IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CATALYST PHARMACEUTICALS, INC. and SERB SA, Plaintiffs, v. LUPIN LTD., LUPIN INC. and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Catalyst Pharmaceuticals, Inc. ("Catalyst") and SERB SA ("SERB") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Defendants"), allege as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Defendants' submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 217996 ("Defendants' ANDA") seeking approval to engage in the commercial manufacture, use, or sale of a generic version of Catalyst's Firdapse® (amifampridine) Tablets, 10 mg drug product ("Defendants' ANDA Product") prior to the expiration of one or more of United States Patent Nos. 10,626,088 ("the '088 patent), 10,793,893 ("the '893 patent"), 11,060,128 ("the '128A patent"), 11,268,128 ("the '128B patent"), 11,274,331 ("the '331 patent"), and 11,274,332 ("the '332 patent") (collectively, the "Patents-in-Suit").

THE PARTIES

2. Plaintiff Catalyst is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 355 Alhambra Circle, Suite 801, Coral Gables, Florida 33134. Catalyst is a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases.

3. Plaintiff SERB is a corporation organized and existing under the laws of Belgium with its principal place of business at 480 Avenue Louise, Brussels, 1050 Belgium.

4. On information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex Bandra (E), Mumbai, 400 051, India, and its registered office at Kalpataru Inspire 3rd Floor, Off Western Express Highway Santacruz (East), Mumbai 400 055, India.

5. On information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202 and 400 Campus Dr., Somerset, New Jersey 08873.

6. On information and belief, Defendant LPI is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

7. On information and belief, Lupin Inc. and LPI are wholly-owned subsidiaries of Lupin Ltd.

JURISDICTION AND VENUE

8. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Lupin Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of Delaware, including directly or indirectly through its subsidiaries, agents, and/or alter egos, Lupin Inc. and LPI, companies organized and existing under the laws of the State of Delaware; and (2) maintains extensive and systematic contacts with the State of Delaware, including through the marketing, distribution, and/or sales of generic pharmaceutical drugs in Delaware including through, directly or indirectly, Lupin Inc. and LPI.

10. This Court has personal jurisdiction over Lupin Ltd. because, on information and belief, Lupin Ltd. derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

11. This Court has personal jurisdiction over Lupin Inc. because, *inter alia*, it: (1) is a corporation organized and existing under the laws of the State of Delaware; (2) has purposefully availed itself of the privilege of doing business in the State of Delaware, including directly or indirectly through its subsidiary, agent, and/or alter ego, LPI; and (3) maintains extensive and systematic contacts with the State of Delaware, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in Delaware including through, directly or indirectly, LPI. On information and belief, Lupin Inc. purposefully has conducted and continues to conduct business in this Judicial District.

12. This Court has personal jurisdiction over Lupin Inc. because, on information and belief, Lupin Inc. derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

13. This Court has personal jurisdiction over LPI because, *inter alia*, it: (1) is a corporation organized and existing under the laws of the State of Delaware; (2) has purposefully availed itself of the privilege of doing business in the State of Delaware; and (3) maintains extensive and systematic contacts with the State of Delaware, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in Delaware. On information and belief, LPI purposefully has conducted and continues to conduct business in this Judicial District.

14. This Court has personal jurisdiction over LPI because, on information and belief, LPI derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

15. On information and belief, Lupin Ltd., Lupin Inc., and LPI are in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, Lupin Ltd., Lupin Inc., and LPI also prepare and/or aid in the preparation and submission of ANDAs to FDA, including Defendants' ANDA.

16. On information and belief, this Judicial District is a likely destination for Defendants' ANDA Product described in Defendants' ANDA.

17. This Court also has personal jurisdiction over Lupin Ltd., Lupin Inc., and LPI because, inter alia, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2). On information and belief, Lupin Ltd., Lupin Inc., and LPI intend 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 Plaintiffs in Delaware and in this Judicial District.

18. On information and belief, Lupin Ltd., Lupin Inc., and LPI work in privity and/or concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

19. On information and belief, each of Lupin Ltd., Lupin Inc., and LPI actively participated in the submission of Defendants' ANDA. On information and belief, Lupin Ltd., Lupin Inc., and LPI will work in privity and/or concert with one another and/or other related entities 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 in Delaware and in this Judicial District, prior to the expiration of the patent-in-suit.

20. On information and belief, Lupin Ltd. intends to benefit directly if Defendants' ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Defendants' ANDA Product.

21. On information and belief, Lupin Inc. intends to benefit directly if Defendants' ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Defendants' ANDA Product.

22. On information and belief, LPI intends to benefit directly if Defendants' ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Defendants' ANDA Product.

