IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DUCHESNAY INC. Plaintiff, v. ACTAVIS LABORATORIES FL, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	CIVIL ACTION 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, against Defendants Actavis Laboratories Fl, Inc. ("Actavis"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Defendants"). This action concerns Abbreviated New Drug Application ("ANDA") No. 212472 submitted by Defendants to the U.S. Food and Drug Administration ("FDA") for approval to market and sell a generic version 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 Teva USA is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090. On information and belief, Defendant Teva USA 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.

5. On information and belief, Teva USA is part of the Teva family of companies, which includes more than 28 U.S. subsidiaries, of which more than 18 are incorporated in Delaware.

6. On information and belief, Defendant Teva Ltd. is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 49131, Israel. On information and belief, Defendant Teva Ltd. develops and manufactures generic medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such generic pharmaceutical products around the world, including in this District.

7. On information and belief, Teva Ltd. is part of the Teva family of companies, which includes more than 28 U.S. subsidiaries, of which more than 18 are incorporated in Delaware.

8. On information and belief, in August of 2016, the Teva Defendants acquired Defendant Actavis. On information and belief, the acquisition included the Defendant Actavis's entire portfolio of generic drugs, including the accused product.

9. On information and belief, Defendant Actavis is a Florida corporation. On information and belief, Defendant Actavis 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.

10. On information and belief, Actavis is part of the Teva family of companies, which includes more than 28 U.S. subsidiaries, of which more than 18 are incorporated in Delaware.

11. On information and belief, Defendant Actavis is an indirect wholly-owned subsidiary of Defendant Teva USA, which is an indirect wholly-owned subsidiary of Defendant Teva Ltd.

12. On information and belief, the acts of each Defendant complained of herein, including the preparation and submission of ANDA No. 212472, were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, the other named Defendants.

JURISDICTION AND VENUE

13. Each of the preceding paragraphs 1 to 12 is re-alleged and re-incorporated as if fully set forth herein.

14. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, the fact that they have 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.

16. Defendant Teva USA is subject to personal jurisdiction in this District because it is incorporated in Delaware.

17. This Court also has personal jurisdiction over Teva USA because, based on the activities alleged herein, at least one provision of 10 Del. C. § 3104(c) is satisfied. Upon information and belief, Teva USA 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").

18. Defendant Teva USA is also subject to personal jurisdiction in this District due to its substantial, systematic, purposeful, and continuous contact in Delaware, including the sale and distribution of generic drugs in Delaware.

19. Defendant Teva USA 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. 212472 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 Teva USA intends that the ANDA product will be sold in Delaware once approved by the FDA. *Acorda*, 817 F.3d at 758.

20. Furthermore, Defendant Teva USA is amenable to suit in this forum based on its conduct in numerous other litigations in this District. In particular, Defendant Teva USA has previously availed itself of the rights and privileges of this forum for the purpose of litigating patent disputes. For example, Defendant Teva USA has filed suit and sought relief in other civil actions initiated in this jurisdiction, including but not limited to: *Teva Pharmaceuticals USA, Inc. et al. v. Biocon Ltd. et al.*, Civ. Action No. 1:16-cv-00278 (D. Del. 2016); *Teva Pharmaceuticals USA, Inc. v. Dr. Reddy's Laboratories, Ltd.*, Civ. Action No. 1:16-cv-01267 (D. Del. 2016). Defendant Teva USA has also previously submitted to personal jurisdiction in this District. *See e.g., Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc., et al,* Civ. Action No. 1:18-cv-01039 (D. Del. 2018); *Galderma Laboratories LP et al. v. Teva Pharmaceuticals USA, Inc. et al.,* Civ. Action No. 1:17-cv-01783 (D. Del. 2017); *Adverio Pharma GmbH et al. v. Teva Pharmaceuticals USA, Inc. et al.,* Civ. Action No. 1:18-cv-00112 (D. Del. 2018).

21. This Court has personal jurisdiction over Defendant Teva USA by virtue of: (1) its incorporation in Delaware; (2) its sale and distribution of generic drugs in Delaware; (3) its involvement in the preparation and submission of ANDA No. 21472 with a Paragraph IV certification regarding the '489, '404, '703, and '132 patents; (4) its purposeful availment of this forum previously for the purpose of litigating patent disputes; and (5) its submission to the Court's jurisdiction in other patent litigations.

22. On information and belief, Defendant Teva Ltd. 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 Teva Ltd. has continuous and systematic contacts with Delaware.

23. This Court also has personal jurisdiction over Teva Ltd. because, based on the activities alleged herein, at least one provision of 10 Del. C. § 3104(c) is satisfied. Upon information and belief, Teva Ltd. 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").

24. On information and belief, Defendant Teva Ltd. 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, including generic drug products manufactured by Defendant Teva USA, throughout the United States and in this District.

25. On information and belief, Defendant Teva. Ltd. 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. 212472 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 Teva Ltd. intends that the ANDA product will be sold in Delaware once approved by the FDA. *Acorda Therapeutics*, 817 F.3d at 758.

