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Attorneys for Defendants and Counterclaim Plaintiffs Taro Pharmaceuticals Inc., and Taro Pharmaceuticals U.S.A. Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, BAUSCH HEALTH US, LLC, and BAUSCH HEALTH AMERICAS, INC., Plaintiffs, v. TARO PHARMACEUTICALS INC., TARO PHARMACEUTICALS U.S.A., INC., and TARO PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. 2:25-cv-2000-MCA-CLW

DEFENDANTS' ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT

Taro Pharmaceuticals Inc. ("Taro Canada") and Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") (collectively, "Taro" or "Defendants")[1] by their undersigned attorneys, for their Answer, Separate Defenses, and Counterclaims to the Complaint of Bausch Health Ireland Limited ("BIRL"), Bausch Health US, LLC ("BHUS"), and Bausch Health Americas, Inc. ("BHA") (collectively, "Bausch Health" or "Plaintiffs"), aver as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent Nos. 8,288,434 ("the '434 Patent"), 9,561,208 ("the '208 Patent"), 10,220,049 ("the '049 Patent"), 10,624,918 ("the '918 Patent"), 11,389,467 ("the '467 Patent"), 12,128,059 ("the '059 Patent"), 12,133,859 ("the '859 Patent"), and 12,138,278 ("the '278 Patent") (collectively, the "Asserted Patents") pursuant to the Patent Laws of the U.S., 35 U.S.C. § 100 et seq., including §§ 271 and 281, and for an order declaring infringement under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro admits that Plaintiffs purport to bring this action under the Patent Laws and the Declaratory Judgment Act of the United States. Taro denies any remaining allegations set forth in paragraph 1.

2. This action arises from the submission of an Abbreviated New Drug Application ("ANDA") by Taro, namely ANDA No. 220097 (the "Taro ANDA"), under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to commercially manufacture, market, offer to sell, sell, and/or import their generic version of Cabtreo® (clindamycin phosphate, adapalene, and benzoyl peroxide (1.2%/0.15%/3.1%) topical gel), hereafter "Taro's Proposed Generic Product" in the U.S. prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro admits that Taro Canada is the owner of ANDA

[1] Pursuant to party agreement, the parties have concurrently filed a joint stipulation dismissing Taro Pharmaceutical Industries Ltd from this action.

No. 220097 and seeks FDA approval of ANDA No. 220097. Taro denies any remaining allegations set forth in paragraph 2.

THE PARTIES

3. Plaintiff BIRL is a corporation organized and existing under the laws of Ireland located at 3013 Lake Drive, Citywest Business Campus, Dublin D24 PPT3, Ireland.

ANSWER: Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 3, and, therefore, denies those allegations.

4. Plaintiff BHUS is a corporation organized and existing under the laws of Delaware with a principal place of business and corporate headquarters located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

ANSWER: Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 4, and, therefore, denies those allegations.

5. Plaintiff BHA is a corporation organized and existing under the laws of Delaware with a principal place of business and corporate headquarters located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

ANSWER: Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 5, and, therefore, denies those allegations.

6. 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. Taro Canada is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic pharmaceutical products, for the U.S. market. Taro Canada is the holder and primary applicant of the Taro ANDA. Taro Canada will commercially manufacture, offer for sale, sell, and/or import Taro's Proposed Generic Product in the U.S.

ANSWER: Taro admits that 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. Taro admits that Taro Canada, among other things, manufactures and sells pharmaceutical products. Taro admits that Taro Canada is the owner of ANDA No. 220097 and

seeks FDA approval of ANDA No. 220097. Taro denies any remaining allegations set forth in paragraph 6.

7. Defendant Taro USA is a corporation organized and existing under the laws of New York, having places of business located at Three Skyline Drive, Hawthorne, New York 10532, and 1 Commerce Drive, Cranbury, New Jersey 08512. Taro USA is in the business of, *inter alia*, distributing, marketing, offering to sell, and/or selling pharmaceutical products, including generic pharmaceutical products, for the U.S. market. Taro USA submitted the Taro ANDA on behalf of Taro Canada, in concert with Taro Ltd. Taro USA will import into the U.S., and market and distribute throughout the U.S., Taro's Proposed Generic Product.

ANSWER: Taro admits that Taro USA is a corporation organized and existing under the laws of New York, having places of business located at Three Skyline Drive, Hawthorne, New York 10532, and 1 Commerce Drive, Cranbury, New Jersey 08512. Taro admits that Taro USA, among other things, manufactures and sells pharmaceutical products. Taro admits that Taro Canada is the owner of ANDA No. 220097 and seeks FDA approval of ANDA No. 220097. Taro denies any remaining allegations set forth in paragraph 7.

8. Defendant 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. Taro Ltd. is in the business of, *inter alia*, manufacturing generic pharmaceutical products for the U.S. market and/or manufacturing active pharmaceutical ingredients ("API") for generic pharmaceutical products for the U.S. market. Taro Ltd. is the holder of Drug Master File for adapalene USP (micronized) (DMF # 021208), one of the three active ingredients in Taro's Proposed Generic Product. Taro Ltd. will commercially manufacture, offer to sell, sell, market, and/or distribute Taro's Proposed Generic Product.

ANSWER: Taro admits that 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. Taro admits that Taro Ltd., among other things, manufactures active pharmaceutical ingredients. Taro admits Taro Ltd. is the holder of FDA Drug Master File No. 021208 for adapalene USP, micronized. Taro denies any remaining allegations set forth in paragraph 8.

9. Taro seeks to commercially manufacture, offer to sell, sell, market, import, and/or distribute Taro's Proposed Generic Product, throughout the U.S., including in this judicial district.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. Taro denies any remaining allegations set forth in paragraph 9.

10. Taro Canada and Taro USA are wholly-owned subsidiaries of Taro Ltd. Taro Ltd. exercises control over Taro Canada and Taro USA.

ANSWER: Taro admits Taro Canada and Taro USA are subsidiaries of Taro Ltd. Taro denies any remaining allegations set forth in paragraph 10.

11. The acts of Taro Canada and Taro USA complained of herein were done with the cooperation, participation, and assistance of, and in concert with, Taro Ltd. Taro Ltd. caused the Taro ANDA to be submitted to the FDA through its wholly owned subsidiaries Taro Canada and Taro USA.

ANSWER: Denied.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required.

13. Taro Canada is subject to personal jurisdiction in New Jersey because, among other things, Taro Canada has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this judicial district in New Jersey. Taro Canada has had persistent and continuous contacts within this judicial district. Taro Canada is in the business of, *inter alia*, directly or indirectly developing, manufacturing, marketing, offering to sell, and/or selling generic drug products throughout the U.S. and in this judicial district, and this judicial district is the destination for Taro's Proposed Generic Product. The conduct of Taro Canada will therefore cause injury to Plaintiffs in New Jersey.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro Canada does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 13.

