personal jurisdiction in this Judicial District for this action.

18. 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, among other things, Ascent: (a) on information and belief, has a regular and established place of business in the State of New Jersey through its affiliated company Camber Pharmaceuticals, Inc., which has offices at 800 Centennial Avenue, Suite 1, Piscataway, New

Jersey 08854; 1035 Centennial Avenue, Piscataway, New Jersey 08854; and 1031 Centennial Avenue, Piscataway, New Jersey 08854; (b) seeks approval from the FDA to market and sell the Ascent ANDA Products in this Judicial District; (c) has engaged in regular and established business within the State of New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making, using, offering to sell, or selling Ascent's products in this Judicial District, and deriving substantial revenue from such activities; (d) has made agreements with retailers, wholesalers and/or distributors providing for the distribution of Ascent's products in the State of New Jersey; and (e) has consented to and/or not contested venue in this Judicial District in the Prior Actions.

19. Ascent has confirmed that it does not contest that venue is proper in this Judicial District for this action.

BACKGROUND

U.S. Patent No. 8,377,474

20. On February 19, 2013, the United States Patent and Trademark Office ("PTO") duly and legally issued United States Patent No. 8,377,474 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Alani. The '474 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 '474 patent is attached as **Exhibit 1**.

U.S. Patent No. 8,454,998

21. On June 4, 2013, the PTO duly and legally issued United States Patent No. 8,454,998 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Alani. The '998 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 '998 patent is attached as **Exhibit 2**.

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

22. On October 15, 2013, the 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 3**.

U.S. Patent No. 9,089,607

23. On July 28, 2015, the PTO duly and legally issued United States Patent No. 9,089,607 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. The '607 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 '607 patent is attached as **Exhibit 4**.

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 5**.

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 6**.

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 7**.

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 8**.

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 are 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 '474, '998, '283, '607, '608, '246, '046, and '640 patents 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, Ascent submitted ANDA No. 219307 (the "Ascent 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 "Ascent ANDA Products").

32. On information and belief, following FDA approval of the Ascent ANDA, Ascent intends to make, use, sell, or offer to sell the Ascent 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 Ascent ANDA, Ascent provided written certification to the FDA, pursuant to 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 Ascent ANDA Products (the "Ascent Paragraph IV Certifications").

34. No earlier than March 8, 2024, Impax received written notice of the Ascent ANDA and the Ascent Paragraph IV Certifications from Ascent ("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 Ascent ANDA Products ("Detailed Statement").

35. By filing the Ascent ANDA, Ascent represented to the FDA that the Ascent 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, Ascent offered confidential access to portions of the Ascent 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 firm access to certain information from the produced portions of the Ascent ANDA. The specific information disclosed to Impax was chosen by Ascent.

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

39. The OCA further requires Impax's outside counsel to return to Ascent's outside litigation counsel the provided excerpts from the Ascent ANDA within thirty-five (35) days of receipt.

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 Ascent ANDA. This prohibition therefore prohibits Impax from including or referencing in this Complaint any information in the limited excerpts from the Ascent ANDA that were provided to Impax's outside counsel under the OCA, beyond general statements as to whether the Ascent ANDA Products meet patent claim limitations.

41. Impax's outside counsel executed the OCA on April 1, 2024.

42. On April 3, 2024, Ascent provided documents to Impax's outside counsel under the OCA.

43. 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 '474 PATENT BY ASCENT

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

45. By submission of the Ascent ANDA with the Ascent Paragraph IV Certifications to the FDA and notice to Impax of same, Ascent declared its intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent ANDA Products prior to the expiration of the '474 patent, in the event that the FDA approves the Ascent ANDA. Accordingly, an actual and immediate controversy exists regarding Ascent's infringement of the '474 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

46. Ascent's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent ANDA Products prior to the expiration of the '474 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

47. In the Notice Letter and Detailed Statement, Ascent sets forth no grounds for non-infringement of claims 1-14, 17, 19-30, 36-43, 46-49, 52-76, 78, 79, and 82 of the '474 patent by the Ascent ANDA Products.

