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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CURRAX PHARMACEUTICALS LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LIMITED, TARO PHARMACEUTICALS INC. and TARO PHARMACEUTICALS U.S.A., INC. Defendants.	C.A. No. 1:24-cv-07446 (CPO)(EAP)

TARO'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO THE COMPLAINT

Defendants Taro Pharmaceutical Industries Limited, Taro Pharmaceuticals Inc. and Taro Pharmaceuticals U.S.A., Inc. (collectively "Taro"), by its counsel, hereby responds to the allegations in the Complaint set forth by the Plaintiff Currax Pharmaceuticals LLC ("Currax") against Taro. This response is based on Taro's current knowledge as to its own activities, and on information and belief as to the activities of others. If not specifically admitted herein, the

allegations of the Complaint are denied. The headings in Plaintiff's complaint are copied herein for convenience only, and any allegations in such headings are denied.

NATURE OF THE ACTION

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

ANSWER: The allegations in paragraph 1 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits Plaintiff purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq.

THE 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.

ANSWER: Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this paragraph of the Complaint and, therefore, denies them.

3. On information and belief, Taro Pharmaceutical Industries Limited ("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.

ANSWER: Taro admits that Taro Ltd. is a company organized and existing under the laws of Israel with a 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).

ANSWER: Taro admits that Taro Ltd.'s website at https://www.taro.com/research includes, among others, as of September 15, 2024, the following statements: "Taro is a research-based international pharmaceutical company that was established on the principal that research and development would be the cornerstone of its growth strategy." "Taro develops high-quality, proprietary and off-patent pharmaceuticals for markets in the US, Canada, Israel and other countries around the world." Taro otherwise denies the remaining allegations in paragraph 4.

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.gcsweb.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.

ANSWER: Taro admits Taro Ltd.'s SEC Form 20-F (fiscal year end March 31, 2023) states on page 44, among other things, that: "[w]e are a multinational, science-based pharmaceutical company. We develop, manufacture and market Rx and OTC pharmaceutical products, primarily in the U.S., Canada, Israel and Japan. We also develop and manufacture APIs primarily for use in

our finished dosage form products." Taro admits Taro Ltd.'s SEC Form 20-F (fiscal year end March 31, 2023) states on page 30, among other things, that "[a]s 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. In addition, there are numerous products for which either development or internal regulatory work is in process. The applications pending before the FDA are at various stages in the review process, and there can be no assurance that we will be able to successfully complete any remaining testing or that, upon completion of such testing, approvals will be granted. In addition, there can be no assurance that the FDA will not grant approvals for competing products submitted by our competitors prior to, simultaneous with or after granting approval to us." Taro admits Taro Ltd.'s SEC Form 20-F (fiscal year end March 31, 2023) states on page 30, among other things, that "[i]n the year ended March 31, 2023, revenue in the U.S. accounted for 63% of total consolidated net sales." Taro admits that Taro Ltd.'s SEC Form 20-F (fiscal year end March 31, 2023 states on page 44, among other things, that "[w]e generate most of our revenue from the sale of Rx and OTC pharmaceutical products." Taro otherwise denies the remaining allegations in paragraph 5.

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 Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Taro in this action, Taro Ltd. does not contest venue or personal jurisdiction for purposes of this action only, and expressly reserves the right to contest venue and personal jurisdiction in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 6.

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.

ANSWER: Taro admits that Taro Pharmaceuticals Inc. ("Taro Canada" or "Taro Inc.") is a corporation organized and existing under the laws of Canada and has a place of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada, and that Taro Canada is a subsidiary of Taro Ltd. Taro otherwise denies the remaining allegations in paragraph 7.

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.

ANSWER: Taro admits that Taro Ltd.'s SEC Form 20-F (fiscal year end March 31, 2023) includes a table with a heading principal activities and under the heading it states the following about "Taro Canada": "Manufactures more than 200 finished dosage form pharmaceutical products for sale in Canada and for export to the U.S. and other markets. Markets and distributes both proprietary and generic products in the Canadian market. Performs research and development", and the following under the heading "Primary Product Lines": Dermatology: Rx and OTC semi-solid products (creams, ointments, lotions and gels) and liquid products; Allergy (Antihistamine): OTC oral dosage products. Taro otherwise denies the remaining allegations in paragraph 8.

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 Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro Inc. admits that it is in the business of marketing and selling drug products in Canada and manufacturing certain finished dosage form pharmaceutical products for export to markets outside of Canada. Taro otherwise denies the remaining allegations in paragraph 9.

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.

ANSWER: Taro admits that Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") is a corporation organized and existing under the laws of New York and has a place of business at 3 Skyline Dr, Hawthorne, NY 10532 and is a subsidiary to Taro Ltd. Taro otherwise denies the remaining allegations in paragraph 10.

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

ANSWER: Taro admits that Taro Ltd.'s SEC Form 20-F (fiscal year end March 31, 2023) includes a table with a heading principal activities and under the heading it states the following about Taro USA: "Markets and distributes both proprietary and generic products in the U.S. market. Performs regulatory, post marketing and clinical activities." Taro otherwise denies the remaining allegations in paragraph 11.

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 Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro USA admits that it is in the business of marketing and/or selling drug products in the United States. Taro otherwise denies the remaining allegations in paragraph 12.