14. Taro Canada has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the commercial marketing of Taro's Proposed Generic Product—that will be purposefully marketed and distributed in New Jersey and

throughout the U.S. Taro Canada's submission of the Taro ANDA constitutes a formal act that reliably indicates its plan to engage in commercial manufacturing, selling, and marketing of Taro's Proposed Generic Product. Taro Canada intends to direct sales of Taro's Proposed Generic Product into New Jersey, among other places, once it has the requested FDA approval to market Taro's Proposed Generic Product. Taro Canada will engage in the commercial manufacturing, marketing, offering for sell, sell, importation, and distribution of Taro's Proposed Generic Product throughout the U.S., including in New Jersey, upon approval of the Taro ANDA.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro Canada does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 14.

15. Taro Canada derives substantial revenue from selling generic pharmaceutical products throughout the U.S., including in this judicial district, directly and/or through its parent company Taro Ltd. and/or Taro USA.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro Canada does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 15.

16. This Court has personal jurisdiction over Taro Canada pursuant to Federal Rule of Civil Procedure 4(k)(2) because Taro Canada has extensive contacts within the U.S., including but not limited to the above-described commercial contacts, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Taro Canada is consistent with the laws of the U.S. and the U.S. Constitution.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro Canada does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 16.

17. Taro Canada has invoked the jurisdiction of the courts of this judicial district as a counterclaim plaintiff in patent infringement actions arising under the Hatch-Waxman Act. *See*, *e.g.*, *Currax Pharms. LLC v. Taro Pharm. Indus., Ltd. et al.*, DNJ 1:24-cv-7446 (Answer at Dkt. No. 2), *Bausch Health Ireland Ltd., et al. v. Taro Pharms. Inc., et al.*, DNJ 1:22-cv-4670 (Answer

at Dkt. No. 17); *Galderma Lab'ys., LP et al v. Taro Pharms., Inc. et al.*, DNJ 3:24-cv-00333 (Answer at Dkt. No. 11).

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro Canada does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 17.

18. Taro Canada has not contested personal jurisdiction in this judicial district. *See*, *e.g.*, *Currax Pharms. LLC v. Taro Pharm. Indus., Ltd. et al.*, DNJ 1:24-cv-7446 (Answer at Dkt. No. 2), *Bausch Health Ireland Ltd., et al. v. Taro Pharms. Inc., et al.*, DNJ 1:22-cv-4670 (Answer at Dkt. No. 17); *Galderma Laby's., LP et al v. Taro Pharms., Inc. et al.*, DNJ 3:24-cv-00333 (Answer at Dkt. No. 11).

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro Canada does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 18.

19. This Court has personal jurisdiction over Taro USA. Taro USA has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this judicial district in New Jersey.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro USA does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 19.

20. Taro USA has purposefully conducted and continues to conduct business in New Jersey. Taro USA operates and maintains a regular and established place of business located at 1 Commerce Drive, Cranbury, New Jersey 08512, where Taro USA will commercially distribute, market, offer for sale and/or sell Taro's Proposed Generic Product. Furthermore, Taro USA: (i) has officers and directors located at 2 Independence Way, Princeton, New Jersey 08540; (ii) is registered to do business in New Jersey as a foreign corporation with a Business ID Number of 0100917783; (iii) has a registered agent (Corporation Service Company) located in New Jersey at Princeton South Corporate Center, 100 Charles Ewing Blvd, Suite 160, Ewing, New Jersey 08628; and (iv) is registered with the State of New Jersey's Department of Health as a wholesaler under Registration Number 5003062.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro USA does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 20.

21. Taro USA is subject to personal jurisdiction in New Jersey, because, among other things, Taro USA has had persistent and continuous contacts within this judicial district. Taro USA is in the business of, *inter alia*, commercially developing, manufacturing, marketing, importing, and/or selling generic drug products throughout the U.S. and in this judicial district, and this judicial district is a destination for Taro's Proposed Generic Product. Taro USA will commercially sell, offer for sale, import, market, and distribute Taro's Proposed Generic Product throughout the U.S., including New Jersey, upon approval of the Taro ANDA. The conduct of Taro USA will therefore cause injury to Plaintiffs in New Jersey.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro USA does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 21.

22. Taro USA derives substantial revenue from selling generic pharmaceutical products throughout the U.S., including in this judicial district, directly and/or through its parent company Taro Ltd.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro USA does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 22.

23. Taro USA has invoked the jurisdiction of the courts of this judicial district as a counterclaim plaintiff in patent infringement actions arising under the Hatch-Waxman Act. *See*, *e.g.*, *Currax Pharms. LLC v. Taro Pharm. Indus., Ltd. et al.*, DNJ 1:24-cv-7446 (Answer at Dkt. No. 2), *Bausch Health Ireland Ltd., et al. v. Taro Pharms. Inc., et al.*, DNJ 1:22-cv-4670 (Answer at Dkt. No. 17); *Galderma Laby's., LP et al v. Taro Pharms., Inc. et al.*, DNJ 3:24-cv-00333 (Answer at Dkt. No. 11).

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro USA

does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 23.

24. Taro USA has not contested personal jurisdiction in this judicial district. *See*, *e.g.*, *Currax Pharms. LLC v. Taro Pharm. Indus., Ltd. et al.*, DNJ 1:24-cv-7446 (Answer at Dkt. No. 2), *Bausch Health Ireland Ltd., et al. v. Taro Pharms. Inc., et al.*, DNJ 1:22-cv-4670 (Answer at Dkt. No. 17); *Galderma Laby's., LP et al v. Taro Pharms., Inc. et al.*, DNJ 3:24-cv-00333 (Answer at Dkt. No. 11).

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro USA does not contest personal jurisdiction in New Jersey. Taro denies any remaining allegations set forth in paragraph 24.

25. Taro Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Taro Ltd. has had persistent and continuous contacts within this judicial district. Taro Ltd. is in the business of, *inter alia*, commercially developing, manufacturing, marketing, and/or selling generic drug products throughout the U.S. and in this judicial district, and this judicial district is a destination for Taro's Proposed Generic Product. The conduct of Taro Ltd. will therefore cause injury to Plaintiffs in New Jersey.

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. Taro denies any remaining allegations set forth in paragraph 25.

26. Taro Ltd. purposefully has conducted and continues to conduct business in this judicial district and derives substantial revenue from selling generic pharmaceutical products throughout the U.S., including in this judicial district, at least, through its wholly owned subsidiaries Taro Canada and Taro USA.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. Taro denies any remaining allegations set forth in paragraph 26.

27. 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 U.S., including but not limited to the above-described commercial contacts, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Taro Ltd. is consistent with the laws of the U.S. and the U.S. Constitution.

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. Taro denies any remaining allegations set forth in paragraph 27.

28. Taro Ltd. was acquired by Sun Pharmaceutical Industries Limited ("Sun Limited") in June 2024. Taro Ltd. is now a wholly-owned subsidiary of Sun Limited. Sun Limited has a U.S. subsidiary, Sun Pharma USA, which has corporate headquarters located at 2 Independence Way, Princeton, New Jersey 08540. The location of Sun Parma USA is the same address listed for Taro USA's Officers and Directors. Sun Pharmaceutical Industries, Inc. also has a place of business at 1 Commerce Drive, Cranbury New Jersey 08512, which is the same address of Taro USA's warehouse.

