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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH IRELAND LIMITED,  
BAUSCH HEALTH US, LLC, and  
BAUSCH HEALTH AMERICAS, INC.,

Plaintiffs,

v.

Civil Action No. 2:23-cv-02684 (SRC)(CLW)

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

Defendants.

**DEFENDANTS' ANSWER, DEFENSES, AND COUNTERCLAIMS IN RESPONSE TO  
PLAINTIFFS' FIRST AMENDED COMPLAINT**

Defendants Taro Pharmaceuticals Inc., Taro Pharmaceuticals U.S.A., Inc., and Taro Pharmaceutical Industries LTD. (collectively, "Taro" or "Defendants"), by and through its undersigned counsel, provides the following answers, defenses, and counterclaims to the First Amended Complaint of patent infringement ("First Amended Complaint") (D.I. 6) of Plaintiffs Bausch Health Ireland Limited, Bausch Health US, LLC, and Bausch Health Americas, Inc.

(collectively, “Bausch” 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 Federal Rule of Civil Procedure 8(b)(3), Taro denies all allegations in Plaintiffs’ First Amended Complaint except those admitted specifically below.

**THE PARTIES**

1. Plaintiff Bausch Ireland is a corporation organized and existing under the laws of Ireland with its office located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

**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.

2. Plaintiff Bausch US is a corporation organized and existing under the laws of Delaware. Its headquarters is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

**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 Bausch Americas is a corporation organized and existing under the laws of Delaware. Its headquarters is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

**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. Upon information and belief, Defendant Taro Canada is a corporation organized and existing under the laws of Canada, having a principal place of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada.

**ANSWER:** Taro admits that Taro Pharmaceuticals Inc. (“Taro Canada”) 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.

5. Upon information and belief, Taro USA is a corporation organized and existing under the laws of New York, having places of business at Three Skyline Drive, Hawthorne, New York 10532 and 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 places of business at Three Skyline Drive, Hawthorne, New York 10532 and 1 Commerce Drive, Cranbury, New Jersey, 08512.

6. Upon information and belief, Taro Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 14 Hakitor Street, Haifa Bay, 2624761, Israel. Upon information and belief, Taro Canada and Taro USA are subsidiaries of Taro Ltd.

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

7. Upon information and belief, Taro seeks to sell, market, and distribute generic pharmaceutical products throughout the United States, including in this 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 7.

**NATURE OF THE ACTION**

8. This is a civil action for infringement of the '256 Patent and the '115 Patent. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

**ANSWER:** Taro admits that Plaintiffs' First Amended Complaint purports to bring an action for patent infringement of the '256 Patent and the '115 Patent under the patent laws of the United States, 35 U.S.C. § 100 et seq., but denies that Plaintiffs are entitled to any relief. Taro otherwise denies the remaining allegations of paragraph 8.

9. This action arises from Taro's filing of ANDA No. 217190 ("Taro ANDA") and its intended marketing of a generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion under the Taro ANDA ("Taro 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 submitted ANDA No. 217190 to the FDA, which included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Taro otherwise denies the remaining allegations of paragraph 9.

10. Based on at least Taro's correspondence to Bausch, Bausch has reason to believe that Taro has submitted an ANDA seeking FDA approval for, and seeks to market, a drug that is bioequivalent to Duobrii®.

**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. 217190 to the FDA, which included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Taro admits that Taro has submitted an ANDA seeking FDA approval for a drug that is bioequivalent to Duobrii®. Taro otherwise denies the remaining allegations of paragraph 10.

**JURISDICTION AND VENUE**

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201–02.

**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 11.

12. Upon information and belief, this Court has personal jurisdiction over Taro Canada. Upon information and belief, Taro Canada is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Taro Canada directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Taro ANDA Product. Upon information and belief, Taro Canada purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Taro Canada has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Taro Canada has submitted to the jurisdiction of this Court, and asserts counterclaims in this jurisdiction, related to the Taro ANDA and Taro’s ANDA Product in *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW).

**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 has not contested jurisdiction and has asserted counterclaims in this jurisdiction related to the Taro ANDA and Taro's ANDA Product in *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW). Taro otherwise denies the remaining allegations of paragraph 12.