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.

ANSWER: The allegations in paragraph 13 comprise speculation of future events and conclusions of law to which no answer is required. To the extent a response is required, Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the Food and Drug Administration ("FDA") seeking approval to market Doxepin Tablets, 3 mg and 6 mg. Taro otherwise denies the remaining allegations in paragraph 13.

JURISDICTION & VENUE

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

ANSWER: The allegations in paragraph 14 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 for the purposes of this matter only. Taro otherwise denies the remaining allegations in paragraph 14.

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

ANSWER: The allegations in paragraph 15 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Taro in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro does not contest venue, and expressly reserves the right to contest venue in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 15.

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 Jersey and throughout the United States.

ANSWER: The allegations in paragraph 16 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Taro in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro Ltd. and Taro USA do not contest personal jurisdiction, and expressly reserve the right to contest personal jurisdiction in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 16, and specifically denies that "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 Jersey 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 Jersey. 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.

ANSWER: The allegations in paragraph 17 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Taro in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro Ltd. does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 17.

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.

ANSWER: The allegations in paragraph 18 comprise speculation of future events and conclusions of law to which no answer is required. To the extent a response is required, Taro admits that Taro Ltd. is in the business of manufacturing, marketing, and selling pharmaceutical products, including generic drug products in the United States. Taro admits that solely for the purposes of Plaintiff's claims against Taro Ltd. in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro Ltd. does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 18.

19. In the alternative, if Taro Ltd.'s contacts with New Jersey 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).

ANSWER: The allegations in paragraph 19 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that solely for the purposes of Plaintiff's claims against Taro Ltd. in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro Ltd. does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 19.

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 Jersey. 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.

ANSWER: The allegations in paragraph 20 comprise speculation of future events and conclusions of law to which no answer is required. To the extent a response is required, denied.

21. In the alternative, if Taro Inc.'s contacts with New Jersey 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).

ANSWER: The allegations in paragraph 21 comprise conclusions of law to which no answer is required. To the extent a response is required, denied.

22. This Court has personal jurisdiction over Taro USA at least because Taro USA maintains a place of business in New Jersey at 1 Commerce Drive, Cranbury, New Jersey 08512. On information and belief, Taro USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100917783 and registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5003062.

ANSWER: The allegations in paragraph 22 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that solely for the purposes of Plaintiff's claims against Taro USA in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro USA does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 22.

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.

ANSWER: The allegations in paragraph 23 comprise speculation of future events and conclusions of law to which no answer is required. To the extent a response is required, Taro admits that Taro USA is in the business of manufacturing, marketing, and selling pharmaceutical products, including generic drug products in the United States. Taro admits that solely for the purposes of Plaintiff's claims against Taro USA in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro USA does not contest personal jurisdiction, and

expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 23.

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.

ANSWER: The allegations in paragraph 24 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Taro in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro Ltd. does not contest venue, and expressly reserves the right to contest venue in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 24.

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.

ANSWER: The allegations in paragraph 25 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Taro in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro Inc. does not contest venue, and expressly reserves the right to contest venue in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 25.

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.

ANSWER: The allegations in paragraph 26 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against

Taro in this case as they apply to Taro's Proposed ANDA Product described in Taro's ANDA No. 219058, Taro USA does not contest venue, and expressly reserves the right to contest venue in any other case as to any other part. Taro otherwise denies the remaining allegations in paragraph 26.

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.

ANSWER: Taro admits that the records of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," indicate that Currax Pharmaceuticals LLC holds New Drug Application ("NDA") No. 22-036 for Silenor® (doxepin hydrochloride) oral tablets (EQ 3 mg base and EQ 6 mg base) and that the NDA was approved by FDA on March 17, 2010. Taro further admits that, according to the records of the FDA, the label for Silenor® states: "SILENOR (doxepin) tablets are indicated for the treatment of insomnia characterized by difficulties with sleep maintenance." Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 7,915,307 ("the '307 patent") states on its face that it was issued on March 29, 2011. Taro admits that Currax purports to attach a copy of the '307 patent to the Complaint as Exhibit A. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 8,513,299 ("the '299 patent") states on its face that it was issued on August 20, 2013. Taro admits that Currax purports to attach a copy of the '299 patent to the Complaint as Exhibit B. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 9,107,898 ("the '898 patent") states on its face that it was issued on August 18, 2015. Taro admits that Currax purports to attach a copy of the '898 patent to the Complaint as Exhibit C. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 9,486,437 ("the '437 patent") states on its face that it was issued on August 18, 2015. Taro admits that Currax purports to attach a copy of the '437 patent to the Complaint as Exhibit D. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 9,572,814 ("the '814 patent") states on its face that it was issued on February 21, 2017. Taro admits that Currax purports to attach a copy of the '814 patent to the Complaint as Exhibit E. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 9,861,607 ("the '607 patent") states on its face that it was issued on January 9, 2018. Taro admits that Currax purports to attach a copy of the '607 patent to the Complaint as Exhibit F. Taro lacks knowledge or information sufficient to form a

belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 10,238,620 ("the '620 patent") states on its face that it was issued on March 26, 2019. Taro admits that Currax purports to attach a copy of the '620 patent to the Complaint as Exhibit G. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 10,653,660 ("the '660 patent") states on its face that it was issued on May 19, 2020. Taro admits that Currax purports to attach a copy of the '660 patent to the Complaint as Exhibit H. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 10,653,662 ("the '662 patent") states on its face that it was issued on May 19, 2020. Taro admits that Currax purports to attach a copy of the '662 patent

to the Complaint as Exhibit I. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that U.S. Patent No. 11,110,074 ("the '074 patent") states on its face that it was issued on September 7, 2021. Taro admits that Currax purports to attach a copy of the '074 patent to the Complaint as Exhibit J. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that the Orange Book identifies the '307, '299, '898, '437, '814, '607, '620, '660, '662, and '074 patents in the Orange Book in connection with SILENOR. Taro lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

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.