48. A justiciable controversy exists regarding Ascent's infringement of the '474 patent.

49. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will infringe, literally or under the doctrine of equivalents, one or more claims of the '474 patent, including at least claim 1, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Ascent ANDA Products. For example, in addition to the act of infringement stemming from the filing of the Ascent ANDA and the Ascent Paragraph IV Certifications, based on a review of the documents produced by Ascent under the OCA (the "OCA Production"), Impax believes that it can show after discovery and analysis that the Ascent ANDA Products practice all the limitations of at least claim 1 of the '474 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim.

50. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will also induce others to infringe of one or more claims of the '474 patent, including at least claim 1, under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of the Ascent ANDA, Ascent will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the '474 patent, by at least its promotional activities and package

inserts for the Ascent ANDA Products, by at least healthcare professionals and patients, with knowledge that its acts are encouraging infringement.

51. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will contributorily infringe one or more claims of the ’474 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Ascent ANDA, Ascent will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and has had and continues to have knowledge that the Ascent ANDA Products constitute a material part of at least one of the claims of the ’474 patent; are especially made or adapted for use in infringing the ’474 patent; and that the Ascent ANDA Products are not suitable for substantial non-infringing use.

52. Impax will be substantially and irreparably harmed if Ascent is permitted to make, use, sell, offer to sell, and/or import the Ascent ANDA Products in or into the United States, and is not enjoined from doing so. Ascent 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 Ascent ANDA to be a date that is not earlier than the expiration date of the ’474 patent, or any later expiration of exclusivity for the ’474 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

53. Ascent has had knowledge of the ’474 patent since at least the date Ascent submitted the Ascent ANDA and the Ascent Paragraph IV Certifications and was aware that submission of the Ascent ANDA and the Ascent 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 numerous claims in the ’474 Patent, including at least claim 1.

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

COUNT II - INFRINGEMENT OF THE '998 PATENT BY ASCENT

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

56. By submission of the Ascent ANDA with the Ascent Paragraph IV Certifications to the FDA and notice to Impax of same, Ascent declared its intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent ANDA Products prior to the expiration of the '998 patent, in the event that the FDA approves the Ascent ANDA. Accordingly, an actual and immediate controversy exists regarding Ascent's infringement of the '998 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

57. Ascent's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent ANDA Products prior to the expiration of the '998 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

58. In the Notice Letter and Detailed Statement, Ascent sets forth no grounds for non-infringement of claims 1-12 and 14-28 of the '998 patent by the Ascent ANDA Products.

59. A justiciable controversy exists regarding Ascent's infringement of the '998 patent.

60. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will infringe, literally or under the doctrine of equivalents, one or more claims of the '998 patent, including at least claim 1, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Ascent ANDA Products.

61. For example, in addition to the act of infringement stemming from the filing of the Ascent ANDA and the Ascent Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Ascent ANDA

Products in combination with at least the label for those products proposed by Ascent in its ANDA submission, practice all the limitations of at least claim 1 of the ’998 patent either literally or under the doctrine of equivalents. In addition to direct infringement of the claims of the ’998 patent, Ascent will also indirectly infringe the methods claimed in the ’998 patent, including without limitation claim 1, by inducing at least healthcare professionals and patients to directly infringe that claim.

62. On information and belief, the Ascent ANDA Products, if approved by FDA, will be prescribed and administered to human patients to treat movement disorders selected from a group consisting of, among other disorders, Parkinson’s disease, which uses will constitute direct infringement of one or more claims of the ’998 patent.

63. On information and belief, these directly infringing uses will occur with Ascent’s specific intent and encouragement and will be uses that Ascent knows or should know will occur.

64. On information and belief, Ascent 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 ’998 patent and will constitute infringement.

65. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will induce others to infringe of one or more claims of the ’998 patent, including at least claim 1, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the Ascent ANDA Products to treat movement disorders selected from a group consisting of, among other disorders, Parkinson’s disease in a manner that meets the limitations of claims in the ’998 patent, including at least claim 1.

66. On information and belief, upon FDA approval of the Ascent ANDA, Ascent will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with

knowledge of the ’998 patent, by at least its promotional activities and package inserts for the Ascent ANDA Products, by at least healthcare professionals and patients, with knowledge that its acts are encouraging infringement.

67. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will contributorily infringe one or more claims of the ’998 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Ascent ANDA, Ascent will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and has had and continues to have knowledge that the Ascent ANDA Products constitute a material part of at least one of the claims of the ’998 patent; are especially made or adapted for use in infringing the ’998 patent; and that the Ascent ANDA Products are not suitable for substantial non-infringing use.

68. Impax will be substantially and irreparably harmed if Ascent is permitted to make, use, sell, offer to sell, and/or import the Ascent ANDA Products in or into the United States, and is not enjoined from doing so. Ascent 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 Ascent ANDA to be a date that is not earlier than the expiration date of the ’998 patent, or any later expiration of exclusivity for the ’998 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

69. Ascent has had knowledge of the ’998 patent since at least the date Ascent submitted the Ascent ANDA and the Ascent Paragraph IV Certifications and was aware that submission of the Ascent ANDA and the Ascent 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 numerous claims in the ’998 Patent, including at least claim 1.

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

COUNT III - INFRINGEMENT OF THE ’283 PATENT BY ASCENT

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

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

73. Ascent’s submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent 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).

74. In the Notice Letter and Detailed Statement, Ascent sets forth no grounds for non-infringement of any claim of the ’283 patent by the Ascent ANDA Products.

75. A justiciable controversy exists regarding Ascent’s infringement of the ’283 patent.

76. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will infringe, literally or 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 Ascent ANDA Products.

77. For example, in addition to the act of infringement stemming from the filing of the Ascent ANDA and the Ascent Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Ascent ANDA Products in combination with at least the label for those products proposed by Ascent in its ANDA submission, practice all the limitations of at least claim 1 of the ’283 patent either literally or under the doctrine of equivalents. In addition to direct infringement of the claims of the ’283 patent, Ascent 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.

78. On information and belief, the Ascent 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.

79. On information and belief, these directly infringing uses will occur with Ascent’s specific intent and encouragement and will be uses that Ascent knows or should know will occur.

80. On information and belief, Ascent 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.

81. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent 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 Ascent 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.

82. On information and belief, upon FDA approval of the Ascent ANDA, Ascent will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the ’283 patent, by at least its promotional activities and package inserts for the Ascent ANDA Products, by at least healthcare professionals and patients, with knowledge that its acts are encouraging infringement.

83. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent 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 Ascent ANDA, Ascent will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and has had and continues to have knowledge that the Ascent 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 Ascent ANDA Products are not suitable for substantial non-infringing use.

84. Impax will be substantially and irreparably harmed if Ascent is permitted to make, use, sell, offer to sell, and/or import the Ascent ANDA Products in or into the United States, and is not enjoined from doing so. Ascent 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 Ascent 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.

85. Ascent has had knowledge of the ’283 patent since at least the date Ascent submitted the Ascent ANDA and the Ascent Paragraph IV Certifications and was aware that submission of the Ascent ANDA and the Ascent 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 the claims in the ’283 Patent, including at least claim 1.

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

COUNT IV - INFRINGEMENT OF THE ’607 PATENT BY ASCENT

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

88. By submission of the Ascent ANDA with the Ascent Paragraph IV Certifications to the FDA and notice to Impax of same, Ascent declared its intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent ANDA Products prior to the expiration of the ’607 patent, in the event that the FDA approves the Ascent ANDA. Accordingly, an actual and immediate controversy exists regarding Ascent’s infringement of the ’607 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

89. Ascent’s submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent ANDA Products prior to the expiration of the ’607 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

90. In the Notice Letter and Detailed Statement, Ascent sets forth no grounds for non-infringement of claims 1-6, 10-11, 13, 15-34, 37-39, 41, and 44-56 of the ’607 patent by the Ascent ANDA Products.

91. A justiciable controversy exists regarding Ascent’s infringement of the ’607 patent.

92. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will infringe, literally or under the doctrine of equivalents, one or more claims of the '607 patent, including at least claim 1, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Ascent ANDA Products. For example, in addition to the act of infringement stemming from the filing of the Ascent ANDA and the Ascent Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Ascent ANDA Products practice all the limitations of at least claim 1 of the '607 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim.

93. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will also induce others to infringe of one or more claims of the '607 patent, including at least claim 1, under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of the Ascent ANDA, Ascent will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the '607 patent, by at least its promotional activities and package inserts for the Ascent ANDA Products, by at least healthcare professionals and patients, with knowledge that its acts are encouraging infringement.

94. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will contributorily infringe one or more claims of the '607 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Ascent ANDA, Ascent will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and has had and continues to have knowledge that the Ascent ANDA Products constitute a material part of at least one of the claims of the '607 patent; are especially made or adapted for use in infringing the '607 patent; and that the Ascent ANDA Products are not suitable for substantial non-infringing use.

95. Impax will be substantially and irreparably harmed if Ascent is permitted to make, use, sell, offer to sell, and/or import the Ascent ANDA Products in or into the United States, and is not enjoined from doing so. Ascent 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 Ascent ANDA to be a date that is not earlier than the expiration date of the '607 patent, or any later expiration of exclusivity for the '607 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

96. Ascent has had knowledge of the '607 patent since at least the date Ascent submitted the Ascent ANDA and the Ascent Paragraph IV Certifications and was aware that submission of the Ascent ANDA and the Ascent 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 numerous claims in the '607 Patent, including at least claim 1.

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

COUNT V - INFRINGEMENT OF THE '608 PATENT BY ASCENT

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

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

100. Ascent's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent 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).

101. In the Notice Letter and Detailed Statement, Ascent sets forth no grounds for non-infringement of claims 1-6, 8-9, and 11-19 of the '608 patent by the Ascent ANDA Products.

102. A justiciable controversy exists regarding Ascent's infringement of the '608 patent.

103. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will infringe, literally or under the doctrine of equivalents, one or more claims of the '608 patent, including at least claim 1, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Ascent ANDA Products. For example, in addition to the act of infringement stemming from the filing of the Ascent ANDA and the Ascent Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Ascent ANDA Products practice all the limitations of at least claim 1 of the '608 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim.

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

105. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will contributorily infringe one or more claims of the ’608 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Ascent ANDA, Ascent will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and has had and continues to have knowledge that the Ascent 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 Ascent ANDA Products are not suitable for substantial non-infringing use.

106. Impax will be substantially and irreparably harmed if Ascent is permitted to make, use, sell, offer to sell, and/or import the Ascent ANDA Products in or into the United States, and is not enjoined from doing so. Ascent 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 Ascent 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.

107. Ascent has had knowledge of the ’608 patent since at least the date Ascent submitted the Ascent ANDA and the Ascent Paragraph IV Certifications and was aware that submission of the Ascent ANDA and the Ascent 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 numerous claims in the ’608 Patent, including at least claim 1.

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

COUNT VI - INFRINGEMENT OF THE '246 PATENT BY ASCENT

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

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

111. Ascent's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent 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).

112. In the Notice Letter and Detailed Statement, Ascent sets forth no grounds for non-infringement of claims 26-50 of the '246 patent by the Ascent ANDA Products.

113. A justiciable controversy exists regarding Ascent's infringement of the '246 patent.

114. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will infringe, literally or 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 Ascent ANDA Products.

115. For example, in addition to the act of infringement stemming from the filing of the Ascent ANDA and the Ascent Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Ascent ANDA Products in combination with at least the label for those products proposed by Ascent in its ANDA submission, practice all the limitations of at least claim 26 of the '246 patent either literally or

under the doctrine of equivalents. In addition to direct infringement of the claims of the ’246 patent, Ascent 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.

116. On information and belief, the Ascent 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.

117. On information and belief, these directly infringing uses will occur with Ascent’s specific intent and encouragement and will be uses that Ascent knows or should know will occur.

118. On information and belief, Ascent 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.

119. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent 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 Ascent 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.

120. On information and belief, upon FDA approval of the Ascent ANDA, Ascent will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the ’246 patent, by at least its promotional activities and package inserts for the Ascent ANDA Products, by at least healthcare professionals and patients, with knowledge that its acts are encouraging infringement.

121. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent 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 Ascent ANDA, Ascent will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and has had and continues to have knowledge that the Ascent 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 Ascent ANDA Products are not suitable for substantial non-infringing use.