13. Taro Canada has taken the costly, significant step of applying to the United States Food & Drug Administration ("FDA") for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, New Jersey and elsewhere. Taro Canada's ANDA filing constitutes a formal act that reliably indicates plans to engage in marketing of the proposed generic drugs. Upon information and belief, Taro Canada intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Taro Canada will engage in marketing of its proposed ANDA products in New Jersey upon approval of its 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 further 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 13.

14. Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Taro Canada pursuant to Federal Rule of Civil Procedure 4(k)(2) because Taro Canada has extensive contacts with the United States, including but not limited to the above-described commercial contact, is not subject to jurisdiction in any particular state, and

exercising jurisdiction over Taro Canada is consistent with the laws of the United States and the United States Constitution.

**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 14.

15. Upon information and belief, this Court has personal jurisdiction over Taro USA. Upon information and belief, Taro USA is in the business of, inter alia, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Taro USA directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Taro ANDA Product. Upon information and belief, Taro USA purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Taro USA operates and maintains a regular and established place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. Upon information and belief, Taro USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting claims and counterclaims in other civil actions initiated in this jurisdiction. For example, Taro USA has submitted to the jurisdiction of this Court, and asserts counterclaims in this jurisdiction, related to the Taro ANDA and Taro's ANDA Product in *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW).

**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 further admits that Taro USA operates and has an established place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. Taro admits that it has not contested jurisdiction and has asserted counterclaims in this jurisdiction related to the Taro ANDA and Taro's ANDA Product in *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW). Taro otherwise denies the remaining allegations of paragraph 15.

16. Upon information and belief, this Court has personal jurisdiction over Taro Ltd. Upon information and belief, Taro Ltd. is in the business of, inter alia, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Taro Ltd. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district through its subsidiaries, and this judicial district is a likely destination for the Taro ANDA Product. Upon information and belief, Taro Ltd. purposefully has conducted and continues to conduct business in this judicial district, at least through its wholly owned subsidiaries Taro Canada and Taro USA. Upon information and belief, Taro Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting claims and counterclaims in other civil actions initiated in this jurisdiction. For example, Taro Ltd. has submitted to the jurisdiction of this Court, and asserts counterclaims in this jurisdiction, related to the Taro ANDA and Taro's ANDA Product in *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW).

**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 admits that it has not contested jurisdiction and has asserted counterclaims in this jurisdiction related to the Taro ANDA and Taro's ANDA Product in *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW). Taro otherwise denies the remaining allegations of paragraph 16.

17. Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Taro Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because Taro Ltd. has extensive contacts with the United States, including but not limited to the above-described commercial contact, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Taro Ltd. is consistent with the laws of the United States and the United States Constitution.

**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 17.

18. Upon information and belief, Taro Canada, Taro USA, and Taro Ltd. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products. Upon information and belief, Taro Ltd. exercises control over Taro Canada and 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 18.

19. Upon information and belief, venue is proper in this district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Taro does not contest venue for 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 19.

20. Venue is proper as to Taro Canada, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district, and because it has previously consented to venue in this jurisdiction. For example, Taro Canada has not challenged venue in this Court in a patent infringement suit related to the Taro ANDA and Taro's ANDA Product, *Bausch Health Ireland Limited et al v. Taro Pharmaceuticals Inc. et al.* (D.N.J. 2:22-cv-04670-SRCCLW).

**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 admits that it has not contested jurisdiction and has asserted counterclaims in this jurisdiction related to the Taro ANDA and Taro's ANDA Product in *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW). Taro otherwise denies the remaining allegations of paragraph 20.

21. Venue is proper as to Taro USA because inter alia, it maintains a regular and established place of business in this judicial district, and it has previously consented to venue in this jurisdiction. For example, Taro USA has not challenged venue in this Court in a patent infringement suit related to the Taro ANDA and Taro's ANDA Product, *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW).

**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 admits that it has not contested jurisdiction and has asserted counterclaims in this jurisdiction related to the Taro ANDA and Taro's ANDA Product in *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW). Taro otherwise denies the remaining allegations of paragraph 21.