23. On information and belief, Lupin Inc. and LPI act at the direction, and for the benefit, of Lupin Ltd. and are controlled and/or dominated by Lupin Ltd.

24. On information and belief, per the website www.lupin.com ("Lupin.com"), Lupin Ltd., Lupin Inc., and LPI act, operate, and/or hold themselves out to the public as a single integrated business.

25. On information and belief, Lupin Ltd., Lupin Inc., and LPI have previously been sued in this District and have not challenged personal jurisdiction. *See, e.g Neurocrine Biosciences, Inc. v. Lupin Limited et al*. Civil Action No. 22-1061 (MN) (D. Del.) and *ZS Pharma, Inc. et al. v. Lupin Limited et al.*, Civil Action No. 22-1055 (GBW) (D. Del.).

26. In the alternative, this Court has personal jurisdiction over Lupin Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Ltd. 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, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process.

27. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

LEMS AND CATALYST'S FIRDAPSE PRODUCT

28. Lambert-Eaton Myasthenic Syndrome ("LEMS") is a rare and debilitating neuromuscular disorder involving impairment of neuromuscular transmission and serious muscle weakness. Clinically, LEMS is characterized by proximal muscle weakness and fatigability, hyporeflexia, or areflexia, and symptoms of autonomic dysfunction such as impotence, dry mouth, and constipation. Other symptoms may include paresthesias, diplopia, and orthostatic hypotension.

29. The neuromuscular symptoms in patients with LEMS typically develop after 40 years of age with a peak incidence between 50 and 70 years of age. Although the exact prevalence

of LEMS in the general population is unknown, it has been estimated to affect approximately 1 in 100,000 people. The diagnosis of LEMS can be challenging since the clinical presentation of subacute progressive fatigue and weakness is unspecific. As a result, diagnosis of LEMS is often delayed for months to decades, and is often misdiagnosed for other diseases such as myasthenia gravis, which is characterized by weakness and rapid fatigue of muscles.

30. Amifampridine, also known as 3,4-diaminopyridine or 3,4-DAP, is a nonspecific voltage-dependent potassium channel blocker. Amifampridine blocks the presynaptic voltage-gated potassium channels resulting in a prolonged action potential and increased influx of calcium, which facilitates the release of acetylcholine from the motor nerve terminal and improves neuromuscular transmission.

31. Catalyst holds New Drug Application ("NDA") No. 208078 for the use of amifampridine tablets, which it sells under the trade name Firdapse. Catalyst's Firdapse product received FDA approval on November 28, 2018, and was the first product that FDA approved for the treatment of LEMS based on clinical data demonstrating safety and efficacy. Prior to its approval, Firdapse received breakthrough therapy designation and orphan drug designation from the FDA.

32. Prior to FDA approval of Firdapse, amifampridine was available in the United States only as an investigational drug product in clinical studies or under the FDA's Expanded Access program, which provides a pathway for a patient to gain treatment to an investigational medical product outside of clinical trials when no comparable or satisfactory alternative therapies are available. No pharmaceutical company, including Defendants, could lawfully market amifampridine for any indication prior to the approval of Firdapse as nobody prior to Catalyst had conducted and submitted the pre-clinical and clinical work necessary to obtain FDA approval.

33. The inventors of the ’088 patent discovered methods of determining the purity of a sample of 3,4 - diaminopyridine comprising determining the presence, absence, or amount of a dimer of 3,4 - diaminopyridine or a dimer of 3,4 - diaminopyridine in the form of a salt , solvate or complex or a combination thereof. The inventors of the ’893, ’128A, ’128B, ’331, and ’332 patents discovered that amifampridine undergoes 3-N-acetylation to form a single major circulating inactive metabolite that subsequently undergoes renal elimination. The inventors also discovered that the acetylation rate of amifampridine varied significantly depending on certain genetic polymorphisms. Based on these discoveries, the inventors developed a method of treating certain diseases with amifampridine. The method accounts for the individual differences in acetylation rates among patients, and administers dosages accordingly.

PATENTS-IN-SUIT

34. Catalyst is the owner of United States Patent No. 10,626,088, which was duly and legally issued on April 21, 2020, and is titled “Determining Degradation of 3,4-Diaminopyridine.” Each and every claim of the ’088 patent is valid and enforceable. A copy of the ’088 patent is attached as Exhibit 1.

35. SERB is the owner of United States Patent No. 10,793,893, which was duly and legally issued on October 6, 2020, and is titled “Methods of Administering 3,4-Diaminopyridine.” Each and every claim of the ’893 patent is valid and enforceable. Catalyst has an exclusive license under the ’893 patent in the United States. A copy of the ’893 patent is attached as Exhibit 2.

