IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CALLIDITAS THERAPEUTICS AB, Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LTD., Defendants.	)	C.A. No. 25-368-JCG **ANDA CASE**

AMENDED COMPLAINT

Calliditas Therapeutics AB ("Calliditas"), by its undersigned attorneys, for its Amended Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Ltd. ("Zydus Lifesciences") (collectively, "Zydus" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., arising from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 218685 ("Defendants' ANDA") to the United States Food and Drug Administration ("FDA"). Defendants' ANDA seeks FDA approval to market and sell 4 mg delayed-release capsules of budesonide ("Defendants' ANDA Product") prior to the expiration of U.S. Patent Nos. 11,896,719, ("the '719 Patent"), 12,171,882 ("the '882 Patent"), 12,171,883 ("the '883 Patent"), and 12,311,057 ("the '057 Patent") (collectively, the "patents-in-suit").

2. Calliditas owns the patents-in-suit and is the holder of FDA approved New Drug Application ("NDA") No. 215935, for the brand name drug TARPEYO® (budesonide). The patents-in-suit generally cover oral dosage forms and methods of use and administration of

budesonide, including TARPEYO®. Defendants' ANDA Product is a proposed generic version of TARPEYO®.

THE PARTIES

3. Plaintiff Calliditas is a corporation organized and existing under the laws of Sweden, having a principal place of business at D5, Kungsbron 1, Stockholm, Sweden.

4. Upon information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Upon information and belief, Zydus USA is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products.

5. Upon information and belief, Defendant Zydus Lifesciences is a company organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat 382481, India. Upon information and belief, Zydus Lifesciences is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products.

6. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Lifesciences.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), and this Court has personal jurisdiction over Defendants.

9. This Court has personal jurisdiction over Zydus Lifesciences by virtue of, *inter alia,* its systematic and continuous contacts with the State of Delaware.

10. On information and belief, Zydus Lifesciences develops, manufactures, distributes, markets, offers to sell and sells generic drug products for sale and use throughout the United States, including within this Judicial District.

11. On information and belief, Zydus Lifesciences acted in concert with or directed Zydus USA to prepare and submit Defendants' ANDA, with the intention of receiving a significant financial benefit from the FDA's approval of Defendants' ANDA.

12. On information and belief, Zydus Lifesciences derives substantial revenue from selling generic products throughout the United States, including in this Judicial District.

13. On information and belief, Zydus Lifesciences intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will continue to lead to foreseeable harm and injury to Calliditas in Delaware, including in this Judicial District.

14. On information and belief, Zydus Lifesciences actively participated in the submission of Defendants' ANDA. On information and belief, Zydus Lifesciences will work in concert with Zydus USA and/or other subsidiaries towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Defendants' ANDA Product, throughout the United States, including Delaware and in this Judicial District, prior to the expiration of the patents-in-suit.

15. On information and belief, Zydus Lifesciences seeks approval from the FDA to sell Defendants' ANDA Product throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination of the generic drug product described in Defendants' ANDA.

16. This Court also has personal jurisdiction over Zydus Lifesciences because Zydus Lifesciences, itself and/or through its subsidiaries, has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Zydus Lifesciences, directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Product. Upon information and belief, Zydus Lifesciences, prepared and filed ANDA No. 218685 with the FDA. Upon information and belief, Zydus Lifesciences will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Product in the United States, including Delaware, upon approval of ANDA No. 218685, and will derive substantial revenue from the use or consumption of Defendants' ANDA Product in Delaware.

17. This Court has personal jurisdiction over Zydus Lifesciences by virtue of, *inter alia*, its presence in Delaware, having conducted business in Delaware; having derived revenue from conducting business in Delaware; and previously consenting to personal jurisdiction in this Court (*see, e.g.*, Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA), Inc. et al.*, C.A. No. 24-1069 (D. Del. Dec. 9, 2024), D.I. 15 at ¶¶ 21-26; Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA), Inc. et al.*, C.A. No. 24-940 (D. Del. Oct. 15, 2024), D.I. 9 at ¶¶ 17-22; Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA), Inc. et al.*, C.A. No. 16-924 (D. Del. Oct. 15, 2024), D.I. 18 at ¶ 19; Answer and Affirmative Defenses, *Pfizer Inc. et al. v. MSN Laboratories Private Ltd. et al.,* C.A. No. 24-315 (D. Del. Sept. 4, 2024), D.I. 21 at ¶ 28; Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 23-819 (D. Del. Aug. 23, 2023),

D.I. 20 at ¶ 21; Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Sandoz Inc. et al*., C.A. No. 20-1589 (D. Del. Mar. 5, 2021), D.I. 60 at ¶ 98).