22. Venue is proper as to Taro Ltd., a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district, and because it has previously consented to venue in this jurisdiction. For example, Taro Ltd. has not challenged venue in this Court in a patent infringement suit related to the Taro ANDA and Taro's ANDA Product, *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW).

**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 admits that it has not contested jurisdiction and has asserted counterclaims in this jurisdiction related to the Taro ANDA and Taro's ANDA Product in *Bausch Health Ireland Limited, et al. v. Taro*

*Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW). Taro otherwise denies the remaining allegations of paragraph 22.

**THE ASSERTED PATENTS**

**The '256 Patent**

23. On May 16, 2023, the '256 Patent entitled “Topical Compositions and Methods for Treating Psoriasis” was duly and legally issued. A copy of the '256 Patent is attached as Exhibit A.

**ANSWER:** Taro admits that the '256 Patent is titled, on its face, “Topical Compositions and Methods for Treating Psoriasis” and bears an issuance date of May 16, 2023. Taro denies that the '256 Patent was duly and legally issued. Taro admits that a purported copy of the '256 patent is attached to the First Amended Complaint as Exhibit A. Taro denies that the '256 Patent is valid and/or enforceable. Taro is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 23, and therefore denies the same.

24. The named inventors of the '256 Patent are Gordon Dow, Radhakrishnan Pillai, and Varsha Bhatt.

**ANSWER:** Taro admits that the '256 Patent lists Gordon Dow, Radhakrishnan Pillai, and Varsha Bhatt as inventors on the face of the patent. Taro is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 24 and therefore denies the same.

25. The FDA’s electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) lists the expiration of the '256 Patent as June 6, 2036.

**ANSWER:** Taro admits that the FDA’s publication, entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”), indicates the

expiration of the '256 Patent as June 6, 2036. Taro is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 25, and therefore denies the same.

26. Bausch Ireland is the assignee of the '256 Patent.

**ANSWER:** Taro admits that Plaintiffs' purported copy of the patent, attached as Exhibit A, lists Bausch Health Ireland Limited, Dublin (IE) as the "Assignee." Taro is without sufficient knowledge and information to confirm the remaining allegations of paragraph 26, and therefore denies the same.

#### **The '115 Patent**

27. On June 20, 2023, the '115 Patent entitled "Topical Compositions and Methods for Treating Psoriasis" was duly and legally issued. A copy of the '115 Patent is attached as Exhibit B.

**ANSWER:** Taro admits that the '115 Patent is titled, on its face, "Topical Compositions and Methods for Treating Psoriasis" and bears an issuance date of June 20, 2023. Taro denies that the '115 Patent was duly and legally issued. Taro admits that a purported copy of the '115 patent is attached to the First Amended Complaint as Exhibit B. Taro denies that the '115 Patent is valid and/or enforceable. Taro is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 27, and therefore denies the same.

28. The named inventors of the '115 Patent are Gordon Dow, Radhakrishnan Pillai, and Varsha Bhatt.

**ANSWER:** Taro admits that the '115 Patent lists Gordon Dow, Radhakrishnan Pillai, and Varsha Bhatt as inventors on the face of the patent. Taro is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 28 and therefore denies the same.

29. The Orange Book lists the expiration of the '115 Patent as June 6, 2036.

**ANSWER:** Taro admits that the FDA's publication, entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), indicates the expiration of the '115 Patent as June 6, 2036. Taro is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 29, and therefore denies the same.

30. Bausch Ireland is the assignee of the '115 Patent.

**ANSWER:** Taro admits that Plaintiffs' purported copy of the patent, attached as Exhibit B, lists Bausch Health Ireland Limited, Dublin (IE) as the "Assignee." Taro is without sufficient knowledge and information to confirm the remaining allegations of paragraph 30, and therefore denies the same.

#### **ACTS GIVING RISE TO THIS ACTION**

31. Bausch Americas holds the approved New Drug Application ("NDA") No. 209354 for Duobrii® (halobetasol propionate 0.01%; tazarotene 0.045%) (the "Duobrii® NDA").

**ANSWER:** Taro admits that the Orange Book indicates that Bausch Health Americas Inc. is the holder of NDA No. 209354 for Duobrii® (halobetasol propionate 0.01% tazarotene 0.045%).

