Gregory D. Miller
Gene Y. Kang
Timothy P. Gonzalez
RIVKIN RADLER LLP
25 Main Street
Court Plaza North, Suite 501
Hackensack, NJ 07601-7082
Telephone: 201-287-2460
Facsimile: 201-489-0495

Of Counsel:
Charles B. Klein (to be admitted *pro hac vice*)
Jovial Wong (to be admitted *pro hac vice*)
WINSTON & STRAWN LLP
1901 L Street, NW Washington,
DC 20036
Telephone: (202) 282-5000

Kevin Boyle (to be admitted *pro hac vice*)
Elise M. LeCrone (to be admitted *pro hac vice*)
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, IL 60601
Telephone: (312) 558-5600

Attorneys for Defendants/Counterclaim Plaintiffs, Taro Pharmaceuticals Inc., Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals U.S.A., Inc.

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

GALDERMA LABORATORIES, L.P., GALDERMA S.A., GALDERMA RESEARCH & DEVELOPMENT, S.N.C., and GALDERMA HOLDING, S.A., Plaintiffs/Counterclaim Defendants, v. TARO PHARMACEUTICALS INC., TARO PHARMACEUTICAL INDUSTRIES LTD., and TARO PHARMACEUTICALS U.S.A., INC., Defendants/Counterclaim Plaintiffs.	C.A. No. 3:24-cv-333-MAS-TJB

DEFENDANTS' ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants Taro Pharmaceuticals Inc., Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals U.S.A., Inc. (collectively, "Taro" or "Defendants"), by and through their undersigned counsel, provide the following answers, defenses, and counterclaims to the Complaint

of patent infringement ("Complaint") (D.I. 1) of Plaintiffs Galderma Laboratories, L.P., Galderma S.A., Galderma Research & Development, S.N.C., and Galderma Holding, S.A. (collectively, "Galderma" or "Plaintiffs"). This pleading is based upon Taro's knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Taro denies all allegations in Plaintiffs' Complaint except those admitted specifically below.

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 9,084,778 ("the '778 patent") (attached as Exhibit A hereto); United States Patent No. 9,498,465 ("the '465 patent") (attached as Exhibit B hereto) (collectively, "the Patents-in-Suit"). This action relates to Taro's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Plaintiff's commercial pharmaceutical product AKLIEF® (trifarotene cream, for topical use), submitted under New Drug Application ("NDA") No. 211527, prior to the expiration of patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for AKLIEF®, including the Patents-in-Suit. Taro has submitted ANDA No. 218978 ("Taro's ANDA"), which seeks approval to market its generic version of AKLIEF® (trifarotene cream (0.005%), for topical use) ("Taro's ANDA Product"), prior to the expiration of the Patents-in-Suit.

ANSWER: Taro admits that Plaintiffs' Complaint purports to bring an action for patent infringement under the patent laws of the United States, Title 35, United States Code, but denies that Plaintiffs are entitled to any relief. Taro further admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of trifarotene cream (0.005%), for topical use ("Taro's ANDA Product"), such that it can be sold in the United States prior to the expiration of United States Patent No. 9,084,778 ("the '778 patent") and United States Patent No. 9,498,465 ("the '465 patent") (collectively, "the Patents-in-Suit"). Taro otherwise denies the remaining allegations of paragraph 1.

THE PARTIES

2. Plaintiff Galderma Laboratories, L.P. is a Texas limited partnership with its principal place of business at 2001 Ross Avenue, Suite 1600, Dallas, Texas 75201. Galderma Laboratories, L.P. distributes AKLIEF® in the United States and its territories.

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

3. Plaintiff Galderma S.A. is a Swiss company with its principal place of business at Zählerweg 10, 6300 Zug, Switzerland. Galderma S.A. is an exclusive licensee of the Patents-in-Suit.

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

4. Galderma Laboratories, L.P. markets AKLIEF® in the United States under NDA No. 211527, approved by the FDA on October 4, 2019. Moreover, Galderma Laboratories, L.P. owns NDA No. 211527.

