

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALMIRALL, LLC, ALMIRALL S.A.,	:	
and, ATNX SPV, LLC,	:	
	:	C.A. No. 1:25-cv-00385-CFC
<i>Plaintiffs,</i>	:	
	:	
v.	:	
	:	
TARO PHARMACEUTICALS, INC.,	:	
	:	
<i>Defendant.</i>	:	
	:	

TARO PHARMACEUTICALS, INC.'S ANSWER TO COMPLAINT

Defendant, Taro Pharmaceuticals, Inc. (herein, “Taro” or “Defendant”), by and through its undersigned counsel, respectfully submits its Answer to Plaintiffs’ Complaint, stating as follows:

Responses to Allegations Concerning the Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Taro’s submission of an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”), by which Taro seeks approval to market a generic version of Almirall LLC’s pharmaceutical product Klisyri® (the “Taro ANDA Product”) prior to the expiration of United States Patent Nos. 7,300,931 (the “‘931 patent”), 7,851,470 (the “‘470 patent”), 10,323,001 (the “‘001 patent”), 10,617,693 (the “‘693 patent”), 10,669,236 (the “‘236 patent”), and 11,497,750 (the “‘750 patent”) (together, the “patents-in-suit”) which cover, inter alia, Klisyri® and/or its use.

RESPONSE: Taro admits Plaintiffs purport to bring a civil action to assert infringement under the Patent Laws of the United States, Title 35 of the United States Code, purportedly arising from the submission of an ANDA seeking regulatory approval to market a pharmaceutical product prior to the expiration of the patents-in-suit. Taro admits submitting ANDA No. 220075 seeking regulatory approval for a pharmaceutical product prior to the expiration of the patents-in-suit (“Taro’s ANDA”). Taro admits the brand product Klisyri® is the reference listed drug for Taro’s ANDA. Upon information and belief, Taro admits Almirall LLC markets the brand product Klisyri®. Taro

denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses To Allegations Concerning the Parties

2. Plaintiff Almirall, LLC is a limited liability company organized and existing under the laws of the Commonwealth of Pennsylvania and has its principal place of business at 101 Lindenwood Drive, Suite 400, Malvern, PA 19355.

RESPONSE: Taro is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

3. Plaintiff Almirall, S.A., is an entity organized and existing under the laws of the Kingdom of Spain and has its principal place of business at Ronda del General Mitre, 151 08022, Barcelona, Spain.

RESPONSE: Taro is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

4. Plaintiffs Almirall, LLC and Almirall, S.A. (collectively, unless otherwise specified, "Almirall") are the exclusive licensees of the patents-in-suit.

RESPONSE: Taro is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

5. Plaintiff ATNX SPV, LLC is a limited liability company organized and existing under the laws of the State of Delaware and has its principal place of business at 1001 Main Street, Suite 600, Buffalo, NY 14203.

RESPONSE: Taro is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

6. On information and belief, Defendant Taro Pharmaceuticals, Inc., is a corporation organized and existing under the laws of Canada and has its principal place of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada.

RESPONSE: Taro admits that Taro Pharmaceuticals, Inc., is a corporation organized and existing under the laws of Canada with a place of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Concerning the Jurisdiction and Venue

7. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

RESPONSE: Paragraph 7 contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that this court has subject matter jurisdiction for Plaintiffs' infringement claims under 28 U.S.C. §§ 1331 and 1338(a). Allegations not expressly admitted are denied.

8. This Court has jurisdiction over Taro because, inter alia, Taro has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and, on information and belief, intends a future course of conduct that includes further acts of patent infringement in this judicial district.

RESPONSE: Paragraph 8 contains legal conclusions to which no answer is required. To the extent a response is required, solely for the purpose of this litigation, Taro does not challenge the Court's exercise of personal jurisdiction over Taro. Taro denies all allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

9. On information and belief, Taro is in the business of, inter alia, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions and through the actions of its agents and subsidiaries, from which Taro derives a substantial portion of its revenue.