32. Duobrii® is indicated for the topical treatment of plaque psoriasis in adults.

**ANSWER:** Taro admits that the Duobrii® label available on the FDA's website states that Duobrii® is used for the topical treatment of plaque psoriasis in adults.

33. Pursuant to 21 U.S.C. §335(b)(1), the '256 Patent and the '115 Patent are listed in the Orange Book for Duobrii® (halobetasol propionate 0.01%; tazarotene 0.045%).

**ANSWER:** Taro admits that the Orange Book lists the '256 Patent and the '115 Patent for Duobrii®.

34. By a letter dated June 7, 2022, (the "Taro Notice Letter"), Taro Canada notified Plaintiffs that it submitted the Taro ANDA to the FDA seeking approval to engage in the

commercial manufacture, use or sale of Taro's ANDA Product, a generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion.

**ANSWER:** Taro admits that it sent Plaintiffs its Notice Letter, that it filed ANDA No. 217190, and further responds that the Notice Letter speaks for itself. Taro denies any remaining allegations of paragraph 34.

35. The Taro Notice Letter stated that Taro Canada had included a certification in the Taro ANDA, pursuant to 21 U.S.C § 355(j)(2)(A)(vii)(IV), that the listed patents in the Orange Book asserting that they are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Taro ANDA Product.

**ANSWER:** Taro admits that it sent Plaintiffs its Notice Letter, that it filed ANDA No. 217190, and further responds that the Notice Letter speaks for itself. Taro denies any remaining allegations of paragraph 35.

36. On the basis of Taro's Notice Letter, Plaintiffs filed suit against Taro in this judicial district for infringement of the then-listed patents in the Orange Book. *See Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW). This litigation is ongoing.

**ANSWER:** Taro admits an action under the caption, *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW) was filed on July 21, 2022. Taro denies any remaining allegations of paragraph 36.

37. Based on at least the information in Taro's Notice Letter, including at least Taro's listing Duobrii® as a reference list drug, Taro's expressed desire to market a product bioequivalent to Duobrii®, its tentative approval for a halobetasol propionate 0.01%; tazarotene 0.045% product, and on information and belief, the Taro ANDA seeks approval for a Taro ANDA Product

substantially similar to Duobrii®, which is covered by at least one claim of the '256 Patent and '115 Patent.

**ANSWER:** Taro admits that it sent a Notice Letter and further responds that the letter speaks for itself. Taro denies any remaining allegations of paragraph 37.

**CLAIMS FOR RELIEF**

**COUNT I (Infringement of the '256 Patent)**

38. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

**ANSWER:** Taro incorporates its responses to each of the preceding paragraphs 1 to 37 in full as if set forth herein.

39. Upon information and belief, Taro has infringed at least one claim of the '256 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Taro ANDA, by which Taro seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Taro ANDA Product prior to the expiration of the '256 Patent.

**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 39.

40. Upon information and belief, the Taro ANDA Product will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '256 Patent.

**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 40.

41. Upon information and belief, Taro will, through the manufacture, use, import, offer for sale, and/or sale of the Taro ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '256 Patent.

**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 41.

42. If Taro's marketing and sale of the Taro ANDA Product prior to the expiration of the '256 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**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 42.

**COUNT II (Declaratory Judgment of Infringement of the '256 Patent)**

43. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

**ANSWER:** Taro incorporates its responses to each of the preceding paragraphs 1 to 42 in full as if set forth herein.

44. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**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 44.

45. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights 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 45.

46. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Taro ANDA Product before the expiration date of the '256 Patent, including Taro's filing of ANDA No. 217190.

**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 46.

47. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '256 Patent.

**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 47.

48. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will constitute infringement of at least one claim of the '256 Patent.

**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 48.

### **COUNT III (Infringement of the '115 Patent)**

49. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

**ANSWER:** Taro incorporates its responses to each of the preceding paragraphs 1 to 48 in full as if set forth herein.

50. Upon information and belief, Taro has infringed at least one claim of the '115 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Taro ANDA, by which Taro seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Taro ANDA Product prior to the expiration of the '115 Patent.