122. Impax will be substantially and irreparably harmed if Ascent is permitted to make, use, sell, offer to sell, and/or import the Ascent ANDA Products in or into the United States, and is not enjoined from doing so. Ascent 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 Ascent 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.

123. Ascent has had knowledge of the ’246 patent since at least the date Ascent submitted the Ascent ANDA and the Ascent Paragraph IV Certifications and was aware that submission of the Ascent ANDA and the Ascent 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 numerous claims in the ’246 Patent, including at least claim 26.

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

COUNT VII - INFRINGEMENT OF THE '046 PATENT BY ASCENT

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

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

127. Ascent's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent 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).

128. In the Notice Letter and Detailed Statement, Ascent sets forth no grounds for non-infringement of claims 1-12, 14-19, and 23-31 of the '046 patent by the Ascent ANDA Products.

129. A justiciable controversy exists regarding Ascent's infringement of the '046 patent.

130. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent will infringe, literally or 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 Ascent ANDA Products.

131. For example, in addition to the act of infringement stemming from the filing of the Ascent ANDA and the Ascent Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Ascent ANDA Products in combination with at least the label for those products proposed by Ascent in its ANDA submission, practice all the limitations of at least claim 1 of the '046 patent either literally or under

the doctrine of equivalents. In addition to direct infringement of the claims of the ’046 patent, Ascent 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.

132. On information and belief, the Ascent 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.

133. On information and belief, these directly infringing uses will occur with Ascent’s specific intent and encouragement and will be uses that Ascent knows or should know will occur.

134. On information and belief, Ascent 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.

135. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent 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 Ascent 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.

136. On information and belief, upon FDA approval of the Ascent ANDA, Ascent will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the ’046 patent, by at least its promotional activities and package inserts for the Ascent ANDA Products, by at least healthcare professionals and patients, with knowledge that its acts are encouraging infringement.

137. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent 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 Ascent ANDA, Ascent will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and has had and continues to have knowledge that the Ascent 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 Ascent ANDA Products are not suitable for substantial non-infringing use.

138. Impax will be substantially and irreparably harmed if Ascent is permitted to make, use, sell, offer to sell, and/or import the Ascent ANDA Products in or into the United States, and is not enjoined from doing so. Ascent 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 Ascent 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.

139. Ascent has had knowledge of the ’046 patent since at least the date Ascent submitted the Ascent ANDA and the Ascent Paragraph IV Certifications and was aware that submission of the Ascent ANDA and the Ascent 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 numerous claims in the ’046 Patent, including at least claim 1.

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

COUNT VIII - INFRINGEMENT OF THE ’640 PATENT BY ASCENT

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

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

143. Ascent’s submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Ascent 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).

144. In the Notice Letter and Detailed Statement, Ascent sets forth no grounds for non-infringement of claims 15-23 of the ’640 patent by the Ascent ANDA Products.

145. A justiciable controversy exists regarding Ascent’s infringement of the ’640 patent.

146. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent 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 Ascent ANDA Products. For example, in addition to the act of infringement stemming from the filing of the Ascent ANDA and the Ascent Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Ascent 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.

147. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent 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 Ascent ANDA, Ascent will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the ’640 patent, by at least its promotional activities and package inserts for the Ascent ANDA Products, by at least healthcare professionals and patients, with knowledge that its acts are encouraging infringement.

148. Unless enjoined by this Court, upon FDA approval of the Ascent ANDA, Ascent 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 Ascent ANDA, Ascent will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and has had and continues to have knowledge that the Ascent 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 Ascent ANDA Products are not suitable for substantial non-infringing use.

149. Impax will be substantially and irreparably harmed if Ascent is permitted to make, use, sell, offer to sell, and/or import the Ascent ANDA Products in or into the United States, and is not enjoined from doing so. Ascent 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 Ascent 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.

150. Ascent has had knowledge of the '640 patent since at least the date Ascent submitted the Ascent ANDA and the Ascent Paragraph IV Certifications and was aware that submission of the Ascent ANDA and the Ascent 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 numerous claims in the '640 Patent, including at least claim 15.

