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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CURRAX PHARMACEUTICALS LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LIMITED, TARO PHARMACEUTICALS INC. and TARO PHARMACEUTICALS U.S.A., INC., Defendants.	)	Case No.: 7:24-cv-05040

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Currax Pharmaceuticals LLC ("Currax"), for its Complaint against Defendants Taro Pharmaceutical Industries Ltd. ("Taro Ltd."), Taro Pharmaceuticals Inc. ("Taro Inc.") and Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") (collectively, "Taro"), hereby alleges as follows:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code.

PARTIES

2. Currax is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 155 Franklin Road, Suite 450, Brentwood, Tennessee 37027.

3. On information and belief, Taro Ltd. is a corporation operating and existing under the laws of Israel, having a principal place of business at 14 Hakitor Street, Haifa Bay, 2624761, Israel.

4. Taro Ltd.'s website states that they are "a research-based international pharmaceutical company[.]" *See* https://www.taro.com/research (accessed on July 1, 2024). Further, their website states "Taro develops high-quality, proprietary and off-patent pharmaceuticals for markets in the US, Canada, Israel and other countries around the world." *See* https://www.taro.com/research (accessed on July 1, 2024).

5. Taro Ltd.'s 2023 Annual Report states that they "are a multinational, science-based pharmaceutical company … [w]e develop, manufacture, and market Rx and OTC pharmaceutical products primarily in the U.S., Canada, Israel, and Japan." *See* https://taro.gcs-web.com/static-files/08c2b8f7-ccdd-4d5c-b99d-6b0cf1427077 (Taro Ltd. SEC Form 20-F (for the fiscal year ended March 31, 2023)) ("Taro Ltd. 20-F") at 29. "As of March 31, 2023, 19 (excluding tentative approvals) of our ANDAs are being reviewed by the FDA. During the fiscal year ended March 31, 2023, we filed 7 ANDAs with the FDA." Taro Ltd. 20-F at 30. The 2023 Annual Report also states that "revenue in the U.S. accounted for 63% of total consolidated net sales" and Taro "generate[s] most of [their] revenue from the sale of Rx and OTC pharmaceutical products." Taro Ltd. 20-F at 32, 44.

6. On information and belief, Taro Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in New York.

7. On information and belief, Taro Inc. is a corporation operating and existing under the laws of Canada, having a principal place of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada. On information and belief, Taro Inc. is a wholly-owned subsidiary of Taro Ltd. Taro Ltd. 20-F at 41.

8. In the 2023 Annual Report, Taro Ltd. states that the "principal activities" for Taro Inc. are "manufactur[ing] more than 200 finished dosage form pharmaceutical products for sale in Canada and for export to the U.S. and other markets[,]" "market[ing] and distribut[ing] both proprietary and generic products in the Canadian market" and "perform[ing] research and development." Taro Ltd. 20-F at 30.

9. On information and belief, Taro Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in New York.

10. On information and belief, Taro USA is a corporation operating and existing under the laws of the State of New York, having places of business at Three Skyline Drive, Hawthorne, NY 10532 and 1 Commerce Drive, Cranbury, New Jersey 08512. On information and belief, Taro USA is a wholly-owned subsidiary of Taro Ltd. Taro Ltd. 20-F at 41.

11. In the 2023 Annual Report, Taro Ltd. states that the "principal activities" for Taro USA are "market[ing] and distribut[ing] both proprietary and generic products in the U.S. market" and "perform[ing] regulatory, post marketing and clinical activities." Taro Ltd. 20-F at 30.

12. On information and belief, Taro USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in New York.

13. On information and belief, Taro filed ANDA No. 219058 ("Taro's ANDA") with the Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, importation, and/or marketing for Taro's 3 mg and 6 mg doxepin hydrochloride oral tablets ("Taro's ANDA Products") and will be involved in the commercial manufacture, use, offer for sale, sale, importation, and/or marketing of Taro's ANDA Products if Taro's ANDA is approved.