ANSWER: Taro admits it is wholly-owned by Sun Pharmaceutical Industries Limited ("Sun Limited"). Taro lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 28, and, therefore, denies those allegations.

29. Taro Ltd. has invoked the jurisdiction of the courts of this judicial district as a counterclaim plaintiff in patent infringement actions arising under the Hatch-Waxman Act. *See*, *e.g.*, *Currax Pharms. LLC v. Taro Pharm. Indus., Ltd. et al.*, DNJ 1:24-cv-7446 (Answer at Dkt. No. 2), *Bausch Health Ireland Ltd., et al. v. Taro Pharms. Inc., et al.*, DNJ 1:22-cv-4670 (Answer at Dkt. No. 17); *Galderma Laby's., LP et al v. Taro Pharms., Inc. et al.*, DNJ 3:24-cv-00333 (Answer at Dkt. No. 11).

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. Taro denies any remaining allegations set forth in paragraph 29.

30. Taro Ltd. has not contested personal jurisdiction in this judicial district. *See*, *e.g.*, *Currax Pharms. LLC v. Taro Pharm. Indus., Ltd. et al.*, DNJ 1:24-cv-7446 (Answer at Dkt. No. 2), *Bausch Health Ireland Ltd., et al. v. Taro Pharms. Inc., et al.*, DNJ 1:22-cv-4670 (Answer at Dkt. No. 17); *Galderma Laby's., LP et al v. Taro Pharms., Inc. et al.*, DNJ 3:24-cv-00333 (Answer at Dkt. No. 11).

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. Taro denies any remaining allegations set forth in paragraph 30.

31. Taro Canada, Taro USA, and Taro Ltd. hold themselves out as a single entity for purposes of commercially manufacturing, marketing, offering to sell, selling and distributing generic products and has acted in concert in submitting the Taro ANDA.

ANSWER: Denied.

32. Pursuant to 28 U.S.C. §§ 1391 and 1400(b) venue is proper in this district as to Taro Canada because, *inter alia*, Taro Canada (i) is a company organized and existing under the laws of Canada and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3) and (ii) has previously consented to venue in this jurisdiction. *See*, *e.g.*, *Bausch Health Ireland Ltd., et al. v. Taro Pharms. Inc., et al.*, DNJ 1:22-cv-4670 (Answer at Dkt. No. 17). Taro Canada has engaged in regular and established business contacts with New Jersey by, among other things, contracting

and engaging in related commercial activities concerning the marketing, making, shipping, using, offering to sell or selling Defendants' generic products in this judicial district, and deriving substantial revenue from such activities. Taro Canada will also directly benefit from the approval of the Taro ANDA.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro Canada does not contest venue. Taro denies any remaining allegations set forth in paragraph 32.

33. Pursuant to 28 U.S.C. §§ 1391 and 1400(b) venue is proper in this district as to Taro USA, because, *inter alia*, Taro USA (i) has committed and will commit acts of infringement in this judicial district; (ii) maintains a regular and established place of business in this judicial district; and (iii) has previously consented to venue in this jurisdiction. *See*, *e.g.*, *Bausch Health Ireland Ltd., et al. v. Taro Pharms. Inc., et al.*, DNJ 1:22-cv-4670 (Answer at Dkt. No. 17). Taro USA has engaged in regular and established business contacts with New Jersey by, among other things, contracting and engaging in related commercial activities concerning the marketing, making, shipping, using, offering to sell or selling Defendants' generic products in this judicial district, and deriving substantial revenue from such activities. Taro USA will also directly benefit from the approval of the Taro ANDA

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Taro USA does not contest venue. Taro denies any remaining allegations set forth in paragraph 33.

34. Pursuant to 28 U.S.C. §§ 1391 and 1400(b) venue is proper in this district as to Taro Ltd. because, *inter alia*, Taro Ltd. (i) is a company organized and existing under the laws of Israel and may be sued in any judicial district, 28 U.S.C. § 1391(c)(3), and (ii) has previously consented to venue in this jurisdiction. *See*, *e.g.*, *Bausch Health Ireland Ltd., et al. v. Taro Pharms. Inc., et al.*, DNJ 1:22-cv-4670 (Answer at Dkt. No. 17). Taro Ltd has engaged in regular and established business contacts with New Jersey by, among other things, contracting and engaging in related commercial activities concerning the marketing, making, shipping, using, offering to sell or selling Defendants' generic products in this judicial district, and deriving substantial revenue from such activities. Taro Ltd. will also directly benefit from the approval of the Taro ANDA.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. Taro denies any remaining allegations set forth in paragraph 34.

THE CABTREO® NDA

35. BHUS is the registered holder of New Drug Application ("NDA") No. 216632 for Cabtreo® (clindamycin phosphate, adapalene, and benzoyl Peroxide (1.2%/0.15%/3.1%) topical gel). The FDA approved NDA No. 216632 for Cabtreo® on October 20, 2023.

ANSWER: Taro admits that the products that are the subject of NDA No. 216632 are marketed under the trade name Cabtreo®. Taro admits that BHUS is indicated in the public records of the FDA as the holder of NDA No. 216632 for Cabtreo (clindamycin phosphate, adapalene, and benzoyl peroxide) topical gel (1.2%/0.15%/3.1%) and that the NDA was approved by the FDA on October 20, 2023. Taro denies any remaining allegations set forth in paragraph 35.

36. The FDA issues a publication entitled Approved Drug Products with Therapeutic Equivalence Evaluation ("the Orange Book"). In accordance with 21 U.S.C. § 355(b)(1), the Asserted Patents are listed in the Orange Book in connection with NDA No. 216632 as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Cabtreo®.

ANSWER: Paragraph 36 states a legal conclusion to which no answer is required. To the extent an answer is required, Taro admits that the Asserted Patents are currently listed in the FDA's online version of the Orange Book in connection with NDA No. 216632. Taro denies the remaining allegations in paragraph 36.

37. Cabtreo® is distributed by BHUS. The Asserted Patents are assigned to and owned by BIRL.

ANSWER: Taro lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 37, and, therefore, denies those allegations.

THE ASSERTED PATENTS

38. On October 16, 2012, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '434 Patent, titled "Topical Pharmaceutical Formulations Containing A Low Concentration Of Benzoyl Peroxide In Suspension In Water And A Water-Miscible Organic Solvent" to inventors Yunik Chang and Gordon J. Dow. A true and correct copy of the '434 Patent is attached hereto as Exhibit A.

ANSWER: Taro admits that Plaintiffs purport to attach a copy of the '434 patent to the Complaint as Exhibit A. Taro admits that the '434 patent states on its face that it was issued on October 16, 2012 and is titled "Topical Pharmaceutical Formulations Containing A Low Concentration Of Benzoyl Peroxide In Suspension In Water And A Water-Miscible Organic

Solvent." Taro admits that the '434 patent lists Yunik Chang and Gordon J. Dow as inventors. Taro denies the remaining allegations in paragraph 38.

