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Amneal Pharmaceuticals LLC
and Impax Laboratories, LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMNEAL PHARMACEUTICALS LLC, and IMPAX LABORATORIES, LLC, Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** (Filed Electronically)

L. CIV. R. 10.1 STATEMENT

The address for Plaintiffs Amneal Pharmaceuticals LLC and Impax Laboratories, LLC is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Plaintiffs are represented by Rebekah Conroy of Stone Conroy LLC, 25 A Hanover Road, Suite 301, Florham Park, NJ 07932. Plaintiffs are also represented by Andrew P. Zappia (*pro hac vice* application to be filed) of Troutman Pepper Locke LLP, 70 Linden Oaks, Suite 210, Rochester, NY 14625 and L. Andrew Tseng (*pro hac vice* application to be filed) of Troutman Pepper Locke LLP, 125 High Street, 19th Floor, Boston, MA 02110.

The listed address for Defendant Sandoz Inc. is 100 College Road West, Princeton, New Jersey 08540-6604.

COMPLAINT

Plaintiffs Amneal Pharmaceuticals LLC ("Amneal") and Impax Laboratories, LLC ("Impax") (individually and collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against Sandoz Inc. ("Sandoz" or "Defendant"), hereby allege 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 CREXONT® (carbidopa and levodopa) extended-release capsules prior to the expiration of United States Patent Nos. 10,098,845 ("the '845 patent"), 10,292,935 ("the '935 patent"), 10,688,058 ("the '058 patent"), 10,973,769 ("the '769 patent"), 10,987,313 ("the '313 patent"), 11,357,733 ("the '733 patent"), 11,622,941 ("the '941 patent"), 11,666,538 ("the '538 patent"), 11,986,449 ("the '449 patent"), 12,064,521 ("the '521 patent"), 12,109,185 ("the '185 patent"), and 12,128,141 ("the '141 patent") (collectively, the "Patents-in-Suit"), and before the expiration dates of these patents listed in the Orange Book for CREXONT®.

THE PARTIES

2. Plaintiff Impax is a limited liability company organized and existing under the laws of the State of Delaware and is wholly-owned by Amneal. Impax's registered business address is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Plaintiff Amneal 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, Sandoz is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 100 College Road West, Princeton, New Jersey 08540-6604.

4. On information and belief, Sandoz is in the business of developing, preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including in 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, Defendant purposefully has conducted and continues to conduct business in this Judicial District.

7. On information and belief, Defendant 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, Defendant directly or indirectly develops, manufactures, imports, markets, distributes, and/or sells 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.

9. On information and belief, Defendant develops and manufactures generic pharmaceutical products, which it then sells in the United States, 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 CREXONT® (carbidopa and levodopa) extended-release capsules for which Defendant seeks FDA approval to manufacture, market, import, offer to sell, and/or sell pursuant to ANDA No. 219989.

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

12. On information and belief, Sandoz is a corporation with its principal place of business in New Jersey and is qualified to do business in New Jersey.

13. On information and belief, Sandoz is registered to do business in the State of New Jersey under Entity Identification Number 0100097265 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732.

14. In view of the foregoing, Sandoz is subject to general personal jurisdiction in New Jersey.

15. On information and belief, Sandoz 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, 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, the distribution

of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

16. On information and belief, Defendant intends to benefit directly if the Sandoz 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 Sandoz ANDA.

17. Sandoz has consented to and/or not contested personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in at least sone of such cases. *See, e.g.*, *Celgene Corporation v. Sandoz Inc.*, Civ. No. 3:18-11026, Dkt. No. 18 (D.N.J. Sept. 25, 2018); *Allergan Sales, LLC v. Sandoz, Inc.*, Civ. No. 2:17-10129, Dkt. No. 18 (D.N.J. Dec. 19, 2017); *Boehringer Ingelheim Pharms., Inc. v. Sandoz, Inc.*, Civ. No. 3:17-08825, Dkt. No. 14 (D.N.J. Jan. 23, 2018); *Mitsubishi Tanabe Pharma Corp. v. MSN Labs. Priv. Ltd.*, Civ. No. 1:17-05302, Dkt. No. 28 (D.N.J. Nov. 17, 2017) (collectively, the "Prior Actions"). Sandoz has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court.

