

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IMPAK LABORATORIES, LLC,

Plaintiff,

v.

SCIEGEN PHARMACEUTICALS, INC.,

Defendant.

C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Impax Laboratories, LLC (“Impax” or “Plaintiff”), by and through its undersigned counsel, for its complaint against Defendant ScieGen Pharmaceuticals, Inc. (“ScieGen” or “Defendant”), hereby alleges and states the following:

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. 8,557,283 (“the ‘283 patent”), 9,089,608 (“the ‘608 patent”), 9,463,246 (“the ‘246 patent”), 9,533,046 (“the ‘046 patent”), and 9,901,640 (“the ‘640 patent”) (collectively, the “Patents-in-Suit”), and other patents listed in the Orange Book for RYTARY®.

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 ScieGen is a corporation organized and existing under the laws of the State of New York, having a place of business at 89 Arkay Drive, Hauppauge, NY 11788.

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

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 conducts business in the United States and in the State of Delaware.

8. 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.

9. 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.

10. 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 Delaware.

11. 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 Defendant seeks FDA approval to manufacture, market, import, offer to sell, and/or sell pursuant to ANDA No. 219953.

12. On information and belief, if the ScieGen ANDA (defined below) is approved, the ScieGen ANDA Products (defined below) will be marketed, distributed, and/or sold, directly or indirectly, by Defendant in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and used by patients in the State of Delaware. Specifically, on information and belief, if Defendant succeeds in obtaining FDA approval, Defendant will, directly or indirectly, market, distribute, and/or sell the ScieGen ANDA Products in the State of Delaware.

13. On information and belief, Defendant is in the business of, *inter alia*: (a) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware, and importing generic pharmaceutical products into the United States, including throughout the State of Delaware; (b) alone and/or in concert with each of its various 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 Delaware; and (c) alone and/or through its various affiliates, the

distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

14. On information and belief, Defendant intends to benefit directly if the ScieGen 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 Delaware, that are the subject of the ScieGen ANDA.

15. On information and belief, Defendant and/or its affiliates have previously submitted to the jurisdiction of this Court and/or have further previously availed themselves of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., AstraZeneca AB et al v. ScieGen Pharmaceuticals, Inc.*, C.A. No. 23-01457-RGA; *Merck Sharp & Dohme Corp. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 21-01616-RGA; *In re: Sitagliptin Phosphate ('708 & '921) Patent Litigation*, C.A. No. 19-02902-RGA; *Genentech, Inc. et al. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 19-131-RGA; *Genentech, Inc. et al. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 19-132-RGA; *UCB Inc. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 13-1217-LPS (collectively, “Prior Actions”). In particular, Defendant has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court. *See, e.g., Genentech, Inc. et al. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 19-131-RGA; *Genentech, Inc. et al. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 19-132-RGA; *UCB Inc. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 13-1217-LPS.

16. This Court also has personal jurisdiction over Defendant because, *inter alia*, Defendant has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Defendant regularly and continuously transacts business within the state of Delaware, including

by selling pharmaceutical products in Delaware, directly and/or through affiliates, and/or by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware. On information and belief, Defendant derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

17. 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 Delaware; (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 Delaware; (c) maintains a distributorship network within the State of Delaware; (d) enjoys income from sales of its generic pharmaceutical products in the State of Delaware; (e) has consented to and/or not contested personal jurisdiction in the Prior Actions; and (f) Defendant, and/or its affiliates, have availed themselves of the jurisdiction of this Court by asserting counterclaims in at least one of the Prior Actions.

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 Defendant has and will continue to engage in infringement activities in the State of Delaware, and Defendant, and/or its affiliates, have previously consented to and/or not contested venue in this Judicial District in at least one of the Prior Actions

19. By email dated September 30, 2025, Defendant, through its counsel, consented to personal jurisdiction and venue in this Judicial District for this Action only.

BACKGROUND

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

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

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

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

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

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

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

23. On January 3, 2017, the PTO duly and legally issued United States Patent No. 9,533,046 entitled “Controlled Release Formulations of Levodopa and Uses Thereof” to inventors Ann Hsu, Jim Kou and Laman Alani. The ’046 patent is owned by assignment by Impax and per

the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '046 patent is attached as **Exhibit 4**.

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

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

RYTARY®

25. 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®.

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

ACTS GIVING RISE TO THIS ACTION

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

28. On information and belief, Defendant submitted ANDA No. 219953 (the "ScieGen 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 "ScieGen ANDA Products").

29. On information and belief, following FDA approval of the ScieGen ANDA, Defendant intends to make, use, sell, or offer to sell the ScieGen ANDA Products throughout the United States, including in the State of Delaware, and/or import that generic product into the United States, including into the State of Delaware.

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

31. No earlier than August 28, 2025, Impax received written notice of the ScieGen ANDA and the ScieGen 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, *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 ScieGen ANDA Products (“Detailed Statement”).

32. By filing the ScieGen ANDA, Defendant represented to the FDA that the ScieGen 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®.