39. On February 7, 2017, the USPTO duly and legally issued the '208 Patent, titled "Topical Pharmaceutical Formulations Containing A Low Concentration Of Benzoyl Peroxide In Suspension In Water And A Water-Miscible Organic Solvent" to inventors Yunik Chang and Gordon J. Dow. A true and correct copy of the '208 Patent is attached hereto as Exhibit B.

ANSWER: Taro admits that Plaintiffs purport to attach a copy of the '208 patent to the Complaint as Exhibit B. Taro admits that the '208 patent states on its face that it was issued on February 7, 2017 and is titled "Topical Pharmaceutical Formulations Containing A Low Concentration Of Benzoyl Peroxide In Suspension In Water And A Water-Miscible Organic Solvent." Taro admits that the '208 patent lists Yunik Chang and Gordon J. Dow as inventors. Taro denies the remaining allegations in paragraph 39.

40. On March 5, 2019, the USPTO duly and legally issued the '049 Patent, titled "Topical Pharmaceutical Formulations Containing A Low Concentration Of Benzoyl Peroxide In Suspension In Water And A Water-Miscible Organic Solvent" to inventors Yunik Chang and Gordon J. Dow. A true and correct copy of the '049 Patent is attached hereto as Exhibit C.

ANSWER: Taro admits that Plaintiffs purport to attach a copy of the '049 patent to the Complaint as Exhibit C. Taro admits that the '049 patent states on its face that it was issued on March 5, 2019 and is titled "Topical Pharmaceutical Formulations Containing A Low Concentration Of Benzoyl Peroxide In Suspension In Water And A Water-Miscible Organic Solvent." Taro admits that the '049 patent lists Yunik Chang and Gordon J. Dow as inventors. Taro denies the remaining allegations in paragraph 40.

41. On April 21, 2020, the USPTO duly and legally issued the '918 Patent, titled "Topical Pharmaceutical Formulations Containing A Low Concentration Of Benzoyl Peroxide In Suspension In Water And A Water-Miscible Organic Solvent" to inventors Yunik Chang, Gordon J. Dow, and Radhakrishnan Pillai. A true and correct copy of the '918 Patent is attached hereto as Exhibit D.

ANSWER: Taro admits that Plaintiffs purport to attach a copy of the '918 patent to the Complaint as Exhibit D. Taro admits that the '918 patent states on its face that it was issued on

April 21, 2020 and is titled "Topical Pharmaceutical Formulations Containing A Low Concentration Of Benzoyl Peroxide In Suspension In Water And A Water-Miscible Organic Solvent." Taro admits that the '918 patent lists Yunik Chang, Gordon J. Dow, and Radhakrishnan Pillai as inventors. Taro denies the remaining allegations in paragraph 41.

42. On July 19, 2022, the USPTO duly and legally issued the '467 Patent, titled "Topical Compositions" to inventors Varsha Bhatt, Radhakrishnan Pillai, and Arturo Angel. A true and correct copy of the '467 Patent is attached hereto as Exhibit E.

ANSWER: Taro admits that Plaintiffs purport to attach a copy of the '467 patent to the Complaint as Exhibit E. Taro admits that the '467 patent states on its face that it was issued on July 19, 2022 and is titled "Topical Compositions." Taro admits that the '467 patent lists Varsha Bhatt, Radhakrishnan Pillai, and Arturo Angel as inventors. Taro denies the remaining allegations in paragraph 42.

43. On October 29, 2024, the USPTO duly and legally issued the '059 Patent, titled "Topical Compositions" to inventors Varsha Bhatt, Radhakrishnan Pillai, and Arturo Angel. A true and correct copy of the '059 Patent is attached hereto as Exhibit F.

ANSWER: Taro admits that Plaintiffs purport to attach a copy of the '059 patent to the Complaint as Exhibit F. Taro admits that the '059 patent states on its face that it was issued on October 29, 2024 and is titled "Topical Compositions." Taro admits that the '059 patent lists Varsha Bhatt, Radhakrishnan Pillai, and Arturo Angel as inventors. Taro denies the remaining allegations in paragraph 43.

44. On November 5, 2024, the USPTO duly and legally issued the '859 Patent, titled "Topical Compositions" to inventors Varsha Bhatt, Radhakrishnan Pillai, and Arturo Angel. A true and correct copy of the '859 Patent is attached hereto as Exhibit G.

ANSWER: Taro admits that Plaintiffs purport to attach a copy of the '859 patent to the Complaint as Exhibit G. Taro admits that the '859 patent states on its face that it was issued on November 5, 2024 and is titled "Topical Compositions." Taro admits that the '859 patent lists

Varsha Bhatt, Radhakrishnan Pillai, and Arturo Angel as inventors. Taro denies the remaining allegations in paragraph 44.

45. On November 12, 2024, the USPTO duly and legally issued the '278 Patent, entitled "Topical Compositions" to inventors Varsha Bhatt, Radhakrishnan Pillai, and Arturo Angel. A true and correct copy of the '278 Patent is attached hereto as Exhibit H.

ANSWER: Taro admits that Plaintiffs purport to attach a copy of the '278 patent to the Complaint as Exhibit H. Taro admits that the '278 patent states on its face that it was issued on November 12, 2024 and is titled "Topical Compositions." Taro admits that the '278 patent lists Varsha Bhatt, Radhakrishnan Pillai, and Arturo Angel as inventors. Taro denies the remaining allegations in paragraph 45.

DEFENDANTS' INFRINGING ANDA SUBMISSION

46. Defendants submitted or caused to be submitted with the FDA the Taro ANDA, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

ANSWER: Taro admits that Taro Canada is the owner of ANDA No. 220097 and seeks FDA approval of ANDA No. 220097. Taro denies any remaining allegations set forth in paragraph 46.

47. The Taro ANDA seeks FDA approval to commercially manufacture, market, import, use, sell and/or offer for sale in the U.S. Taro's Proposed Generic Product, which is specifically intended to be a generic version of Bausch Health's Cabtreo® drug product.

ANSWER: Taro admits that Taro Canada is the owner of ANDA No. 220097 and seeks FDA approval of ANDA No. 220097 and that ANDA No. 220097 was filed with a Paragraph IV Certification with respect to the '434, '208, '049, '918, '467, '059, '859, and '278 patents. Taro denies any remaining allegations set forth in paragraph 47.

48. Plaintiffs received a letter dated February 5, 2025, purporting to be a Notice of Paragraph IV Certification regarding the Taro ANDA ("Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95.

ANSWER: Taro admits that in compliance with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 a letter was sent on February 5, 2025 to Plaintiffs notifying in writing that ANDA No. 220097 had been filed containing a Paragraph IV Certification pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 with respect to the '434, '208, '049, '918, '467, '059, '859, and '278 patents. Taro denies any remaining allegations set forth in paragraph 48.