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

5. Galderma Research & Development, S.N.C. is a French corporation with its principal place of business at 2400 Route Des Colles, Les Templiers, Biot, France 06410. Galderma Research & Development, S.N.C. is the current owner of the Patents-in-Suit. Galderma Research & Development, S.N.C. granted to Galderma S.A. an exclusive and worldwide license, with the right to grant sublicenses, to use and exploit the Patents-in-Suit.

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

6. Plaintiff Galderma Holding S.A. is a Swiss company with its principal place of business at Zählerweg 10, 6300 Zug, Switzerland. Galderma Laboratories, L.P. and Galderma S.A. are subsidiaries of Galderma Holding S.A.

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

7. On information and belief, Defendant Taro Pharmaceuticals is a corporation organized and existing under the laws of Canada and has places of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada and 1 Commerce Drive, Cranbury, New Jersey, 08512.

ANSWER: Taro admits that Taro Pharmaceuticals 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 at 3 Skyline Dr., Hawthorne, NY 10532.

8. On information and belief, Defendant Taro USA is a corporation organized and existing under the laws of New York and has a place of business at 1 Commerce Drive, Cranbury, New Jersey, 08512.

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.

9. On information and belief, Defendant Taro Ltd. is a corporation organized and existing under the laws of Israel and has a place of business at 14 Hakitor Street, Haifa Bay, 2624761, Israel.

ANSWER: Taro admits that Taro Pharmaceutical Industries, Ltd. ("Taro Ltd.") is a corporation organized and existing under the laws of Israel and has a place of business at 14 Hakitor Street, Haifa Bay, 2624761, Israel.

10. On information and belief, Defendant Taro Pharmaceuticals and Taro U.S.A. are subsidiaries of Taro Ltd.

ANSWER: Taro admits that Taro Pharmaceuticals Inc. and Taro USA are subsidiaries of Taro Ltd.

11. On information and belief, Taro 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.

ANSWER: Taro admits that it is in the business of manufacturing, marketing, and selling generic drug products in the United States. Taro denies any remaining allegations of paragraph 11.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Taro does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, or 2202 for the purposes of this action only. Taro otherwise denies the remaining allegations of paragraph 12.

13. This Court has personal jurisdiction over the Defendants by virtue of the fact that, *inter alia*, each Defendant 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 Galderma in the State of New Jersey and throughout the United States. For example, on information and belief, by and through Taro Pharmaceuticals, Defendants prepared and submitted Taro's ANDA to FDA. Further, on information and belief, following approval of Taro's ANDA, Defendants will make, use, import, sell, and/or offer for sale Taro's ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 13.

14. This Court has personal jurisdiction over Taro Pharmaceuticals because Taro Pharmaceuticals has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Taro Pharmaceuticals regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Taro Pharmaceuticals derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Taro Pharmaceuticals derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical

ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is in the business of manufacturing, marketing, and selling generic drug products in the United States. Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 14.

15. On information and belief, Taro Pharmaceuticals 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 Taro's ANDA Product. On information and belief, Taro Pharmaceuticals also prepares and/or aids in the preparation and submission of ANDAs to FDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is in the business of manufacturing, marketing, and/or selling generic drug products in the United States. Taro further admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro otherwise denies the remaining allegations of paragraph 15.

16. On information and belief, Taro Pharmaceuticals maintains a regular and established, physical place of business in this Judicial District, in at least Cranbury, New Jersey. In recent court filings, Taro has admitted that Taro, including Taro Pharmaceuticals, has a "a place of business" in Cranbury, New Jersey. *See*, *e.g.*, *Bausch Health Ireland Ltd. v. Taro Pharm., Inc.*, et al., No. 23-2684, ECF No. 13 at 24 ¶ 6 (D.N.J. Oct. 4, 2023). On information and belief, Taro Pharmaceuticals purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Taro Pharmaceuticals.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of

this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 16.

