Melissa E. Flax
CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.
5 Becker Farm Road
Roseland, New Jersey 07068
(973) 994-1700
Attorneys for Defendant Padagis Israel Pharmaceuticals Ltd

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INCYTE CORP. and INCYTE HOLDINGS CORP., Plaintiffs, v. PADAGIS ISRAEL PHARMACEUTICALS LTD, Defendant.	Civil Action No. 2:25-cv-05380-MCA-SDA

ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS OF DEFENDANT PADAGIS ISRAEL PHARMACEUTICALS LTD TO PLAINTIFFS' COMPLAINT

Defendant Padagis Israel Pharmaceuticals Ltd. ("Padagis" or "Defendant"), by and through the undersigned attorneys, hereby answers the Complaint of Plaintiffs Incyte Corporation and Incyte Holdings Corporation (collectively, "Plaintiffs") as follows:

Nature of the Action[1]

COMPLAINT:

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 Padagis's submission of Abbreviated New Drug Application ("ANDA") No. 218657 ("Padagis's ANDA") to the United States Food and Drug Administration

[1] Padagis has incorporated the headings that appear in the Complaint for convenience. Doing so thus does not indicate that Padagis agrees with the characterizations of the headings. Padagis maintains all rights to object to those characterizations.

("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: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Plaintiffs' Complaint is for alleged patent infringement of United States Patent No. 12,226,419 (the "'419 patent"), but denies that Plaintiffs are entitled to any relief. Answering further, Padagis admits that Padagis submitted Abbreviated New Drug Application ("ANDA") No. 218657 to the U.S. Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j); that Padagis amended its ANDA to include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") to the '419 patent; and that Padagis seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Ruxolitinib Cream, 1.5%, before the expiration of the '419 patent. Padagis further admits that the reference listed drug ("RLD") identified in Padagis's ANDA No. 218657 is Opzelura® (ruxolitinib) cream. Answering further, Padagis admits that, according to the online records of the United States Patent and Trademark Office ("USPTO"), the current assignees for the '419 patent are Incyte Corporation and Incyte Holdings Corporation. Padagis denies any suggestion that the '419 patent was duly and legally issued, as well as any suggestion or implication that the '419 patent is valid or enforceable or that Padagis infringes any claims of the '419 patent. Padagis denies any remaining allegations contained in this paragraph.

The Parties

COMPLAINT:

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: On information and belief, admitted.

COMPLAINT:

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: On information and belief, admitted.

COMPLAINT:

4. On information and belief, Defendant Padagis is an Israeli corporation having a principal place of business at 1 Zvi Borenstein Street, Yeruham, Israel 80500.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis is an Israeli corporation with a place of business at 1 Zvi Borenstein Street, Yeruham, Israel 80500. Answering further, Padagis states that Padagis does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Padagis denies any remaining allegations of this paragraph.

The Patent-in-Suit

COMPLAINT:

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 an answer is required, Padagis admits that, according to the face of the patent, the '419 patent is entitled "Topical Formulation for a JAK Inhibitor," and issued on February 18, 2025. Further answering, Padagis states that what purports to be a copy of the '419 patent is attached to Plaintiffs' Complaint as Exhibit A. Padagis denies any remaining allegations contained in this paragraph, including that the '419 patent was duly and legally issued, as well as any suggestion or implication that the patent's claims are valid or enforceable or that Padagis infringes any claims of the patent.

The Opzelura® Drug Product

COMPLAINT:

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: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that, according to FDA's online records, "INCYTE CORP" is the holder of New Drug Application ("NDA") No. 215309 for Opzelura® (ruxolitinib phosphate), Cream, 1.5%, and "Sep 21, 2021" is identified as the "Approval Date" for NDA No. 215309. Padagis denies any remaining allegations of this paragraph.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

COMPLAINT:

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: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that one or more Plaintiffs caused, amongst others, the '419 patent to be currently listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in conjunction with NDA No. 215309 for Opzelura® (ruxolitinib phosphate), Cream, 1.5%. Padagis denies any remaining allegations of this paragraph.

Jurisdiction and Venue

COMPLAINT:

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, Padagis admits that Plaintiffs' Complaint is for alleged patent infringement under the patent laws of the United States, but denies that Plaintiffs are entitled to any relief. Answering further, Padagis admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims with respect to the '419 patent against Padagis under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

10. On information and belief, Padagis 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 an answer is required, denied. Answering further, Padagis does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only.