JURISDICTION AND VENUE

14. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

16. This Court has personal jurisdiction over Taro by virtue of the fact that, *inter alia*, Taro has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Currax in the State of New York and throughout the United States.

17. This Court also has personal jurisdiction over Taro Ltd. by virtue of, *inter alia*, its systemic and continuous contacts with the State of New York. On information and belief, Taro Ltd.'s 2023 Annual Report states that they "are a multinational, science-based pharmaceutical company … [w]e develop, manufacture, and market Rx and OTC pharmaceutical products primarily in the U.S., Canada, Israel, and Japan." *See* Taro Ltd. 20-F at 29.

18. On information and belief, Taro Ltd. is 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, this judicial district will be a destination for the generic drug products described in Taro's ANDA No. 219058.

19. In the alternative, if Taro Ltd.'s contacts with New York and/or Taro USA are insufficient to confer personal jurisdiction, upon information and belief, Taro Ltd. is not subject to jurisdiction of any state court of general jurisdiction, and this Court can exercise jurisdiction consistent with the United States Constitution and laws under Fed. R. Civ. P. 4(k)(2).

20. This Court also has personal jurisdiction over Taro Inc. by virtue of, *inter alia*, its systemic and continuous contacts with the State of New York. On information and belief, Taro Inc. is 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, this judicial district will be a destination for the generic drug products described in Taro's ANDA No. 219058.

21. In the alternative, if Taro Inc.'s contacts with New York are insufficient to confer personal jurisdiction, upon information and belief, Taro Inc. is not subject to jurisdiction of any state court of general jurisdiction, and this Court can exercise jurisdiction consistent with the United States Constitution and laws under Fed. R. Civ. P. 4(k)(2).

22. This Court has personal jurisdiction over Taro USA at least because Taro USA maintains its principal place of business in New York at Three Skyline Drive, Hawthorne, NY 10532. On information and belief, Taro USA is incorporated in the State of New York under DOS ID #185681 as a "domestic business corporation."

23. On information and belief, Taro USA is 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, this judicial district will be a destination for the generic drug products described in Taro's ANDA No. 219058.

24. Venue is proper as to Taro Ltd. in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Taro Ltd. is organized under the laws of Israel and may be sued in any jurisdiction.

25. Venue is proper as to Taro Inc. in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Taro Inc. is organized under the laws of Canada and may be sued in any jurisdiction.

26. Venue is proper as to Taro USA in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because it maintains a regular and established place of business in the judicial district, and it has previously consented to venue in this jurisdiction.

THE SILENOR® NDA

27. Currax holds approved New Drug Application ("NDA") No. 22-036 for SILENOR® (doxepin hydrochloride) tablets for oral administration (3 mg and 6 mg dosage strengths), which contain the active ingredient doxepin. SILENOR® tablets were approved by the United States Food and Drug Administration ("FDA") on March 17, 2010. SILENOR® tablets are indicated for the treatment of insomnia characterized by difficulties with sleep maintenance. SILENOR® tablets are sold in the United States by Currax.

THE PATENTS-IN-SUIT

28. Currax is the owner of U.S. Patent No. 7,915,307 ("the '307 patent"). The '307 patent was duly and legally issued on March 29, 2011. A true copy of the '307 patent is attached as Exhibit A.

29. Currax is an owner of and the exclusive licensee with all substantial rights to U.S. Patent No. 8,513,299 ("the '299 patent"). The '299 patent was duly and legally issued on August 20, 2013. A true copy of the '299 patent is attached as Exhibit B.

30. Currax is an owner of and the exclusive licensee with all substantial rights to U.S. Patent No. 9,107,898 ("the '898 patent"). The '898 patent was duly and legally issued on August 18, 2015. A true copy of the '898 patent is attached as Exhibit C.

31. Currax is an owner of and the exclusive licensee with all substantial rights to U.S. Patent No. 9,486,437 ("the '437 patent"). The '437 patent was duly and legally issued on November 8, 2016. A true copy of the '437 patent is attached as Exhibit D.