49. The Notice Letter claims Taro Canada had included a certification in the Taro ANDA, pursuant to 21 U.S.C § 355(j)(2)(A)(vii)(IV), and alleges the Asserted Patents, which are listed in the Orange Book, are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of Taro's Proposed Generic Product.

ANSWER: Taro admits that in compliance with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 a letter was sent on February 5, 2025 to Plaintiffs notifying in writing that ANDA No. 220097 had been filed containing a Paragraph IV Certification pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 with respect to the '434, '208, '049, '918, '467, '059, '859, and '278 patents. Taro denies any remaining allegations set forth in paragraph 49.

50. The Notice Letter claims the Taro ANDA has been submitted to the FDA seeking approval to commercially manufacture, use, and/or sell Taro's Proposed Generic Product that is specifically intended to be a generic version of Cabtreo®, which is the reference listed drug ("RLD") as identified by Defendants.

ANSWER: Taro admits that in compliance with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 a letter was sent on February 5, 2025 to Plaintiffs notifying in writing that ANDA No. 220097 had been filed containing a Paragraph IV Certification pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 with respect to the '434, '208, '049, '918, '467, '059, '859, and '278 patents. Taro denies any remaining allegations set forth in paragraph 50.

51. The Notice Letter claims the Taro ANDA contains "any required bioavailability or bioequivalence data or information," for Taro's Proposed Generic Product.

ANSWER: Taro admits that in compliance with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 a letter was sent on February 5, 2025 to Plaintiffs notifying in writing that ANDA No. 220097 had been filed containing a Paragraph IV Certification pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 with respect to the '434, '208, '049, '918, '467, '059, '859, and '278 patents. Taro denies any remaining allegations set forth in paragraph 51.

52. The Taro ANDA seeks approval of Taro's Proposed Generic Product that is the same, or substantially the same, as Cabtreo®.

ANSWER: Denied.

53. At least one claim of each of the Asserted Patents is infringed by the submission of the Taro ANDA to the FDA that seeks approval of Taro's Proposed Generic Product.

ANSWER: Denied.

54. Defendants had actual and constructive notice of the Asserted Patents prior to submitting the Taro ANDA with the FDA because, *inter alia*: (i) Defendants collaborated in the research, development, preparation, and submission of the Taro ANDA; (ii) Taro's Notice Letter, includes, at least, Taro's listing of Cabtreo® as the RLD; (iii) the FDA requirements for ANDA submissions; (iv) Taro's expressed desire to market a product equivalent to Cabtreo®; and (v) Taro's submission of bioequivalence data to the FDA purporting that Taro's Proposed Generic Product contains the same active ingredients in the same dosages as Cabtreo®.

ANSWER: Paragraph 54 states a legal conclusion to which no answer is required. Taro denies the remaining allegations set forth in paragraph 54.

55. Plaintiffs commenced this lawsuit within 45 days of the date they received Taro's Notice Letter concerning the Taro ANDA.

ANSWER: Paragraph 55 states a legal conclusion to which no answer is required. Taro denies the remaining allegations set forth in paragraph 55.

COUNT I

Infringement of the '434 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-55 as if fully set forth herein.

57. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '434 Patent by submitting the Taro ANDA to the FDA seeking approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale within the U.S., or importation into the U.S. of Taro's Proposed Generic Product prior to the expiration of the '434 Patent.

ANSWER: Denied.

58. Taro's Proposed Generic Product will, if approved and marketed, infringe as least one claim of the '434 Patent.

ANSWER: Denied.

59. Defendants commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product prior to the expiration of the '434 Patent would infringe, contribute to the infringement of, and/or induce the infringement of at least one claim of the '434 Patent.

ANSWER: Denied.

60. If Defendants' marketing, manufacturing, offering to sell and sale of Taro's Proposed Generic Product prior to the expiration of the '434 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT II

Declaratory Judgment of Infringement of the '434 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-60 as if fully set forth herein.

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

ANSWER: Paragraph 62 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies any remaining allegations set forth in paragraph 62.

63. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '434 Patent such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution. This actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations of infringement set forth in paragraph 63.

64. Taro will launch Taro's Proposed Generic Product upon approval after the 30-month stay if not enjoined from infringing or actively inducing or contributing to infringement of the '434 Patent. The mean approval time by the FDA for ANDA applications is about 39 months and median is about 26 months. Therefore, there is sufficient immediacy to justify a declaration of infringement of the '434 Patent.

ANSWER: Paragraph 64 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 64, and, therefore, denies those allegations.

65. Taro has made, and will continue to make, substantial preparations in the U.S. to manufacture, import, use, sell, and/or offer for sale within the U.S. Taro's Proposed Generic Product before the expiration date of the '434 Patent, including Taro's submission of the Taro ANDA.

ANSWER: Denied.

66. Any commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '434 Patent.

ANSWER: Denied.

67. Plaintiffs are entitled to an order declaring that future commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product will constitute infringement of at least one claim of the '434 Patent.

ANSWER: Denied.

COUNT III

Infringement of the '208 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-67 as if fully set forth herein.

69. Taro has infringed at least one claim of the '208 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Taro ANDA with a Paragraph IV certification, by which Taro seeks approval from the FDA to engage in the commercial manufacture, importation, use, sale, and/or offer for sale within the U.S., or importation into the U.S. of Taro's Proposed Generic Product prior to the expiration of the '208 Patent.

ANSWER: Denied.

70. Taro's commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product prior to the expiration of the '208 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '208 Patent.

ANSWER: Denied.

71. If Defendants' marketing, manufacturing, offering to sell and sale of Taro's Proposed Generic Product prior to the expiration of the '208 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT IV

Declaratory Judgment of Infringement of the '208 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-71 as if fully set forth herein.

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

ANSWER: Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies any remaining allegations set forth in paragraph 73.

74. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '208 Patent such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution. This actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations of infringement set forth in paragraph 74.

75. Taro will launch Taro's Proposed Generic Product upon approval after the 30-month stay if not enjoined from infringing or actively inducing or contributing to infringement of the '208 Patent. The mean approval time by the FDA for ANDA applications is about 39 months and median is about 26 months. Therefore, there is sufficient immediacy to justify a declaration of infringement of the '208 Patent.

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 75, and, therefore, denies those allegations.

76. Taro has made, and will continue to make, substantial preparation in the U.S. to manufacture, import, use, sell, and/or offer for sale within the U.S. Taro's Proposed Generic Product before the expiration date of the '208 Patent, including Taro's submission of the Taro ANDA.

ANSWER: Denied.

77. Any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '208 Patent.

ANSWER: Denied.

78. Plaintiffs are entitled to an order declaring that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will constitute infringement of at least one claim of the '208 Patent.

ANSWER: Denied.

COUNT V

Infringement of the '049 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-78 as if fully set forth herein.

80. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '049 Patent by submitting the Taro ANDA to the FDA seeking approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale within the U.S., or importation into the U.S. of Taro's Proposed Generic Product prior to the expiration of the '049 Patent.

ANSWER: Denied.

81. Taro's commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product prior to the expiration of the '049 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '049 Patent.