COMPLAINT:

12. On information and belief, Padagis submitted ANDA No. 218657 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 Padagis's ANDA ("Padagis'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: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis's ANDA No. 218657 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis amended its ANDA to include a paragraph IV certification to the '419 patent; and that Padagis seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Ruxolitinib Cream, 1.5%, before the expiration of the '419 patent. Answering further, Padagis does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

15. Padagis 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. Padagis Israel Pharm. Ltd.*, No. 23-21826 (MCA)(SDA) (D.N.J.) (D.I. 46); *Evofem Biosciences, Inc., et al. v. Padagis Israel Pharm. Ltd., et al.,* No. 23-3003 (ZNQ)(DEA) (D.N.J.) (D.I. 10).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that it is a named defendant in the amended complaint filed in *Incyte Corp., et al. v. Padagis Israel Pharm. Ltd.*, No. 23-21826 (MCA) (SDA) (D.N.J.) (D.I. 46); and that Padagis asserted counterclaims in the same. Padagis also admits that it was a named defendant in the complaint filed in *Evofem Biosciences, Inc., et al. v. Padagis Israel Pharm. Ltd., et al.,* No. 23-3003 (ZNQ)(DEA) (D.N.J.) (D.I. 10); and that Padagis asserted counterclaims in the same. Answering further, Padagis does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Padagis does not contest venue in the District of New Jersey solely for the limited purpose of this action only.

Acts Giving Rise To This Suit

COMPLAINT:

17. Pursuant to Section 505 of the FFDCA, Padagis submitted ANDA No. 218657 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product before the patent-in-suit expires.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis's ANDA No. 218657 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis amended its ANDA to include a paragraph IV certification to the '419 patent; and that Padagis seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Ruxolitinib Cream, 1.5%, before the expiration of the '419 patent. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis's ANDA No. 218657 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis amended its ANDA to include a paragraph IV certification to the '419 patent; and that Padagis seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Ruxolitinib Cream, 1.5%,

before the expiration of the '419 patent. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

19. On information and belief, in connection with the submission of ANDA No. 218657 as described above, Padagis provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Padagis'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 Padagis's ANDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis's ANDA No. 218657 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis amended its ANDA to include a paragraph IV certification to the '419 patent; and that Padagis seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Ruxolitinib Cream, 1.5%, before the expiration of the '419 patent. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

20. No earlier than April 22, 2025, Padagis sent to Incyte a written notice of Padagis's Paragraph IV Certification ("Padagis's Notice Letter"). Padagis'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 Padagis's ANDA. Padagis's Notice Letter conveyed that Padagis seeks approval to market Padagis's Proposed Product before the patent-in-suit expires.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis's ANDA No. 218657 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis amended its ANDA to include a paragraph IV certification to the '419 patent; and that Padagis seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Ruxolitinib Cream, 1.5%, before the expiration of the '419 patent. Padagis further admits that by letter dated April 22, 2025,

written notification of the paragraph IV certification for the '419 patent contained in Padagis's ANDA was given to, *inter alia*, Incyte Holdings Corporation and Incyte Corporation, pursuant to 21 U.S.C. § 355(j)(2)(B). Padagis denies any remaining allegations contained in this paragraph.

Count I: Infringement of the '419 Patent

COMPLAINT:

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

ANSWER: Padagis restates and incorporates each of its responses to the preceding paragraphs 1-20 as if fully set forth herein.

COMPLAINT:

22. Padagis's submission of ANDA No. 218657, 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 Padagis'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: Denied.

COMPLAINT:

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 an answer is required, Padagis admits that 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.

COMPLAINT:

24. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.

ANSWER: Denied.

COMPLAINT:

25. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the '419 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

COMPLAINT:

26. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that Padagis'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 Padagis's Proposed Product.

ANSWER: Denied.

COMPLAINT:

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

ANSWER: Denied.

COMPLAINT:

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

ANSWER: Denied.

COMPLAINT:

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: Denied.

