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*Attorneys for Defendant Taro Pharmaceuticals Inc.*

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

INCYTE CORP. and INCYTE HOLDINGS CORP.,

Plaintiffs,

v.

TARO PHARMACEUTICALS INC.,

Defendant.

C.A. No. 2:25-cv-07243-MCA-SDA

**DEFENDANT TARO'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**

Defendant Taro Pharmaceuticals Inc. (“Taro”), by and through its undersigned counsel, provide the following answers, separate defenses, and counterclaims to the complaint of patent infringement (“Complaint”) (D.I. 1) of Plaintiffs Incyte Corporation and Incyte Holdings Corporation (collectively, “Incyte” or “Plaintiffs”). This pleading is based upon Taro’s knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R.

Civ. P. 8(b)(3), Taro denies all allegations in Plaintiffs' Complaint except those admitted specifically below.

#### **NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, arising from Taro's submission of Abbreviated New Drug Application ("ANDA") No. 219040 ("Taro's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of Incyte's Opzelura® (ruxolitinib) drug product prior to the expiration of United States Patent No. 12,226,419 (the "'419 patent" or "the patent-in-suit"). The patent-in-suit is owned by Incyte Corporation and/or Incyte Holdings Corporation.

**ANSWER:** Taro admits that Plaintiffs' Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, but denies that Plaintiffs are entitled to any relief. Taro further admits that it submitted ANDA No. 219040 to the FDA and that it is seeking FDA approval of its generic product ("Taro's ANDA Product"), such that it can be sold in the United States. Taro denies the remaining allegations in paragraph 1.

#### **THE PARTIES**

2. Plaintiff Incyte Corporation is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

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

3. Plaintiff Incyte Holdings Corporation is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

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

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

**ANSWER:** Admitted.

#### **THE PATENT-IN-SUIT**

5. On February 18, 2025, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’419 patent, entitled, “Topical Formulation for a JAK Inhibitor.” A copy of the ’419 patent is attached hereto as Exhibit A.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Taro admits that the ’419 patent states on its face that it issued on February 18, 2025, and is titled “Topical Formulation for a JAK Inhibitor.” Taro admits that a purported copy of the ’419 patent is attached to the Complaint as Exhibit A. Taro denies the remaining allegations in paragraph 5.

#### **THE OPZELURA® DRUG PRODUCT**

6. Incyte Corporation holds an approved New Drug Application (“NDA”) under Section 505(a) of the Federal Food Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(a), for Opzelura® (ruxolitinib) cream (NDA No. 215309).

**ANSWER:** Taro admits that the Orange Book indicates that Incyte Corporation is the holder of NDA No. 215309 for OPZELURA® (ruxolitinib) cream. Taro denies the remaining allegations in paragraph 6.

7. The claims of the patent-in-suit cover, *inter alia*, pharmaceutical compositions comprising ruxolitinib.

**ANSWER:** Taro admits that the '419 patent states on its face that it covers pharmaceutical compositions comprising ruxolitinib. Taro denies the remaining allegations of paragraph 7.

8. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patent-in-suit is listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Opzelura®.

**ANSWER:** Taro admits that the patent-in-suit is listed in the Orange Book with respect to Opzelura®. Taro denies the remaining allegations in paragraph 8.

#### **JURISDICTION AND VENUE**

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

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Taro does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, or 2202 for the purposes of this action only. Taro denies the remaining allegations of paragraph 9.

10. On information and belief, Taro is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest venue or personal jurisdiction for purposes of this action only. Taro further admits that it is seeking FDA approval of Taro’s ANDA Product, such that it can be sold in the United States. Taro denies the remaining allegations of paragraph 10.

11. This Court has personal jurisdiction over Taro pursuant to Federal Rule of Civil Procedure 4(k)(2), including because: (a) Incyte’s claims arise under federal law; (b) Taro is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c)

Taro has sufficient contacts with the United States as a whole, including, without limitation, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Taro satisfies due process.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only. Taro further admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies the remaining allegations of paragraph 11.

12. On information and belief, Taro submitted ANDA No. 219040 seeking FDA approval to engage in the manufacture, use, importation, distribution, offer to sell, and/or sale of the generic drug product that is the subject of Taro's ANDA ("Taro's Proposed Product"), throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patent-in-suit.

**ANSWER:** Taro admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro further admits that Taro's ANDA No. 219040 contains a Paragraph IV certification that the patent-in-suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations of paragraph 12.

13. On information and belief, this Judicial District is a likely destination for Taro's Proposed Product.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only. Taro denies the remaining allegations of paragraph 13.

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

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies the remaining allegations of paragraph 14.