ANSWER: Denied.

82. If Defendants' marketing, manufacturing, offering to sell and sale of Taro's Proposed Generic Product prior to the expiration of the '049 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT VI

Declaratory Judgment of Infringement of the '049 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-82 as if fully set forth herein.

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

ANSWER: Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations set forth in paragraph 84.

85. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '049 Patent such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution. This actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the remaining allegations of infringement set forth in paragraph 85.

86. Taro will launch Taro's Proposed Generic Product upon approval after the 30-month stay if not enjoined from infringing or actively inducing or contributing to infringement of the '049 Patent. The mean approval time by the FDA for ANDA applications is about 39 months and median is about 26 months. Therefore, there is sufficient immediacy to justify a declaration of infringement of the '049 Patent.

ANSWER: Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 86, and, therefore, denies those allegations.

87. Taro has made, and will continue to make, substantial preparation in the U.S. to manufacture, import, use, sell, and/or offer for sale within the U.S. Taro's Proposed Generic Product before the expiration date of the '049 Patent, including Taro's submission of the Taro ANDA.

ANSWER: Denied.

88. Any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '049 Patent.

ANSWER: Denied.

89. Plaintiffs are entitled to an order declaring that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will constitute infringement of at least one claim of the '049 Patent.

ANSWER: Denied.

COUNT VII

Infringement of the '918 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-89 as if fully set forth herein.

91. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '918 Patent by submitting the Taro ANDA to the FDA seeking approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale within the U.S., or importation into the U.S. of Taro's Proposed Generic Product prior to the expiration of the '918 Patent.

ANSWER: Denied.

92. Taro's commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product prior to the expiration of the '918 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '918 Patent.

ANSWER: Denied.

93. If Defendants' marketing, manufacturing, offering to sell and sale of Taro's Proposed Generic Product prior to the expiration of the '918 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT VIII

Declaratory Judgment of Infringement of the '918 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-93 as if fully set forth herein.

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

ANSWER: Paragraph 95 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations set forth in paragraph 95.

96. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '918 Patent such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution. This actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 96 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations of infringement set forth in paragraph 96.

97. Taro will launch Taro's Proposed Generic Product upon approval after the 30-month stay if not enjoined from infringing or actively inducing or contributing to infringement of the '918 Patent. The mean approval time by the FDA for ANDA applications is about 39 months and median is about 26 months. Therefore, there is sufficient immediacy to justify a declaration of infringement of the '918 Patent.

ANSWER: Paragraph 97 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 97, and, therefore, denies those allegations.

98. Taro has made, and will continue to make, substantial preparation in the U.S. to manufacture, import, use, sell, and/or offer for sale within the U.S. Taro's Proposed Generic Product before the expiration date of the '918 Patent, including Taro's submission of the Taro ANDA.

ANSWER: Denied.

99. Any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '918 Patent.

ANSWER: Denied.

100. Plaintiffs are entitled to an order declaring that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will constitute infringement of at least one claim of the '918 Patent.

ANSWER: Denied.

COUNT IX

Infringement of the '467 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-100 as if fully set forth herein.

102. By way of the Notice Letter, Defendants do not contest infringement of claims 1-2, 4-8, 10, 12, 14-19, and 21 of the '467 Patent.

ANSWER: Denied.

103. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '467 Patent by submitting the Taro ANDA to the FDA seeking approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale within the U.S., or importation into the U.S. of Taro's Proposed Generic Product prior to the expiration of the '467 Patent.

ANSWER: Denied.

104. Taro's commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product prior to the expiration of the '467 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '467 Patent.

ANSWER: Denied.

105. If Defendants' marketing, manufacturing, offering to sell and sale of Taro's Proposed Generic Product prior to the expiration of the '467 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT X

Declaratory Judgment of Infringement of the '467 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-105 as if fully set forth herein.

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

ANSWER: Paragraph 107 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations set forth in paragraph 107.

108. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '467 Patent such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution. This actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 108 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations of infringement set forth in paragraph 108.

109. The mean approval time by the FDA for ANDA applications is about 39 months and median is about 26 months. Taro will launch Taro's Proposed Generic Product upon approval after the 30-month stay if not enjoined from infringing or actively inducing or contributing to infringement of the '467 Patent. Therefore, there is sufficient immediacy to justify a declaration of infringement of the '467 Patent.

ANSWER: Paragraph 109 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 109, and, therefore, denies those allegations.

110. Taro has made, and will continue to make, substantial preparation in the U.S. to manufacture, import, use, sell, and/or offer for sale within the U.S. Taro's Proposed Generic Product before the expiration date of the '467 Patent, including Taro's submission of the Taro ANDA.

ANSWER: Denied.

111. Any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '467 Patent.

ANSWER: Denied.

112. Plaintiffs are entitled to an order declaring that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will constitute infringement of at least one claim of the '467 Patent.

ANSWER: Denied.

COUNT XI

Infringement of the '059 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-112 as if fully set forth herein.

114. By way of the Notice Letter, Defendants do not contest infringement of claims 1-2, 4-8, 11, 13-17, and 19 of the '059 Patent.

ANSWER: Denied.

115. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '059 Patent by submitting the Taro ANDA to the FDA seeking approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale within the U.S., or importation into the U.S. of Taro's Proposed Generic Product prior to the expiration of the '059 Patent.

ANSWER: Denied.

116. Taro's commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product prior to the expiration of the '059 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '059 Patent.

ANSWER: Denied.

117. If Defendants' marketing, manufacturing, offering to sell and sale of Taro's Proposed Generic Product prior to the expiration of the '059 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT XII

Declaratory Judgment of Infringement of the '059 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-117 as if fully set forth herein.

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

ANSWER: Paragraph 119 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations set forth in paragraph 119.

120. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '059 Patent such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution. This actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 120 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations of infringement set forth in paragraph 120.

121. Taro will launch Taro's Proposed Generic Product upon approval after the 30-month stay if not enjoined from infringing or actively inducing or contributing to infringement of the '059 Patent. The mean approval time by the FDA for ANDA applications is about 39 months and median is about 26 months. Therefore, there is sufficient immediacy to justify a declaration of infringement of the '059 Patent.

ANSWER: Paragraph 121 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 121, and, therefore, denies those allegations.

122. Taro has made, and will continue to make, substantial preparation in the U.S. to manufacture, import, use, sell, and/or offer for sale within the U.S. Taro's Proposed Generic Product before the expiration date of the '059 Patent, including Taro's submission of the Taro ANDA.

ANSWER: Denied.

123. Any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '059 Patent.

ANSWER: Denied.

124. Plaintiffs are entitled to an order declaring that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will constitute infringement of at least one claim of the '059 Patent.

ANSWER: Denied.

COUNT XIII

Infringement of the '859 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-124 as if fully set forth herein.

126. By way of the Notice Letter, Defendants do not contest infringement of claims 1-2, 4-8, 10, 12-17, and 19-20 of the '859 Patent.

ANSWER: Denied.

127. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '859 Patent by submitting the Taro ANDA to the FDA seeking approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale within the U.S., or importation into the U.S. of Taro's Proposed Generic Product prior to the expiration of the '859 Patent.

ANSWER: Denied.

128. Taro's commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product prior to the expiration of the '859 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '859 Patent.

ANSWER: Denied.

129. If Defendants' marketing, manufacturing, offering to sell and sale of Taro's Proposed Generic Product prior to the expiration of the '859 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT XIV

Declaratory Judgment of Infringement of the '859 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-129 as if fully set forth herein.

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

ANSWER: Paragraph 131 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations set forth in paragraph 131.

132. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '859 Patent such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution. This actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 132 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations of infringement set forth in paragraph 132.

133. Taro will launch Taro's Proposed Generic Product upon approval after the 30-month stay if not enjoined from infringing or actively inducing or contributing to infringement of the '859 Patent. The mean approval time by the FDA for ANDA applications is about 39 months and median is about 26 months. Therefore, there is sufficient immediacy to justify a declaration of infringement of the '859 Patent.

ANSWER: Paragraph 133 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 133, and, therefore, denies those allegations.

134. Taro has made, and will continue to make, substantial preparation in the U.S. to manufacture, import, use, sell, and/or offer for sale within the U.S. Taro's Proposed Generic Product before the expiration date of the '859 Patent, including Taro's submission of the Taro ANDA.

ANSWER: Denied.

135. Any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '859 Patent.

ANSWER: Denied.

136. Plaintiffs are entitled to an order declaring that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will constitute infringement of at least one claim of the '859 Patent.

ANSWER: Denied.

COUNT XV

Infringement of the '278 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-136 as if fully set forth herein.

138. By way of the Notice Letter, Defendants do not contest infringement of claims 1-3, 5-8, 10, 12-16, and 18-20 of the '278 Patent.

ANSWER: Denied.

139. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '278 Patent by submitting the Taro ANDA to the FDA seeking approval to engage in the commercial manufacture, importation, use, sale, and/or offer for sale within the U.S., or

importation into the U.S. of Taro's Proposed Generic Product prior to the expiration of the '278 Patent.

ANSWER: Denied.

140. Taro's commercial manufacture, importation, use, sale, and/or offer for sale of Taro's Proposed Generic Product prior to the expiration of the '278 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '278 Patent.

ANSWER: Denied.

141. If Defendants' marketing, manufacturing, offering to sell and sale of Taro's Proposed Generic Product prior to the expiration of the '278 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT XVI

Declaratory Judgment of Infringement of the '278 Patent

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

ANSWER: Taro hereby incorporates by reference its responses to paragraphs 1-141 as if fully set forth herein.

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

ANSWER: Paragraph 143 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations set forth in paragraph 143.

144. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '278 Patent such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution. This actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 144 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro denies the allegations of infringement set forth in paragraph 144.

145. Taro will launch Taro's Proposed Generic Product upon approval after the 30-month stay if not enjoined from infringing or actively inducing or contributing to infringement of the '278 Patent. The mean approval time by the FDA for ANDA applications is about 39 months and median is about 26 months. Therefore, there is sufficient immediacy to justify a declaration of infringement of the '278 Patent.

ANSWER: Paragraph 145 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Taro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 145, and, therefore, denies those allegations.

146. Taro has made, and will continue to make, substantial preparation in the U.S. to manufacture, import, use, sell, and/or offer for sale within the U.S. Taro's Proposed Generic Product before the expiration date of the '278 Patent, including Taro's submission of the Taro ANDA.

ANSWER: Denied.

147. Any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '278 Patent.

ANSWER: Denied.

148. Plaintiffs are entitled to an order declaring that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's Proposed Generic Product will constitute infringement of at least one claim of the '278 Patent.

ANSWER: Denied.

REQUEST FOR RELIEF

Taro denies that Plaintiffs are entitled to any judgment or relief against Taro and, therefore specifically denies paragraphs i through ix of Plaintiffs' Prayer for Relief.

GENERAL DENIAL

Taro denies all remaining allegations not specifically admitted herein. Taro further denies that Plaintiffs are entitled to any judgment or relief requested in the Complaint, or to any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the responses and denials set forth in Taro's Answer, without admitting any allegations of the Complaint not expressly admitted, and without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs, Taro asserts the following separate defenses to the Complaint:

FIRST DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

The claims of United States Patent Nos. 8,288,434 ("the '434 Patent"); 9,561,208 ("the '208 Patent"); 10,220,049 ("the '049 Patent"); 10,624,918 ("the '918 Patent"); 11,389,467 ("the '467 Patent"); 12,128,059 ("the '059 Patent"); 12,133,859 ("the '859 Patent"); and 12,138,278 ("the '278 Patent") (collectively, the "Patents-in-Suit") are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

THIRD DEFENSE

Taro does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the Patents-in-Suit, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH DEFENSE

The Complaint fails to state a claim for an exceptional case and/or willful infringement 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.

FIFTH DEFENSE

Plaintiffs may not seek injunctive relief against Taro because Plaintiffs' alleged damages are not immediate or irreparable.

ADDITIONAL DEFENSES

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

COUNTERCLAIMS

Counterclaim-Plaintiffs Taro Pharmaceuticals Inc. ("Taro Canada") and Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") (collectively, "Counterclaim-Plaintiffs"), by and through the undersigned attorneys, hereby assert the following counterclaims against Plaintiffs/Counterclaim-Defendants Bausch Health Ireland Limited ("BIRL"), Bausch Health US, LLC ("BHUS"), and Bausch Health Americas, Inc. ("BHA") (collectively, "Bausch Health" or "Counterclaim-Defendants").

THE PARTIES

1. Counterclaim-Plaintiff Taro Canada is a corporation organized and existing under the laws of Canada, having a principal place of business in Brampton, Canada.

2. Counterclaim-Plaintiff Taro USA is a company incorporated under the laws of the state of New York, having a place of business in Hawthorne, New York.

3. Taro Canada is the owner of ANDA No. 220097 and seeks FDA approval of ANDA No. 220097.

4. According to Plaintiffs/Counterclaim-Defendants' allegations, BIRL purports to be a corporation organized and existing under the laws of Ireland located at 3013 Lake Drive, Citywest Business Campus, Dublin D24 PPT3, Ireland.

5. According to Plaintiffs/Counterclaim-Defendants' allegations, BHUS purports to be a corporation organized and existing under the laws of Delaware with a principal place of business and corporate headquarters located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

6. According to Plaintiffs/Counterclaim-Defendants' allegations, BHA purports to be a corporation organized and existing under the laws of Delaware with a principal place of business

and corporate headquarters located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

NATURE OF THE ACTION

7. Counterclaim-Plaintiffs seek a declaratory judgment that the claims of the '434, '208, '049, '918, '467, '059, '859, and '278 patents are invalid and/or will not be infringed by Counterclaim-Plaintiffs.