17. This Court has personal jurisdiction over Taro USA by virtue of the fact that Taro USA is at home in New Jersey as reflected by the fact that it maintains a place of business in New Jersey, regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, including by selling its pharmaceutical products in New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Taro USA conducts marketing and sales activities in the State of New Jersey, including, but not limited to, distribution, marketing, and/or sales of pharmaceutical products to New Jersey residents that are continuous and systematic. Additionally, on information and belief, Taro USA intends to market and sell Taro's ANDA Product in the State of New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro further admits that it is in the business of manufacturing, marketing, and/or selling generic drug products in the United States. Taro otherwise denies the remaining allegations of paragraph 17.

18. On information and belief, Taro USA maintains a regular and established, physical place of business in this Judicial District, in at least Cranbury, New Jersey. 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. On information and belief, Taro USA is registered with the State of New Jersey's Department of Health as a drug manufacturer under Registration No. 5003062. In recent court filings, Taro has admitted that Taro USA has a "a place of business" in Cranbury, New Jersey. *See*, *e.g.*, *Bausch Health Ireland Ltd. v. Taro Pharm., Inc.*, et al., No. 23-2684, ECF No. 13 at 3 ¶ 5 (D.N.J. Oct. 4, 2023). On information and belief, Taro USA purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Taro USA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of

this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro further admits that it is in the business of manufacturing, marketing, and/or selling generic drug products in the United States. Taro otherwise denies the remaining allegations of paragraph 18.

19. On information and belief, Taro USA is involved in the preparation and development of the Taro ANDA Product. Taro USA is also listed as the Sponsor and Responsible Party for Clinical Trial ID No. NCT06063473 titled "A Study Comparing Trifarotene Cream 0.005% to AKLIEF® Cream in the Treatment of Acne Vulgaris."

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro further admits that, according to the records of clinicaltrials.gov, Taro Pharmaceuticals USA is listed as a "Sponsor" and as a "Information provided by (Responsible Party)" for Clinical Trial ID No. NCT06063473 titled "A Study Comparing Trifarotene Cream 0.005% to AKLIEF® Cream in the Treatment of Acne Vulgaris." Taro otherwise denies the remaining allegations of paragraph 19.

20. This Court has personal jurisdiction over Taro Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, Taro USA, a company registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler and a company registered with the State of New Jersey as a business operating in New Jersey; and (2) maintained extensive and systematic contacts with the State of New Jersey, including preparation and submission of Taro's ANDA to FDA in New Jersey including through, directly or indirectly, Taro Pharmaceuticals, and/or the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Taro USA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 20.

21. On information and belief, Taro Ltd. is involved in the preparation and development of the Taro ANDA Product. Taro Ltd. is also the holder of Drug Master File (DMF) No. 38005 for trifarotene, submitted March 31, 2023.

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro further admits that Taro Ltd. is also the holder of Drug Master File (DMF) No. 38005 for trifarotene. Taro otherwise denies the remaining allegations of paragraph 21.

22. This Court has personal jurisdiction over Taro Ltd. because Taro Ltd. derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District. Taro Industries's Securities and Exchange Commission Form 20-F filing states that it "develop[s], manufacture[s] and market[s] prescription ('Rx') and over-the-counter ('OTC') pharmaceutical products primarily in the United States (the 'U.S.'), Canada, Israel and Japan," and also "develop[s] and manufacture[s] active pharmaceutical ingredients ('APIs') primarily for use in our finished dosage form products." Taro Pharmaceutical Industries Ltd. Securities and Exchange Commission Form 20-F (for the fiscal year ended March 31, 2023) ("Taro Ltd. Form 20-F") at (i). The Taro Ltd. Form 20-F further states that its annual sales in the U.S. segment were $363 million. *Id*. at 44. It further states that "[w]e generate most of our revenue from the sale of Rx and OTC pharmaceutical products." *Id*.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is in the business of manufacturing, marketing, and/or selling generic drug products in the United States. Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 22.

23. On information and belief, Taro Pharmaceuticals, Taro USA, and Taro Ltd. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is in the business of manufacturing, marketing, and/or selling generic drug products in the United States. Taro does not contest personal jurisdiction

for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 23.