15. Taro has purposefully availed itself of the rights, benefits, and privileges of New Jersey, including by asserting counterclaims in this Court. *See, e.g., Incyte Corp., et al. v. Taro Pharm. Inc., et al.*, No 25-1858 (D.N.J.), *Currax Pharms. LLC v. Taro Pharm. Indus., Ltd., et al.*, No. 24-7446 (D.N.J.); *Galderma Labs., LP, et al. v. Taro Pharm., Inc., et al.*, No. 24-333 (D.N.J.); *Bausch Health Ireland Ltd., et al. v. Taro Pharm., Inc., et al.*, No. 23-2684 (D.N.J.).

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest personal jurisdiction for the purposes of this action only. Taro denies the remaining allegations of paragraph 15.

16. Venue is proper in this Judicial District for Taro pursuant to 28 U.S.C. §§ 1391 and/or 1400(b), including, for example, because Taro is a company organized and existing under the laws of Canada and may be sued in any judicial district.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro does not contest venue for the purposes of this action only. Taro denies the remaining allegations of paragraph 16.

**ACTS GIVING RISE TO THIS SUIT**

17. Pursuant to Section 505 of the FFDCA, Taro submitted ANDA No. 219040 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed Product before the patent-in-suit expires.

**ANSWER:** Taro admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro further admits that Taro's ANDA No. 219040 contains a Paragraph IV certification that the patent-in-suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations of paragraph 17.

18. On information and belief, following FDA approval of Taro's ANDA, Taro will make, use, sell, or offer to sell Taro's Proposed Product throughout the United States, and/or import such generic product into the United States.

**ANSWER:** Taro admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies the remaining allegations of paragraph 18.

19. On information and belief, in connection with the submission of ANDA No. 219040 as described above, Taro provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Taro's Paragraph IV Certification"), alleging that the claims of the patent-in-suit are invalid and/or will not be infringed by the activities described in Taro's ANDA.

**ANSWER:** Taro admits that Taro's ANDA No. 219040 contains a Paragraph IV certification that the patent-in-suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro denies the remaining allegations of paragraph 19.

20. No earlier than April 22, 2025, Taro sent to Incyte a written notice of Taro's Paragraph IV Certification ("Taro's Notice Letter"). Taro's Notice Letter alleged that the claims of the patent-in-suit are invalid and/or will not be infringed by the activities described in Taro's ANDA. Taro's Notice Letter conveyed that Taro seeks approval to market Taro's Proposed Product before the patent-in-suit expires.

**ANSWER:** Taro admits that on April 22, 2025, Taro sent Incyte a written notice of Taro's Paragraph IV Certification that the patent-in-suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Taro's Proposed ANDA Product. Taro further admits that it is seeking FDA approval of Taro's ANDA Product, such that it can be sold in the United States. Taro denies the remaining allegations of paragraph 20.

**COUNT I: INFRINGEMENT OF THE '419 PATENT**

21. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Taro incorporates its responses to each of the preceding paragraphs 1 to 20 in full, as if set forth herein.

22. Taro's submission of ANDA No. 219040, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Taro's Proposed Product, prior to the expiration of the '419 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 22.

23. There is a justiciable controversy between the parties hereto as to the infringement of the '419 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies that it infringes the '419 patent. Taro agrees there is a justiciable controversy between Plaintiffs and Taro as to the infringement of the '419 patent. Taro denies the remaining allegations of paragraph 23.

24. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro will infringe one or more claims of the '419 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Taro's Proposed Product in the United States.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 24.

25. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro will induce infringement of one or more claims of the '419 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Taro's Proposed Product in the United States. On information and belief, upon FDA approval of Taro's ANDA, Taro will intentionally encourage acts of direct infringement with knowledge of the '419 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 25.

26. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro will contributorily infringe one or more claims of the '419 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Taro's Proposed Product in the United States. On information and belief, Taro has had and continues to have knowledge that Taro's Proposed

Product is especially adapted for a use that infringes one or more claims of the '419 patent and that there is no substantial non-infringing use for Taro's Proposed Product.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 26.

27. Incyte will be substantially and irreparably damaged and harmed if Taro's infringement of the '419 patent is not enjoined.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 27.

28. Incyte does not have an adequate remedy at law.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 28.

29. This case is an exceptional one, and Incyte is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Taro denies the allegations of paragraph 29.

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

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

#### **SEPARATE DEFENSES**

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

supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

**FIRST DEFENSE**

The claims of the patent-in-suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or based on other judicially created bases for invalidation.

**SECOND DEFENSE**

Taro does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the patent-in-suit. If Taro's ANDA Product was marketed, Taro would not infringe any valid and enforceable claim of the patent-in-suit.

**THIRD DEFENSE**

Taro has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patent-in-suit. If Taro's ANDA Products were marketed, Taro would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patent-in-suit.

**FOURTH DEFENSE**

Claims of the patent-in-suit are barred in whole or in part by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

**FIFTH DEFENSE**

Plaintiffs have not satisfied the requirements for injunctive relief.

**SIXTH DEFENSE**

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

**SEVENTH DEFENSE**

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

**EIGHTH DEFENSE**

Any additional defenses that discovery may reveal.