36. SERB is the owner of United States Patent No. 11,060,128, which was duly and legally issued on July 13, 2021, and is titled “Methods of Administering 3,4-Diaminopyridine.” Each and every claim of the ’128A patent is valid and enforceable. Catalyst has an exclusive license under the ’128A patent in the United States. A copy of the ’128A patent is attached as Exhibit 3.

37. SERB is the owner of United States Patent No. 11,268,128, which was duly and legally issued on March 8, 2022, and is titled "Methods of Administering 3,4-Diaminopyridine." Each and every claim of the '128B patent is valid and enforceable. Catalyst has an exclusive license under the '128B patent in the United States. A copy of the '128B patent is attached as Exhibit 4.

38. SERB is the owner of United States Patent No. 11,274,331, which was duly and legally issued on March 15, 2022, and is titled "Methods of Administering 3,4-Diaminopyridine." Each and every claim of the '331 patent is valid and enforceable. Catalyst has an exclusive license under the '331 patent in the United States. A copy of the '331 patent is attached as Exhibit 5.

39. SERB is the owner of United States Patent No. 11,274,332, which was duly and legally issued on March 15, 2022, and is titled "Methods of Administering 3,4-Diaminopyridine." Each and every claim of the '332 patent is valid and enforceable. Catalyst has an exclusive license under the '332 patent in the United States. A copy of the '332 patent is attached as Exhibit 6.

ACTS GIVING RISE TO THIS ACTION

40. Catalyst is the holder of NDA No. 208078, by which FDA granted approval for 10 mg amifampridine tablets. Catalyst markets these tablets in the United States under the tradename Firdapse.

41. Firdapse and the use of Firdapse in accordance with its label are covered by one or more claims of the Patents-in-Suit.

42. FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists the Patents-in-Suit in connection with Firdapse.

43. By letter dated January 26, 2023 (the "Notice Letter"), Defendants notified Catalyst and SERB that they had submitted to FDA Defendants' ANDA, seeking approval for the

commercial manufacture, use, and sale of Defendants' ANDA Product in the United States prior to the expiration of the Patents-in-Suit.

44. In the Notice Letter, Defendants notified Catalyst and SERB that, as a part of Defendants' ANDA, they had filed a certification under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Patents-in-Suit, asserting that those patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Defendants' ANDA Product in the United States.

45. By filing Defendants' ANDA, Defendants have necessarily represented to FDA that, upon approval, Defendants' ANDA Product will have the same active ingredient, method of administration, dosage form, and strength as Firdapse, and will be bioequivalent to Firdapse.

46. The Notice Letter contained an offer of confidential access, the terms of which the parties have begun negotiating in good faith in an effort to reach a mutually acceptable agreement, and under which Defendants' ANDA would be provided to Plaintiffs. The parties have been unable to reach agreement.

47. The Complaint has been filed before the expiration of forty-five days from the date Catalyst and SERB received the Notice Letter.

COUNT I: INFRINGEMENT OF THE '088 PATENT

48. Plaintiffs reallege paragraphs 1-47 as if fully set forth herein.

49. Defendants' submission of Defendants' ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Defendants' ANDA Product in or into the United States, prior to the expiration of the '088 patent, constitutes direct and indirect infringement of the '088 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

50. On information and belief, Defendants' ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Defendants or on their behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '088 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Defendants' ANDA Product will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '088 patent.

51. On information and belief, Defendants' manufacturing, use, offer for sale, sale, and/or importation of Defendants' ANDA Product, once Defendants' ANDA is approved by FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '088 patent, either literally or under the doctrine of equivalents. On information and belief, Defendants intend that Defendants' ANDA Product be used by patients and medical professionals. Also, on information and belief, Defendants know that Defendants' ANDA Product is especially made or adapted for use in infringing the '088 patent, and that Defendants' ANDA Product is not suitable for substantial non-infringing use.

52. Plaintiffs will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Defendants' ANDA Product in or into the United States, and are not enjoined from doing so. Plaintiffs are entitled to relief 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 Defendants' ANDA be a date that is not earlier than the expiration date of the '088 patent, or any later expiration of exclusivity for the '088 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

53. Defendants have had knowledge of the '088 patent since at least the date Defendants submitted Defendants' ANDA and were aware that submission of Defendants' ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

54. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '893 PATENT

55. Plaintiffs reallege paragraphs 1-54 as if fully set forth herein.

56. Defendants' submission of Defendants' ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product in or into the United States, prior to the expiration of the '893 patent, constitutes infringement of the '893 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

57. On information and belief, Defendants' manufacturing, use, offer for sale, sale, and/or importation of Defendants' ANDA Product, once Defendants' ANDA is approved by FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '893 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

58. On information and belief, Defendants' ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Defendants or on their behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which

will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '893 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Defendants' ANDA Product will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '893 patent.