24. On information and belief, Taro Pharmaceuticals and Taro USA are United States agents acting at the direction of, and for the benefit of, Taro Ltd. regarding Taro's ANDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 24.

25. On information and belief, Taro Pharmaceuticals and Taro USA are generic pharmaceutical companies that, in coordination with each other at the direction of Taro Ltd., are in the business of making and selling generic pharmaceutical products, which they distribute throughout the United States including in this Judicial District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is in the business of manufacturing, marketing, and/or selling generic drug products in the United States. Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 25.

26. On information and belief, Taro Pharmaceuticals, Taro USA, and Taro Ltd. operate as a single integrated business.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 26.

27. On information and belief, Taro Pharmaceuticals intends to benefit directly if Taro's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Taro's ANDA Product.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro otherwise denies the remaining allegations of paragraph 27.

28. On information and belief, Taro USA intends to benefit directly if Taro's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Taro's ANDA Product.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro otherwise denies the remaining allegations of paragraph 28.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro otherwise denies the remaining allegations of paragraph 29.

30. On information and belief, Taro Pharmaceuticals, Taro USA, and Taro Ltd. actively participated in the submission of Taro's ANDA. On information and belief, Taro Pharmaceuticals, Taro USA, and Taro Ltd. work in privity and in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including Taro's ANDA Product, throughout the United States, including in this Judicial District, prior to the expiration of the Patents-in-Suit.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case

as to any party. Taro admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro otherwise denies the remaining allegations of paragraph 30.

31. On information and belief, Taro Pharmaceuticals, Taro USA, and Taro Ltd. has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous patent infringement actions.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 31.

32. In the alternative, this Court has personal jurisdiction over Taro Pharmaceuticals because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Taro Pharmaceuticals is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Taro Pharmaceuticals has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Taro Pharmaceuticals satisfies due process.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 32.

33. In the alternative, this Court has personal jurisdiction over Taro Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Taro Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Taro Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Taro Ltd. satisfies due process.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of

this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 33.

34. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest venue for the purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party. Taro otherwise denies the remaining allegations of paragraph 34.

FACTS AS TO ALL COUNTS

35. Galderma Laboratories LP is the owner of NDA No. 211527, which was approved by the FDA for the manufacture and sale of AKLIEF®. AKLIEF® is the trade name for trifarotene cream (0.005%), for topical use and is approved for the for the topical treatment of acne vulgaris in patients 9 years of age and older.

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 Galderma Laboratories LP is the holder of NDA No. 211527 for AKLIEF® (trifarotene 0.005%), for topical use. Taro further admits that, according to the records of the FDA, the label for AKLIEF® states: "AKLIEF Cream is a retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older." 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 the same.

36. Pursuant to 21 U.S.C. § 355(b)(1), the Patents-in-Suit are listed in the Orange Book as covering the AKLIEF® product.

ANSWER: Taro admits that the Orange Book lists the '778 and '465 Patents for Trifarotene (AKLIEF®) cream 0.005%.

37. Galderma Research & Development S.N.C. owns the Patents-in-Suit.

ANSWER: Taro admits that Plaintiffs' purported copies of the Patents-in-Suit, attached as Exhibits A and B, list Galderma Research & Development, Biot (FR) as the Assignee. Taro is without sufficient knowledge and information to confirm the remaining allegations of paragraph 37, and therefore denies the same.

38. Galderma Laboratories, L.P. markets Galderma's patented products in the United States, including AKLIEF®.

ANSWER: Taro is without sufficient knowledge and information to confirm the allegations of paragraph 38, and therefore denies the same.

39. The '778 patent, titled "Topical Compositions Containing a Retinoid of the Oil-In-Water Emulsion Type," was duly and legally issued on July 21, 2015. The '778 patent is generally directed to pharmaceutical formulations comprising trifarotene.