33. Pursuant to the Notice Letter, Defendant offered confidential access to portions of the ScieGen ANDA for the sole purpose of permitting Impax to determine whether to file an infringement action under 35 U.S.C. § 271(e)(2) (the “OCA”).

34. The OCA permitted one in-house attorney at Impax, and outside attorneys engaged or employed by Impax (collectively, “Recipients”) and their in-firm professional staff to access certain information from the produced portions of the ScieGen ANDA. The specific information disclosed to Impax was chosen by Defendant.

35. Pursuant to the OCA, Recipients are prohibited from sharing the selected portions of the ScieGen ANDA with any other person or entity, including without limitation, any expert or scientific consultant.

36. The OCA further requires Recipients to destroy, with notice to Defendant’s outside counsel, the provided excerpts from the ScieGen ANDA, and any notes, analyses, studies, or other documents containing information from the ScieGen ANDA excerpts, within thirty (30) days after the expiration of the forty-five (45) day period following receipt of the Notice Letter and Detailed Statement.

37. Pursuant to the terms of the OCA, Recipients are also prohibited from publicly disclosing any information in the produced portions of the ScieGen ANDA. This prohibition therefore prohibits Plaintiff from including or referencing in this Complaint any information in the limited excerpts from the ScieGen ANDA that were provided to Recipients under the OCA, beyond general statements as to whether the ScieGen ANDA Products meet patent claim limitations.

38. Impax’s outside counsel executed the OCA on September 11, 2025.

39. On September 24, 2025, Defendant provided at least significant portions of the ScieGen ANDA to Plaintiff’s outside counsel under the OCA (the “OCA Production”).

40. Defendant’s delay in producing the OCA Production has limited Impax’s ability to assess Defendant’s non-infringement assertions in the Notice Letter and Detailed Statement.

41. This action is being commenced before the expiration of forty-five (45) days from the date Impax received the Notice Letter dated August 25, 2025, under 21 U.S.C. § 355(j)(5)(B)(iii) and thus triggers the thirty (30) month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I - INFRINGEMENT OF THE '283 PATENT BY SCIEGEN

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

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

44. Defendant'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 ScieGen 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).

45. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for invalidity of any claim of the '283 patent.

46. In the Notice Letter and Detailed Statement, Defendant's basis for asserting that the ScieGen ANDA Products do not literally infringe claims 1-9 of the '283 patent is a claim construction argument.

47. A justiciable controversy exists regarding Defendant's infringement of the '283 patent.

48. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant will infringe, for example at least under the doctrine of equivalents, one or more claims of the '283 patent, including at least claim 1.

49. For example, in addition to the act of infringement stemming from the filing of the ScieGen ANDA and the ScieGen Paragraph IV Certifications, Impax believes that it can show after discovery and analysis that the ScieGen ANDA Products in combination with at least the label for those products proposed by Defendant 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. For example, on information and belief, the ScieGen ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '283 patent under 35 U.S.C. § 271(e)(2)(A), Defendant will also indirectly infringe one or more claims of the '283 patent, including without limitation claim 1, by inducing at least healthcare professionals and patients to directly infringe that claim.

50. On information and belief, the ScieGen 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.

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

52. 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 Impax's rights under the '283 patent and will constitute infringement.

53. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant will induce others to infringe 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 ScieGen 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.

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

55. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant 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 ScieGen ANDA, Defendant will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and has had and continues to have knowledge that the ScieGen 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 ScieGen ANDA Products are not suitable for substantial non-infringing use.

56. Impax will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the ScieGen ANDA Products in or into the United States, and is not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ScieGen ANDA 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.

57. Defendant has had knowledge of the '283 patent since at least the date Defendant submitted the ScieGen ANDA and the ScieGen Paragraph IV Certifications and was aware that submission of the ScieGen ANDA and the ScieGen Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT II - INFRINGEMENT OF THE '608 PATENT BY SCIEGEN

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

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

61. Defendant'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 ScieGen 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).

62. In the Notice Letter and Detailed Statement, Defendant's basis for asserting that the ScieGen ANDA Products do not literally infringe claims 1-20 of the '608 patent is a claim construction argument.

63. A justiciable controversy exists regarding Defendant's infringement of the '608 patent.

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

65. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant will also induce others to infringe one or more claims of the '608 patent, including at least claims 1 and/or 21, under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of the ScieGen ANDA, Defendant 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 ScieGen ANDA Products, by at least healthcare professionals and patients, with knowledge that its acts are encouraging infringement.

66. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant will contributorily infringe one or more claims of the '608 patent, including at least claim 1 and/or 21, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the ScieGen ANDA, Defendant 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 ScieGen 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 ScieGen ANDA Products are not suitable for substantial non-infringing use.

67. Impax will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the ScieGen ANDA Products in or into the United States, and is not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ScieGen ANDA 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.

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

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

COUNT III - INFRINGEMENT OF THE '246 PATENT BY SCIEGEN

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

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

72. Defendant'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 ScieGen 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).

73. A justiciable controversy exists regarding Defendant's infringement of the '246 patent.

74. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant will infringe, for example at least under the doctrine of equivalents, one or more claims of the '246 patent, including at least claim 26.