**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 50.

51. Upon information and belief, the Taro ANDA Product will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '115 Patent.

**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. Upon information and belief, Taro will, through the manufacture, use, import, offer for sale, and/or sale of the Taro ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '115 Patent.

**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. If Taro's marketing and sale of the Taro ANDA Product prior to the expiration of the '115 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**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.

**COUNT IV (Declaratory Judgment of Infringement of the '115 Patent)**

54. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

**ANSWER:** Taro incorporates its responses to each of the preceding paragraphs 1 to 53 in full as if set forth herein.

55. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**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 55.

56. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights 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 56.

57. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Taro ANDA Product before the expiration date of the '115 Patent, including Taro's filing of ANDA No. 217190.

**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 57.

58. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '115 Patent.

59. **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 58. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will constitute infringement of at least one claim of the '115 Patent.

**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 59.

#### **RESPONSE TO PRAYER FOR RELIEF**

The remainder of Plaintiffs' First Amended 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 First Amended 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 '256 and '115 Patents)**

Taro does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '256 and '115 Patents. 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 '256 and '115 Patents.

**SECOND DEFENSE**

**(No Induced Infringement of the '256 and '115 Patents)**

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 '256 and '115 Patents. 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 '256 and '115 Patents.

**THIRD DEFENSE**

**(Invalidity of the '256 and '115 Patents)**

The claims of the '256 and '115 Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

**FOURTH DEFENSE**

The claims of the '256 and '115 Patents are barred in whole or in part by the doctrine of prosecution history estoppel, unclean hands, patent misuse, and bad faith. On information and belief, Plaintiffs misused Taro's confidential information relating to Taro's ANDA product formulation to obtain claims that Plaintiffs did not invent and then asserted those claims against Taro.

On information and belief, Plaintiffs drafted and prosecuted claims of the '256 Patent that do not require diethyl sebacate in an improper attempt to cover Taro's ANDA Product, which Plaintiffs did not invent. Plaintiffs began prosecuting patent claims that do not require diethyl sebacate only after Plaintiffs gained access to Taro's confidential information describing Taro's

ANDA Product in connection with this lawsuit. Plaintiffs knew or should have known that claims of the '256 Patent that lack diethyl sebacate are invalid under at least 35 U.S.C. § 112 and 35 U.S.C. § 103.

Therefore all Plaintiffs' claims are unenforceable and barred in whole or in part by the doctrine of unclean hands, patent misuse, and bad faith.

#### **FIFTH DEFENSE**

To the extent the First Amended Complaint purports to seek injunctive relief against Taro, the First Amended 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 First Amended Complaint purports to seek an "exceptional case" determination, the First Amended Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or § 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' First Amended Complaint fails to state a claim upon which relief may be granted.

#### **EIGHTH DEFENSE**

Any additional defenses that discovery may reveal.

#### **COUNTERCLAIMS**

For its Counterclaims against Bausch Health Ireland Limited, Bausch Health US, LLC, and Bausch Health Americas, Inc. (collectively, "Bausch" or "Counterclaim Defendants/Plaintiffs"), Counterclaim Plaintiffs/Defendants Taro Pharmaceuticals Inc., Taro Pharmaceuticals U.S.A., Inc., and

Taro Pharmaceutical Industries Ltd. (“Taro” or “Counterclaim Plaintiffs/Defendants”), states as follows:

**THE PARTIES**

1. On information and belief, Bausch Ireland is a corporation organized and existing under the laws of Ireland with its office located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.
2. On information and belief, Bausch US is a corporation organized and existing under the laws of Delaware. Its headquarters is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.
3. On information and belief, Bausch Americas is a corporation organized and existing under the laws of Delaware. Its headquarters is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.
4. On information and belief, Bausch is the current assignee of the '256 and '115 Patents.
5. On information and belief, Bausch Health Americas Inc. is the holder of New Drug Application (“NDA”) No. 209354.
6. 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, New York 10532. Taro has a place of business in New Jersey located at 1 Commerce Drive, Cranbury, New Jersey 08512.

**JURISDICTION AND VENUE**

7. 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.

8. 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.