18. For at least the foregoing reasons set forth above, this Court has personal jurisdiction over Defendant because, on information and belief, Defendant: (a) 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 Defendant'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 their generic pharmaceutical products in the State of New Jersey; (e) is located in and/or 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.

19. For at least the foregoing reasons, 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, on information and belief, (a) Sandoz has a principal place of business in New Jersey, and has and will continue to engage in infringement activities in New Jersey, and (b) Sandoz has 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. 10,098,845

20. On October 16, 2018, the United States Patent & Trademark Office ("PTO"), duly and legally issued United States Patent No. 10,098,845 ("the '845 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '845 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '845 patent is attached as **Exhibit 1**.

U.S. Patent No. 10,292,935

21. On May 21, 2019, the PTO duly and legally issued United States Patent No. 10,292,935 ("the '935 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '935 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '935 patent is attached as **Exhibit 2**.

U.S. Patent No. 10,688,058

22. On June 23, 2020, the PTO duly and legally issued United States Patent No. 10,688,058 ("the '058 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '058 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '058 patent is attached as **Exhibit 3**.

U.S. Patent No. 10,973,769

23. On April 13, 2021, the PTO duly and legally issued United States Patent No. 10,973,769 ("the '769 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '769 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '769 patent is attached as **Exhibit 4**.

U.S. Patent No. 10,987,313

24. On April 27, 2021, the PTO duly and legally issued United States Patent No. 10,987,313 ("the '313 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '313 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '313 patent is attached as **Exhibit 5**.

U.S. Patent No. 11,357,733

25. On June 14, 2022, the PTO duly and legally issued United States Patent No. 11,357,733 ("the '733 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '733 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '733 patent is attached as **Exhibit 6**.

U.S. Patent No. 11,622,941

26. On April 11, 2023, the PTO duly and legally issued United States Patent No. 11,622,941 ("the '941 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '941 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '941 patent is attached as **Exhibit 7**.

U.S. Patent No. 11,666,538

27. On June 6, 2023, the PTO duly and legally issued United States Patent No. 11,666,538 ("the '538 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '538 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '538 patent is attached as **Exhibit 8**.

U.S. Patent No. 11,986,449

28. On May 21, 2024, the PTO duly and legally issued United States Patent No. 11,986,449 ("the '449 patent") entitled "Levodopa dosing regimen" to inventors Richard D'Souza, Hester Visser, and Suneel Gupta. The '449 patent is owned by assignment by Amneal and per the FDA Orange Book patent data will expire on December 21, 2041. A true and correct copy of the '449 patent is attached as **Exhibit 9**.

U.S. Patent No. 12,064,521

29. On August 20, 2024, the PTO duly and legally issued United States Patent No. 12,064,521 ("the '521 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '521 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '521 patent is attached as **Exhibit 10**.

U.S. Patent No. 12,109,185

30. On October 8, 2024, the PTO duly and legally issued United States Patent No. 12,109,185 ("the '185 patent") entitled "Levodopa dosing regimen" to inventors Richard D'Souza, Hester Visser, and Suneel Gupta. The '185 patent is owned by assignment by Amneal and per the FDA Orange Book patent data will expire on December 21, 2041. A true and correct copy of the '185 patent is attached as **Exhibit 11**.

U.S. Patent No. 12,128,141

31. On October 29, 2024, the PTO duly and legally issued United States Patent No. 12,128,141 ("the '141 patent") entitled "Muco-adhesive, controlled release formulation of

levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '141 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '141 patent is attached as **Exhibit 12**.

CREXONT®

32. Impax is the holder of New Drug Application ("NDA") No. 217186 ("the NDA"), for carbidopa and levodopa extended-release capsules, for oral use, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg dosages, which is sold under the Proprietary Name CREXONT®.

33. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, at least the '845, '935, '058, '769, '313, '733, '941, '538, '449, '521, '185, and '141 patents are listed in the FDA "Orange Book" with respect to CREXONT®. Plaintiffs are owners by assignment of the Patents-in-Suit.

ACTS GIVING RISE TO THIS ACTION

34. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

35. On information and belief, Defendant submitted ANDA No. 219989 (the "Sandoz 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 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg dosages (the "Sandoz ANDA Products").