18. In the alternative, this Court has personal jurisdiction over Zydus Lifesciences because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Calliditas' claims arise under federal law; (b) Zydus Lifesciences is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Zydus Lifesciences has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Lifesciences satisfies due process.

19. At least because, on information and belief, Zydus Lifesciences is a foreign company, venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

20. This Court has personal jurisdiction over Zydus USA by virtue of, *inter alia,* its systematic and continuous contacts with the State of Delaware.

21. On information and belief, Zydus USA develops, manufactures, distributes, markets, offers to sell and sells generic drug products for sale and use throughout the United States, including within this Judicial District.

22. On information and belief, Zydus USA prepares and/or aids in the submission of ANDAs to the FDA.

23. On information and belief, Zydus USA derives substantial revenue from selling generic products throughout the United States, including in this Judicial District.

24. On information and belief, Zydus USA intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will continue to lead to foreseeable harm and injury to Calliditas in Delaware, including in this Judicial District.

25. On information and belief, Zydus USA actively participated in the submission of Defendants' ANDA. On information and belief, Zydus USA will work in concert with other subsidiaries towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Defendants' ANDA Product, throughout the United States, including Delaware and in this Judicial District, prior to the expiration of the patents-in-suit.

26. On information and belief, Zydus USA seeks approval from the FDA to sell Defendants' ANDA Product throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination of the generic drug product described in Defendants' ANDA.

27. This Court also has personal jurisdiction over Zydus USA because Zydus USA, itself and/or through its subsidiaries, has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Zydus USA, directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Product. Upon information and belief, Zydus USA, prepared and filed ANDA No. 218685 with the FDA. Upon information and belief, Zydus USA will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Product in the United States, including Delaware, upon approval of

ANDA No. 218685, and will derive substantial revenue from the use or consumption of Defendants' ANDA Product in Delaware.

28. This Court has personal jurisdiction over Zydus USA by virtue of, *inter alia*, its presence in Delaware, having conducted business in Delaware; having derived revenue from conducting business in Delaware; previously consenting to personal jurisdiction in this Court (*see, e.g.*, Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA), Inc. et al.*, C.A. No. 24-1069 (D. Del. Dec. 9, 2024), D.I. 15 at ¶¶ 21-26; Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA), Inc. et al.*, C.A. No. 24-940 (D. Del. Oct. 15, 2024), D.I. 9 at ¶¶ 17-22; Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA), Inc. et al.*, C.A. No. 16-924 (D. Del. Oct. 15, 2024), D.I. 18 at ¶ 19; Answer and Affirmative Defenses, *Pfizer Inc. et al. v. MSN Laboratories Private Ltd. et al.,* C.A. No. 24-315 (D. Del. Sept. 4, 2024), D.I. 21 at ¶ 30; Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 23-819 (D. Del. Aug. 23, 2023), D.I. 20 at ¶ 21; Answer and Affirmative Defenses, *Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589 (D. Del. Mar. 5, 2021), D.I. 60 at ¶ 98).

PATENTS-IN-SUIT

29. On February 13, 2024, the '719 Patent, titled "Pharmaceutical Compositions," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Calliditas is the assignee of the '719 Patent. A true copy of the '719 Patent is attached hereto as **Exhibit A**.

30. On December 24, 2024, the '882 Patent, titled "Pharmaceutical Compositions," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Calliditas is the assignee of the '882 Patent. A true copy of the '882 Patent is attached hereto as **Exhibit B**.

31. On December 24, 2024, the '883 Patent, titled "Pharmaceutical Compositions," was duly and lawfully issued by the USPTO. Calliditas is the assignee of the '883 Patent. A true copy of the '883 Patent is attached hereto as **Exhibit C**.

32. On May 27, 2025, the '057 Patent, titled "Pharmaceutical Compositions," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Calliditas is the assignee of the '057 Patent. A true copy of the '057 Patent is attached hereto as **Exhibit D**.

CALLIDITAS' TARPEYO®

33. Calliditas holds approved NDA No. 215935 for delayed-release capsules containing the active ingredient budesonide. Calliditas markets and sells budesonide delayed-release capsules under the trade name TARPEYO®.