32. Currax is the owner of U.S. Patent No. 9,572,814 ("the '814 patent"). The '814 patent was duly and legally issued on February 21, 2017. A true copy of the '814 patent is attached as Exhibit E.

33. Currax is an owner of and the exclusive licensee with all substantial rights to U.S. Patent No. 9,861,607 ("the '607 patent"). The '607 patent was duly and legally issued on January 9, 2018. A true copy of the '607 patent is attached as Exhibit F.

34. Currax is an owner of and the exclusive licensee with all substantial rights to U.S. Patent No. 10,238,620 ("the '620 patent"). The '620 patent was duly and legally issued on March 26, 2019. A true copy of the '620 patent is attached as Exhibit G.

35. Currax is the owner of U.S. Patent No. 10,653,660 ("the '660 patent"). The '660 patent was duly and legally issued on May 19, 2020. A true copy of the '660 patent is attached as Exhibit H.

36. Currax is an owner of and the exclusive licensee with all substantial rights to U.S. Patent No. 10,653,662 ("the '662 patent"). The '662 patent was duly and legally issued on May 19, 2020. A true copy of the '662 patent is attached as Exhibit I.

37. Currax is the owner of U.S. Patent No. 11,110,074 ("the '074 patent"). The '074 patent was duly and legally issued on September 7, 2021. A true copy of the '074 patent is attached as Exhibit J.

38. The '307, '299, '898, '437, '814, '607, '620, '660, '662, and '074 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Currax's SILENOR® tablets.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

39. On information and belief, Taro submitted its ANDA to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, and sale of Taro's ANDA Products as generic versions of Currax's SILENOR® tablets.

40. By a letter dated May 21, 2024 ("Notice Letter"), Taro advised Currax that it had submitted its ANDA to the FDA seeking approval to engage in the manufacture, use, or sale of Taro's ANDA Products before the expiration of the '307, '299, '898, '437, '814, '607, '620, '660, '662, and '074 patents.

41. On information and belief, when Taro filed its ANDA, it was aware of the '307, '299, '898, '437, '814, '607, '620, '660, '662, and '074 patents and it was aware that the filing of its ANDA was an act of infringement of those patents.

42. By submitting its ANDA, Taro has necessarily represented to the FDA that, upon approval, Taro's ANDA Products will have the same active ingredient, method of

administration, dosage form, and strength as Currax's SILENOR® tablets, and will be bioequivalent to Currax's SILENOR® tablets.

43. On information and belief, Taro's ANDA seeks FDA approval of Taro's ANDA Products to be indicated for the treatment of insomnia characterized by difficulties with sleep maintenance.

44. On information and belief, Taro has taken and continues to take active steps towards the manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Products, including seeking approval of those products under Taro's ANDA.

45. Currax will be substantially and irreparably harmed by the infringing activities described in the Counts below unless those activities are precluded by this Court. Currax has no adequate remedy at law.

COUNT I
INFRINGEMENT OF THE '307 PATENT

46. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

47. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Products throughout the United States, including in this judicial district, prior to expiration of the '307 patent. By submitting its ANDA, Taro committed an act of infringement of the '307 patent under 35 U.S.C. § 271(e)(2)(A).

48. On information and belief, Taro's manufacture, use, offer for sale, sale, and/or importation into the United States of Taro's ANDA Products prior to the expiration of the '307 patent will infringe the '307 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the '307 patent.

49. The ’307 patent claims, *inter alia*, methods for providing sleep therapy wherein doxepin is administered at least three hours after consuming a meal. For example, claim 1 of the ’307 patent claims the following:

> A method for providing sleep therapy comprising administering a 3 mg or a 6 mg dose of doxepin to an individual at least three hours after consuming a meal, thereby providing a faster onset of action and reducing next day residual effects.

