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

**INCYTE CORP. and INCYTE
HOLDINGS CORP.,**

Plaintiffs,

v.

**PADAGIS ISRAEL
PHARMACEUTICALS LTD.,**

Defendant.

**Civil Action No. 23-21826 (MCA)(SDA)
Civil Action No. 25-5380 (MCA)(SDA)
(consolidated)**

(Filed Electronically)

**PLAINTIFFS' ANSWER TO
PADAGIS ISRAEL PHARMACEUTICALS LTD.'S COUNTERCLAIMS**

Plaintiffs Incyte Corporation and Incyte Holdings Corporation (together, "Incyte"), by their undersigned attorneys, hereby answer the Counterclaims to their Complaint for Patent Infringement by Defendant Padagis Israel Pharmaceuticals Ltd. ("Padagis" or "Defendant"), dated June 17, 2025 (the "Counterclaims"), as follows. Except as expressly admitted, all allegations are denied.

PADAGIS ISRAEL PHARMACEUTICALS LTD.'S COUNTERCLAIMS

The Parties

1. Padagis is an Israeli corporation with a place of business at 1 Rakefet Street, Shoham, Israel 6083705.

ANSWER: Incyte admits on information and belief the allegations of paragraph 1.

2. On information and belief, and according to its Complaint, 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. (Complaint at ¶ 2).

ANSWER: Incyte admits the allegations of paragraph 2.

3. On information and belief, and according to its Complaint, Incyte Holdings 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. (Complaint at ¶ 3).

ANSWER: Incyte admits the allegations of paragraph 3.

Jurisdiction and Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”) (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

ANSWER: Paragraph 4 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that this Court has subject matter jurisdiction over Padagis’s counterclaims as to United States Patent No. 12,226,419 (the “’419 patent” or the “patent-in-suit”), but denies that Padagis is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 4.

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

ANSWER: Paragraph 5 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that this Court has subject matter jurisdiction

over Padagis's counterclaims as to the patent-in-suit, but denies that Padagis is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 5.

6. This Court has personal jurisdiction over Plaintiffs because they have purposefully availed themselves of the rights and privileges of this forum by suing Padagis in this District, and, on information and belief, because Plaintiffs conduct substantial business in, and have regular systematic contact with, this District.

ANSWER: Paragraph 6 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that this Court has personal jurisdiction over Incyte for purposes of this action only, but denies that Padagis is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 6.

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

ANSWER: Paragraph 7 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that venue is proper to adjudicate this action and, except as so admitted, denies the allegations of paragraph 7.

Background

8. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the MMA, sets forth a statutory framework that the U.S. Food and Drug Administration ("FDA") follows for the approval of both brand-name and generic drugs.

ANSWER: Paragraph 8 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* contains statutory provisions relating to food and drugs, refers to the statutes for the terms thereof, and, except as so admitted, denies the allegations of paragraph 8.

9. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

ANSWER: Paragraph 9 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* contains statutory provisions relating to food and drugs, refers to the statutes for the terms thereof, and, except as so admitted, denies the allegations of paragraph 9.

10. An NDA includes, among other things, the number of any patent that the NDA holder asserts 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 unauthorized party. *See* 21 U.S.C. §§ 355(b)(1) and 355(c)(2); 21 C.F.R. §§ 314.53(b) and 314.53(c)(2). The decision to submit patent information to FDA rests solely with the NDA holder.

ANSWER: Paragraph 10 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* and 21 C.F.R. § 314 contain statutory provisions and/or regulations relating to the filing, contents, and/or approval of New Drug Applications, refers to the statutes and regulations for the terms thereof, and, except as so admitted, denies the allegations of paragraph 10.

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

ANSWER: Paragraph 11 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* contains statutory provisions relating to the filing, contents, and/or approval of New Drug Applications, refers to the statutes for the terms thereof, and, except as so admitted, denies the allegations of paragraph 11.

12. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application (“ANDA”). *See* 21 U.S.C. § 355(j).

ANSWER: Paragraph 12 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* contains statutory provisions relating to the filing, contents, and/or approval of Abbreviated New Drug Applications, refers to the statutes for the terms thereof, and, except as so admitted, denies the allegations of paragraph 12.