34. TARPEYO® is a corticosteroid indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression. A copy of the complete prescribing information for TARPEYO® is attached hereto as **Exhibit E.**

35. Pursuant to 21 U.S.C. § 355(b)(1) and related FDA regulations, Calliditas listed the '719, '882, '883, and '057 Patents in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to TARPEYO®. The prescribing information for TARPEYO® instructs and encourages physicians, other healthcare workers and patients to administer TARPEYO® capsules according to one or more of the methods claimed in the patents-in-suit.

ACTS GIVING RISE TO THIS ACTION

36. By letter dated February 12, 2025 ("February 12 Notice Letter"), Zydus notified Calliditas that Zydus had submitted ANDA No. 218685 to the FDA under Section 505(j) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Calliditas received the February 12 Notice Letter no earlier than February 13, 2025.

37. The February 12 Notice Letter states that Zydus seeks approval from the FDA to engage in the commercial manufacture, use, sale, offer to sell, and/or importation into the United States of Defendants' ANDA Product before expiration of the '719 Patent. Upon information and belief, Defendants intend to, directly or indirectly, engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product promptly upon receiving FDA approval.

38. By filing ANDA No. 218685, Defendants have necessarily represented to the FDA that Defendants' ANDA Product has the same active ingredient, the same dosage form, the same route of administration, and the same strengths as TARPEYO®. By submitting ANDA No. 218685, Defendants also have necessarily represented to the FDA that Defendants' ANDA Product is bioequivalent to TARPEYO®. Upon information and belief, Defendants are seeking approval to market and sell their ANDA Product for the same approved indications as TARPEYO®.

39. In the February 12 Notice Letter, Zydus states that Defendants' ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") asserting that the claims of the '719 Patent are not infringed. The February 12 Notice Letter does not contest that the claims of the '719 Patent are valid and enforceable.

40. In the February 12 Notice Letter, Zydus does not address the '882 Patent, even though it is listed in the Orange Book. The February 12 Notice Letter does not contest that the claims of the '882 Patent are valid, enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants' ANDA Product.

41. In the February 12 Notice Letter, Zydus does not address the '883 Patent, even though it is listed in the Orange Book. The February 12 Notice Letter does not contest that the claims of the '883 Patent are valid, enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants' ANDA Product.

42. By letter dated September 15, 2025 ("September 15 Notice Letter"), Zydus notified Calliditas that Zydus seeks approval from the FDA to engage in the commercial manufacture, use, sale, offer to sell, and/or importation into the United States of Defendants' ANDA Product before the expiration of the '057 Patent. In the September 15 Notice Letter, Zydus states that Defendants' ANDA contains a Paragraph IV Certification with respect to the '057 Patent.

COUNT I
INFRINGEMENT OF THE '719 PATENT

43. Calliditas repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

44. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Product, prior to the expiration of the '719 Patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

45. Upon information and belief, Defendants' ANDA Product and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '719 Patent.

46. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '719 Patent.

47. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '719 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States.

48. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Product, Defendants will induce infringement of one or more claims of the '719 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Product, Defendants will intentionally encourage acts of direct infringement with knowledge of the '719 Patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '719 Patent.

49. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Product, Defendants will contributorily infringe one or more claims of the '719 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Product is especially adapted for a use that infringes one or more claims of the '719 Patent and that there is no substantial non-infringing use for Defendants' ANDA Product.

50. Calliditas will be substantially and irreparably damaged and harmed if Defendants' infringement of the '719 Patent is not enjoined.

51. Calliditas does not have an adequate remedy at law.

52. Upon information and belief, Defendants had knowledge of the '719 Patent prior to filing their ANDA with the FDA.

53. This case is an exceptional one, and Calliditas is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
INFRINGEMENT OF THE '882 PATENT

54. Calliditas repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

55. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Product, prior to the expiration of the '882 Patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

56. Upon information and belief, Defendants' ANDA Product and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '882 Patent.

57. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '882 Patent.

58. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '882 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States.

59. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Product, Defendants will induce infringement of one or more claims of the '882 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Product, Defendants will intentionally encourage acts of direct infringement with knowledge of

the ’882 Patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the ’882 Patent.