RESPONSE: Paragraph 9 contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that Taro or certain Taro entities business includes activities

relating to the development, manufacturing, marketing, importing, and selling of pharmaceutical products, including generic products. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

10. On information and belief, Taro, through its own actions and through the actions of its agents and subsidiaries, has engaged in the research and development for, and the preparation and filing of, ANDA No. 220075, continues to engage in seeking FDA approval of this ANDA, intends to engage in the commercial manufacture, marketing, offer for sale, sale, and importation of Taro's ANDA Product throughout the United States, including within this judicial district, and stands accordingly to benefit from any approval of ANDA No. 220075.

RESPONSE: Paragraph 10 contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that Taro or certain Taro entities researched and developed the drug product that is the subject of Taro's ANDA and prepared and filed Taro's ANDA with FDA. This paragraph of the Complaint includes speculative allegations regarding future, uncertain events, which Taro denies on those grounds. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

11. On information and belief, Taro, through its own actions and through the actions of its agents and subsidiaries, prepared and submitted ANDA No. 220075, including, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), certain Paragraph IV Certifications in respect of the patents-in-suit.

RESPONSE: Paragraph 11 contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that Taro or certain Taro entities prepared and submitted Taro's ANDA, including Paragraph IV Certifications pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV). Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

12. On information and belief, following any FDA approval of its ANDA No. 220075, Taro intends that the Taro ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States, including within this judicial district.

RESPONSE: Paragraph 12 contains legal conclusions to which no answer is required. To the extent a response is required, this paragraph of the Complaint includes speculative allegations

regarding future, uncertain events, which Taro denies on those grounds. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

13. Venue is proper as to Taro in this District under 28 U.S.C. §§ 1391(c)(3) and/or 1400(b), because venue in a patent infringement action against a foreign defendant is proper in any judicial district. *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 581 U.S. 258, 267–68 n.2 (2017) (citing *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 711–14 (1972)).

RESPONSE: Paragraph 13 contains legal conclusions to which no answer is required. To the extent a response is required, solely for the purpose of this litigation, Taro does not contest venue in this judicial district. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Concerning the Patents-in-Suit

14. On November 27, 2007, the United States Patent and Trademark Office issued the '931 patent, entitled "Compositions for Treating Cell Proliferation Disorders," a copy of which is attached to this Complaint as **Exhibit A**. ATNX SPV, LLC is the owner of all right, title, and interest in the '931 patent.

RESPONSE: Taro admits Exhibit A appears to be a copy of the '931 patent, which is the best evidence of its contents. Taro admits that the '931 patent on its face is titled "Compositions for Treating Cell Proliferation Disorders" and identifies November 27, 2007, as the date the '931 patent issued. Taro is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

15. On December 14, 2010, the United States Patent and Trademark Office issued the '470 patent, entitled "Composition and Methods for Modulating a Kinase Cascade," a copy of which is attached to this Complaint as **Exhibit B**. ATNX SPV, LLC is the owner of all right, title, and interest in the '470 patent.

RESPONSE: Taro admits Exhibit B appears to be a copy of the '470 patent, which is the best evidence of its contents. Taro admits that the '470 patent on its face is titled "Composition and

Methods for Modulating a Kinase Cascade” and identifies December 14, 2010, as the date the ’470 patent issued. Taro is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

16. On June 18, 2019, the United States Patent and Trademark Office issued the ’001 patent, entitled “Compositions for Modulating a Kinase Cascade and Methods of Use Thereof,” a copy of which is attached to this Complaint as Exhibit C. ATNX SPV, LLC is the owner of all right, title, and interest in the ’001 patent.

RESPONSE: Taro admits Exhibit C appears to be a copy of the ’001 patent, which is the best evidence of its contents. Taro admits that the ’001 patent on its face is titled “Compositions for Modulating a Kinase Cascade and Methods of Use Thereof” and identifies June 18, 2019, as the date the ’001 patent issued. Taro is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

17. On April 14, 2020, the United States Patent and Trademark Office issued the ’693 patent, entitled “Methods of Treating and/or Preventing Actinic Keratosis,” a copy of which is attached to this Complaint as Exhibit D. ATNX SPV, LLC is the owner of all right, title, and interest in the ’693 patent.