JURISDICTION AND VENUE

8. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. The Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Without prejudice, venue is proper in this District for purposes of these counterclaims because Plaintiffs/Counterclaim-Defendants have commenced and continue to prosecute this action in this District.

11. Plaintiffs/Counterclaim-Defendants are subject to personal jurisdiction in this District because they commenced and continue to prosecute this action in this District.

BACKGROUND

12. Plaintiffs/Counterclaim-Defendants have alleged in the instant action that they are the owners of all legal rights, title, and interests in the '434, '208, '049, '918, '467, '059, '859, and '278 patents.

13. Upon information and belief, and according to Plaintiffs/Counterclaim-Defendants' allegations, BHUS is the registered holder of New Drug Application ("NDA") No. 216632 for Cabtreo® (clindamycin phosphate, adapalene, and benzoyl peroxide (1.2%/0.15%/3.1%) topical gel).

14. The ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents are listed in the electronic version of the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) for Cabtreo®.

15. Taro Canada is the owner of ANDA No. 220097 and seeks FDA approval of ANDA No. 220097 to market in the United States the products described therein.

16. A letter was sent on February 5, 2025 to Plaintiffs/Counterclaim-Defendants’ notifying in writing that ANDA No. 220097 had been filed containing a Paragraph IV Certification pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 with respect to the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents.

17. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), the Notice Letter was accompanied by a detailed statement of the factual and legal bases for the Paragraph IV Certifications with respect to the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents.

COUNT 1

(Declaratory Judgment of Noninfringement of the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 Patents)

18. Paragraphs 1-17 of the Counterclaims are incorporated as if fully set forth herein.

19. Plaintiffs/Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents in connection with ANDA No. 220097.

20. Counterclaim-Plaintiffs have not infringed, will not infringe, and are not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents.

21. Unless Plaintiffs/Counterclaim-Defendants are enjoined, Counterclaim-Plaintiffs believe that Plaintiffs/Counterclaim-Defendants will continue to assert that Counterclaim-Plaintiffs are infringing the claims of the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents, and will continue to interfere with Counterclaim-Plaintiffs’ business.

22. Counterclaim-Plaintiffs will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents and from interfering with Counterclaim-Plaintiffs’ business.

23. A definite and concrete, real and substantial, justiciable controversy exists between Counterclaim-Plaintiffs and Plaintiffs/Counterclaim-Defendants concerning Counterclaim-Plaintiffs’ noninfringement of the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

24. Counterclaim-Plaintiffs are entitled to declaratory judgment that Counterclaim-Plaintiffs’ proposed Clindamycin Phosphate, Adapalene, and Benzoyl Peroxide Gel product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents.

COUNT 2

(Declaratory Judgment of Invalidity of the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 Patents)

25. Paragraphs 1-24 of the Counterclaims are incorporated as if fully set forth herein.

26. The claims of the ’434, ’208, ’049, ’918, ’467, ’059, ’859, and ’278 patents are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

27. The alleged inventions of the '434, '208, '049, '918, '467, '059, '859, and '278 patents do 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 '434, '208, '049, '918, '467, '059, '859, and '278 patents is no 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 '434, '208, '049, '918, '467, '059, '859, and '278 patents and would have had a reasonable expectation of success in doing so.

28. The claims of the '434, '208, '049, '918, '467, '059, '859, and '278 patents are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '434, '208, '049, '918, '467, '059, '859, and '278 patents and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or 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.

29. Unless Plaintiff/Counterclaim-Defendants are enjoined, Counterclaim-Plaintiffs believe that Plaintiffs/Counterclaim-Defendants will continue to assert that Counterclaim-Plaintiffs infringe the claims of the '434, '208, '049, '918, '467, '059, '859, and '278 patents and will continue to interfere with Counterclaim-Plaintiffs' business.

30. Counterclaim-Plaintiffs will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the '434, '208, '049, '918, '467, '059, '859, and '278 patents and from interfering with Counterclaim-Plaintiffs' business.

31. A definite and concrete, real and substantial, justiciable controversy exists between Counterclaim-Plaintiffs and Plaintiffs/Counterclaim-Defendants concerning the invalidity of the

'434, '208, '049, '918, '467, '059, '859, and '278 patents, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

32. Counterclaim-Plaintiffs are entitled to a declaratory judgment that the claims of the '434, '208, '049, '918, '467, '059, '859, and '278 patents are invalid.

COUNT 3

(Declaratory Judgment of No Injunctive Remedy for the '434, '208, '049, '918, '467, '059, '859, and '278 Patents)

33. Paragraphs 1-32 of the Counterclaims are incorporated as if fully set forth herein.

34. Plaintiffs/Counterclaim-Defendants cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages even if infringement of a valid and enforceable patent were presumed.

35. Plaintiffs/Counterclaim-Defendants are not entitled to any injunctive remedy of any kind.

36. A definite and concrete, real and substantial, justiciable controversy exists between Counterclaim-Plaintiffs and Plaintiffs/Counterclaim-Defendants concerning the existence of no injunctive remedy for alleged infringement of the '434, '208, '049, '918, '467, '059, '859, and '278 patents, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

37. Counterclaim-Plaintiffs are entitled to a declaratory judgment that Plaintiffs/Counterclaim-Defendants are not entitled to any injunctive remedy of any kind regarding any alleged infringement of the claims of the '434, '208, '049, '918, '467, '059, '859, and '278 patents.

EXCEPTIONAL CASE

38. This case is an exceptional one, and Counterclaim-Plaintiffs are entitled to an award of their reasonable attorneys' fees, costs, and expenses under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs respectfully request that this Court enter judgment:

a. Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment be entered in favor of Counterclaim-Plaintiffs;

b. Declaring that Plaintiffs/Counterclaim-Defendants are not entitled to any declaratory or injunctive relief or any alleged damages for alleged patent infringement by Counterclaim-Plaintiffs;

c. Declaring that Counterclaim-Plaintiffs do not infringe, are not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '434, '208, '049, '918, '467, '059, '859, and '278 patents;

d. Declaring that the '434, '208, '049, '918, '467, '059, '859, and '278 patents are invalid;

e. Enjoining Plaintiffs/Counterclaim-Defendants and their officers, employees, agents, representatives, attorneys, and others acting on their behalf from representing to anyone, either directly or indirectly, that Counterclaim-Plaintiffs have infringed, are infringing, or will infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claim of the '434, '208, '049, '918, '467, '059, '859, and '278 patents;

f. Awarding Counterclaim-Plaintiffs their costs;

g. Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Counterclaim-Plaintiffs their attorneys' fees; and

h. Awarding to Counterclaim-Plaintiffs such further relief as this Court may deem necessary, just, and proper.

DATED: July 7, 2025

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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.

Dated: July 7, 2025

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: July 7, 2025

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

I hereby certify that, on July 7, 2025, the foregoing document described as **DEFENDANT TARO'S ANSWER TO COMPLAINT, SEPARATE DEFENSES AND COUNTERCLAIMS** was served on all counsel of record indicated below via electronic mail.

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Dated: July 7, 2025

s/ Gregory D. Miller
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