50. On information and belief, Taro will knowingly provide Taro’s ANDA Products with instructions for administering those products in a manner that directly infringes one or more claims of the ’307 patent. On information and belief, if Taro’s ANDA is approved, physicians and/or patients following said instructions will directly infringe the ’307 patent. On information and belief, if Taro’s ANDA is approved, Taro will actively encourage, recommend, or promote this infringement with knowledge of the ’307 patent and knowledge that its acts will induce infringement of the ’307 patent.

COUNT II

INFRINGEMENT OF THE ’299 PATENT

51. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

52. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro’s ANDA Products throughout the United States, including in this judicial district, prior to expiration of the ’299 patent. By submitting its ANDA, Taro committed an act of infringement of the ’299 patent under 35 U.S.C. § 271(e)(2)(A).

53. On information and belief, Taro’s manufacture, use, offer for sale, sale, and/or importation into the United States of Taro’s ANDA Products prior to the expiration of the ’299 patent will infringe the ’299 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the ’299 patent.

54. The ’299 patent claims, *inter alia*, methods wherein doxepin or a pharmaceutically acceptable salt thereof is administered to reduce or prevent early awakenings. For example, claim 1 of the ’299 patent claims the following:

> A method for reducing or preventing early awakenings in a patient in need thereof, comprising: identifying a patient having a sleep disorder in which, for a given 8 hour period of desired sleep, the patient experiences a sleep period that terminates during the final 60 minutes of said period; and providing to the patient doxepin or a pharmaceutically acceptable salt thereof in a dosage between about 0.5 and 6 mg that is effective to lengthen the sleep period.

55. On information and belief, Taro will knowingly provide Taro’s ANDA Products with instructions for administering those products in a manner that directly infringes one or more claims of the ’299 patent. On information and belief, if Taro’s ANDA is approved, physicians and/or patients following said instructions will directly infringe the ’299 patent. On information and belief, if Taro’s ANDA is approved, Taro will actively encourage, recommend, or promote this infringement with knowledge of the ’299 patent and knowledge that its acts will induce infringement of the ’299 patent.

COUNT III

INFRINGEMENT OF THE ’898 PATENT

56. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

57. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro’s ANDA Products throughout the United States, including in this judicial district, prior to expiration of the ’898 patent. By submitting its ANDA, Taro committed an act of infringement of the ’898 patent under 35 U.S.C. § 271(e)(2)(A).

58. On information and belief, Taro’s manufacture, use, offer for sale, sale, and/or importation into the United States of Taro’s ANDA Products prior to the expiration of the ’898

patent will infringe the '898 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the '898 patent.

59. The '898 patent claims, *inter alia*, methods wherein doxepin or a pharmaceutically acceptable salt thereof is administered to treat sleep maintenance insomnia characterized by fragmented sleep. For example, claim 1 of the '898 patent claims the following:

> A method for treating sleep maintenance insomnia characterized by fragmented sleep during the 8th hour of sleep in a patient in need thereof, comprising: identifying an elderly patient having a sleep disorder in which, for a given 8 hour period of desired sleep, the patient experiences fragmented sleep during the final 60 minutes of said period; and administering to the patient, prior to the start of the sleep period, doxepin or a pharmaceutically acceptable salt thereof in dosage that is effective to improve sleep maintenance insomnia by reducing fragmented sleep during the 8^{th} hour of the sleep period, wherein the dosage is at least 3 mg, and up to 6 mg.

60. On information and belief, Taro will knowingly provide Taro's ANDA Products with instructions for administering those products in a manner that directly infringes one or more claims of the '898 patent. On information and belief, if Taro's ANDA is approved, physicians and/or patients following said instructions will directly infringe the '898 patent. On information and belief, if Taro's ANDA is approved, Taro will actively encourage, recommend, or promote this infringement with knowledge of the '898 patent and knowledge that its acts will induce infringement of the '898 patent.

