IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DUCHESNAY INC. Plaintiff, v. ALKEM LABORATORIES LTD. Defendant.	)	C.A. No. ____

COMPLAINT

Plaintiff Duchesnay Inc. ("Duchesnay"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271, against Defendant Alkem Laboratories Ltd. ("Alkem" or "Defendant"). This action concerns Abbreviated New Drug Application ("ANDA") No. 215950, which Alkem filed or caused to be filed under 21 U.S.C. § 355(j) with the U.S. Food and Drug Administration ("FDA") for approval to market and sell in the United States a generic copy of Duchesnay's Bonjesta®, doxylamine succinate and pyridoxine hydrochloride extended release tablets, prior to the expiration of United States Patent Nos. 9,089,489 ("the '489 patent"), 9,375,404 ("the '404 patent"), 9,526,703 ("the '703 patent"), and 9,937,132 ("the '132 patent"), which are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Bonjesta®.

THE PARTIES

2. The preceding paragraph is re-alleged and re-incorporated as if fully set forth herein.

3. Plaintiff Duchesnay Inc. is a Canadian corporation having its corporate office at 950 Boulevard Michèle-Bohec, Blainville, Québec, Canada J7C 5E2. Duchesnay is engaged in the business of research, development, manufacture, and sale of pharmaceutical products for women's health.

4. On information and belief, Defendant Alkem is an Indian corporation having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, India 400 013.

5. On information and belief, Defendant Alkem develops and manufactures generic medicines and, either by itself or through subsidiaries, parents, and/or partners, markets and distributes such generic pharmaceutical products throughout the United States, including in this District.

JURISDICTION AND VENUE

6. Each of the preceding paragraphs 1 to 5 is re-alleged and re-incorporated as if fully set forth herein.

7. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Defendant Alkem by virtue of, *inter alia*, the fact that it has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff in this District.

10. On information and belief, Defendant Alkem is subject to personal jurisdiction in this District because it regularly does or solicits business in Delaware, engages in other persistent

courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Defendant Alkem has continuous and systematic contacts with Delaware.

11. This Court also has personal jurisdiction over Defendant Alkem because, based on the activities alleged herein, at least one provision of 10 Del. C. § 3104(c) is satisfied. Upon information and belief, Alkem satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), and § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State").

12. On information and belief, Defendant Alkem purposefully has conducted and continues to conduct business in this District by directly, or indirectly through its wholly owned subsidiaries, manufacturing, marketing, and selling generic drug products.

13. On information and belief, Defendant Alkem is also subject to personal jurisdiction in this District due to, on information and belief, its involvement in the preparation and submission of ANDA No. 215950 with a Paragraph IV certification regarding the '489, '404, '703, and '132 patents. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016). As in *Acorda*, on information and belief, Defendant Alkem intends that the ANDA product will be sold in Delaware once approved by the FDA. *Acorda Therapeutics*, 817 F.3d at 758.

14. Furthermore, Defendant Alkem is amenable to suit in this forum based on its conduct in numerous other litigations in this District. In particular, Defendant Alkem has been

sued multiple times in this District without challenging personal jurisdiction and Alkem has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See e.g., Novartis Pharmaceuticals Corporation v. Alkem Laboratories Ltd.* 22-32 (D. Del. Jan. 2022); *Anacor Pharmaceuticals, Inc. et al v. Alkem Laboratories Ltd.* 21-1348 (D. Del. Sept. 2021); *Allergan USA, Inc.et al v. Alkem Laboratories Ltd.* 21-1061 (D. Del. Aug. 2021).

15. This Court has personal jurisdiction over Defendant Alkem by virtue of, among other things: (1) its substantial, continuous, and systematic contacts with Delaware, (2) its sale and distribution of generic drugs in Delaware; (3) its involvement in the preparation and submission of ANDA No. 215950 with a Paragraph IV certification regarding the '489, '404, '703, and '132 patents; and (4) its submission to the Court's jurisdiction in other patent litigations.

16. Exercising personal jurisdiction over Alkem in this District would not be unreasonable given its contacts in Delaware, and the interest of Delaware in resolving disputes related to products to be sold herein.

17. This Court has personal jurisdiction over Alkem, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Alkem is organized under the laws of India.

18. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because Alkem is incorporated in India and may be sued in any judicial district in the United States. *See also In re HTC Corp.*, 889 F.3d 1349 (Fed. Cir. 2018).