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

### **BACKGROUND**

10. Upon information and belief, Bausch Health Americas Inc. is the holder of NDA No. 209354 for DUOBRII® (halobetasol propionate 0.01% tazarotene 0.045%) in the form of topical treatment.

11. 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).

12. 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).

13. U.S. Patent No 11,648,256 (the “’256 Patent”) entitled “Topical Compositions and Methods for Treating Psoriasis” was issued on May 16, 2023.

14. U.S. Patent No. 11,679,115 (the “’115 Patent”) entitled “Topical Compositions and Methods for Treating Psoriasis” was issued on June 20, 2023.

15. Upon information and belief, Bausch is the assignee of the ’256 Patent and the ’115 Patent.

16. Upon information and belief, Counterclaim Defendants/Plaintiffs caused Patents '256 and '115 to be listed in the FDA's electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") with an expiration of June 6, 2036.

17. In June 2022, Taro submitted Abbreviated New Drug Application ("ANDA") No. 217190 ("Taro's ANDA") with a Paragraph IV Patent Certification stating that U.S. Patent Nos. 8,809,307; 10,478,502; 10,251,895; and 10,426,787 ("the Original Patents-in-Suit") are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's halobetasol propionate and tazarotene lotion that are the subject of ANDA No. 217190 ("Taro's ANDA Products").

18. By letter dated June 7, 2022 ("Taro's 2022 Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Taro notified Counterclaim Defendants/Plaintiffs that ANDA No. 217190 includes a Paragraph IV Certification with respect to the other patents held by Bausch. Taro's 2022 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 Original Patents-in-Suit are invalid, not infringed, and/or unenforceable.

19. In Taro's 2022 Notice Letter, Taro did not disclose the ANDA formulation, but did say "Taro's ANDA product does not meet the claim limitation of 'diethyl sebacate.'"

20. On July 21, 2022, Counterclaim Defendants/Plaintiffs filed a complaint in the matter *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW) ("Bausch's July 2022 Complaint").

21. On September 20, 2022, Taro answered Bausch's July 2022 Complaint and produced Taro's ANDA, which included the formulation for Taro's ANDA product. This was answered and produced on an outside-attorney's eyes-only basis.

22. Upon information and belief, on or about November 2022, Bausch began seeking broader claims as asserted in the '256 Patent.

23. On May 16, 2023, the '256 Patent entitled "Topical Compositions and Methods for Treating Psoriasis" was improperly issued.

24. On May 17, 2023, Counterclaim Defendants/Plaintiffs filed this instant lawsuit alleging infringement of the '256 Patent.

25. By letter dated August 10, 2023 ("Taro's 2023 Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Taro notified Counterclaim Defendants/Plaintiffs that ANDA No. 217190 includes a Paragraph IV Certification with respect to the '256 and '115 Patents. 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 '256 and '115 Patents are invalid, not infringed, and/or unenforceable.

## COUNT I

### **(Declaratory Judgment of Non-Infringement of the '256 Patent)**

26. Taro re-alleges and incorporates by reference the allegations in Paragraphs 1 through 25 of its Counterclaims as though fully set forth herein.

27. Counterclaim Defendants/Plaintiffs allege ownership of the '256 Patent and have brought claims against Taro alleging infringement of the '256 Patent.

28. 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 '256 Patent.

29. Taro has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '256 Patent and is not liable for such infringement.

30. Taro is entitled to a declaration that the manufacture, use, or sale of Taro's ANDA Products would not infringe any valid or enforceable claim of the '256 Patent.

**COUNT II**

**(Declaratory Judgment of Invalidity or Unenforceability of the '256 Patent)**

31. Taro re-alleges and incorporates by reference the allegations in Paragraphs 1 through 30 of its Counterclaims as though fully set forth herein.

32. Counterclaim Defendants/Plaintiffs allege ownership of the '256 Patent and have brought claims against Taro alleging infringement of the '256 Patent.

33. One or more claims of the '256 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.

34. The '256 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.

35. The alleged invention of the '256 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 '256 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 '256 Patent and would have had a reasonable expectation of success in doing so.

36. The subject matter claimed in the '256 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.

37. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Taro's ANDA No. 217190 and/or the commercial marketing of Taro's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '256 Patent.