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) seeking approval

to market Doxepin Tablets, 3 mg and 6 mg and that Taro's Proposed ANDA Product identifies Currax's Silenor® (doxepin) tablets as the reference listed drug. Taro otherwise denies the remaining allegations in paragraph 39.

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.

ANSWER: Taro admits that, on May 21, 2024, Taro USA sent a letter ("Notice Letter") to Plaintiff. Taro admits that, according to the Notice Letter, Taro USA seeks approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Taro's Proposed ANDA Products prior to the expiration of the '307, '299, '898, '437, '814, '607, '620, '660, '662, and '074 patents pursuant to the patent laws. Taro denies the remaining allegations in paragraph 40.

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.

ANSWER: The allegations in paragraph 41 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits it had knowledge of the '307, '299, '898, '437, '814, '607, '620, '660, '662, and '074 patents as of the time it submitted a Paragraph IV certification. Taro denies the remaining allegations in paragraph 41.

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.

ANSWER: Taro admits that the active ingredient in Taro's Proposed ANDA Products is doxepin hydrochloride, the method of administration is orally, the dosage form is tablets, the strengths are EQ 3 mg and EQ 6 mg, and that Taro's ANDA contains information demonstrating the bioequivalence of Taro's Proposed ANDA Product to the reference listed drug, which is Currax's doxepin tablets. Taro denies the remaining allegations in paragraph 42.

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.

ANSWER: Taro admits that the prescribing information for Taro's Proposed ANDA Products states Taro's Proposed ANDA Products are indicated for the treatment of insomnia characterized by difficulties with sleep maintenance. Taro denies the remaining allegations in paragraph 43.

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.

ANSWER: The allegations in paragraph 44 comprise speculation of future events and conclusions of law to which no answer is required. To the extent a response is required, Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 to the FDA under 21 U.S.C. § 355(j) seeking approval to market Taro's Proposed ANDA Products. Taro denies the remaining allegations in paragraph 44.

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.

ANSWER: Denied.

COUNT 1
INFRINGEMENT OF THE '307 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-45 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro's ANDA No. 219058 contains a Paragraph IV Certification that the '307 patent, among others, is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations in paragraph 47.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in paragraph 49 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the '307 patent attached to Plaintiff's Complaint states: "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." Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

COUNT II
INFRINGEMENT OF THE '299 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-50 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro's ANDA No. 219058 contains a Paragraph IV Certification that the '299 patent, among others, is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations in paragraph 52.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in paragraph 54 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the '299 patent attached to Plaintiff's Complaint states: "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." Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

COUNT III
INFRINGEMENT OF THE '898 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-55 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro's ANDA No. 219058 contains a Paragraph IV Certification that the '898 patent, among others, is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations in paragraph 57.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in paragraph 59 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the '898 patent attached to Plaintiff's Complaint states: "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 8th hour of the sleep period, wherein the dosage is at least 3 mg, and up to 6 mg." Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

COUNT IV
INFRINGEMENT OF THE '437 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-60 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro's ANDA No. 219058 contains a Paragraph IV Certification that the '437 patent, among others, is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations in paragraph 62.

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.

ANSWER: Denied.

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 8th 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.

ANSWER: The allegations in paragraph 64 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the '437 patent attached to Plaintiff's Complaint states: "A method for treating sleep maintenance insomnia characterized by fragmented sleep during the 8th 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." Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

COUNT V
INFRINGEMENT OF THE '814 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-65 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro's ANDA No. 219058 contains a Paragraph IV Certification that the '814 patent, among others, is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations in paragraph 67.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in paragraph 69 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the '814 patent attached to Plaintiff's Complaint states: "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." Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

COUNT VI
INFRINGEMENT OF THE '607 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-70 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro's

ANDA No. 219058 contains a Paragraph IV Certification that the '607 patent, among others, is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations in paragraph 72.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in paragraph 74 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the '607 patent attached to Plaintiff's Complaint states: "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." Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

COUNT VII
INFRINGEMENT OF THE '620 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-75 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro's ANDA No. 219058 contains a Paragraph IV Certification that the '620 patent, among others, is

invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations in paragraph 77.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in paragraph 79 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the '620 patent attached to Plaintiff's Complaint states: "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." Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

COUNT VIII
INFRINGEMENT OF THE '660 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-80 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro's ANDA No. 219058 contains a Paragraph IV Certification that the '660 patent, among others, is

invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations in paragraph 82.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in paragraph 84 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the '660 patent attached to Plaintiff's Complaint states: "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." Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

COUNT IX
INFRINGEMENT OF THE ’662 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-85 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro’s ANDA No. 219058 (Taro’s Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro’s ANDA No. 219058 contains a Paragraph IV Certification that the ’662 patent, among others, is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro’s Proposed ANDA Product. Taro denies the remaining allegations in paragraph 87.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in paragraph 89 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the '662 patent attached to Plaintiff's Complaint states: "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." Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

COUNT X
INFRINGEMENT OF THE '074 PATENT

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

ANSWER: Taro realleges its answers to the allegations of paragraphs 1-90 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).