60. Unless enjoined by this Court, upon FDA approval of Defendants’ ANDA Product, Defendants will contributorily infringe one or more claims of the ’882 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants’ ANDA Product in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants’ ANDA Product is especially adapted for a use that infringes one or more claims of the ’882 Patent and that there is no substantial non-infringing use for Defendants’ ANDA Product.

61. Calliditas will be substantially and irreparably damaged and harmed if Defendants’ infringement of the ’882 Patent is not enjoined.

62. Calliditas does not have an adequate remedy at law.

63. Upon information and belief, Defendants had knowledge of the ’882 Patent prior to filing their ANDA with the FDA.

64. This case is an exceptional one, and Calliditas is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE ’883 PATENT

65. Calliditas repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

66. Defendants’ submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants’ ANDA Product, prior to the expiration of the ’883 Patent, constitutes infringement of

one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

67. Upon information and belief, Defendants' ANDA Product and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '883 Patent.

68. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '883 Patent.

69. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '883 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States.

70. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Product, Defendants will induce infringement of one or more claims of the '883 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Product, Defendants will intentionally encourage acts of direct infringement with knowledge of the '883 Patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '883 Patent.

71. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Product, Defendants will contributorily infringe one or more claims of the '883 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Product is especially adapted for a use that infringes one or

more claims of the ’883 Patent and that there is no substantial non-infringing use for Defendants’ ANDA Product.

72. Calliditas will be substantially and irreparably damaged and harmed if Defendants’ infringement of the ’883 Patent is not enjoined.

73. Calliditas does not have an adequate remedy at law.

74. Upon information and belief, Defendants had knowledge of the ’883 Patent prior to filing their ANDA with the FDA.

75. This case is an exceptional one, and Calliditas is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT IV
INFRINGEMENT OF THE ’057 PATENT

76. Calliditas repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

77. Defendants’ submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants’ ANDA Product, prior to the expiration of the ’057 Patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

78. Upon information and belief, Defendants’ ANDA Product and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the ’057 Patent.

79. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the ’057 Patent.

80. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '057 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States.

81. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Product, Defendants will induce infringement of one or more claims of the '057 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Product, Defendants will intentionally encourage acts of direct infringement with knowledge of the '057 Patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '057 Patent.

82. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Product, Defendants will contributorily infringe one or more claims of the '057 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Product in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Product is especially adapted for a use that infringes one or more claims of the '057 Patent and that there is no substantial non-infringing use for Defendants' ANDA Product.

83. Calliditas will be substantially and irreparably damaged and harmed if Defendants' infringement of the '057 Patent is not enjoined.

84. Calliditas does not have an adequate remedy at law.

85. Upon information and belief, Defendants had knowledge of the '057 Patent prior to filing their ANDA with the FDA.

86. This case is an exceptional one, and Calliditas is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Calliditas respectfully requests the following relief:

A. An entry of Judgment that Defendants have infringed the patents-in-suit through the submission of ANDA No. 218685 to the FDA;

B. An entry of Judgment that, Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing Defendants' ANDA Product will infringe one or more claims of the patents-in-suit;

C. The issuance of an order that the effective date of any FDA approval of Defendants' ANDA Product shall be no earlier than the expiration date of the patents-in-suit and any additional periods of exclusivity to which Calliditas is or becomes entitled;

D. An entry of a preliminary and permanent injunctions enjoining Defendants and others acting in concert with Defendants from commercially manufacturing, using, selling, offering for sale, and/or importing Defendants' ANDA Product within the United States, until after the expiration date of the patents-in-suit and any additional periods of exclusivity to which Calliditas is or becomes entitled;

E. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from practicing any compositions or methods claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Calliditas is or becomes entitled;

F. A Declaration that the commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of Defendants' ANDA Product will directly infringe, induce, and/or contribute to infringement of the patents-in-suit;

G. To the extent that Defendants have committed any acts with respect to the compositions or methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Calliditas be awarded damages for such acts;

H. If Defendants engage in the commercial manufacture, use, sale, or offer for sale, or importation into the United States of Defendants' ANDA Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Calliditas resulting from such infringement, together with interest;

I. An award to Calliditas of attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

J. An award to Calliditas of costs and expenses in this action; and

K. An award to Calliditas of any further and additional relief that this Court deems just and proper.

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October 31, 2025

CERTIFICATE OF SERVICE

I hereby certify that on October 31, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on October 31, 2025, upon the following in the manner indicated:

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