75. For example, in addition to the act of infringement stemming from the filing of the ScieGen ANDA and the ScieGen Paragraph IV Certifications, Impax believes that it can show after discovery and analysis that the ScieGen ANDA Products in combination with at least the label for those products proposed by Defendant 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. For example, on information and belief, the ScieGen ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '246 patent under 35 U.S.C. § 271(e)(2)(A), Defendant will also indirectly infringe one or more claims of the '246 patent, including without limitation claim 26, by inducing at least healthcare professionals and patients to directly infringe that claim.

76. On information and belief, the ScieGen 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.

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

78. 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 Impax's rights under the '246 patent and will constitute infringement.

79. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant will induce others to infringe 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 ScieGen 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.

80. On information and belief, upon FDA approval of the ScieGen ANDA, Defendant will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '246 patent, by at least its promotional activities and package

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

81. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant 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 ScieGen ANDA, Defendant will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and has had and continues to have knowledge that the ScieGen 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 ScieGen ANDA Products are not suitable for substantial non-infringing use.

82. Impax will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the ScieGen ANDA Products in or into the United States, and is not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ScieGen ANDA 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.

83. Defendant has had knowledge of the '246 patent since at least the date Defendant submitted the ScieGen ANDA and the ScieGen Paragraph IV Certifications and was aware that submission of the ScieGen ANDA and the ScieGen Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT IV - INFRINGEMENT OF THE '046 PATENT BY SCIEGEN

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

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

87. Defendant'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 ScieGen 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).

88. A justiciable controversy exists regarding Defendant's infringement of the '046 patent.

89. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant will infringe, for example at least under the doctrine of equivalents, one or more claims of the '046 patent, including at least claim 1.

90. For example, in addition to the act of infringement stemming from the filing of the ScieGen ANDA and the ScieGen Paragraph IV Certifications, Impax believes that it can show after discovery and analysis that the ScieGen ANDA Products in combination with at least the label for those products proposed by Defendant 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. For example, on information and belief, the ScieGen ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention,

and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '046 patent under 35 U.S.C. § 271(e)(2)(A), Defendant will also indirectly infringe one or more claims of the '046 patent, including without limitation claim 1, by inducing at least healthcare professionals and patients to directly infringe that claim.

91. On information and belief, the ScieGen 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.

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

93. 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 Impax's rights under the '046 patent and will constitute infringement.

94. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant will induce others to infringe 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 ScieGen 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.

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

96. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant 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 ScieGen ANDA, Defendant will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and has had and continues to have knowledge that the ScieGen 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 ScieGen ANDA Products are not suitable for substantial non-infringing use.

97. Impax will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the ScieGen ANDA Products in or into the United States, and is not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ScieGen ANDA 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.

98. Defendant has had knowledge of the '046 patent since at least the date Defendant submitted the ScieGen ANDA and the ScieGen Paragraph IV Certifications and was aware that submission of the ScieGen ANDA and the ScieGen Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

COUNT V - INFRINGEMENT OF THE '640 PATENT BY SCIEGEN

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

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

102. Defendant'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 ScieGen 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).

103. In the Notice Letter and Detailed Statement, Defendant provides no basis for asserting that the ScieGen ANDA Products do not infringe claims 1-25 of the '640 patent.

104. A justiciable controversy exists regarding Defendant's infringement of the '640 patent.

105. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant 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 ScieGen ANDA Products. For example, in addition to the act of infringement stemming from the filing of the ScieGen ANDA and the ScieGen Paragraph IV Certifications, Impax believes that it can show after discovery and analysis that the ScieGen ANDA Products practice all the limitations of at least claim 15 of the '640 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim. For example, with regard to the doctrine of equivalents, on information and belief, in addition to literal infringement, the

ScieGen ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial.

106. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant will also induce others to infringe 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 ScieGen ANDA, Defendant 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 ScieGen ANDA Products, by at least healthcare professionals and patients, with knowledge that its acts are encouraging infringement.

107. Unless enjoined by this Court, upon FDA approval of the ScieGen ANDA, Defendant 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 ScieGen ANDA, Defendant 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 ScieGen 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 ScieGen ANDA Products are not suitable for substantial non-infringing use.

108. Impax will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the ScieGen ANDA Products in or into the United States, and is not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ScieGen ANDA 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.

109. Defendant has had knowledge of the '640 patent since at least the date Defendant submitted the ScieGen ANDA and the ScieGen Paragraph IV Certifications and was aware that submission of the ScieGen ANDA and the ScieGen Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

110. 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 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 Patents-in-Suit through Defendant's submission of the ScieGen ANDA and the ScieGen 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 ScieGen 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 Defendant's commercial manufacture, use, offer to sell, sale, and/or importation in or into the United States of the ScieGen 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 ScieGen 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 Defendant, 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 ScieGen 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 Defendant commercially manufactures, uses, offers to sell, sells, and/or imports in or into the United States the ScieGen 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.

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Dated: October 6, 2025