ANSWER: Taro admits that Taro USA, on behalf of Taro Ltd., submitted Taro's ANDA No. 219058 (Taro's Proposed ANDA Product) to the FDA under 21 U.S.C. § 355(j) and that Taro's ANDA No. 219058 contains a Paragraph IV Certification that the '074 patent, among others, is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations in paragraph 92.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in paragraph 94 comprise conclusions of law to which no answer is required. To the extent a response is required, Taro admits that claim 1 of the ’074 patent attached to Plaintiff’s Complaint states: “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.” Taro lacks sufficient information to form a belief as to the truth of the remaining allegations, and therefore, denies them.

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.

ANSWER: Denied.

PRAYER FOR RELIEF

Taro denies that Plaintiff is entitled to judgment or any of the relief sought against Taro in paragraphs (a)-(f) under the heading "PRAYER FOR RELIEF" in the Complaint. Taro demands judgment in its favor.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, Taro pleads the following separate defenses in response to Plaintiff's allegations. Taro reserves the right to allege any and all defenses not presently known or revealed during discovery or other analysis.

FIRST DEFENSE

Plaintiff has failed to state a claim for which relief can be granted.

SECOND DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '307 patent.

THIRD DEFENSE

The claims of the '307 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

FOURTH DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '299 patent.

FIFTH DEFENSE

The claims of the '299 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

SIXTH DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '898 patent.

SEVENTH DEFENSE

The claims of the '898 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

EIGHTH DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '437 patent.

NINTH DEFENSE

The claims of the '437 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

TENTH DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '814 patent.

ELEVENTH DEFENSE

The claims of the '814 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

TWELFTH DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '607 patent.

THIRTEENTH DEFENSE

The claims of the '607 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

FOURTEENTH DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '620 patent.

FIFTEENTH DEFENSE

The claims of the '620 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

SIXTEENTH DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '660 patent.

SEVENTEENTH DEFENSE

The claims of the '660 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

EIGHTEENTH DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '662 patent.

NINETEENTH DEFENSE

The claims of the '662 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

TWENTIETH DEFENSE

Taro has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '074 patent.

TWENTY-FIRST DEFENSE

The claims of the '074 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

TWENTY-SECOND DEFENSE

Plaintiff may not seek injunctive relief against Taro for at least the reason that Plaintiff's alleged damages are not immediate or irreparable and Plaintiff therefore has an adequate remedy at law.

TWENTY-THIRD DEFENSE

Plaintiff has failed to allege any facts supporting this is an exceptional case or an award of attorneys' fees under 35 U.S.C. § 285 or otherwise. Plaintiff is not entitled to a finding that this case is exceptional under 35 U.S.C. § 285 or otherwise.

TWENTY-FOURTH DEFENSE

Plaintiff lacks subject matter jurisdiction for any infringement claim under 35 U.S.C. § 271 (a), (b), and (c).

ADDITIONAL DEFENSES

Taro reserves the right to allege additional separate defenses as they become known through the course of discovery.

COUNTERCLAIMS

Without admitting any of the allegations of Plaintiff/Counterclaim-Defendant Currax Pharmaceuticals, LLC ("Plaintiff/Counterclaim-Defendant" or "Currax") other than those expressly admitted herein, and without prejudice to Defendant/Counterclaim-Plaintiff Taro Pharmaceutical Industries Limited and Taro Pharmaceuticals USA, Inc. ("Taro") to plead additional counterclaims as the facts of the matter warrant, Taro asserts the following counterclaims against Currax:

NATURE OF THE ACTION

1. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and seek a declaratory judgment that Taro's proposed products in Abbreviated New Drug Application ("ANDA") No. 219058 do not and will not infringe any valid and enforceable claim of U.S. Patent Nos. 11,110,074 ("the '074 patent"), 10,653,662 ("the '662 patent"), 10,653,660 ("the '660 patent"), 10,238,620 ("the '620 patent"), 9,861,607 ("the '607 patent"), 9,572,814 ("the '814 patent"), 9,486,437 ("the '437 patent"), 9,107,898 ("the '898 patent"), 8,513,299 ("the '299 patent"), 7,915,307 ("the '307 patent"), 11,234,954 ("the '954 patent"), 11,096,920 ("the '920 patent"), 9,907,780 ("the '780 patent"), 9,532,971 ("the '971 patent"), and 10,548,871 ("the '871 patent") (collectively, "the patents-in-suit"), and that each and every claim of the patents-in-suit are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

2. Upon information and belief, a true and complete copy of the '307 patent is attached to the Complaint (D.I. 1) as Exhibit A.

3. Upon information and belief, a true and complete copy of the '299 patent is attached to the Complaint (D.I. 1) as Exhibit B.

4. Upon information and belief, a true and complete copy of the ’898 patent is attached to the Complaint (D.I. 1) as Exhibit C.