COUNT IV

INFRINGEMENT OF THE '437 PATENT

61. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

62. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Products throughout

the United States, including in this judicial district, prior to expiration of the '437 patent. By submitting its ANDA, Taro committed an act of infringement of the '437 patent under 35 U.S.C. § 271(e)(2)(A).

63. On information and belief, Taro's manufacture, use, offer for sale, sale, and/or importation into the United States of Taro's ANDA Products prior to the expiration of the '437 patent will infringe the '437 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the '437 patent.

64. The '437 patent claims, *inter alia*, methods wherein doxepin or a pharmaceutically acceptable salt thereof is administered to treat sleep maintenance insomnia characterized by fragmented sleep. For example, claim 1 of the '437 patent claims the following:

> A method for treating sleep maintenance insomnia characterized by fragmented sleep during the 8^{th} hour of sleep, the method comprising: administering a dosage of doxepin or a pharmaceutically acceptable salt thereof to a patient having a sleep disorder in which, for a given 8 hour period of desired sleep, the patient experiences fragmented sleep during the final 60 minutes of said period, wherein the dosage of doxepin is between about 0.5 and about 6 mg and is administered prior to the start of the sleep period.

65. On information and belief, Taro will knowingly provide Taro's ANDA Products with instructions for administering those products in a manner that directly infringes one or more claims of the '437 patent. On information and belief, if Taro's ANDA is approved, physicians and/or patients following said instructions will directly infringe the '437 patent. On information and belief, if Taro's ANDA is approved, Taro will actively encourage, recommend, or promote this infringement with knowledge of the '437 patent and knowledge that its acts will induce infringement of the '437 patent.

COUNT V

INFRINGEMENT OF THE '814 PATENT

66. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

67. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Products throughout the United States, including in this judicial district, prior to expiration of the '814 patent. By submitting its ANDA, Taro committed an act of infringement of the '814 patent under 35 U.S.C. § 271(e)(2)(A).

68. On information and belief, Taro's manufacture, use, offer for sale, sale, and/or importation into the United States of Taro's ANDA Products prior to the expiration of the '814 patent will infringe the '814 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the '814 patent.

69. The '814 patent claims, *inter alia*, methods for treating insomnia wherein doxepin is administered at least three hours after consuming a meal. For example, claim 1 of the '814 patent claims the following:

> A method of treating insomnia, the method comprising administering between about 0.5 mg and about 7 mg doxepin to a patient in need thereof, wherein the doxepin is administered before bedtime and at least three hours after consuming a meal, thereby providing a faster onset of action and reducing next day residual effects.

70. On information and belief, Taro will knowingly provide Taro's ANDA Products with instructions for administering those products in a manner that directly infringes one or more claims of the '814 patent. On information and belief, if Taro's ANDA is approved, physicians and/or patients following said instructions will directly infringe the '814 patent. On information and belief, if Taro's ANDA is approved, Taro will actively encourage, recommend, or promote

this infringement with knowledge of the '814 patent and knowledge that its acts will induce infringement of the '814 patent.

COUNT VI

INFRINGEMENT OF THE '607 PATENT

71. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

72. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Products throughout the United States, including in this judicial district, prior to expiration of the '607 patent. By submitting its ANDA, Taro committed an act of infringement of the '607 patent under 35 U.S.C. § 271(e)(2)(A).

73. On information and belief, Taro's manufacture, use, offer for sale, sale, and/or importation into the United States of Taro's ANDA Products prior to the expiration of the '607 patent will infringe the '607 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the '607 patent.

74. The '607 patent claims, *inter alia*, methods wherein doxepin or a pharmaceutically acceptable salt thereof is administered to treat insomnia characterized by difficulties with sleep maintenance. For example, claim 1 of the '607 patent claims the following:

> A method for treating insomnia characterized by difficulties with sleep maintenance, the method comprising: administering a dosage of doxepin or a pharmaceutically acceptable salt thereof to a patient having a sleep disorder in which, for a given 8 hour period of desired sleep, the patient experiences fragmented sleep during the final 60 minutes of said period, wherein the dosage of doxepin is between about 1 and about 6 mg and is administered prior to the start of the sleep period.