PATENTS-IN-SUIT

19. Each of the preceding paragraphs 1 to 18 is re-alleged and re-incorporated as if fully set forth herein.

20. The '489 patent, titled "Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof," was duly and legally issued to inventors Manon Vranderick, Jean-Luc St-Onge, Christelle Gedeon, Michele Gallo and Éric Gervais by the United States Patent

and Trademark Office ("PTO") on July 28, 2015. The '489 patent is assigned to Duchesnay Inc. and expires on February 18, 2033. A true and correct copy of the '489 patent is attached as **Exhibit A**.

21. The '404 patent, titled "Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof," was duly and legally issued to inventors Manon Vranderick, Jean-Luc St-Onge, Christelle Gedeon, Michele Gallo and Éric Gervais by the PTO on June 28, 2016. The '404 patent is assigned to Duchesnay Inc. and expires on February 18, 2033. A true and correct copy of the '404 patent is attached as **Exhibit B**.

22. The '703 patent, titled "Plurimodal Release Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof," was duly and legally issued to inventors Manon Vranderick, Jean-Luc St-Onge, Michele Gallo and Éric Gervais by the PTO on December 27, 2016. The '703 patent is assigned to Duchesnay Inc. and expires on February 18, 2033. A true and correct copy of the '703 patent is attached as **Exhibit C**.

23. The '132 patent, titled "Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof," was duly and legally issued to inventors Manon Vranderick, Jean-Luc St-Onge, Christelle Gedeon, Michele Gallo and Éric Gervais by the PTO on April 10, 2018. The '132 patent is assigned to Duchesnay Inc. and expires on February 18, 2033. A true and correct copy of the '132 patent is attached as **Exhibit D**.

24. Plaintiff Duchesnay is the holder of New Drug Application ("NDA") No. 209661 for Bonjesta®, doxylamine succinate and pyridoxine hydrochloride extended release tablets for the treatment of nausea and vomiting in pregnancy ("NVP"). The FDA approved NDA No. 209661 on November 7, 2016. The '489, '404, '703, and '132 patents are listed in the Orange Book for

NDA No. 209661. Plaintiff markets and sells Bonjesta® throughout the United States via its subsidiary, Duchesnay USA Inc.

INFRINGEMENT BY DEFENDANT ALKEM

25. Each of the preceding paragraphs 1 to 24 is re-alleged and re-incorporated as if fully set forth herein.

26. In a letter dated May 27, 2022 ("the Notice Letter"), Defendant Alkem notified Plaintiff Duchesnay that it had submitted ANDA No. 215950 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

27. The Notice Letter states that Alkem is seeking approval from the FDA to market and sell generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '489, '404, '703, and '132 patents.

28. On information and belief, Defendant Alkem seeks approval of at least one indication for generic versions of the doxylamine succinate and pyridoxine hydrochloride extended-release tablets and uses that are claimed in the '489, '404, '703, and '132 patents.

29. On information and belief, Defendant Alkem intends to engage in the commercial manufacture, use, and sale of generic versions of doxylamine succinate and pyridoxine hydrochloride extended-release tablets in this District upon receiving FDA approval to do so.

30. The Notice Letter states that ANDA No. 215950 contains a "Paragraph IV certification" asserting that each of the '489, '404, '703, and '132 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the proposed generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets.

31. This Complaint is being filed before expiration of the forty-five days from the date Duchesnay received the Notice Letter.

COUNT I
(Infringement of the '489 patent)

32. Each of the preceding paragraphs 1 to 31 is re-alleged and re-incorporated as if fully set forth herein.

33. Defendant's submission of ANDA No. 215950 seeking FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '489 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

34. On information and belief, Defendant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R § 314.95(c)(2), a certification that the claims of the '489 patent are purportedly invalid, unenforceable, and/or not infringed.

35. On information and belief, in its ANDA No. 215950, Defendant has represented to the FDA that Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are pharmaceutically and therapeutically equivalent to Duchesnay's Bonjesta®, doxylamine succinate and pyridoxine hydrochloride extended release tablets.

36. In the Notice Letter, Defendant did not allege non-infringement of claims 1-26 and 29-30 of the '489 patent, and therefore admits infringement of those claims. On information and belief, Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets comprise the "dual release oral dosage form" of claim 1 and also satisfy all other limitations of at least claims 1-26 and 29-30 of the '489 patent.