5. Upon information and belief, a true and complete copy of the ’437 patent is attached to the Complaint (D.I. 1) as Exhibit D.

6. Upon information and belief, a true and complete copy of the ’814 patent is attached to the Complaint (D.I. 1) as Exhibit E.

7. Upon information and belief, a true and complete copy of the ’607 patent is attached to the Complaint (D.I. 1) as Exhibit F.

8. Upon information and belief, a true and complete copy of the ’620 patent is attached to the Complaint (D.I. 1) as Exhibit G.

9. Upon information and belief, a true and complete copy of the ’660 patent is attached to the Complaint (D.I. 1) as Exhibit H.

10. Upon information and belief, a true and complete copy of the ’662 patent is attached to the Complaint (D.I. 1) as Exhibit I.

11. Upon information and belief, a true and complete copy of the ’074 patent is attached to the Complaint (D.I. 1) as Exhibit J.

12. Upon information and belief, a true and complete copy of the ’954 patent is attached to Taro’s Counterclaims as Exhibit K.

13. Upon information and belief, a true and complete copy of the ’920 patent is attached to Taro’s Counterclaims as Exhibit L.

14. Upon information and belief, a true and complete copy of the ’780 patent is attached to Taro’s Counterclaims as Exhibit M.

15. Upon information and belief, a true and complete copy of the '971 patent is attached to Taro's Counterclaims as Exhibit N.

16. Upon information and belief, a true and complete copy of the '871 patent is attached to Taro's Counterclaims as Exhibit O.

PARTIES

17. Defendant/Counterclaim-Plaintiff Taro Pharmaceutical Industries Limited ("Taro Ltd." or "Taro") is a company incorporated under the laws of Israel, having a place of business in Haifa Bay, Israel.

18. Defendant/Counterclaim-Plaintiff Taro Pharmaceuticals USA, Inc. ("Taro USA" or "Taro") is a company incorporated under the laws of the state of New York, having a place of business in Hawthorne, New York.

19. On information and belief, and based on Plaintiff/Counterclaim-Defendant's allegations, Plaintiff/Counterclaim-Defendant 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.

20. Currax purports to be a lawful owner of the '307, '299, '898, '437, '814, '607, '620, '660, '662, '074, '954, '920, '780, '871, and '971 patents (collectively, "Patents-in-Suit").

21. Currax purports to hold the New Drug Application ("NDA") No. 22-036 for Silenor® (doxepin hydrochloride) 3 mg and 6 mg tablets and purports to market, distribute, and sell the doxepin products.

JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an

actual controversy among the parties, arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

23. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant based on, *inter alia*, its filing of this lawsuit in this jurisdiction, and/or Plaintiff/Counterclaim-Defendant's substantial business in and regular systematic contact with this District. Counterclaim-defendant has also availed itself of this forum in other pending actions, *e.g.*, *Currax Pharmaceuticals LLC v. Aurolife Pharma LLC*, Civil Action No. 1-21-cv-20765; *Currax Pharmaceuticals LLC v. Ajanta Pharma Limited et al*, Civil Action No. 1-23-cv-03937.

24. Venue is proper in this judicial district based on 28 U.S.C. §§ 1391 and 1400 and 21 U.S.C. § 355(j)(5)(C)(i)(II).

BACKGROUND

25. According to the United States Food & Drug Administration ("FDA") publication titled Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), Currax holds an approved New Drug Application ("NDA") No. 22-036 for doxepin hydrochloride 3 mg and 6 mg tablets.

26. Under 21 U.S.C. § 355(b)(1), an NDA holder must provide to FDA the patent numbers and expiration dates of any patent(s) that the NDA holder believes "claims the drug for which the applicant submitted the [NDA]" or which "claims a method of using such drug." FDA ministerially publishes these patents in the Orange Book.

27. Upon information and belief, and as stated in the Complaint in this matter, Currax is the owner of the '307, '814, '660, and '074 patents.

28. Upon information and belief, and as stated in the Complaint in this matter, Currax is an owner of and the exclusive licensee with all substantial rights to the ’299, ’898, ’437,’607, ’620, and ’662 patents.

29. Upon information and belief Currax is the owner of the ’954, ’920, ’971, ’780, and ’871 patents.

30. Upon information and belief, Currax, itself or through its agents, caused the Patents-in-Suit to be listed in the Orange Book as patents that claim its doxepin products or a method of using its doxepin products.

31. The ’307 patent, on its face, is titled “Methods of Improving the Pharmacokinetics of Doxepin” and has an issue date of March 29, 2011.

32. The ’299 patent, on its face, is titled “Methods of Using Low-Dose Doxepin for the Improvement of Sleep” and has an issue date of August 20, 2013.

33. The ’898 patent, on its face, is titled “Methods of Using Low-Dose Doxepin for the Improvement of Sleep” and has an issue date of August 18, 2015.

34. The ’437 patent, on its face, is titled “Methods of Using Low-Dose Doxepin for the Improvement of Sleep” and has an issue date of November 8, 2016.

35. The ’814 patent, on its face, is titled “Methods of Improving the Pharmacokinetics of Doxepin” and has an issue date of February 21, 2017.