26. On information and belief, Defendant Teva Ltd. is amenable to suit in this forum based on its conduct in numerous other litigations in this District. In particular, Defendant Teva

Ltd. has previously availed itself of the rights and privileges of this forum for the purpose of litigating patent disputes. For example, Defendant Teva Ltd. has filed suit and sought relief in other civil actions initiated in this jurisdiction, including but not limited to: *Teva Pharmaceuticals USA, Inc. et al. v. Biocon Ltd. et al.*, C.A. No. 1:16-cv-00278 (D. Del. 2016); *Teva Pharmaceuticals USA Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 1:15-cv-00306 (D. Del. 2015). Additionally, Defendant Teva Ltd. has previously submitted to personal jurisdiction in this District. *See, e.g., Adverio Pharma GmbH et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. Action No. 1:18-cv-00112 (D. Del. 2018).

27. This Court has personal jurisdiction over Defendant Teva Ltd. 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. 21472 with a Paragraph IV certification regarding the '489, '404, '703, and '132 patents; (4) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (5) its submission to the Court's jurisdiction in other patent litigations.

28. Defendant Actavis is subject to personal jurisdiction in this District due to its substantial, systematic, purposeful, and continuous contact in Delaware, including the sale and distribution of generic drugs in Delaware.

29. This Court also has personal jurisdiction over Actavis because, based on activities alleged herein, at least one provision of 10 Del. C. § 3104(c) is satisfied. Upon information and belief, Actavis 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").

30. Defendant Actavis 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. 212472 with a Paragraph IV certification regarding the '489, '404, '703, and '132 patents. *See Acorda*, 817 F.3d 755. As in *Acorda*, on information and belief, Defendant Actavis intends that the ANDA product will be sold in Delaware once approved by the FDA. *Acorda Therapeutics*, 817 F.3d at 758.

31. Furthermore, Defendant Actavis is amenable to suit in this forum based on its conduct in numerous other litigations in this District. In particular, Defendant Actavis has been sued multiple times in this District without challenging personal jurisdiction and Actavis has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See e.g., Cosmo Technologies Ltd. v. Actavis Laboratories FL, Inc. et al.*, Civ. Action No. 1:18-cv-01006 (D. Del. 2018); *Valeant Pharmaceuticals Intl. et al. v. Actavis Laboratories FL, Inc. et al.*, Civ. Action No. 1:18-cv-01288 (D. Del. 2018); *Shire Development LLC et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. Action No. 1:17-cv-01696 (D. Del. 2017).

32. This Court has personal jurisdiction over Defendant Actavis by virtue of: (1) its sale and distribution of generic drugs in Delaware; (2) its involvement in the preparation and submission of ANDA No. 21472 with a Paragraph IV certification regarding the '489, '404, '703, and '132 patents; (3) its purposeful availment of this forum previously for the purpose of

litigating patent disputes; and (4) its submission to the Court's jurisdiction in other patent litigations.

33. Exercising personal jurisdiction over Teva USA, Teva Ltd., and Actavis in this District would not be unreasonable given their contacts in Delaware, and the interest of Delaware in resolving disputes related to products to be sold herein.

34. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *See also Acorda Therapeutics*, 817 F.3d at 758; *Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, 2017 WL 3980155 (D. Del.); *In re HTC Corp.*, 889 F.3d 1349 (Fed. Cir. 2018).

PATENTS-IN-SUIT

35. Each of the preceding paragraphs 1 to 34 is re-alleged and re-incorporated as if fully set forth herein.

36. 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**.

37. 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**.

38. 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**.

39. 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**.

40. 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 DEFENDANTS

41. Each of the preceding paragraphs 1 to 40 is re-alleged and re-incorporated as if fully set forth herein.

42. In a letter dated October 16, 2018 ("the Notice Letter"), Defendant Teva USA notified Plaintiff Duchesnay that it had submitted ANDA No. 212472 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

43. The Notice Letter states that Teva 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.

44. On information and belief, Defendants Teva USA, Teva Ltd., and Actavis were involved in the preparation and submission of ANDA No. 212472.

45. On information and belief, Defendants seek 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.

46. On information and belief, Defendants intend 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.

47. The Notice Letter states that ANDA No. 21472 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.

48. 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)

49. Each of the preceding paragraphs 1 to 48 is re-alleged and re-incorporated as if fully set forth herein.

50. Defendants' submission of ANDA No. 212472 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).

51. In the Notice Letter, Defendants did not allege non-infringement of claims 1-26 and 29-30 of the '489 patent, and therefore admit infringement of those claims. On information

and belief, Defendants' 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.

52. On information and belief, upon FDA approval of Defendants' ANDA No. 212472, Defendants 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 their 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 enjoined by the Court.

53. On information and belief, Defendants have knowledge of the '489 patent and have filed ANDA No. 212472 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States. On information and belief, if the FDA approves ANDA No. 212472, physicians, health care providers, and/or patients will use Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendants' 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.

54. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendants' 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).