13. To receive approval of its ANDA, an applicant generally must, *inter alia*, show that its generic drug is “bioequivalent” to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

ANSWER: Paragraph 13 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* contains statutory provisions relating to the filing, contents, and/or approval of Abbreviated New Drug Applications, refers to the statutes for the terms thereof, and, except as so admitted, denies the allegations of paragraph 13.

14. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant generally must also “certif[y]” that any patent information listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

ANSWER: Paragraph 14 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* and 21 C.F.R. § 314 contain statutory provisions and/or regulations relating to the filing, contents, and/or approval of Abbreviated New Drug Applications, refers to the statutes and regulations for the terms thereof, and, except as so admitted, denies the allegations of paragraph 14.

15. When seeking FDA approval to market prior to patent expiration, an ANDA applicant generally submits a so-called “paragraph IV” certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

ANSWER: Paragraph 15 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* contains statutory

provisions relating to the filing, contents, and/or approval of Abbreviated New Drug Applications, refers to the statutes for the terms thereof, and, except as so admitted, denies the allegations of paragraph 15.

16. An applicant submitting an ANDA containing a paragraph IV certification must notify both the purported patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

ANSWER: Paragraph 16 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* contains statutory provisions relating to the filing, contents, and/or approval of Abbreviated New Drug Applications, refers to the statutes for the terms thereof, and, except as so admitted, denies the allegations of paragraph 16.

17. If the patent holder brings suit within 45 days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B), FDA typically cannot approve the ANDA for 30 months, unless the District Court enters an order that shortens that period. *See* 21 U.S.C. § 355(j)(5)(B)(iii). For this reason alone, patentees and NDA holders have a significant financial incentive to bring an infringement suit against an ANDA applicant without regard to the merit of that infringement suit.

ANSWER: Paragraph 17 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that 21 U.S.C. § 301 *et seq.* contains statutory provisions relating to the filing, contents, and/or approval of Abbreviated New Drug Applications, refers to the statutes for the terms thereof, and, except as so admitted, denies the allegations of paragraph 17.

18. On or about February 18, 2025, according to the electronic records of the U.S. Patent and Trademark Office (“USPTO”), U.S. Patent No. 12,226,419 (the “‘419 patent”), entitled “Topical Formulation for a JAK Inhibitor,” issued. The ‘419 patent is assigned on its face to Incyte Corporation and Incyte Holdings Corporation. The named inventors on the face of the ‘419 patent are Bhavnish Parikh, Bhavesh Shah, and Krishnaswamy Yeleswaram. What purports to be a true and correct copy of the ‘419 patent is attached to Plaintiffs’ Complaint as Exhibit A.

ANSWER: Incyte admits that, on February 18, 2025, the USPTO duly and lawfully issued the '419 patent, entitled "Topical Formulation for a JAK Inhibitor," refers to the '419 patent for the contents thereof, admits that the '419 patent is owned by Incyte Corporation and/or Incyte Holdings Corporation, admits that a copy of the '419 patent is attached to the Complaint as Exhibit A, and, except as so admitted, denies the allegations of paragraph 18 and/or lacks information sufficient to form a belief as to the truth of the remaining allegations of paragraph 18 and, therefore, denies those allegations.

19. Plaintiffs assert that the '419 patent is "owned by Incyte Corporation and/or Incyte Holdings Corporation." (Complaint at ¶ 1).

ANSWER: Incyte admits the allegations of paragraph 19.

20. According to the online records of FDA, "INCYTE CORP" is identified as the holder of NDA No. 215309 for Opzelura[®] (ruxolitinib phosphate), Cream, 1.5%, and "Sep 21, 2021" is identified as the "Approval Date" for NDA No. 215309.

ANSWER: Incyte admits that Incyte Corporation is the holder of NDA No. 215309 for Opzelura[®].

21. On information and belief, Incyte Corporation, or someone on Incyte Corporation's behalf, submitted the '419 patent to FDA for listing in the Orange Book in connection with NDA No. 215309.