36. The ’607 patent, on its face, is titled “Methods of Using Low-Dose Doxepin for the Improvement of Sleep” and has an issue date of January 9, 2018.

37. The ’620 patent, on its face, is titled “Methods of Using Low-Dose Doxepin for the Improvement of Sleep ” and has an issue date of March 26, 2019.

38. The ’660 patent, on its face, is titled “Methods ofImproving the Pharmacokinetics of Doxepin ” and has an issue date of May 19, 2020.

39. The ’662 patent, on its face, is titled “Methods of Using Low-Dose Doxepin for the Improvement of Sleep” and has an issue date of May 19, 2020.

40. The ’074 patent, on its face, is titled “Methods of Improving the Pharmacokinetics of Doxepin” and has an issue date of September 7, 2021.

41. The ’954 patent, on its face, is titled “Low-Dose Doxepin for Treatment of Sleep Disorders in Elderly Patients” and has an issue date of February 1, 2022.

42. The ’971 patent, on its face, is titled “Low-Dose Doxepin Formulations and Methods of Making and Using the Same” and has an issue date of January 3, 2017.

43. The ’780 patent, on its face, is titled “Low-Dose Doxepin Formulations and Methods of Making and Using the Same” and has an issue date of March 6, 2018.

44. The ’871 patent, on its face, is titled “Low-Dose Doxepin Formulations and Methods of Making and Using the Same” and has an issue date of February 4, 2020.

45. The ’920 patent, on its face, is titled “Low-Dose Doxepin Formulations and Methods of Making and Using the Same” and has an issue date of August 24, 2021.

46. Taro USA, on behalf of Taro Ltd., submitted Taro’s ANDA No. 219058 (Taro’s Proposed ANDA Product) to the Food and Drug Administration (“FDA”) seeking approval to market the products described therein (“Taro’s Proposed ANDA Product”) in the United States.

47. ANDA No. 219058 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Taro’s Proposed ANDA Product.

48. On or around May 21, 2024, Taro sent a notice letter providing notice of its submission of ANDA No. 219058 to FDA ("the Notice Letter") to Currax. The Notice Letter contains notification of Taro's Paragraph IV Certification to FDA that the Patents-in-Suit are invalid, unenforceable, and/or not infringed by Taro's Proposed ANDA Product and the factual and legal bases in support thereof. The Notice Letter also contained an offer of confidential access to ANDA No. 219058 in accordance with 21 U.S.C. § 355(j)(5)(C).

49. On or around July 1, 2024, Plaintiff/Counterclaim-Defendant filed a lawsuit, alleging, *inter alia*, infringement of the '307, '299, '898, '437, '814, '607, '620, '660, '662, and '074 patents based on Taro's filing of ANDA No. 219058 (hereinafter, "Complaint").

50. Plaintiff/Counterclaim-Defendant did not allege infringement of the '954, '971, '780, '871, and '920 patents in its Complaint against Taro despite receiving Taro's Notice Letter that included these patents.

51. Taro denies it infringes any valid claim of the Patents-in-Suit.

52. Absent a ruling from this Court finding the Patents-in-Suit are invalid, unenforceable, and/or not infringed by Taro or the products described in ANDA No. 219058, Currax will continue to assert the '307, '299, '898, '437, '814, '607, '620, '660, '662, and '074 patents against Taro, hindering the ability of Taro to obtain regulatory approval and to market in the United States the products described in ANDA No. 219058, causing irreparable harm to Taro's businesses and denying Taro patent certainty.

53. Absent a ruling from this Court finding the Patents-in-Suit are invalid, unenforceable, and/or not infringed by Taro or the products described in ANDA No. 219058, Currax may later assert the '954, '971, '780, '871, and '920 patents against Taro, hindering the ability of Taro to obtain regulatory approval and to market in the United States the products

described in ANDA No. 219058, causing irreparable harm to Taro's businesses and denying Taro patent certainty.

54. Currax has requested both injunctive relief and damages against Taro. Taro has invested significant financial and other resources into the development of Taro's Proposed ANDA Product and in seeking FDA approval. Currax's threats against Taro will continue as long as the disputes identified with respect to the infringement and validity of the Patents-in-Suit remain.

55. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Currax and Taro regarding the Patents-in-Suit, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

COUNT 1
(Declaration of Invalidity of the '307 Patent)

56. Taro incorporates by reference Paragraphs 1 through 55 as if fully set forth herein.

57. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the invalidity of the '307 patent.

58. One or more of the claims of the '307 patent is invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

59. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Taro is entitled to a declaratory judgment that one or more claims of the '307 patent is/are invalid.

COUNT II

(Declaration of Non-Infringement of the '307 Patent)

60. Taro incorporates by reference Paragraphs 1 through 59 as if fully set forth herein.

61. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '307 patent.

62. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '307 patent, either literally or under the doctrine of equivalents, at least because the claims of the '307 patent are invalid, and an invalid claim cannot be infringed.

63. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '307 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '307 patent.

64. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly

or indirectly, any valid and enforceable claim of the '307 patent, either literally or under the doctrine of equivalents.

COUNT III
(Declaration of Invalidity of the '814 Patent)

65. Taro incorporates by reference Paragraphs 1 through 64 as if fully set forth herein.

66. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the invalidity of the '814 patent.