ANSWER: Taro admits that the '778 patent is titled, on its face, "Topical Compositions Containing a Retinoid of the Oil-In-Water Emulsion Type," and bears an issuance date of July 21, 2015. Taro denies that the '778 patent was duly and legally issued. Taro denies that the '778 patent is valid and/or enforceable. Taro is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 39, and therefore denies the same.

40. The '465 patent, titled "Topical Compositions In the Form of a Gel Containing a Particular Solubilized Retinoid," was duly and legally issued on November 22, 2016. The '465 patent is generally directed to pharmaceutical formulations comprising trifarotene.

ANSWER: Taro admits that the '465 patent is titled, on its face, "Topical Compositions In the Form of a Gel Containing a Particular Solubilized Retinoid," and bears an issuance date of November 22, 2016. Taro denies that the '465 patent was duly and legally issued. Taro denies that the '465 patent is valid and/or enforceable. Taro is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 40, and therefore denies the same.

41. Taro prepared, submitted, and filed Taro's ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval

to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic trifarotene cream (0.005%), for topical use before the expiration of the Patents-in-Suit.

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies any remaining allegations of paragraph 41.

42. On information and belief, Taro will market and distribute Taro's ANDA Product throughout the United States, if approved.

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies any remaining allegations of paragraph 42.

43. Taro Pharmaceuticals sent a letter to Galderma Laboratories LP and Galderma Research & Development purporting to provide notification that Taro's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") with regard to the Patents-in-Suit ("the Taro Notice Letter").

ANSWER: Taro admits that it sent Plaintiffs its Notice Letter and that it filed ANDA No. 218978. Taro further responds that the Notice Letter speaks for itself. Taro denies any remaining allegations of paragraph 43.

44. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(7)(i)–(ii).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it submitted ANDA No. 218978 to the FDA,

which included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Taro further responds that it sent Plaintiffs its Notice Letter and that the Notice Letter speaks for itself. Taro denies any remaining allegations of paragraph 44.

45. The Taro Notice Letter does not provide a full and detailed explanation of Taro's factual and legal basis of noninfringement, invalidity, and/or unenforceability for any claim of any patent for which Taro has made a paragraph IV certification.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it sent Plaintiffs its Notice Letter and that the Notice Letter speaks for itself. Taro denies any remaining allegations of paragraph 45.

FIRST COUNT

(Infringement of the '778 Patent by Defendants[1])

46. Galderma repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Taro incorporates its responses to each of the preceding paragraphs 1 to 45 in full, as if set forth herein.

47. On information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of Taro's ANDA Product.

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies any remaining allegations of paragraph 47.

48. On information and belief, in connection with Taro's ANDA, Defendants submitted a paragraph IV certification to the '778 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Taro's ANDA Product before the expiration of the '778 patent.

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States prior

[1] To the extent an answer is required to this subheading for First Count, denied.

to the expiration of the '778 patent. Taro denies any remaining allegations of paragraph 48.

49. On information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import Taro's ANDA Product upon FDA approval of Taro's ANDA.

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies any remaining allegations of paragraph 49.

50. On information and belief, as of the date of the Taro Notice Letter, Taro's was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro further responds that it sent Plaintiffs its Notice Letter and that the Notice Letter speaks for itself. Taro denies any remaining allegations of paragraph 50.

51. The inclusion of a paragraph IV certification to the '778 patent in Taro's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Taro's ANDA Product before the expiration of the '778 patent is an act of infringement by Defendants of one or more claims of the '778 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 51.

52. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's ANDA Product that is the subject of Taro's ANDA will infringe one or more claims of the '778 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 52.

53. On information and belief, Defendants are aware of the existence of the '778 patent. On information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringement of the '778 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 53.

54. The acts of infringement set forth above will cause Galderma irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 54.

SECOND COUNT
(Infringement of the '465 Patent by Defendants[2])

55. Galderma repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Taro incorporates its responses to each of the preceding paragraphs 1 to 54 in full, as if set forth herein.

56. On information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of Taro's ANDA Product.

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies any remaining allegations of paragraph 56.