RESPONSE: Taro admits Exhibit D appears to be a copy of the ’693 patent, which is the best evidence of its contents. Taro admits that the ’693 patent on its face is titled “Methods of Treating and/or Preventing Actinic Keratosis” and identifies April 14, 2020, as the date the ’693 patent issued. Taro is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

18. On June 2, 2020, the United States Patent and Trademark Office issued the '236 patent, entitled "Solid Forms of 2-(5-(4-(2-Morpholino-ethoxy)Phenyl)Pyridin-2-yl)-NBenzylacetamide," a copy of which is attached to this Complaint as Exhibit E. ATNX SPV, LLC is the owner of all right, title, and interest in the '236 patent.

RESPONSE: Taro admits Exhibit E appears to be a copy of the '236 patent, which is the best evidence of its contents. Taro admits that the '236 patent on its face is titled "Solid Forms of 2-(5-(4-(2-Morpholino-ethoxy)Phenyl)Pyridin-2-yl)-NBenzylacetamide" and identifies June 2, 2020, as the date the '236 patent issued. Taro is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

19. On November 15, 2022, the United States Patent and Trademark office issued the '750 patent, entitled "Methods of Treating and/or Preventing Actinic Keratosis," a copy of which is attached to this Complaint as Exhibit F. ATNX SPV, LLC is the owner of all right, title, and interest in the '750 patent.

RESPONSE: Taro admits Exhibit F appears to be a copy of the '750 patent, which is the best evidence of its contents. Taro admits that the '750 patent on its face is titled "Methods of Treating and/or Preventing Actinic Keratosis" and identifies November 15, 2022, as the date the '750 patent issued. Taro is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Concerning Klisyri®

20. Almirall, LLC holds approved New Drug Application No. 213189 (the "Klisyri® NDA") for *tirbanibulin* topical ointment 1%, which Almirall, LLC sells under the trade name Klisyri®.

RESPONSE: Taro admits that the FDA's Orange Book identifies Almirall, LLC as the applicant holder for NDA No. 213189 and that the trade name for the product approved under NDA No.

213189 is Klisyri®. Taro is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

21. The claims of the patents-in-suit cover, *inter alia*, Klisyri® and/or its use.

RESPONSE: Paragraph 21 contains legal conclusions to which no answer is required. To the extent a response is required, Taro is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

22. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulation, the '931, '470, '001, '693, '236, and '750 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Klisyri®.

RESPONSE: Taro admits the patents-in-suit are listed in the Orange Book with respect to Klisyri®. Taro is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Concerning Taro's ANDA

23. On information and belief, Taro submitted ANDA No. 220075 ("Taro's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of *tirbanibulin* topical ointment 1%.

RESPONSE: Paragraph 23 contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that Taro or certain Taro entities submitted Taro's ANDA to FDA under 21 U.S.C. § 355(j) seeking regulatory approval of Taro's tirbanibulin topical ointment 1%. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

24. On information and belief, Taro's ANDA refers to and relies on the Klisyri® NDA and contains data that, according to Taro, demonstrate the bioequivalence of Taro's generic version of tirbanibulin topical ointment 1% and Klisyri®.

RESPONSE: Taro admits Klisyri® is the reference listed drug for Taro's ANDA. Taro states that Taro's ANDA speaks for itself. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

25. By letter to Almirall, LLC, dated February 14, 2025 (the "Notice Letter"), Taro stated that Taro's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '931, '470, '001, '693, '236, and '750 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Taro's generic version of *tirbanibulin* topical ointment 1% (the "Paragraph IV Certification").