75. On information and belief, Taro will knowingly provide Taro's ANDA Products with instructions for administering those products in a manner that directly infringes one or more

claims of the ’607 patent. On information and belief, if Taro’s ANDA is approved, physicians and/or patients following said instructions will directly infringe the ’607 patent. On information and belief, if Taro’s ANDA is approved, Taro will actively encourage, recommend, or promote this infringement with knowledge of the ’607 patent and knowledge that its acts will induce infringement of the ’607 patent.

COUNT VII

INFRINGEMENT OF THE ’620 PATENT

76. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

77. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro’s ANDA Products throughout the United States, including in this judicial district, prior to expiration of the ’620 patent. By submitting its ANDA, Taro committed an act of infringement of the ’620 patent under 35 U.S.C. § 271(e)(2)(A).

78. On information and belief, Taro’s manufacture, use, offer for sale, sale, and/or importation into the United States of Taro’s ANDA Products prior to the expiration of the ’620 patent will infringe the ’620 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the ’620 patent.

79. The ’620 patent claims, *inter alia*, methods to treat insomnia wherein doxepin or a pharmaceutically acceptable salt thereof is administered prior to bedtime. For example, claim 1 of the ’620 patent claims the following:

> A method for treating insomnia, the method comprising: administering an oral formulation comprising doxepin or a pharmaceutically acceptable salt thereof to a patient having a sleep disorder in which, for a given 8 hour period of desired sleep, the patient experiences fragmented sleep during the final 60 minutes of said period, wherein the oral formulation comprises a dosage of

doxepin between about 1 and about 7 mg and is administered prior to bedtime.

80. On information and belief, Taro will knowingly provide Taro's ANDA Products with instructions for administering those products in a manner that directly infringes one or more claims of the '620 patent. On information and belief, if Taro's ANDA is approved, physicians and/or patients following said instructions will directly infringe the '620 patent. On information and belief, if Taro's ANDA is approved, Taro will actively encourage, recommend, or promote this infringement with knowledge of the '620 patent and knowledge that its acts will induce infringement of the '620 patent.

COUNT VIII

INFRINGEMENT OF THE '660 PATENT

81. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

82. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Products throughout the United States, including in this judicial district, prior to expiration of the '660 patent. By submitting its ANDA, Taro committed an act of infringement of the '660 patent under 35 U.S.C. § 271(e)(2)(A).

83. On information and belief, Taro's manufacture, use, offer for sale, sale, and/or importation into the United States of Taro's ANDA Products prior to the expiration of the '660 patent will infringe the '660 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the '660 patent.

84. The '660 patent claims, *inter alia*, methods for treating insomnia wherein doxepin is administered at least three hours after consuming a meal. For example, claim 1 of the '660 patent claims the following:

> A method of treating insomnia in a patient in need thereof, the method comprising: administering between about 0.5 mg and about 7 mg doxepin to the patient, wherein the doxepin is administered at least 3 hours after consuming a meal to provide faster onset of action and minimize potential for next day sedation effects.

85. On information and belief, Taro will knowingly provide Taro's ANDA Products with instructions for administering those products in a manner that directly infringes one or more claims of the '660 patent. On information and belief, if Taro's ANDA is approved, physicians and/or patients following said instructions will directly infringe the '660 patent. On information and belief, if Taro's ANDA is approved, Taro will actively encourage, recommend, or promote this infringement with knowledge of the '660 patent and knowledge that its acts will induce infringement of the '660 patent.

COUNT IX

INFRINGEMENT OF THE '662 PATENT

86. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

87. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Products throughout the United States, including in this judicial district, prior to expiration of the '662 patent. By submitting its ANDA, Taro committed an act of infringement of the '662 patent under 35 U.S.C. § 271(e)(2)(A).