57. On information and belief, in connection with Taro's ANDA, Defendants submitted a paragraph IV certification to the '465 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Taro's ANDA Product before the expiration of the '465 patent.

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States prior to the expiration of the '465 patent. Taro denies any remaining allegations of paragraph 57.

[2] To the extent an answer is required to this subheading for Second Count, denied.

58. On information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import Taro's ANDA Product upon FDA approval of Taro's ANDA.

ANSWER: Taro admits that it submitted ANDA No. 218978 to the FDA and that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies any remaining allegations of paragraph 58.

59. On information and belief, as of the date of the Taro Notice Letter, Taro was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro further responds that it sent Plaintiffs its Notice Letter and that the Notice Letter speaks for itself. Taro denies any remaining allegations of paragraph 59.

60. The inclusion of a paragraph IV certification to the '465 patent in Taro's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Taro's ANDA Product before the expiration of the '465 patent is an act of infringement by Defendants of one or more claims of the '465 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 60.

61. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's ANDA Product that is the subject of Taro's ANDA will infringe one or more claims of the '465 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 61.

62. On information and belief, Defendants are aware of the existence of the '465 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '465 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 62.

63. The acts of infringement set forth above will cause Galderma irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 63.

RESPONSE TO PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief for which no response is required. To the extent a response is required, Taro denies that Plaintiffs are entitled to any remedy or relief.

DEFENSES

Taro asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Taro does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Taro reserves the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE

(No Direct Infringement of the Patents-in-Suit)

Taro does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit. If Taro's ANDA Product was manufactured, used, offered for sale, or sold within the United States, or imported into the United States, Taro would not infringe any valid and enforceable claim of the Patents-in-Suit.

SECOND DEFENSE

(No Induced Infringement of the Patents-in-Suit)

Taro has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit. If Taro's ANDA Product

was manufactured, used, offered for sale, or sold within the United States, or imported into the United States, Taro would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit.

THIRD DEFENSE

(Invalidity of the Patents-in-Suit)

The claims of the Patents-in-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

FOURTH DEFENSE

The claims of the Patents-in-Suit are barred in whole or in part by the doctrine of prosecution history estoppel and/or judicial estoppel.

FIFTH DEFENSE

To the extent the Complaint purports to seek injunctive relief against Taro, the Complaint fails to state a claim for injunctive relief because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

SIXTH DEFENSE

To the extent the Complaint purports to seek an "exceptional case" determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Taro's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

EIGHTH DEFENSE

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

For their Counterclaims against Plaintiffs Galderma Laboratories, L.P., Galderma S.A., Galderma Research & Development, S.N.C., and Galderma Holding, S.A. (collectively, "Galderma" or "Counterclaim Defendants/Plaintiffs"), Counterclaim Plaintiffs/Defendants Taro Pharmaceuticals Inc., Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals U.S.A., Inc. (collectively, "Taro" or "Counterclaim Plaintiffs/Defendants"), state as follows:

THE PARTIES

1. On information and belief, Plaintiff Galderma Laboratories, L.P. is a Texas limited partnership with its principal place of business at 2001 Ross Avenue, Suite 1600, Dallas, Texas 75201.

2. On information and belief, Plaintiff Galderma S.A. is a Swiss company with its principal place of business at Zählerweg 10, 6300 Zug, Switzerland.

3. On information and belief, Galderma Research & Development, S.N.C. is a French corporation with its principal place of business at 2400 Route Des Colles, Les Templiers, Biot, France 06410.

4. On information and belief, Plaintiff Galderma Holding S.A. is a Swiss company with its principal place of business at Zählerweg 10, 6300 Zug, Switzerland.

5. On information and belief, Galderma Research & Development, S.N.C. is the current assignee of the Patents-in-Suit.

6. On information and belief, Galderma Laboratories LP is the holder of New Drug Application ("NDA") No. 211527.

7. Taro is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 3 Skyline Dr, Hawthorne, NY 10532.

JURISDICTION AND VENUE

8. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Counterclaim Defendants/Plaintiffs on the basis of, *inter alia*, their contacts with New Jersey relating to the subject matter of this action, including having filed suit.

10. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

11. Upon information and belief, Galderma Laboratories, L.P. is the holder of NDA No. 211527 for AKLIEF® (trifarotene cream 0.005%).

12. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1)–(c)(2); 21 C.F.R. § 314.53(b)–(c)(2).

13. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

14. U.S. Patent No. 9,084,778 ("the '778 Patent"), titled "Topical Compositions Containing a Retinoid of the Oil-In-Water Emulsion Type," issued on July 21, 2015.

15. Upon information and belief, Galderma is the assignee of the '778 Patent.

16. Upon information and belief, Counterclaim Defendants/Plaintiffs caused the '778 Patent to be listed in the Orange Book as a patent that claims such a drug for which Galderma

submitted NDA No. 211527.

17. U.S. Patent No. 9,498,465 ("the '465 Patent"), titled "Topical Compositions In the Form of a Gel Containing a Particular Solubilized Retinoid," issued on November 22, 2016.

18. Upon information and belief, Galderma is the assignee of the '465 Patent.

19. Upon information and belief, Counterclaim Defendants/Plaintiffs caused the '465 Patent to be listed in the Orange Book as a patent that claims such a drug for which Galderma submitted NDA No. 211527.

20. In October 2023, Taro submitted Abbreviated New Drug Application ("ANDA") No. 218978 ("Taro's ANDA") with a Paragraph IV Patent Certification stating that the Patents-in-Suit are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's trifarotene cream (0.005%), for topical use, that is the subject of ANDA No. 218978 ("Taro's ANDA Product").

21. By letter dated December 8, 2023 ("Taro's 2023 Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Taro notified Counterclaim Defendants/Plaintiffs that ANDA No. 218978 includes a Paragraph IV Certification with respect to the Patents-in-Suit. Taro's 2023 Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Taro's Paragraph IV Certification that the claims of the Patents-in-Suit are invalid, not infringed, and/or unenforceable.

22. On January 19, 2024, Counterclaim Defendants/Plaintiffs filed this instant lawsuit alleging infringement of the Patents-in-Suit.

COUNT I

(Declaratory Judgment of Non-Infringement of the '778 Patent)

23. Taro re-alleges and incorporates by reference the allegations in Paragraphs 1 through 22 of its Counterclaims as though fully set forth herein.

24. Counterclaim Defendants/Plaintiffs allege ownership of the '778 Patent and have brought claims against Taro alleging infringement of the '778 Patent.

25. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Taro's ANDA and/or the commercial marketing of Taro's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '778 Patent.

26. Taro has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '778 Patent and is not liable for such infringement.

27. Taro is entitled to a declaration that the manufacture, use, or sale of Taro's ANDA Product would not infringe any valid or enforceable claim of the '778 Patent.

COUNT II

(Declaratory Judgment of Invalidity or Unenforceability of the '778 Patent)

28. Taro re-alleges and incorporates by reference the allegations in Paragraphs 1 through 27 of its Counterclaims as though fully set forth herein.

29. Counterclaim Defendants/Plaintiffs allege ownership of the '778 Patent and have brought claims against Taro alleging infringement of the '778 Patent.

30. One or more claims of the '778 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

31. The '778 Patent describes and claims an alleged method, the development of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

32. The alleged invention of the '778 Patent does no more than combine familiar

elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '778 Patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '778 Patent and would have had a reasonable expectation of success in doing so.

33. The subject matter claimed in the '778 Patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

34. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Taro's ANDA No. 218978 and/or the commercial marketing of Taro's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '778 Patent.

35. Taro is entitled to a declaration that all claims of the '778 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

COUNT III

(Declaratory Judgment of Non-Infringement of the '465 Patent)

36. Taro re-alleges and incorporates by reference the allegations in Paragraphs 1 through 35 of its Counterclaims as though fully set forth herein.

37. Counterclaim Defendants/Plaintiffs allege ownership of the '465 Patent and have brought claims against Taro alleging infringement of the '465 Patent.

38. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Taro's ANDA and/or the commercial marketing of Taro's

ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '465 Patent.

39. Taro has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '465 Patent and is not liable for such infringement.

40. Taro is entitled to a declaration that the manufacture, use, or sale of Taro's ANDA Product would not infringe any valid or enforceable claim of the '465 Patent.

COUNT IV

(Declaratory Judgment of Invalidity or Unenforceability of the '465 Patent)

41. Taro re-alleges and incorporates by reference the allegations in Paragraphs 1 through 40 of its Counterclaims as though fully set forth herein.

42. Counterclaim Defendants/Plaintiffs allege ownership of the '465 Patent and have brought claims against Taro alleging infringement of the '465 Patent.

43. One or more claims of the '465 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

44. The '465 Patent describes and claims an alleged method, the development of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

45. The alleged invention of the '465 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '465 Patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '465 Patent and would

have had a reasonable expectation of success in doing so.

46. The subject matter claimed in the '465 Patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

47. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Taro's ANDA No. 218978 and/or the commercial marketing of Taro's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '465 Patent.

48. Taro is entitled to a declaration that all claims of the '465 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

PRAYER FOR RELIEF

WHEREFORE, Taro respectfully requests judgment in its favor and against Counterclaim Defendants/Plaintiffs as follows:

a. Declaring that the filing of Taro's ANDA No. 218978 has not infringed and does not infringe any valid and enforceable claim of the '778 Patent;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Taro's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '778 Patent;

c. Declaring that the claims of the '778 Patent are invalid;

d. Declaring that the filing of Taro's ANDA No. 218978 has not infringed and does not infringe any valid and enforceable claim of the '465 Patent;

e. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the

United States of Taro's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '465 Patent;

f. Declaring that the claims of the '465 Patent are invalid;

g. Declaring this an exceptional case in favor of Taro and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in common law that would be appropriate;

h. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and

i. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: March 27, 2024

RIVKIN RADLER LLP

s/ Gregory D. Miller

Gregory D. Miller
Gene Y. Kang
Timothy P. Gonzalez
25 Main Street
Court Plaza North, Suite 501
Hackensack, NJ 07601
Telephone: (201) 287-2460
Facsimile: (201) 489-0945
gregory.miller@rivkin.com
gene.kang@rivkin.com
timothy.gonzalez@rivkin.com

OF COUNSEL:
Charles B. Klein (to be admitted *pro hac vice*)
Jovial Wong (to be admitted *pro hac vice*)
WINSTON & STRAWN LLP
1901 L Street, NW
Washington, DC 20036
Telephone: (202) 282-5000
CKlein@winston.com
Jwong@winston.com

Kevin Boyle (to be admitted *pro hac vice*)
Elise M. LeCrone (to be admitted *pro hac vice*)
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, IL 60601
Telephone: (312) 558-5600
KJBoyle@winston.com
ELeCrone@winston.com

Attorneys for Defendants/Counterclaim Plaintiffs, Taro Pharmaceuticals Inc., Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals U.S.A., Inc.

LOCAL CIVIL 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: March 27, 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: March 27, 2024

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

I hereby certify that, on March 27, 2024, the foregoing document described as **DEFENDANTS' ANSWER TO COMPLAINT, DEFENSES AND COUNTERCLAIMS** was served on all counsel of record indicated below via electronic mail.

Charles H. Chevalier
Stephen R. Donat
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102 (973) 596-4500
cchevalier@gibbonslaw.com
sdonat@gibbonslaw.com

OF COUNSEL
Edgar H. Haug (pro hac vice forthcoming)
Andrew S. Roper (pro hac vice forthcoming)
Kaitlin M. Farrell (pro hac vice forthcoming)
HAUG PARTNERS LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800
ehaug@haugpartners.com
aroper@haugpartners.com
kfarrell@haugpartners.com

Attorneys for Plaintiffs, Galderma Laboratories L.P., Galderma S.A., Galderma Research & Development, S.N.C., and Galderma Holding, S.A.

s/ Gregory D. Miller
Gregory D. Miller