* * *

RESPONSE TO PRAYER FOR RELIEF

Padagis denies that Plaintiffs are entitled to any relief whatsoever, and further requests that Plaintiffs' Complaint be dismissed with prejudice and that Padagis be awarded its attorneys' fees and costs incurred in defending this suit under 35 U.S.C. § 285.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted (and, for purposes of clarity, those allegations not specifically admitted are denied), and without undertaking any of the burdens imposed by law on Plaintiffs, Padagis asserts the following defenses to the Complaint:

First Defense

The manufacture, use, or sale of the Ruxolitinib Cream, 1.5%, product described in Padagis's ANDA No. 218657 has not infringed, does not infringe, and would not, if marketed, sold, or used, infringe any valid and enforceable claim of the '419 patent.

Second Defense

The claims of the '419 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. § 101 *et seq.*

Third Defense

Any additional defenses or counterclaims that discovery may reveal, as Plaintiffs have not begun producing discovery to Padagis with respect to the '419 patent, and Padagis has not yet had the opportunity to pursue any relevant third-party discovery.

PADAGIS ISRAEL PHARMACEUTICALS LTD'S COUNTERCLAIMS

Padagis Israel Pharmaceuticals Ltd ("Padagis"), for its Counterclaims against Incyte Corporation ("Incyte Corporation") and Incyte Holdings Corporation ("Incyte Holdings") (collectively, "Plaintiffs"), alleges as follows:

The Parties

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

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).

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).

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)).

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)).

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.

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

Background

A. FDA Approval Of New Brand-Name Drugs.

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.

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.

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.

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).

B. Generic Competition – Abbreviated New Drug Applications.

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).

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).

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).

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).

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).

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 merits of that infringement suit.

C. Ruxolitinib Cream, 1.5%, And The Patent-In-Suit.

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.

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

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.

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.

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.

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.

D. Padagis's Ruxolitinib Cream, 1.5%, ANDA.

24. Padagis filed an ANDA with FDA seeking approval for Ruxolitinib Cream, 1.5% ("Padagis's ANDA").

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

26. Padagis's ANDA identifies OPZELURA™ (ruxolitinib) cream as the reference listed drug ("RLD").

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.

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").

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.

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

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

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.

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

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

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.

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.

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.

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

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

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

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.

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.

REQUEST FOR RELIEF

WHEREFORE, Padagis respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs/Counterclaim-Defendants Incyte Corporation and Incyte Holdings as follows:

(a) Declaring that the manufacture, sale, offer for sale, use, or importation of the Ruxolitinib Cream, 1.5%, product described in Padagis's ANDA No. 218657 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '419 patent;

(b) Declaring that the claims of the '419 patent are invalid;

(c) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment be entered in favor of Padagis;

(d) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Padagis attorneys' fees, costs, and expenses in this action; and

(e) Awarding Padagis any further and additional relief as the Court deems just and proper.

Dated: June 17, 2025

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.

By: */s/ Melissa E. Flax*

Melissa E. Flax
5 Becker Farm Road
Roseland, New Jersey 07068
(973) 994-1700
mflax@carellabyrne.com

Attorneys for Defendant Padagis Israel Pharmaceuticals Ltd

OF COUNSEL

Christine J. Siwik (*pro hac vice* forthcoming)
William A. Rakoczy (*pro hac vice* forthcoming)
Gregory A. Duff (*pro hac vice* forthcoming)
Lauren M. Lesko (*pro hac vice* forthcoming)
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60654
(312) 222-6304
csiwik@rmmslegal.com
wrakoczy@rmmslegal.com
gduff@rmmslegal.com
llesko@rmmslegal.com

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter in controversy is related to *Incyte Corp., et al. v. Padagis Israel Pharmaceuticals Ltd*, Civil Action No. 23-21826 (MCA)(ESK) ("*Incyte I*") currently pending in this Judicial District.

I further certify that, to the best of my knowledge, other than *Incyte I*, 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: June 17, 2025

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.

By: */s/ Melissa E. Flax*
MELISSA E. FLAX

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, I hereby certify that the causes of action asserted herein as counterclaims seek primarily declaratory judgment relief and as such, this is not appropriate for compulsory arbitration.

Dated: June 17, 2025

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.

By: */s/ Melissa E. Flax*
MELISSA E. FLAX

CERTIFICATE OF SERVICE

The undersigned certifies that, on June 17, 2025, a true and accurate copy of the Answer, Separate Defenses, and Counterclaims of Defendant Padagis Israel Pharmaceuticals Ltd to Plaintiffs' Complaint was filed with the Court and served on all counsel of record via the Court's electronic filing system.

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.

By: */s/ Melissa E. Flax*
MELISSA E. FLAX