88. On information and belief, Taro's manufacture, use, offer for sale, sale, and/or importation into the United States of Taro's ANDA Products prior to the expiration of the '662 patent will infringe the '662 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the '662 patent.

89. The ’662 patent claims, *inter alia*, methods to treat insomnia wherein doxepin or a pharmaceutically acceptable salt thereof is administered prior to bedtime. For example, claim 1 of the ’662 patent claims the following:

> A method for treating insomnia, the method comprising: administering an oral formulation comprising doxepin or a pharmaceutically acceptable salt thereof to a patient having a sleep disorder in which, for a given 8 hour period of desired sleep, the patient has difficulty staying asleep during the final 60 minutes of said period, wherein the oral formulation comprises a dosage of doxepin between about 1 and about 7 mg and is administered prior to the bedtime.

90. On information and belief, Taro will knowingly provide Taro’s ANDA Products with instructions for administering those products in a manner that directly infringes one or more claims of the ’662 patent. On information and belief, if Taro’s ANDA is approved, physicians and/or patients following said instructions will directly infringe the ’662 patent. On information and belief, if Taro’s ANDA is approved, Taro will actively encourage, recommend, or promote this infringement with knowledge of the ’662 patent and knowledge that its acts will induce infringement of the ’662 patent.

COUNT X

INFRINGEMENT OF THE ’074 PATENT

91. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

92. Taro submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Taro’s ANDA Products throughout the United States, including in this judicial district, prior to expiration of the ’074 patent. By submitting its ANDA, Taro committed an act of infringement of the ’074 patent under 35 U.S.C. § 271(e)(2)(A).

93. On information and belief, Taro’s manufacture, use, offer for sale, sale, and/or importation into the United States of Taro’s ANDA Products prior to the expiration of the ’074

patent will infringe the ’074 patent under 35 U.S.C. § 271(b). Taro will infringe one or more of the claims of the ’074 patent.

94. The ’074 patent claims, *inter alia*, methods for treating insomnia wherein doxepin is administered at least three hours after consuming a meal. For example, claim 1 of the ’074 patent claims the following:

> A method of treating insomnia, the method comprising: administering between about 0.5 mg and 7 mg doxepin to a patient in need thereof, wherein the doxepin is administered at least 3 hours after consuming a meal to provide faster onset of action.

95. On information and belief, Taro will knowingly provide Taro’s ANDA Products with instructions for administering those products in a manner that directly infringes one or more claims of the ’074 patent. On information and belief, if Taro’s ANDA is approved, physicians and/or patients following said instructions will directly infringe the ’074 patent. On information and belief, if Taro’s ANDA is approved, Taro will actively encourage, recommend, or promote this infringement with knowledge of the ’074 patent and knowledge that its acts will induce infringement of the ’074 patent.

PRAYER FOR RELIEF

WHEREFORE, Currax respectfully requests the following relief:

A. A judgment that Taro has infringed one or more claims of the ’307, ’299, ’898, ’437, ’814, ’607, ’620, ’660, ’662, and/or ’074 patents by submitting its ANDA seeking FDA approval for the manufacture, use, offer for sale, sale, and/or importation of Taro’s ANDA Products under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Taro’s manufacture, use, offer for sale, sale, and/or importation into the United States of Taro’s ANDA Products will infringe one or more claims of the ’307, ’299, ’898, ’437, ’814, ’607, ’620, ’660, ’662, and/or ’074 patents under 35 U.S.C. § 271 (b);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Taro, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the manufacture, use, offer for sale, sale, and/or importation into the United States of Taro's ANDA Products prior to the expiration dates of the '307, '299, '898, '437, '814, '607, '620, '660, '662, and/or '074 patents;

D. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Taro's ANDA shall be a date that is not earlier than the expiration dates of the '307, '299, '898, '437, '814, '607, '620, '660, '662, and/or '074 patents;

E. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorney fees;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: July 2, 2024

/s/ Zachary L. Garrett

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