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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GALDERMA LABORATORIES, L.P., GALDERMA S.A., GALDERMA RESEARCH & DEVELOPMENT, S.N.C., and GALDERMA HOLDING, S.A.,

Plaintiffs,

v.

TARO PHARMACEUTICALS INC., TARO PHARMACEUTICAL INDUSTRIES LTD., and TARO PHARMACEUTICALS U.S.A., INC.

Defendants.

Civil Action No. _____

Document Electronically Filed

COMPLAINT

Plaintiffs Galderma Laboratories, L.P., Galderma S.A., Galderma Research & Development, S.N.C., and Galderma Holding, S.A., (collectively, "Galderma" or "Plaintiffs"), by its undersigned attorneys, for its Complaint against defendants Taro Pharmaceuticals Inc. ("Taro Pharmaceuticals"), Taro Pharmaceutical Industries Ltd. ("Taro Ltd."), and Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") (collectively, "Taro" or "Defendants") herein, allege as follows:

NATURE OF THE ACTION

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

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.

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.

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.

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.

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.

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.

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.

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.

10. On information and belief, Defendant Taro Pharmaceuticals and Taro U.S.A. 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.

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.

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.

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.

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.

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.

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.

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.

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."

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.

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.

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.*

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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

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.

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.

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

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

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.

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.

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.

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

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").

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).

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.

FIRST COUNT
(Infringement of the '778 Patent by Defendants)

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

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.

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.

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).

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.

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).

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.

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.

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

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

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.

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.

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).

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.

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).

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Galderma respectfully requests the following relief:

i. A judgment declaring that the ’778 patent is valid and enforceable;

ii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of Taro’s ANDA with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Taro’s ANDA was an act of infringement of the ’778 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Taro’s ANDA prior to the expiration of the ’778 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of Taro’s ANDA shall be no earlier than the date on which the ’778 patent expires including any regulatory extensions;

v. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and

permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of Taro's ANDA until the expiration of the '778 patent including any regulatory extensions;

vi. A judgment awarding Galderma damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Taro's ANDA that infringes the '778 patent;

vii. A judgment declaring that infringement of the '778 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Taro's ANDA that infringes the '778 patent;

viii. A judgment declaring that the '465 patent is valid and enforceable;

ix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of Taro's ANDA with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Taro's ANDA was an act of infringement of the '465 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

x. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Taro's ANDA prior to the expiration of the '465 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or

contributory infringement;

xi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of Taro's ANDA shall be no earlier than the date on which the '465 patent expires including any regulatory extensions;

xii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of Taro's ANDA until the expiration of the '465 patent including any regulatory extensions;

xiii. A judgment awarding Galderma damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Taro's ANDA that infringes the '465 patent;

xiv. A judgment declaring that infringement of the '465 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Taro's ANDA that infringes the '465 patent;

xv. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Galderma its attorneys' fees and costs;

xvi. Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Dated: January 19, 2024
Newark, New Jersey

s/ Charles H. Chevalier
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