ANSWER: Incyte admits that it submitted the patent-in-suit to the FDA for listing in the Orange Book in connection with NDA No. 215309, and, except as so admitted, denies the allegations of paragraph 21.

22. By virtue of the submission of the '419 patent to FDA, FDA listed the '419 patent in the Orange Book in connection with the approved NDA No. 215309.

ANSWER: Incyte admits that it submitted the patent-in-suit to the FDA for listing in the Orange Book in connection with NDA No. 215309, and, except as so admitted, denies the allegations of paragraph 22.

23. On or about May 23, 2025, Incyte Corporation and Incyte Holdings purport to have brought suit against Padagis, asserting infringement of “one or more claims” of the ‘419 patent, but not otherwise identifying the asserted claims of the ‘419 patent.

ANSWER: Paragraph 23 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that, on May 23, 2025, it filed the Complaint in the above-captioned litigation alleging, *inter alia*, Padagis’s infringement of the patent-in-suit, including that Padagis has infringed and will infringe the patent-in-suit by submitting ANDA No. 218657 and by making, using, offering to sell, selling, and/or importing into the United States Padagis’s Proposed Product, and, except as so admitted, denies the allegations of paragraph 23.

24. Padagis filed an ANDA with FDA seeking approval for Ruxolitinib Cream, 1.5% (“Padagis’s ANDA”).

ANSWER: Incyte admits on information and belief the allegations of paragraph 24.

25. FDA assigned Padagis’s ANDA No. 218657.

ANSWER: Incyte admits on information and belief the allegations of paragraph 25.

26. Padagis’s ANDA identifies OPZELURA™ (ruxolitinib) cream as the reference listed drug (“RLD”).

ANSWER: Incyte admits on information and belief the allegations of paragraph 26.

27. Because Padagis’s ANDA seeks FDA approval to market its generic Ruxolitinib Cream, 1.5%, before expiration of the Orange Book-listed ‘419 patent, Padagis’s ANDA was amended to include a paragraph IV certification to the ‘419 patent.

ANSWER: Paragraph 27 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits on information and belief that, in connection with the submission of ANDA No. 218657, Padagis provided written certifications to the FDA pursuant to Section 505 of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Padagis’s Paragraph IV Certification”), denies the allegations set forth in Padagis’s Paragraph IV Certification, and, except as so admitted, denies the allegations of paragraph 27.

28. By letter dated April 22, 2025, in accordance with 21 U.S.C. § 355(j)(2)(B) and applicable regulations, Padagis provided, *inter alia*, Incyte Corporation and Incyte Holdings with notice that Padagis amended its ANDA No. 218657 to include a paragraph IV certification to, *inter alia*, the ‘419 patent (“Padagis’s Notice Letter”).

ANSWER: Paragraph 28 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits on information and belief that, no earlier than April 22, 2025, Padagis sent a written notice of Padagis’s Paragraph IV Certification to Incyte (“Padagis’s April 22 Notice Letter”) and, except as so admitted, denies the allegations of paragraph 28.

29. Padagis’s Notice Letter included a detailed statement setting forth factual and legal bases as to why each claim of, *inter alia*, the ‘419 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Padagis’s ANDA No. 218657, and, *inter alia*, expressly reserved the right to raise additional defenses in the event that suit was filed on the ‘419 patent.

ANSWER: Paragraph 29 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte refers to Padagis’s April 22 Notice Letter for the contents thereof, denies the arguments in Padagis’s April 22 Notice Letter, and, except as so admitted, denies the allegations of paragraph 29.

30. Incyte Corporation received a copy of Padagis’s Notice Letter.

ANSWER: Paragraph 30 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that it received a copy of Padagis’s April 22 Notice Letter and, except as so admitted, denies the allegations of paragraph 30.

31. Incyte Holdings received a copy of Padagis’s Notice Letter.

ANSWER: Paragraph 31 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that it received a copy of Padagis’s April 22 Notice Letter and, except as so admitted, denies the allegations of paragraph 31.

32. The claims of the '419 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Padagis's ANDA No. 218657.

ANSWER: Incyte denies the allegations of paragraph 32.