RESPONSE: Taro admits sending Taro's Notice Letter to, *inter alia*, Almirall, LLC, on February 14, 2025. Taro admits Taro's Notice Letter informed Plaintiffs that Taro's ANDA contained Paragraph IV Certifications directed to the '931, '470, '001, '693, '236 and '750 patents. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

26. Taro attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certification.

RESPONSE: Taro admits that Taro's Notice Letter included a Detailed Statement providing a legal and factual basis for Taro's Paragraph IV Certifications. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

27. Plaintiffs file [sic] this Civil Action within 45 days of Almirall's receipt of the Notice Letter.

RESPONSE: Upon information and belief, admitted.

Responses to Count I: Alleged Infringement of U.S. Patent No. 7,300,931

28. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1–27 of this Complaint.

RESPONSE: Taro incorporates its responses to paragraphs 1–27 as if fully set forth herein.

29. Taro has infringed the '931 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Taro's ANDA, by which Taro seeks approval from the FDA to manufacture, use, offer to sell, and sell Taro's ANDA Product prior to the expiration of the '931 patent.

RESPONSE: Denied.

30. Claims 1–11 of the '931 patent are directed to compounds and compositions to treat cell proliferation disorders. Taro's manufacture, use, offer for sale, or sale of Taro's ANDA Product within the United States, or importation of Taro's ANDA Product into the United States, during the term of the '931 patent would infringe claims 1–11 of the '931 patent.

RESPONSE: Paragraph 30 contains legal conclusions to which no answer is required. To the extent a response is required, Taro states that the '931 patent speaks for itself. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

31. Plaintiffs will be harmed substantially and irreparably if Taro is not enjoined from infringing the '931 patent.

RESPONSE: Denied.

32. Plaintiffs have no adequate remedy at law.

RESPONSE: Denied.

33. Taro was aware of the '931 patent when it submitted its ANDA. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

RESPONSE: Taro admits being aware of the '931 patent as of the date it submitted its Paragraph IV Certification regarding the same. Taro denies that Plaintiffs are entitled to a finding that this case is exceptional under 35 U.S.C. § 285. Taro denies that Plaintiffs are entitled to an award of attorney's fees under 35 U.S.C. § 285. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Count II: Alleged Infringement of U.S. Patent No. 7,851,470

34. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1–27 of this Complaint.

RESPONSE: Taro incorporates its responses to paragraphs 1–27 as if fully set forth herein.

35. Taro has infringed the '470 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Taro's ANDA, by which Taro seeks approval from the FDA to manufacture, use, offer to sell, and sell Taro's ANDA Product prior to the expiration of the '470 patent.

RESPONSE: Denied.

36. Claims 1–7 and 25 of the '470 patent are directed to compositions and processes for the synthesis of substantially pure N-benzyl-2-(5-(4-(2-morpholinoethoxy)phenyl)pyridin-2-yl)acetamide (KX2-391), and salts thereof. Claims 8–24 are directed to methods of treatment using such compositions. Taro's manufacture, use, offer for sale, or sale of Taro's ANDA Product within the United States, or importation of Taro's ANDA Product into the United States, during the term of the '470 patent would infringe claims 1–25 of the '470 patent.

RESPONSE: Paragraph 36 contains legal conclusions to which no answer is required. To the extent a response is required, Taro states that the '470 patent speaks for itself. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

37. Plaintiffs will be harmed substantially and irreparably if Taro is not enjoined from infringing the '470 patent.

RESPONSE: Denied.

38. Plaintiffs have no adequate remedy at law.

RESPONSE: Denied.

39. Taro was aware of the '470 patent when it submitted its ANDA. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

RESPONSE: Taro admits being aware of the '470 patent as of the date it submitted its Paragraph IV Certification regarding the same. Taro denies that Plaintiffs are entitled to a finding that this

case is exceptional under 35 U.S.C. § 285. Taro denies that Plaintiffs are entitled to an award of attorney's fees under 35 U.S.C. § 285. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Count III: Alleged Infringement of U.S. Patent No. 10,323,001

40. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1–27 of this Complaint.

RESPONSE: Defendant incorporates its responses to paragraphs 1–27 as if fully set forth herein.