36. On information and belief, following any FDA approval of the Sandoz ANDA, Defendant intends to make, use, sell, or offer to sell the Sandoz 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.

37. On information and belief, in connection with the submission of the Sandoz ANDA, Defendant provided written certification to the FDA, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that claims of the '845, '935, '058, '769, '313, '733, '941, '538, '449, and '521 patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of the Sandoz ANDA Products (the "Sandoz Paragraph IV Certifications").

38. No earlier than November 25, 2024, Plaintiffs received written notice of the Sandoz ANDA and the Sandoz Paragraph IV Certifications from Defendant ("Notice Letter"). The Notice Letter included a Detailed Statement of the Factual and Legal Basis for Paragraph IV Certification(s), alleging that claims of the '845, '935, '058, '769, '313, '733, '941, '538, '449, and '521 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Sandoz ANDA Products ("Detailed Statement"). The '185 and '141 patents are also listed in the Orange Book for CREXONT® and were listed in the Orange Book at the time Defendant served the Notice Letter. To date, Defendant has failed and/or refused to provide a notice letter for the '185 and '141 patents.

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

40. This action is being commenced before the expiration of forty-five (45) days from the date Plaintiffs 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 '845 PATENT BY SANDOZ

41. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

42. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '845 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '845 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

43. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '845 patent constituted an act of infringement of one or more claims of the '845 patent under 35 U.S.C. § 271(e)(2)(A).

44. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '845 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '845 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

45. Upon information and belief, Defendant intends to, and will, infringe at least claim 1 of the '845 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

46. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '845 patent.

47. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-4, 6-8, 11-16, and 18-22. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '845 patent.

48. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '845 patent, including at least claim 17, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '845 patent, either literally or under the doctrine of equivalents.

49. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '845 patent.

50. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

51. On information and belief, Defendant 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 Plaintiffs' rights under the '845 patent and will constitute infringement.

52. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '845 patent. Defendant will do so through its promotional

activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '845 patent.

53. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '845 patent, including at least claim 17, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '845 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more claims of the '845 patent and are not suitable for substantial non-infringing use.

54. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '845 patent, or any later expiration of exclusivity for the '845 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

55. Defendant has had knowledge of the '845 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT II: INFRINGEMENT OF THE '935 PATENT BY SANDOZ

57. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

58. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '935 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '935 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

59. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '935 patent constituted an act of infringement of one or more claims of the '935 patent under 35 U.S.C. § 271(e)(2)(A).

60. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '935 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '935 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

61. Upon information and belief, Defendant intends to, and will, infringe at least claim 1 of the '935 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

62. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '935 patent.

63. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-17, 19, and 20. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '935 patent.

64. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '935 patent, including at least claim 18, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of the claims of the '935 patent, either literally or under the doctrine of equivalents.

65. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '935 patent.

66. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

67. On information and belief, Defendant 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 Plaintiffs' rights under the '935 patent and will constitute infringement.

68. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '935 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '935 patent.

69. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '935 patent, including at least claim 18, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '935 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '935 patent and are not suitable for substantial non-infringing use.

70. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '935 patent, or any later expiration of exclusivity for the '935 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

71. Defendant has had knowledge of the '935 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT III: INFRINGEMENT OF THE '058 PATENT BY SANDOZ

73. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

74. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '058 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '058 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

75. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '058 patent constituted an act of infringement of one or more claims of the '058 patent under 35 U.S.C. § 271(e)(2)(A).

76. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '058 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '058 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

77. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '058 patent.

78. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '058 patent.

79. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '058 patent, including at least claims 1 and 20, under 35 U.S.C. § 271(b). On information and belief,

Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '058 patent, either literally or under the doctrine of equivalents.

80. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '058 patent.

81. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

82. On information and belief, Defendant 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 Plaintiffs' rights under the '058 patent and will constitute infringement.

83. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '058 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '058 patent.

84. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '058 patent, including at least claims 1 and 20, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '058 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are

especially made or adapted for use in infringing one or more of the claims of the '058 patent and are not suitable for substantial non-infringing use.

85. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '058 patent, or any later expiration of exclusivity for the '058 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

86. Defendant has had knowledge of the '058 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz 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 '769 PATENT BY SANDOZ

88. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

89. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '769 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '769 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

90. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '769 patent constituted an act of infringement of one or more claims of the '769 patent under 35 U.S.C. § 271(e)(2)(A).

91. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '769 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '769 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

92. Upon information and belief, Defendant intends to, and will, infringe at least claim 14 of the '769 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

93. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '769 patent.

94. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 14-16 and 18-27. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '769 patent.

95. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '769 patent, including at least claims 1 and 10, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare

professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '769 patent, either literally or under the doctrine of equivalents.

96. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '769 patent.

97. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

98. On information and belief, Defendant 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 Plaintiffs' rights under the '769 patent and will constitute infringement.

99. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '769 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '769 patent.

100. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '769 patent, including at least claims 1 and 10, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '769 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are

especially made or adapted for use in infringing one or more of the claims of the '769 patent and are not suitable for substantial non-infringing use.

101. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '769 patent, or any later expiration of exclusivity for the '769 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

102. Defendant has had knowledge of the '769 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz 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 '313 PATENT BY SANDOZ

104. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

105. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '313 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '313 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

106. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '313 patent constituted an act of infringement of one or more claims of the '313 patent under 35 U.S.C. § 271(e)(2)(A).

107. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '313 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '313 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

108. Upon information and belief, Defendant intends to, and will, infringe at least claim 1 of the '313 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

109. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '313 patent.

110. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-5, and 7-19. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '313 patent.

111. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '313 patent, including at least claim 20, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and

patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '313 patent, either literally or under the doctrine of equivalents.

112. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '313 patent.

113. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

114. On information and belief, Defendant 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 Plaintiffs' rights under the '313 patent and will constitute infringement.

115. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '313 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '313 patent claims.

116. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '313 patent, including at least claim 20, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '313 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are

especially made or adapted for use in infringing one or more of the claims of the '313 patent and are not suitable for substantial non-infringing use.

117. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '313 patent, or any later expiration of exclusivity for the '313 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

118. Defendant has had knowledge of the '313 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT VI: INFRINGEMENT OF THE '733 PATENT BY SANDOZ

120. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

121. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '733 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '733 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

122. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '733 patent constituted an act of infringement of one or more claims of the '733 patent under 35 U.S.C. § 271(e)(2)(A).

123. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '733 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '733 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

124. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 24, and 40 of the '733 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

125. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '733 patent.

126. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-6, 8-32, and 35-40. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '733 patent.

127. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '733 patent, including at least claims 1, 24, and 40, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare

professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '733 patent, either literally or under the doctrine of equivalents.

128. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

129. On information and belief, Defendant 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 Plaintiffs' rights under the '733 patent and will constitute infringement.

130. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '733 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '733 patent.

131. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '733 patent, including at least claims 1, 24, and 40, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '733 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '733 patent and are not suitable for substantial non-infringing use.

132. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from

doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '733 patent, or any later expiration of exclusivity for the '733 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

133. Defendant has had knowledge of the '733 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT VII: INFRINGEMENT OF THE '941 PATENT BY SANDOZ

135. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

136. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '941 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '941 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

137. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '941 patent constituted an act of infringement of one or more claims of the '941 patent under 35 U.S.C. § 271(e)(2)(A).

138. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '941 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '941 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

139. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 18, and 28 of the '941 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

140. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '941 patent.

141. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for non-infringement, other than invalidity, for any claim of the '941 patent. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '941 patent.

142. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '941 patent, including at least claims 1, 18 and 28, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '941 patent, either literally or under the doctrine of equivalents.

143. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

144. On information and belief, Defendant 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 Plaintiffs' rights under the '941 patent and will constitute infringement.

145. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '941 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '941 patent.

146. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '941 patent, including at least claims 1, 18, and 28, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '941 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '941 patent and are not suitable for substantial non-infringing use.

147. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '941 patent, or any later expiration of exclusivity for the '941 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

148. Defendant has had knowledge of the '941 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT VIII - INFRINGEMENT OF THE '538 PATENT BY SANDOZ

150. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

151. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '538 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '538 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

152. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '538 patent constituted an act of infringement of one or more claims of the '538 patent under 35 U.S.C. § 271(e)(2)(A).

153. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '538 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '538 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

154. Upon information and belief, Defendant intends to, and will, infringe at least claims 1 and 20 of the '538 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

155. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '538 patent.

156. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-9, 11-17, and 19-21. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '538 patent.

157. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '538 patent, including at least claim 18, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '538 patent, either literally or under the doctrine of equivalents.

158. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '538 patent.

159. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

160. On information and belief, Defendant 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 Plaintiffs' rights under the '538 patent and will constitute infringement.

161. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '538 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '538 patent.

162. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '538 patent, including at least claim 18, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '538 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '538 patent and are not suitable for substantial non-infringing use.

163. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '538 patent, or any later expiration of exclusivity for the '538 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

164. Defendant has had knowledge of the '538 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT IX: INFRINGEMENT OF THE '449 PATENT BY SANDOZ

166. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

167. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '449 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '449 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

168. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '449 patent constituted an act of infringement of one or more claims of the '449 patent under 35 U.S.C. § 271(e)(2)(A).

169. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '449 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '449 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

170. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '449 patent.

171. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '449 patent.

172. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '449 patent, including at least claims 1, 10, and 11, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '449 patent, either literally or under the doctrine of equivalents.

173. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '449 patent.

174. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

175. On information and belief, Defendant 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 Plaintiffs' rights under the '449 patent and will constitute infringement.

176. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '449 patent. Defendant will do so through its promotional

activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '449 patent claims.

177. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '449 patent, including at least claims 1, 10 and 11, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '449 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '449 patent and are not suitable for substantial non-infringing use.

178. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '449 patent, or any later expiration of exclusivity for the '449 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

179. Defendant has had knowledge of the '449 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT X: INFRINGEMENT OF THE '521 PATENT BY SANDOZ

181. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

182. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '521 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '521 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

183. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '521 patent constituted an act of infringement of one or more claims of the '521 patent under 35 U.S.C. § 271(e)(2)(A).

184. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '521 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '521 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

185. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 11, and 20 of the '521 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

186. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '521 patent.

187. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for non-infringement, other than invalidity, for any claim of the ’521 patent. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe at least one claim of the ’521 patent.

188. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the ’521 patent, including at least claims 1, 11, and 20, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the ’521 patent, either literally or under the doctrine of equivalents.

189. On information and belief, these direct infringing uses will occur with Defendant’s specific intent and encouragement and will be uses that Defendant knows or should know will occur.

190. On information and belief, Defendant 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 Plaintiffs’ rights under the ’521 patent and will constitute infringement.

191. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the ’521 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the ’521 patent.

192. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the ’521 patent, including at least claims 1, 11 and 20, under 35 U.S.C.

§ 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '521 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '521 patent and are not suitable for substantial non-infringing use.

193. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '521 patent, or any later expiration of exclusivity for the '521 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

194. Defendant has had knowledge of the '521 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT XI: INFRINGEMENT OF THE '185 PATENT BY SANDOZ

196. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

197. The '185 patent was issued October 8, 2024, and was listed in the Orange Book on October 11, 2024 in connection with Impax's NDA No. 217186 for carbidopa and levodopa extended-release capsules, for oral use, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg dosages, which is sold under the Proprietary Name CREXONT®. Despite this

listing, Defendant's Notice Letter and Detailed Statement do not address the '185 patent. Defendant has to date also failed and/or refused to provide a notice letter to address the '185 patent.

198. Defendant has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting the Sandoz ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("Act") for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products, the use of which is claimed by one or more claims of the '185 patent, before the expiration of that patent.

199. By submission of the Sandoz ANDA with Paragraph IV Certifications on other Orange Book listed patents and notice to Plaintiffs of the same, Defendant indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '185 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '185 patent under at least 35 U.S.C. §§ 271(b) and/or (c). This controversy is concrete and immediate, since Plaintiffs will suffer substantial and irreparable harm, including loss of market share, damage to reputation, and financial harm, if Defendant is allowed to proceed with its infringing activities.

200. Additionally, pursuant to 28 U.S.C. § 2201, Plaintiffs are also entitled to a declaratory judgment that Defendant's making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, inducement thereof or contribution thereto, will infringe the '185 patent, either literally or under the doctrine of equivalents, pursuant to at least 35 U.S.C. §§ 271(b) and/or (c).

201. Upon information and belief, by virtue of its listing in the Orange Book, Defendant has knowledge of the '185 patent.

202. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '185 patent, including at least claims 1, 10, and 17, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '185 patent, either literally or under the doctrine of equivalents.

203. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '185 patent.

204. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

205. On information and belief, Defendant 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 Plaintiffs' rights under the '185 patent and will constitute infringement.

206. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '185 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '185 patent.

207. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '185 patent, including at least claims 1, 10, and 17, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to

the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '185 patent. Upon information and belief, Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '185 patent and are not suitable for substantial non-infringing use.

208. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '185 patent, or any later expiration of exclusivity for the '185 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

209. Upon information and belief, Defendant had knowledge of the '185 patent from at least a time at or around the date the '185 patent was listed in the Orange Book.

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

COUNT XII: INFRINGEMENT OF THE '141 PATENT BY SANDOZ

211. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

212. The '141 patent was issued October 29, 2024, and was listed in the Orange Book on November 13, 2024, in connection with Impax's NDA No. 217186 for carbidopa and levodopa extended-release capsules, for oral use, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg dosages, which is sold under the Proprietary Name CREXONT®. Despite this listing, Defendant's Notice Letter and Detailed Statement does not address the '141 patent. Defendant has to date also failed and/or refused to provide a notice letter to address the '141 patent.

213. Defendant has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting the Sandoz ANDA under the Act for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products, said products and their use claimed by one or more claims of the '141 patent, before the expiration of that patent.

214. By submission of the Sandoz ANDA with Paragraph IV Certifications on other Orange Book listed patents and notice to Plaintiffs of the same, Defendant indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '141 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '141 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). This controversy is concrete and immediate, since Plaintiffs will suffer substantial and irreparable harm, including loss of market share, damage to reputation, and financial harm, if Defendant is allowed to proceed with its infringing activities.

215. Additionally, pursuant to 28 U.S.C. § 2201, Plaintiffs are also entitled to a declaratory judgment that Defendant's making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, inducement thereof or contribution thereto, will infringe the '141 patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

216. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 11, and 13 of the '141 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

217. Upon information and belief, by virtue of its listing in the Orange Book, Defendant has knowledge of the '141 patent.

218. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '141 patent, including at least claim 18, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '141 patent, either literally or under the doctrine of equivalents.

219. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '141 patent.

220. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

221. On information and belief, Defendant 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 Plaintiffs' rights under the '141 patent and will constitute infringement.

222. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '141 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '141 patent.

223. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '141 patent, including at least claim 18, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '141 patent. Upon information and belief, Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '141 patent and are not suitable for substantial non-infringing use.

224. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '141 patent, or any later expiration of exclusivity for the '141 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

225. Upon information and belief, Defendant had knowledge of the '141 patent from at least a time at or around the date the '141 patent was listed in the Orange Book.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Defendant and for the following relief:

a. A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendant has infringed at least one claim of the '845, '935, '058, '769, '313, '733, '941, '538, '449, '521, '185, and '141 patents

pursuant to Defendant's submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before the expiration of such patents;

b. A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of the Sandoz ANDA Products, or any other drug product covered by or whose use is covered by at least the '185 patent and/or '141 patent, prior to the expiration of said patents, will infringe, induce the infringement of, and/or contribute to infringement by others of said patents;

c. A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz 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;

d. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the Sandoz 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;

e. The entry of a preliminary and/or permanent injunction enjoining Defendant, its affiliates and subsidiaries, and each of its 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 Sandoz ANDA until the expiration of the Patents-in-Suit or such other later time as the Court may determine;

f. Damages or other monetary relief to Plaintiffs if Defendant commercially manufactures, uses, offers to sell, sells, and/or imports in or into the United States the Sandoz ANDA Products prior to the expiration of the Patents-in-Suit, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

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

h. A judgment awarding Plaintiffs their costs and expenses incurred in this action; and

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

Dated: January 7, 2025

STONE CONROY LLC

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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, to the best of my knowledge, the matter in controversy is not the subject of any pending litigation in any court or arbitration or administrative proceeding, nor are there any non-parties known to Plaintiffs 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.

Dated: January 7, 2025

STONE CONROY LLC

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and 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 Plaintiffs seek, *inter alia*, injunctive relief.

Dated: January 7, 2025

STONE CONROY LLC

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