59. On information and belief, Defendants' manufacturing, use, offer for sale, sale, and/or importation of Defendants' ANDA Product, once Defendants' ANDA is approved by FDA, would contribute to infringement of one or more claims of the '893 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Defendants know that Defendants' ANDA Product is especially made or adapted for use in infringing the '893 patent, and that Defendants' ANDA Product is not suitable for substantial non-infringing use.

60. Plaintiffs will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Defendants' ANDA Product in or into the United States, and are not enjoined from doing so. Plaintiffs are entitled to relief 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 Defendants' ANDA be a date that is not earlier than the expiration date of the '893 patent, or any later expiration of exclusivity for the '893 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

61. Defendants have had knowledge of the '893 patent since at least the date Defendants submitted Defendants' ANDA and were aware that submission of Defendants' ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

62. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF THE '128A PATENT

63. Plaintiffs reallege paragraphs 1-62 as if fully set forth herein.

64. Defendants' submission of Defendants' ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product in or into the United States, prior to the expiration of the '128A patent, constitutes infringement of the '128A patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

65. On information and belief, Defendants' manufacturing, use, offer for sale, sale, and/or importation of Defendants' ANDA Product, once Defendants' ANDA is approved by FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '128A patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

66. On information and belief, Defendants' ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Defendants or on their behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '128A patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Defendants' ANDA Product will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '128A patent.

67. On information and belief, Defendants' manufacturing, use, offer for sale, sale, and/or importation of Defendants' ANDA Product, once Defendants' ANDA is approved by FDA, would contribute to infringement of one or more claims of the '128A patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Defendants know that Defendants' ANDA Product is especially made or adapted for use in infringing the '128A patent, and that Defendants' ANDA Product is not suitable for substantial non-infringing use.

68. Plaintiffs will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Defendants' ANDA Product in or into the United States, and are not enjoined from doing so. Plaintiffs are entitled to relief 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 Defendants' ANDA be a date that is not earlier than the expiration date of the '128A patent, or any later expiration of exclusivity for the '128A patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

69. Defendants' have had knowledge of the '128A patent since at least the date Defendants submitted Defendants' ANDA and were aware that submission of Defendants' ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

70. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF THE '128B PATENT

71. Plaintiffs reallege paragraphs 1-70 as if fully set forth herein.

72. Defendants' submission of Defendants' ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product in or into the United States, prior to the expiration of the '128B patent, constitutes

infringement of the ’128B patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

73. On information and belief, Defendants’ manufacturing, use, offer for sale, sale, and/or importation of Defendants’ ANDA Product, once Defendants’ ANDA is approved by FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’128B patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

74. On information and belief, Defendants’ ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Defendants or on their behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’128B patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Defendants’ ANDA Product will occur with Defendants’ specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs’ rights under the ’128B patent.

75. On information and belief, Defendants’ manufacturing, use, offer for sale, sale, and/or importation of Defendants’ ANDA Product, once Defendants’ ANDA is approved by FDA, would contribute to infringement of one or more claims of the ’128B patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Defendants know that Defendants’ ANDA Product is especially made or adapted for use in infringing the

’128B patent, and that Defendants’ ANDA Product is not suitable for substantial non-infringing use.

76. Plaintiffs will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Defendants’ ANDA Product in or into the United States, and are not enjoined from doing so. Plaintiffs are entitled to relief 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 Defendants’ ANDA be a date that is not earlier than the expiration date of the ’128B patent, or any later expiration of exclusivity for the ’128B patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

77. Defendants have had knowledge of the ’128B patent since at least the date Defendants submitted Defendants’ ANDA and were aware that submission of Defendants’ ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

78. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT V: INFRINGEMENT OF THE ’331 PATENT

79. Plaintiffs reallege paragraphs 1-78 as if fully set forth herein.

80. Defendants’ submission of Defendants’ ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants’ ANDA Product in or into the United States, prior to the expiration of the ’331 patent, constitutes infringement of the ’331 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

81. On information and belief, Defendants’ manufacturing, use, offer for sale, sale, and/or importation of Defendants’ ANDA Product, once Defendants’ ANDA is approved by FDA,

would actively, intentionally, and knowingly induce infringement of one or more claims of the '331 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

82. On information and belief, Defendants' ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Defendants or on their behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '331 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Defendants' ANDA Product will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '331 patent.