151. 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 Ascent and for the following relief:

a. A judgment under 35 U.S.C. § 271(e)(2)(A) that Ascent has infringed at least one claim of the Patents-in-Suit through Ascent's submission of the Ascent ANDA and the Ascent 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 Ascent 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 Ascent's commercial manufacture, use, offer to sell, sale, and/or importation in or into the United States of the Ascent 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 Ascent 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 Ascent, and its 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 Ascent 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 Ascent commercially manufactures, uses, offers to sell, sells, and/or imports in or into the United States the Ascent 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: April 18, 2024

TROUTMAN PEPPER HAMILTON SANDERS LLP

By: */s/Stephanie L. Jonaitis*

Stephanie L. Jonaitis
301 Carnegie Center, Suite 400
Princeton, NJ 08540
Tel.: (609) 951-4212
Fax: (609) 452-1147
Email: Stephanie.Jonaitis@troutman.com

Of counsel:

Andrew P. Zappia (*pro hac vice* to be filed)
70 Linden Oaks, Suite 210
Rochester, NY 14625
Tel.: (585) 270-2102
Email: Andrew.Zappia@troutman.com

Maia H. Harris (*pro hac vice* to be filed)
L. Andrew Tseng (*pro hac vice* to be filed)
125 High Street, 19th Floor
Boston, MA 02110
Tel.: (617) 204-5108
Tel.: (617) 204-5122
Email: Maia.Harris@troutman.com
Andrew.Tseng@troutman.com

Attorneys for Plaintiff Impax Laboratories, LLC

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

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not related to any other matter currently pending in this Judicial District.

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 five (5) of the same patents as the matter in controversy, including U.S. Patent Nos. 8,377,474; 8,454,998; 8,557,283; 9,089,607; 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 seven (7) of the same patents as the matter in controversy, including U.S. Patent Nos. 8,377,474; 8,454,998; 8,557,283; 9,089,607; 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 seven (7) of the same patents as the matter in controversy, including U.S. Patent Nos. 8,377,474; 8,454,998; 8,557,283; 9,089,607; 9,089,608; 9,463,246; and 9,533,046.

Dated: April 18, 2024

TROUTMAN PEPPER HAMILTON SANDERS LLP

By: */s/Stephanie L. Jonaitis*
Stephanie L. Jonaitis
301 Carnegie Center, Suite 400
Princeton, NJ 08540
Tel.: (609) 951-4212
Fax: (609) 452-1147
Email: Stephanie.Jonaitis@troutman.com

Of counsel:
Andrew P. Zappia (*pro hac vice* to be filed)
70 Linden Oaks, Suite 210
Rochester, NY 14625
Tel.: (585) 270-2102
Email: Andrew.Zappia@troutman.com

Maia H. Harris (*pro hac vice* to be filed)
L. Andrew Tseng (*pro hac vice* to be filed)
125 High Street, 19th Floor
Boston, MA 02110
Tel.: (617) 204-5108
Tel.: (617) 204-5122
Email: Maia.Harris@troutman.com
Andrew.Tseng@troutman.com

Attorneys for Plaintiff Impax Laboratories, LLC

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: April 18, 2024

TROUTMAN PEPPER HAMILTON SANDERS LLP

By: */s/Stephanie L. Jonaitis*

Stephanie L. Jonaitis
301 Carnegie Center, Suite 400
Princeton, NJ 08540
Tel.: (609) 951-4212
Fax: (609) 452-1147
Email: Stephanie.Jonaitis@troutman.com

Of counsel:
Andrew P. Zappia (*pro hac vice* to be filed)
70 Linden Oaks, Suite 210
Rochester, NY 14625
Tel.: (585) 270-2102
Email: Andrew.Zappia@troutman.com

Maia H. Harris (*pro hac vice* to be filed)
L. Andrew Tseng (*pro hac vice* to be filed)
125 High Street, 19th Floor
Boston, MA 02110
Tel.: (617) 204-5108
Tel.: (617) 204-5122
Email: Maia.Harris@troutman.com
Andrew.Tseng@troutman.com

Attorneys for Plaintiff Impax Laboratories, LLC