38. Taro is entitled to a declaration that all claims of the '256 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

39. On information and belief, Counterclaim Defendants/Plaintiffs drafted and prosecuted claims of the '256 Patent that do not require diethyl sebacate in an improper attempt to cover Taro's ANDA Product, which Plaintiffs did not invent.

40. Counterclaim Defendants/Plaintiffs began prosecuting patent claims that do not require diethyl sebacate only *after* Plaintiffs gained access to Taro's confidential information describing Taro's ANDA Product in connection with this lawsuit.

41. On information and belief, Counterclaim Defendants/Plaintiffs misused Taro's confidential information relating to Taro's ANDA product formulation to obtain claims that Counterclaim Defendants/Plaintiffs did not invent and then asserted those claims against Taro.

42. Counterclaim Defendants/ Plaintiffs knew or should have known that claims of the '256 Patent that lack diethyl sebacate are invalid under at least 35 U.S.C. § 112.

43. Taro is entitled to a declaration that all claims of the '256 Patent are unenforceable and barred in whole or in part by the doctrine of unclean hands and bad faith.

**COUNT III**

**(Declaratory Judgment of Non-Infringement of the '115 Patent)**

44. Taro re-alleges and incorporates by reference the allegations in Paragraphs 1 through 43 of its Counterclaims as though fully set forth herein.

45. Counterclaim Defendants/Plaintiffs allege ownership of the '115 Patent and have brought claims against Taro alleging infringement of the '115 Patent.

46. 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 '115 Patent.

47. Taro has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '115 Patent and is not liable for such infringement.

48. Taro is entitled to a declaration that the manufacture, use, or sale of Taro's ANDA Products would not infringe any valid or enforceable claim of the '115 Patent.

**COUNT IV**

**(Declaratory Judgment of Invalidity or Unenforceability of the '115 Patent)**

49. Taro re-alleges and incorporates by reference the allegations in Paragraphs 1 through 48 of its Counterclaims as though fully set forth herein.

50. Counterclaim Defendants/Plaintiffs allege ownership of the '115 Patent and have brought claims against Taro alleging infringement of the '115 Patent.

51. One or more claims of the '115 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.

52. The '115 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.

53. The alleged invention of the '115 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 '115 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 '115 Patent and would have had a reasonable expectation of success in doing so.

54. The subject matter claimed in the '115 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.

55. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Taro's ANDA No. 217190 and/or the commercial marketing of Taro's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '115 Patent.

56. Taro is entitled to a declaration that all claims of the '115 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. Dismissing the First Amended Complaint and the claims for relief set forth therein, with prejudice;
- b. Declaring that the filing of Taro's ANDA No. 217190 has not infringed and does not infringe any valid and enforceable claim of the '256 Patent;
- c. 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 '256 Patent;
- d. Declaring that the claims of the '256 Patent are invalid and unenforceable;
- e. Declaring that the filing of Taro's ANDA No. 217190 has not infringed and does not infringe any valid and enforceable claim of the '115 Patent;
- f. 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 '115 Patent;
- g. Declaring that the claims of the '115 Patent are invalid and unenforceable;
- h. 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;
- i. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and
- j. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: October 4, 2023

**RIVKIN RADLER LLP**

s/ *Gregory D. Miller*

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*Taro Pharmaceuticals Inc., and Taro*

*Pharmaceutical Industries Ltd.*

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Pursuant to Local Civil Rule 11.2, 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 but is related to the following action: *Bausch Health Ireland Limited, et al. v. Taro Pharmaceuticals Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW) pending in the United States District Court, District of New Jersey before the Honorable Stanley R. Chesler, U.S.D.J.

Dated: October 4, 2023

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 4, 2023

s/ *Gregory D. Miller*  
Gregory D. Miller

**CERTIFICATE OF SERVICE**

The undersigned attorney certifies that a copy of the foregoing Taro's Answer, Defenses, and Counterclaims to Plaintiffs' First Amended Complaint was filed and served on all counsel of record on October 4, 2023 via ECF.

Dated: October 4, 2023

s/ *Gregory D. Miller*  
Gregory D. Miller