41. Taro has infringed the '001 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Taro's ANDA, by which Taro seeks approval from the FDA to manufacture, use, offer to sell, and sell Taro's ANDA Product prior to the expiration of the '001 patent.

RESPONSE: Denied.

42. Claim 1 of the '001 patent is directed to pharmaceutical compositions comprising 2-(5-(4-(2-morpholinoethoxy)phenyl)pyridin-2-yl)-N-benzylacetamide free base. Taro's manufacture, use, offer for sale, or sale of Taro's ANDA Product within the United States, or importation of Taro's ANDA Product into the United States, during the term of the '001 patent would infringe claim 1 of the '001 patent.

RESPONSE: Paragraph 42 contains legal conclusions to which no answer is required. To the extent a response is required, Taro states that the '001 patent speaks for itself. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

43. Plaintiffs will be harmed substantially and irreparably if Taro is not enjoined from infringing the '001 patent.

RESPONSE: Denied.

44. Plaintiffs have no adequate remedy at law.

RESPONSE: Denied.

45. Taro was aware of the '001 patent when it submitted its ANDA. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

RESPONSE: Taro admits being aware of the '001 patent as of the date it submitted its Paragraph IV Certification regarding the same. Taro denies that Plaintiffs are entitled to a finding that this case is exceptional under 35 U.S.C. § 285. Taro denies that Plaintiff are entitled to an award of attorney's fees under 35 U.S.C. § 285. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Count IV: Alleged Infringement of U.S. Patent No. 10,617,693

46. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1–27 of this Complaint.

RESPONSE: Taro incorporates its responses to paragraphs 1-27 as if fully set forth herein.

47. Taro has infringed the '693 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Taro's ANDA, by which Taro seeks approval from the FDA to manufacture, use, offer to sell, and sell Taro's ANDA Product prior to the expiration of the '693 patent.

RESPONSE: Denied.

48. Claims 1–25 of the '693 patent are directed to methods of treating and/or preventing actinic keratosis. Taro's manufacture, use, offer for sale, or sale of Taro's ANDA Product within the United States, or importation of Taro's ANDA Product into the United States, during the term of the '001 patent would infringe claims 1–25 of the '693 patent.

RESPONSE: Paragraph 48 contains legal conclusions to which no answer is required. To the extent a response is required, Taro states that the '693 patent speaks for itself. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

49. Plaintiffs will be harmed substantially and irreparably if Taro is not enjoined from infringing the '693 patent.

RESPONSE: Denied.

50. Plaintiffs have no adequate remedy at law.

RESPONSE: Denied.

51. Taro was aware of the '693 patent when it submitted its ANDA. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

RESPONSE: Taro admits being aware of the '693 patent as of the date it submitted its Paragraph IV Certification regarding the same. Taro denies that Plaintiffs are entitled to a finding that this case is exceptional under 35 U.S.C. § 285. Taro denies that Plaintiff are entitled to an award of attorney's fees under 35 U.S.C. § 285. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Count V: Alleged Infringement of U.S. Patent No. 10,669,236

52. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1–27 of this Complaint.

RESPONSE: Taro incorporates its responses to paragraphs 1–27 as if fully set forth herein.

53. Taro has infringed the '236 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Taro's ANDA, by which Taro seeks approval from the FDA to manufacture, use, offer to sell, and sell Taro's ANDA Product prior to the expiration of the '236 patent.

RESPONSE: Denied.

54. Claims 1–10 of the '236 patent are directed to polymorphs of 2-(5-(4-(2-morpholinoethoxy)phenyl)pyridin-2-yl)-N-benzylacetamide, and methods of preparing and using same. Taro's manufacture, use, offer for sale, or sale of Taro's ANDA Product within the United States, or importation of Taro's ANDA Product into the United States, during the term of the '001 patent would infringe claims 1–10 of the '236 patent.

RESPONSE: Paragraph 54 contains legal conclusions to which no answer is required. To the extent a response is required, Taro states that the '236 patent speaks for itself. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

55. Plaintiffs will be harmed substantially and irreparably if Taro is not enjoined from infringing the '236 patent.

RESPONSE: Denied.