67. One or more of the claims of the '814 patent is invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

68. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Taro is entitled to a declaratory judgment that one or more claims of the '814 patent is/are invalid.

COUNT IV
(Declaration of Non-Infringement of the '814 Patent)

69. Taro incorporates by reference Paragraphs 1 through 68 as if fully set forth herein.

70. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '814 patent.

71. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '814 patent, either literally or under the doctrine of equivalents, at least because the claims of the '814 patent are invalid, and an invalid claim cannot be infringed.

72. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '814 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '814 patent.

73. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '814 patent, either literally or under the doctrine of equivalents.

COUNT V
(Declaration of Invalidity of the '660 Patent)

74. Taro incorporates by reference Paragraphs 1 through 73 as if fully set forth herein.

75. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and

reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the invalidity of the '660 patent.

76. One or more of the claims of the '660 patent is invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

77. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Taro is entitled to a declaratory judgment that one or more claims of the '660 patent is/are invalid.

COUNT VI
(Declaration of Non-Infringement of the '660 Patent)

78. Taro incorporates by reference Paragraphs 1 through 77 as if fully set forth herein.

79. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '660 patent.

80. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '660 patent, either literally or under the doctrine of equivalents, at least because the claims of the '660 patent are invalid, and an invalid claim cannot be infringed.

81. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe),

induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '660 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '660 patent.

82. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '660 patent, either literally or under the doctrine of equivalents.

COUNT VII
(Declaration of Invalidity of the '074 Patent)

83. Taro incorporates by reference Paragraphs 1 through 82 as if fully set forth herein.

84. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the invalidity of the '074 patent.

85. One or more of the claims of the '074 patent is invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

86. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Taro is entitled to a declaratory judgment that one or more claims of the '074 patent is/are invalid.

COUNT VIII
(Declaration of Non-Infringement of the '074 Patent)

87. Taro incorporates by reference Paragraphs 1 through 86 as if fully set forth herein.

88. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '074 patent.

89. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '074 patent, either literally or under the doctrine of equivalents, at least because the claims of the '074 patent are invalid, and an invalid claim cannot be infringed.

90. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '074 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '074 patent.

91. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '074 patent, either literally or under the doctrine of equivalents.

COUNT IX
(Declaration of Invalidity of the '299 Patent)

92. Taro incorporates by reference Paragraphs 1 through 91 as if fully set forth herein.

93. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the invalidity of the '299 patent.

94. One or more of the claims of the '299 patent is invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

95. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Taro is entitled to a declaratory judgment that one or more claims of the '299 patent is/are invalid.

COUNT X
(Declaration of Non-Infringement of the '299 Patent)

96. Taro incorporates by reference Paragraphs 1 through 95 as if fully set forth herein.

97. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '299 patent.

98. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will

contribute) to the infringement of any valid or enforceable claim of the ’299 patent, either literally or under the doctrine of equivalents, at least because the claims of the ’299 patent are invalid, and an invalid claim cannot be infringed.

99. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro’s ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro’s Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the ’299 patent, either literally or under the doctrine of equivalents, at least because Taro’s Proposed ANDA Product is not covered by the claims of the ’299 patent.

100. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the ’299 patent, either literally or under the doctrine of equivalents.

COUNT XI
(Declaration of Non-Infringement of the ’898 Patent)

101. Taro incorporates by reference Paragraphs 1 through 100 as if fully set forth herein.

102. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the ’898 patent.

103. Neither the submission of Taro’s ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro’s Proposed ANDA Product

infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '898 patent, either literally or under the doctrine of equivalents, at least because the claims of the '898 patent are invalid, and an invalid claim cannot be infringed.

104. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '898 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '898 patent.

105. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '898 patent, either literally or under the doctrine of equivalents.

COUNT XII
(Declaration of Non-Infringement of the '437 Patent)

106. Taro incorporates by reference Paragraphs 1 through 105 as if fully set forth herein.

107. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '437 patent.

108. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '437 patent, either literally or under the doctrine of equivalents, at least because the claims of the '437 patent are invalid, and an invalid claim cannot be infringed.

109. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '437 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '437 patent.

110. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '437 patent, either literally or under the doctrine of equivalents.

COUNT XIII
(Declaration of Non-Infringement of the '607 Patent)

111. Taro incorporates by reference Paragraphs 1 through 110 as if fully set forth herein.

112. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and

reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the ’607 patent.

113. Neither the submission of Taro’s ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro’s Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the ’607 patent, either literally or under the doctrine of equivalents, at least because the claims of the ’607 patent are invalid, and an invalid claim cannot be infringed.

114. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro’s ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro’s Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the ’607 patent, either literally or under the doctrine of equivalents, at least because Taro’s Proposed ANDA Product is not covered by the claims of the ’607 patent.

115. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the ’607 patent, either literally or under the doctrine of equivalents.

COUNT XIV
(Declaration of Non-Infringement of the ’620 Patent)

116. Taro incorporates by reference Paragraphs 1 through 115 as if fully set forth herein.

117. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial,

and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '620 patent.

118. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '620 patent, either literally or under the doctrine of equivalents, at least because the claims of the '620 patent are invalid, and an invalid claim cannot be infringed.

119. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '620 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '620 patent.

120. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '620 patent, either literally or under the doctrine of equivalents.