83. On information and belief, Defendants' manufacturing, use, offer for sale, sale, and/or importation of Defendants' ANDA Product, once Defendants' ANDA is approved by FDA, would contribute to infringement of one or more claims of the '331 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Defendants know that Defendants' ANDA Product is especially made or adapted for use in infringing the '331 patent, and that Defendants' ANDA Product is not suitable for substantial non-infringing use.

84. Plaintiffs will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Defendants' ANDA Product in or into the United States, and are not enjoined from doing so. Plaintiffs are entitled to relief 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 Defendants' ANDA be

a date that is not earlier than the expiration date of the ’331 patent, or any later expiration of exclusivity for the ’331 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

85. Defendants have had knowledge of the ’331 patent since at least the date Defendants submitted Defendants’ ANDA and were aware that submission of Defendants’ ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

86. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT VI: INFRINGEMENT OF THE ’332 PATENT

87. Plaintiffs reallege paragraphs 1-86 as if fully set forth herein.

88. Defendants’ submission of Defendants’ ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants’ ANDA Product in or into the United States, prior to the expiration of the ’332 patent, constitutes infringement of the ’332 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

89. On information and belief, Defendants’ manufacturing, use, offer for sale, sale, and/or importation of Defendants’ ANDA Product, once Defendants’ ANDA is approved by FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’332 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

90. On information and belief, Defendants’ ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Defendants or on their behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims

of the ’332 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Defendants’ ANDA Product will occur with Defendants’ specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs’ rights under the ’332 patent.

91. On information and belief, Defendants’ manufacturing, use, offer for sale, sale, and/or importation of Defendants’ ANDA Product, once Defendants’ ANDA is approved by FDA, would contribute to infringement of one or more claims of the ’332 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Defendants know that Defendants’ ANDA Product is especially made or adapted for use in infringing the ’332 patent, and that Defendants’ ANDA Product is not suitable for substantial non-infringing use.

92. Plaintiffs will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Defendants’ ANDA Product in or into the United States, and are not enjoined from doing so. Plaintiffs are entitled to relief 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 Defendants’ ANDA be a date that is not earlier than the expiration date of the ’332 patent, or any later expiration of exclusivity for the ’332 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

93. Defendants have had knowledge of the ’332 patent since at least the date Defendants submitted Defendants’ ANDA and were aware that submission of Defendants’ ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

94. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '088 patent through Defendants' submission of ANDA No. 217996 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Defendants' ANDA Product before the expiration of the '088 patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Defendants' ANDA Product before the expiration of the '088 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '088 patent;

(c) A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '893 patent through Defendants' submission of ANDA No. 217996 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Defendants' ANDA Product before the expiration of the '893 patent;

(d) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Defendants' ANDA Product before the expiration of the '893 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '893 patent;

(e) A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '128A patent through Defendants' submission of ANDA No. 217996 to

FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Defendants' ANDA Product before the expiration of the '128A patent;

(f) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Defendants' ANDA Product before the expiration of the '128A patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '128A patent;

(g) A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '128B patent through Defendants' submission of ANDA No. 217996 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Defendants' ANDA Product before the expiration of the '128B patent;

(h) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Defendants' ANDA Product before the expiration of the '128B patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '128B patent;

(i) A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '331 patent through Defendants' submission of ANDA No. 217996 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Defendants' ANDA Product before the expiration of the '331 patent;

(j) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Defendants' ANDA Product before the expiration of the '331 patent will infringe,

actively induce infringement, and/or contribute to the infringement of at least one claim of the '331 patent;

(k) A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '332 patent through Defendants' submission of ANDA No. 217996 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Defendants' ANDA Product before the expiration of the '332 patent;

(l) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Defendants' ANDA Product before the expiration of the '332 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '332 patent;

(m) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Defendants' ANDA, shall not be earlier than the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(n) The entry of a permanent and/or preliminary injunction enjoining Defendants, and their affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, and importing in or into the United States Defendants' ANDA Product, or any product that infringes the Patents-in-Suit, or inducing or contributing to the infringement of the Patents-in-Suit until after the latest expiration date of the Patents-in-Suit, including any extension and/or additional periods of exclusivity to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(o) The entry of a permanent and/or preliminary injunction enjoining Defendants, and their affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of Defendants' ANDA until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(p) Damages or other monetary relief to Plaintiffs if Defendants engage in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of Defendants' ANDA Product prior to the expiration of the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(q) 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; and

(r) Such further relief as this Court deems proper and just.

Dated: March 2, 2023

By: /s/ Christopher Viceconte
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