55. On information and belief, if the FDA approves ANDA No. 212472, Defendants will sell or offer to sell their generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets specifically labeled for use in practicing one or more claims of the ’489 patent, wherein Defendants’ generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are a material part of the invention claimed in the ’489 patent, wherein Defendants know that physicians will prescribe and patients will use Teva’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, Defendants will thus contribute to the infringement of the ’489 patent under 35 U.S.C. § 271(c).

56. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants as to liability for infringement of the ’489 patent claims. Defendants’ actions have created in Plaintiff a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Defendants’ 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)

57. Each of the preceding paragraphs 1 to 56 is re-alleged and re-incorporated as if fully set forth herein.

58. Defendants’ submission of ANDA No. 212472 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).

59. In the Notice Letter, Defendants did not allege non-infringement of claims 1-14, 16, and 18-19 of the '404 patent, and therefore admit infringement of those claims. On information and belief, Defendants' 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.

60. On information and belief, upon FDA approval of Defendants' ANDA No. 212472, Defendants 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 their 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 enjoined by the Court.

61. On information and belief, Defendants have knowledge of the '404 patent and have filed ANDA No. 212472 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States. On information and belief, if the FDA approves ANDA No. 212472, physicians, health care providers, and/or patients will use Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendants' 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.

62. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendants' 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).

63. On information and belief, if the FDA approves ANDA No. 212472, Defendants will sell or offer to sell their generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets specifically labeled for use in practicing one or more claims of the '404 patent, wherein Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are a material part of the invention claimed in the '404 patent, wherein Defendants know that physicians will prescribe and patients will use Teva'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, Defendants will thus contribute to the infringement of the '404 patent under 35 U.S.C. § 271(c).

64. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants as to liability for infringement of the '404 patent claims. Defendants' actions have created in Plaintiff a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Defendants' 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)

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

66. Defendants' submission of ANDA No. 212472 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).

67. In the Notice Letter, Defendants did not allege non-infringement of claims 1-24, 28, and 30 of the '703 patent, and therefore admit infringement of those claims. On information and belief, Defendants' 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.

68. On information and belief, upon FDA approval of Defendants' ANDA No. 212472, Defendants 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 their 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 enjoined by the Court.

69. On information and belief, Defendants have knowledge of the '703 patent and have filed ANDA No. 212472 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States. On information and belief, if the FDA approves ANDA

No. 212472, physicians, health care providers, and/or patients will use Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendants' 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.

70. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendants' 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).

71. On information and belief, if the FDA approves ANDA No. 212472, Defendants will sell or offer to sell their generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets specifically labeled for use in practicing one or more claims of the '703 patent, wherein Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are a material part of the invention claimed in the '703 patent, wherein Defendants know that physicians will prescribe and patients will use Teva'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, Defendants will thus contribute to the infringement of the '703 patent under 35 U.S.C. § 271(c).

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

'703 patent claims. Defendants' actions have created in Plaintiff a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Defendants' 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)

73. Each of the preceding paragraphs 1 to 72 is re-alleged and re-incorporated as if fully set forth herein.

74. Defendants' submission of ANDA No. 212472 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).

75. In the Notice Letter, Defendants did not allege non-infringement of claims 1-12, 14, and 16-21 of the '132 patent, and therefore admit infringement of those claims. On information and belief, Defendants' 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.

76. On information and belief, upon FDA approval of Defendants' ANDA No. 212472, Defendants 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 enjoined by the Court.

77. On information and belief, Defendants have knowledge of the '132 patent and have filed ANDA No. 212472 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets in the United States. On information and belief, if the FDA approves ANDA No. 212472, physicians, health care providers, and/or patients will use Defendants' generic

doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendants' 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.

78. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets according to Defendants' 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).

79. On information and belief, if the FDA approves ANDA No. 212472, Defendants will sell or offer to sell their generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets specifically labeled for use in practicing one or more claims of the '132 patent, wherein Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets are a material part of the invention claimed in the '132 patent, wherein Defendants know that physicians will prescribe and patients will use Teva'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, Defendants will thus contribute to the infringement of the '132 patent under 35 U.S.C. § 271(c).

80. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants as to liability for infringement of the '132 patent claims. Defendants' actions have created in Plaintiff a reasonable apprehension of

imminent, irreparable, and substantial harm resulting from Defendants' 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 judgment that the claims of United States Patent Nos. 9,089,489, 9,375,404, 9,526,703, and 9,937,132 are not invalid or unenforceable, and are infringed by Defendants' submission of its ANDA No. 212472 under 35 U.S.C. § 271(e)(2)(A), and that Defendants' making, using, offer to sell, or selling in the United States, or importing into the United States, Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets will infringe said patents under 35 U.S.C. §§ 271(a), (b), and/or (c);

B. An order that the effective date of any FDA approval for Defendants' 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);

C. An order permanently enjoining Defendants, and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Defendants' generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets within the United States, or importing Defendants' 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;

D. Damages or other monetary relief to Plaintiff if Defendants engage in commercial manufacture, use, offers to sell, sale, or importation in or into the Untied States of Defendants' 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);

E. 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: November 29, 2018

McCARTER & ENGLISH LLP

/s/ Daniel M. Silver

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