37. On information and belief, upon FDA approval of Defendant's ANDA No. 215950, Defendant will infringe at least claims 1-26 and 29-30 of the '489 patent, literally and/or through the doctrine of equivalents, by making, using, offering to sell, and selling its generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States and/or

importing such tablets into the United States in violation of 35 U.S.C. § 271(a), and/or will induce and/or contribute to the infringement of one or more claims of the '489 patent under 35 U.S.C. §§ 271(b) and/or (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215950 shall be no earlier than the expiration of the '489 patent and any additional periods of exclusivity.

38. On information and belief, Defendant has knowledge of the '489 patent and has filed ANDA No. 215950 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States. On information and belief, if the FDA approves ANDA No. 215950, physicians, health care providers, and/or patients will use Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendant's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '489 patent in violation of Plaintiff's patent rights.

39. On information and belief, Defendant knows and intends that physicians, health care providers, and/or patients will use Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendant's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '489 patent with the requisite intent under 35 U.S.C. § 271(b).

40. On information and belief, if the FDA approves ANDA No. 215950, Defendant will sell or offer to sell its generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets specifically labeled for use in practicing one or more claims of the '489 patent, wherein Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are a material part of the invention claimed in the '489 patent, wherein Defendant

knows that physicians will prescribe and patients will use Alkem's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets for practicing one or more claims in the '489 patent, and wherein doxylamine succinate and pyridoxine hydrochloride extended-release tablets are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendant will thus contribute to the infringement of the '489 patent under 35 U.S.C. § 271(c).

41. On information and belief, Alkem's actions relating to Alkem's ANDA No. 215950 complained of herein were done by and for the benefit of Alkem.

42. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant as to liability for infringement of the '489 patent claims. Defendant's actions have created in Plaintiff a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Defendant's threatened imminent actions, unless those actions are enjoined by this Court. Plaintiff has no adequate remedy at law.

COUNT II
(Infringement of the '404 Patent)

43. Each of the preceding paragraphs 1 to 42 is re-alleged and re-incorporated as if fully set forth herein.

44. Defendant's submission of ANDA No. 215950 seeking FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '404 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

45. On information and belief, Defendant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R § 314.95(c)(2), a certification that the claims of the '404 patent are purportedly invalid, unenforceable, and/or not infringed.

46. On information and belief, in its ANDA No. 215950, Defendant has represented to the FDA that Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are pharmaceutically and therapeutically equivalent to Duchesnay's Bonjesta®, doxylamine succinate and pyridoxine hydrochloride extended release tablets.

47. In the Notice Letter, Defendant did not allege non-infringement of claims 1-14, 16, and 18-19 of the '404 patent, and therefore admits infringement of those claims. On information and belief, Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets comprise the "oral dosage form" of claim 1 and also satisfy all other limitations of at least claims 1-14, 16, and 18-19 of the '404 patent.

48. On information and belief, upon FDA approval of Defendant's ANDA No. 215950, Defendant will infringe at least claims 1-14, 16, and 18-19 of the '404 patent, literally and/or through the doctrine of equivalents, by making, using, offering to sell, and selling its generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. § 271(a), and/or will induce and/or contribute to the infringement of one or more claims of the '404 patent under 35 U.S.C. §§ 271(b) and/or (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215950 shall be no earlier than the expiration of the '404 patent and any additional periods of exclusivity.

49. On information and belief, Defendant has knowledge of the '404 patent and has filed ANDA No. 215950 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States. On information and belief, if the FDA approves ANDA No. 215950, physicians, health care providers, and/or patients will use Defendant's generic doxylamine

succinate and pyridoxine hydrochloride extended-release tablets according to Defendant's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '404 patent in violation of Plaintiff's patent rights.

50. On information and belief, Defendant knows and intends that physicians, health care providers, and/or patients will use Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendant's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '404 patent with the requisite intent under 35 U.S.C. § 271(b).

51. On information and belief, if the FDA approves ANDA No. 215950, Defendant will sell or offer to sell its generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets specifically labeled for use in practicing one or more claims of the '404 patent, wherein Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are a material part of the invention claimed in the '404 patent, wherein Defendant knows that physicians will prescribe and patients will use Alkem's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets for practicing one or more claims in the '404 patent, and wherein doxylamine succinate and pyridoxine hydrochloride extended-release tablets are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendant will thus contribute to the infringement of the '404 patent under 35 U.S.C. § 271(c).

52. On information and belief, Alkem's actions relating to Alkem's ANDA No. 215950 complained of herein were done by and for the benefit of Alkem.

53. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant as to liability for infringement of the '404

patent claims. Defendant's actions have created in Plaintiff a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Defendant's threatened imminent actions, unless those actions are enjoined by this Court. Plaintiff has no adequate remedy at law.

COUNT III
(Infringement of the '703 Patent)

54. Each of the preceding paragraphs 1 to 53 is re-alleged and re-incorporated as if fully set forth herein.

55. Defendant's submission of ANDA No. 215950 seeking FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '703 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

56. On information and belief, Defendant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R § 314.95(c)(2), a certification that the claims of the '703 patent are purportedly invalid, unenforceable, and/or not infringed.

57. On information and belief, in its ANDA No. 215950, Defendant has represented to the FDA that Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are pharmaceutically and therapeutically equivalent to Duchesnay's Bonjesta®, doxylamine succinate and pyridoxine hydrochloride extended release tablets.

58. In the Notice Letter, Defendant did not allege non-infringement of claims 1-24, 28, and 30 of the '703 patent, and therefore admits infringement of those claims. On information and belief, Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets comprise the "solid oral dosage form" of claim 1 and also satisfy all other limitations of at least claims 1-24, 28, and 30 of the '703 patent.

59. On information and belief, upon FDA approval of Defendant's ANDA No. 215950, Defendant will infringe at least claims 1-24, 28, and 30 of the '703 patent, literally and/or through the doctrine of equivalents, by making, using, offering to sell, and selling its generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. § 271(a), and/or will induce and/or contribute to the infringement of one or more claims of the '703 patent under 35 U.S.C. §§ 271(b) and/or (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215950 shall be no earlier than the expiration of the '703 patent and any additional periods of exclusivity.

60. On information and belief, Defendant has knowledge of the '703 patent and has filed ANDA No. 215950 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States. On information and belief, if the FDA approves ANDA No. 215950, physicians, health care providers, and/or patients will use Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendant's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '703 patent in violation of Plaintiff's patent rights.

61. On information and belief, Defendant knows and intends that physicians, health care providers, and/or patients will use Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendant's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '703 patent with the requisite intent under 35 U.S.C. § 271(b).

62. On information and belief, if the FDA approves ANDA No. 215950, Defendant will sell or offer to sell its generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets specifically labeled for use in practicing one or more claims of the '703 patent, wherein Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are a material part of the invention claimed in the '703 patent, wherein Defendant knows that physicians will prescribe and patients will use Alkem's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets for practicing one or more claims in the '703 patent, and wherein doxylamine succinate and pyridoxine hydrochloride extended-release tablets are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendant will thus contribute to the infringement of the '703 patent under 35 U.S.C. § 271(c).

63. On information and belief, Alkem's actions relating to Alkem's ANDA No. 215950 complained of herein were done by and for the benefit of Alkem.

64. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant as to liability for infringement of the '703 patent claims. Defendant's actions have created in Plaintiff a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Defendant's threatened imminent actions, unless those actions are enjoined by this Court. Plaintiff has no adequate remedy at law.

COUNT IV
(Infringement of the '132 Patent)

65. Each of the preceding paragraphs 1 to 64 is re-alleged and re-incorporated as if fully set forth herein.

66. Defendant's submission of ANDA No. 215950 seeking FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxylamine succinate and

pyridoxine hydrochloride extended-release tablets before expiration of the '132 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

67. On information and belief, Defendant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R § 314.95(c)(2), a certification that the claims of the '132 patent are purportedly invalid, unenforceable, and/or not infringed.

68. On information and belief, in its ANDA No. 215950, Defendant has represented to the FDA that Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are pharmaceutically and therapeutically equivalent to Duchesnay's Bonjesta®, doxylamine succinate and pyridoxine hydrochloride extended release tablets.

69. In the Notice Letter, Defendant did not allege non-infringement of claims 1-12, 14, and 16-21 of the '132 patent, and therefore admits infringement of those claims. On information and belief, Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets comprise the "dual release oral dosage form" of claim 1 and also satisfy all other limitations of at least claims 1-12, 14, and 16-21 of the '132 patent.

70. On information and belief, upon FDA approval of Defendant's ANDA No. 215950, Defendant will induce and/or contribute to the infringement of one or more claims of the '132 patent under 35 U.S.C. §§ 271(b) and/or (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215950 shall be no earlier than the expiration of the '132 patent and any additional periods of exclusivity.