56. Plaintiffs have no adequate remedy at law.

RESPONSE: Denied.

57. Taro was aware of the '236 patent when it submitted its ANDA. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

RESPONSE: Taro admits being aware of the '236 patent as of the date it submitted its Paragraph IV Certification regarding the same. Taro denies that Plaintiffs are entitled to a finding that this case is exceptional under 35 U.S.C. § 285. Taro denies that Plaintiff are entitled to an award of attorney's fees under 35 U.S.C. § 285. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Count VI: Alleged Infringement of U.S. Patent No. 11,497,750

58. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1–27 of this Complaint.

RESPONSE: Defendant incorporates its responses to paragraphs 1–27 as if fully set forth herein.

59. Taro has infringed the '750 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Taro's ANDA, by which Taro seeks approval from the FDA to manufacture, use, offer to sell, and sell Taro's ANDA Product prior to the expiration of the '750 patent.

RESPONSE: Denied.

60. Claims 1–23 of the '750 patent are directed to a method of treating and/or preventing actinic keratosis. Taro's manufacture, use, offer for sale, or sale of Taro's ANDA Product within the United States, or importation of Taro's ANDA Product into the United States, during the term of the '001 patent would infringe claims 1–23 of the '750 patent.

RESPONSE: Paragraph 60 contains legal conclusions to which no answer is required. To the extent a response is required, Taro states that the '750 patent speaks for itself. Taro denies all

further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

61. Plaintiffs will be harmed substantially and irreparably if Taro is not enjoined from infringing the '750 patent.

RESPONSE: Denied.

62. Plaintiffs have no adequate remedy at law.

RESPONSE: Denied.

63. Taro was aware of the '750 patent when it submitted its ANDA. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

RESPONSE: Taro admits being aware of the '750 patent as of the date it submitted its Paragraph IV Certification regarding the same. Taro denies that Plaintiffs are entitled to a finding that this case is exceptional under 35 U.S.C. § 285. Taro denies that Plaintiff are entitled to an award of attorney's fees under 35 U.S.C. § 285. Taro denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

**GENERAL DENIAL AND RESPONSE TO
PLAINTIFFS' REQUEST FOR RELIEF**

All allegations in Plaintiffs' Complaint not expressly admitted by Taro are hereby denied. Having answered Plaintiffs' Complaint, Taro denies Plaintiffs are entitled to any of the relief requested in the Complaint or any relief whatsoever. With respect to Plaintiffs' request for relief, Taro denies that Plaintiffs are entitled to any relief for the allegations and claims made in the Complaint, including the relief requested in paragraphs A-L of the Prayer for Relief set forth in the Complaint.

SEPARATE DEFENSES

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

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the product(s) that is the subject of Taro's ANDA has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the patents-in-suit.

SECOND SEPARATE DEFENSE

Each of the claims of the patents-in-suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or Obviousness Type Double Patenting for at least the reasons set forth in Taro's Notice Letter.

THIRD SEPARATE DEFENSE

Each of the claims of the patents-in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102 or 103, respectively, for example, for at least the reasons set forth in Taro's Notice Letter.

FOURTH SEPARATE DEFENSE

Each of the claims of the patents-in-suit is invalid, pursuant to 35 U.S.C. § 112, as, for example, indefinite, not enabled and/or failing to provide adequate written description for at least the reasons set forth in Taro's Notice Letter.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the patents-in-suit, and specifically prosecution history estoppel, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the patents-in-suit is infringed by the product that is the subject of Taro's ANDA.

SIXTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

SEVENTH SEPARATE DEFENSE

Taro reserves the right to allege any and all additional defenses and counterclaims that discovery may reveal.

RESERVATION OF ADDITIONAL DEFENSES

Taro reserves the right to assert additional separate defenses that may be developed through discovery, or otherwise, in this action, such as claims of inequitable conduct during the prosecution of the patents-in-suit.

WHEREFORE, Taro hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patents-in-suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: May 27, 2025

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/s/ R Touhey Myer

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