**COUNTERCLAIMS**

For its Counterclaims against Plaintiffs Incyte Corporation and Incyte Holdings Corporation (collectively, "Incyte" or "Counterclaim Defendants/Plaintiffs"), Counterclaim Plaintiff/Defendant Taro Pharmaceuticals Inc., ("Taro" or "Counterclaim Plaintiff/Defendant"), states as follows:

**THE PARTIES**

1. On information and belief, Incyte Corporation is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

2. Upon information and belief, Incyte Holdings Corporation is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

3. Taro is a corporation organized and existing under the laws of Canada, having a place of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada.

**JURISDICTION AND VENUE**

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

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

including having filed suit.

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

7. There is an actual and justiciable controversy between Taro and Counterclaim Defendants/Plaintiffs as to the infringement of the patent-in-suit.

### **BACKGROUND**

8. Upon information and belief, Incyte Corporation is the holder of New Drug Application (“NDA”) No. 215309.

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

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

11. U.S. Patent No. 12,226,419 (“the ’419 patent”), titled “Topical Formulation for a JAK Inhibitor,” issued on February 18, 2025.

12. Upon information and belief, Incyte Holdings Corporation and Incyte Corporation are the assignees of the ’419 patent.

13. Upon information and belief, Counterclaim Defendants/Plaintiffs caused the ’419 patent (“the patent-in-suit”) to be listed in the Orange Book as a patent that claims such a drug for which Incyte Corporation submitted NDA No. 215309.

14. In November 2024, Taro submitted Abbreviated New Drug Application (“ANDA”) No. 219040 (“Taro’s ANDA”) with a Paragraph IV certification stating that the patent-

in-suit is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's ruxolitinib cream (1.5%), for topical use, that is the subject of ANDA No. 219040 ("Taro's ANDA Product").

15. On April 22, 2025, Taro submitted an amended Paragraph IV certification to the FDA stating that the patent-in-suit is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Taro's ruxolitinib cream (1.5%), for topical use, that is the subject of ANDA No. 219040 ("Taro's ANDA Product").

16. By letter dated April 22, 2025 ("Taro's Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Taro notified Counterclaim Defendants/Plaintiffs that ANDA No. 219040 includes an amended Paragraph IV certification with respect to the patent-in-suit. Taro's Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Taro's amended Paragraph IV certification that the claims of the patent-in-suit are invalid, not infringed, and/or unenforceable.

17. On June 4, 2025, Counterclaim Defendants/Plaintiffs filed this instant lawsuit alleging infringement of the patent-in-suit.

## **COUNT I**

### **(Declaratory Judgment of Non-Infringement of the '419 Patent)**

18. Taro re-alleges and incorporates by reference the allegations in paragraphs 1 through 17 of its Counterclaims as though fully set forth herein.

19. Counterclaim Defendants/Plaintiffs allege ownership of the '419 patent and have brought claims against Taro alleging infringement of the '419 patent.

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

'419 patent.

21. Taro has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '419 patent and is not liable for such infringement.

22. Taro is entitled to a declaration that the manufacture, use, or sale of Taro's ANDA Product would not infringe any valid or enforceable claim of the '419 patent.

## **COUNT II**

### **(Declaratory Judgment of Invalidity of the '419 Patent)**

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

24. Counterclaim Defendants/Plaintiffs allege ownership of the '419 patent and have brought claims against Taro alleging infringement of the '419 patent.

25. One or more claims of the '419 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity or unenforceability.

26. The '419 patent describes and claims pharmaceutical formulations for topical skin application comprising (R)-3-cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile, or a pharmaceutically acceptable salt thereof, and use in the treatment of skin disorders.

27. The alleged invention of the '419 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '419 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '419 patent and would

have had a reasonable expectation of success in doing so.

28. The subject matter claimed in the '419 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

29. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Taro's ANDA No. 219040 and/or the commercial marketing of Taro's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '419 patent.

30. Taro is entitled to a declaration that all claims of the '419 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity or unenforceability.

**PRAYER FOR RELIEF**

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

- a. Declaring that the filing of Taro's ANDA No. 219040 has not infringed and does not infringe any valid and enforceable claim of the '419 patent;
- b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Taro's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '419 patent;
- c. Declaring that the claims of the '419 patent are invalid;
- d. Declaring this an exceptional case in favor of Taro and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in

- common law that would be appropriate;
- e. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and
  - f. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: August 22, 2025

**RIVKIN RADLER LLP**

s/ Gregory D. Miller

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*Attorneys for Defendant Taro Pharmaceuticals Inc.*

**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: August 22, 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: August 22, 2025

s/ Gregory D. Miller  
Gregory D. Miller

**CERTIFICATE OF SERVICE**

I hereby certify that, on August 22, 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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*Attorneys for Plaintiffs Incyte Corporation  
and Incyte Holdings Corporation*

Dated: August 22, 2025

s/ Gregory D. Miller  
Gregory D. Miller