COUNT I
(Declaration of Alleged Non-Infringement of the '419 Patent)

33. Padagis realleges and incorporates by reference the allegations of Paragraphs 1-32.

ANSWER: Incyte incorporates its answers to the preceding paragraphs as if fully set forth herein.

34. A present, genuine, and justiciable controversy exists between Plaintiffs and Padagis regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Ruxolitinib Cream, 1.5%, product described in Padagis's ANDA would infringe any valid and enforceable claim of the '419 patent.

ANSWER: Paragraph 34 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that there is a justiciable controversy between Incyte and Padagis regarding the '419 patent, and, except as so admitted, denies the allegations of paragraph 34.

35. The manufacture, use, offer for sale, sale, or importation of the Ruxolitinib Cream, 1.5%, product described in Padagis's ANDA would not infringe any valid and enforceable claim of the '419 patent, either literally or under the doctrine of equivalents, directly or indirectly.

ANSWER: Incyte denies the allegations of paragraph 35.

36. Padagis is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Ruxolitinib Cream, 1.5%, product described in Padagis's ANDA would not infringe any valid and enforceable claim of the '419 patent.

ANSWER: Incyte denies the allegations of paragraph 36.

COUNT II
(Declaration of Alleged Invalidity of the '419 Patent)

37. Padagis realleges and incorporates by reference the allegations of Paragraphs 1-36.

ANSWER: Incyte incorporates its answers to the preceding paragraphs as if fully set forth herein.

38. A present, genuine, and justiciable controversy exists between Plaintiffs and Padagis regarding, *inter alia*, the invalidity of the '419 patent.

ANSWER: Paragraph 38 states legal conclusions for which no answer is required. To the extent that an answer is required, Incyte admits that there is a justiciable controversy between Incyte and Padagis regarding the '419 patent, and, except as so admitted, denies the allegations of paragraph 38.

39. The claims of the '419 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112, the bases for which include, at the very least, one or more of the following:

- a. The alleged invention of the '419 patent was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.
- b. The alleged invention of the '419 patent was patented or described in a printed publication in this or a foreign country, or in public use or on sale in this country, more than one year prior to the date of the application for the '419 patent in the United States.
- c. Any differences between the claimed subject matter of the '419 patent and the prior art are such that the claimed subject matter as a whole would have been obvious at the time the alleged invention was made to a person having ordinary skill in the art to which the claimed subject matter pertains.
- d. The alleged claimed invention of the '419 patent was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.
- e. The alleged claimed invention of the '419 patent was described in a patent issued under 35 U.S.C. § 151, or in an application for patent published or deemed published under 35 U.S.C. § 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.
- f. Any differences between the alleged claimed invention of the '419 patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.
- g. The alleged claimed invention of the '419 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '419 patent over the prior art is no more than the

predictable use of prior art elements according to their established functions. A person of ordinary 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.

- h. The '419 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to which it pertains, or to which it is most nearly connected, to make and use the same.
- i. The claims of the '419 patent are invalid because they do not inform those skilled in the art about the scope of the alleged invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.
- j. The subject matter claimed in the '419 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the claimed invention as a whole would have been obvious at the time the alleged invention was made, and/or before the effective filing date of the claimed invention, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed invention pertains. Non-limiting examples of prior art rendering each of the claims of the '419 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, but are expressly not limited to, one or more (or a combination of one or more) of the references and/or products set forth and discussed in Padagis's Notice Letter dated April 22, 2025.

ANSWER: Incyte denies the allegations of paragraph 39.

40. Padagis is entitled to a declaration that the claims of the '419 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

ANSWER: Incyte denies the allegations of paragraph 40.

PADAGIS'S REQUEST FOR RELIEF

Incyte denies that Padagis is entitled to any relief on its Counterclaims, either as prayed for in its pleading or otherwise.

INCYTE'S AFFIRMATIVE DEFENSE

Without prejudice to the denials set forth in this Answer and to the ability to amend this Answer to seek and allege any and all defenses not presently known or that are revealed during the course of discovery or otherwise, Incyte asserts the following affirmative defense in response to Padagis's Counterclaims:

Failure to State a Claim

The Counterclaims fail to state any claim for which relief may be granted.

Dated: July 9, 2025

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