COUNT XV
(Declaration of Non-Infringement of the '662 Patent)

121. Taro incorporates by reference Paragraphs 1 through 120 as if fully set forth herein.

122. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '662 patent.

123. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '662 patent, either literally or under the doctrine of equivalents, at least because the claims of the '662 patent are invalid, and an invalid claim cannot be infringed.

124. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '662 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '662 patent.

125. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '662 patent, either literally or under the doctrine of equivalents.

COUNT XVI
(Declaration of Non-Infringement of the '954 Patent)

126. Taro incorporates by reference Paragraphs 1 through 125 as if fully set forth herein.

127. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '954 patent.

128. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '954 patent, either literally or under the doctrine of equivalents, at least because the claims of the '954 patent are invalid, and an invalid claim cannot be infringed.

129. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '954 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '954 patent.

130. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '954 patent, either literally or under the doctrine of equivalents.

COUNT XVII
(Declaration of Non-Infringement of the '920 Patent)

131. Taro incorporates by reference Paragraphs 1 through 130 as if fully set forth herein.

132. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '920 patent.

133. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '920 patent, either literally or under the doctrine of equivalents, at least because the claims of the '920 patent are invalid, and an invalid claim cannot be infringed.

134. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '920 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '920 patent.

135. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly

or indirectly, any valid and enforceable claim of the '920 patent, either literally or under the doctrine of equivalents.

COUNT XVIII
(Declaration of Non-Infringement of the '971 Patent)

136. Taro incorporates by reference Paragraphs 1 through 135 as if fully set forth herein.

137. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '971 patent.

138. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '971 patent, either literally or under the doctrine of equivalents, at least because the claims of the '971 patent are invalid, and an invalid claim cannot be infringed.

139. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '971 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '971 patent.

140. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '971 patent, either literally or under the doctrine of equivalents.

COUNT XVIV
(Declaration of Invalidity of the '971 Patent)

141. Taro incorporates by reference Paragraphs 1 through 140 as if fully set forth herein.

142. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the invalidity of the '971 patent.

143. One or more of the claims of the '971 patent is invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

144. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Taro is entitled to a declaratory judgment that one or more claims of the '971 patent is/are invalid.

COUNT XX
(Declaration of Non-Infringement of the '780 Patent)

145. Taro incorporates by reference Paragraphs 1 through 144 as if fully set forth herein.

146. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and

reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the '780 patent.

147. Neither the submission of Taro's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '780 patent, either literally or under the doctrine of equivalents, at least because the claims of the '780 patent are invalid, and an invalid claim cannot be infringed.

148. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '780 patent, either literally or under the doctrine of equivalents, at least because Taro's Proposed ANDA Product is not covered by the claims of the '780 patent.

149. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '780 patent, either literally or under the doctrine of equivalents.

COUNT XXI
(Declaration of Non-Infringement of the '871 Patent)

150. Taro incorporates by reference Paragraphs 1 through 149 as if fully set forth herein.

151. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial,

and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Currax concerning the non-infringement of the ’871 patent.

152. Neither the submission of Taro’s ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Taro’s Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the ’871 patent, either literally or under the doctrine of equivalents, at least because the claims of the ’871 patent are invalid, and an invalid claim cannot be infringed.

153. Additionally, for at least the reasons set forth in the Notice Letter of May 21, 2024, neither the submission of Taro’s ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Taro’s Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the ’871 patent, either literally or under the doctrine of equivalents, at least because Taro’s Proposed ANDA Product is not covered by the claims of the ’871 patent.

154. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the ’871 patent, either literally or under the doctrine of equivalents.

EXCEPTIONAL CASES

This case is an exceptional one, and Taro is entitled to an award of its reasonable attorney fees, expenses, and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Taro respectfully requests the Court enter judgement in its favor, granting the following relief:

A. Dismissing the Complaint, with prejudice, and deny Plaintiff the reliefs requested in the Complaint and any relief whatsoever;

B. Deny Plaintiff any award of damages, costs, or fees;

C. Declaration that Taro has not and will not infringe any valid and enforceable claim of the Patents-in-Suit;

D. Declaration that all claims of the '307, '814, '660, '074, '299, and '971 patents are invalid;

E. Declaration that all claims of the Patents-in-Suit are not infringed and will not be infringed by the submission of Taro's ANDA or the manufacture, use, sale, offer for sale, marketing, or importation into the United States of Taro's Proposed ANDA Product;

F. Declaration that this is an exceptional case in favor of Taro under 35 U.S.C. § 285;

G. Declaration that Taro is the prevailing party and awarding its fees, costs, and expenses in this action pursuant to 35 U.S.C. § 285, or any other applicable statute or law;

H. An award to Taro of its costs and expenses in this action pursuant to 28 U.S.C. § 1920, or any other applicable statute; and

I. An award to Taro of such other and further relief as the Court deems just and proper.

Dated: October 10, 2024

Respectfully submitted,

s/ Gregory D. Miller

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LOCAL RULE 11.2 AND 40.1 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: October 10, 2024

s/ Gregory D. Miller
Gregory D. Miller

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, inter alia, injunctive and declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: October 10, 2024

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

I hereby certify that on October 10, 2024, the foregoing document described as **DEFENDANTS' ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS TO THE COMPLAINT** was served on all counsel of record indicated below via electronic mail.

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