71. On information and belief, Defendant has knowledge of the '132 patent and has filed ANDA No. 215950 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States. On information and belief, if the FDA approves ANDA No. 215950,

physicians, health care providers, and/or patients will use Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendant's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '132 patent in violation of Plaintiff's patent rights.

72. On information and belief, Defendant knows and intends that physicians, health care providers, and/or patients will use Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendant's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '132 patent with the requisite intent under 35 U.S.C. § 271(b).

73. On information and belief, if the FDA approves ANDA No. 215950, Defendant will sell or offer to sell its generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets specifically labeled for use in practicing one or more claims of the '132 patent, wherein Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are a material part of the invention claimed in the '132 patent, wherein Defendant knows that physicians will prescribe and patients will use Alkem's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets for practicing one or more claims in the '132 patent, and wherein doxylamine succinate and pyridoxine hydrochloride extended-release tablets are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendant will thus contribute to the infringement of the '132 patent under 35 U.S.C. § 271(c).

74. On information and belief, Alkem's actions relating to Alkem's ANDA No. 215950 complained of herein were done by and for the benefit of Alkem.

75. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant as to liability for infringement of the '132 patent claims. Defendant's actions have created in Plaintiff a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Defendant's threatened imminent actions, unless those actions are enjoined by this Court. Plaintiff has no adequate remedy at law.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully requests that this Court grant the following relief:

A. A declaration that United States Patent Nos. 9,089,489, 9,375,404, 9,526,703, and 9,937,132 remain valid and enforceable;

B. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendant has infringed at least one claim of United States Patent No. 9,089,489 through Defendant's submission of its ANDA No. 215950 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '489 patent;

C. The entry of judgment under § 271(a), (b), and/or (c) that Defendant's making, using, offering to sell, selling, or importing Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets prior to expiration of the '489 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '489 patent under 35 U.S.C. § 271(a), (b), and/or (c);

D. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendant has infringed at least one claim of United States Patent No. 9,375,404 through Defendant's submission of its ANDA No. 215950 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or

sell Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '404 patent;

E. The entry of judgment under § 271(a), (b), and/or (c) that Defendant's making, using, offering to sell, selling, or importing Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets prior to expiration of the '404 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '404 patent under 35 U.S.C. § 271(a), (b), and/or (c);

F. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendant has infringed at least one claim of United States Patent No. 9,526,703 through Defendant's submission of its ANDA No. 215950 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '703 patent;

G. The entry of judgment under § 271(a), (b), and/or (c) that Defendant's making, using, offering to sell, selling, or importing Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets prior to expiration of the '703 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '703 patent under 35 U.S.C. § 271(a), (b), and/or (c);

H. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendant has infringed at least one claim of United States Patent No. 9,937,132 through Defendant's submission of its ANDA No. 215950 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '132 patent;

I. The entry of judgment under § 271(a), (b), and/or (c) that Defendant's making, using, offering to sell, selling, or importing Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets prior to expiration of the '132 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '132 patent under 35 U.S.C. § 271(a), (b), and/or (c);

J. An order that the effective date of any FDA approval for Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets shall be no earlier than the latest expiration date of United States Patent Nos. 9,089,489, 9,375,404, 9,526,703, and 9,937,132, including any exclusivities or extensions to which Plaintiff is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

K. The order of a preliminary and/or permanent injunction, enjoining Defendant, and all persons acting in concert with Defendant, from commercially manufacturing, using, offering for sale, or selling Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets within the United States, or importing Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets into the United States, until the latest expiration of United States Patent Nos. 9,089,489, 9,375,404, 9,526,703, and 9,937,132, including any exclusivities or extensions to which Plaintiff is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

L. The order of a preliminary and/or permanent injunction, enjoining Defendant, and all persons acting in concert with Defendant, from seeking, obtaining, or maintaining approval of ANDA No. 215950 until the latest expiration of United States Patent Nos. 9,089,489, 9,375,404, 9,526,703, and 9,937,132, including any exclusivities or extensions to which Plaintiff is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

M. Damages or other monetary relief to Plaintiff if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendant's generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets prior to the latest expiration of United States Patent Nos. 9,089,489, 9,375,404, 9,526,703, and 9,937,132, including any exclusivities or extensions to which Plaintiff is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(C);

N. Such further and additional relief to Plaintiff that this Court deems just and proper, including any appropriate relief under 35 U.S.C. § 285.

Dated: July 11, 2022

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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