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

INCYTE CORP. and INCYTE HOLDINGS CORP., Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMACEUTICAL INDUSTRIES LTD., Defendants.	C.A. No. 1:25-cv-13225 (CPO)(MJS)

DEFENDANTS SUN PHARMACEUTICAL INDUSTRIES, INC. AND SUN PHARMACEUTICAL INDUSTRIES LTD.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS

Defendants Sun Pharmaceutical Industries, Inc. ("Sun USA") and Sun Pharmaceutical Industries Ltd. ("Sun India") (together, "Sun"), by and through their undersigned counsel, provide the following answers, 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 Sun'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), Sun 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 Sun's submission of Abbreviated New Drug Application ("ANDA") No. 219852 ("Sun'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 Jakafi® (ruxolitinib) drug product, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg tablets, prior to the expiration of United States Patent Nos. 8,722,693 (the "'693 patent"); 8,822,481 (the "'481 patent"); 8,829,013 (the "'013 patent"); and 10,016,429 (the "'429 patent") (collectively, the "patents-in-suit"). The patents-in-suit are owned by Incyte Corporation and/or Incyte Holdings Corporation.

ANSWER: Sun admits that Plaintiffs' Complaint purports to bring an action for infringement of United States Patent Nos. 8,722,693 (the "'693 patent"); 8,822,481 (the "'481 patent"); 8,829,013 (the "'013 patent"); and 10,016,429 (the "'429 patent") (collectively, the "patents-in-suit") under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, but denies that Plaintiffs are entitled to any relief. Sun further admits that Sun India submitted ANDA No. 219852 to the FDA and that it is seeking FDA approval of its generic product ("Sun's ANDA

Product"), such that it can be sold in the United States, and that Sun USA is the listed Authorized U.S. Agent for the ANDA. Sun 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: Sun 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: Sun 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 Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 2 Independence Way, Princeton, New Jersey 08540.

ANSWER: Admitted.

5. On information and belief, Defendant Sun Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of India, having a place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, 400063, India.

ANSWER: Admitted.

THE PATENT-IN-SUIT

6. On May 13, 2014, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '693 patent, entitled, "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile." A copy of the '693 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, Sun admits that the '693 patent states on its face that it issued on May 13, 2014, and is titled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile." Sun admits that a purported copy of the '693 patent is attached to the Complaint as Exhibit A. Sun denies the remaining allegations in paragraph 6.

7. On September 2, 2014, the USPTO duly and lawfully issued the '481 patent, entitled, "Salts of the janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d] pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile." A copy of the '481 patent is attached hereto as Exhibit B.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Sun admits that the '481 patent states on its face that it issued on September 2, 2014, and is titled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile." Sun admits that a purported copy of the '481 patent is attached to the Complaint as Exhibit B. Sun denies the remaining allegations in paragraph 7.

8. On September 9, 2014, the USPTO duly and lawfully issued the '013 patent, entitled, "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-D]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile." A copy of the '013 patent is attached hereto as

Exhibit C.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Sun admits that the '013 patent states on its face that it issued on September 9, 2014, and is titled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile." Sun admits that a purported copy of the '013 patent is attached to the Complaint as Exhibit C. Sun denies the remaining allegations in paragraph 8.

9. On July 10, 2018, the USPTO duly and lawfully issued the '429 patent, entitled, "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-D]pyrimidin-4-yl)-1H- pyrazol-1-yl)-3-cyclopentylpropanenitrile." A copy of the '429 patent is attached hereto as Exhibit D.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Sun admits that the '429 patent states on its face that it issued on July 10, 2018, and is titled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile." Sun admits that a purported copy of the '429 patent is attached to the Complaint as Exhibit D. Sun denies the remaining allegations in paragraph 9.

THE JAKAFI® DRUG PRODUCT

10. 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 Jakafi® (ruxolitinib) (NDA No. 202192).

ANSWER: Sun admits that the Orange Book indicates that Incyte Corporation is the holder of NDA No. 202192 for Jakafi® (ruxolitinib) cream. Sun denies the remaining allegations in paragraph 10.

11. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Jakafi®.

ANSWER: Sun admits that the patents-in-suit are listed in the Orange Book with respect to Jakafi®. Sun denies the remaining allegations in paragraph 11.

12. The FDA-approved prescribing information for Jakafi® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Jakafi® according to one or more of the methods claimed in the patents-in-suit.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of paragraph 12.

JURISDICTION AND VENUE

13. 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, Sun does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, or 2202 for the purposes of this action only. Sun denies the remaining allegations of paragraph 13.

14. This Court has personal jurisdiction over Sun by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction for purposes of this action only. Sun denies the remaining allegations of paragraph 14.

15. On information and belief, Sun purposefully has conducted and continues to conduct business in this Judicial District.

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

16. On information and belief, Sun 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, Sun does not contest venue or personal jurisdiction for purposes of this action only. Sun further admits that Sun India is seeking FDA approval of Sun's ANDA Product, such that it can be sold in the United States, and that Sun USA is the listed Authorized U.S. Agent for the ANDA. Sun denies the remaining allegations of paragraph 16.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction for purposes of this action only. Sun further admits that Sun India is a foreign defendant and is seeking FDA approval of Sun's ANDA Product, such that it can be sold in the United States. Sun denies the remaining allegations of paragraph 17.

18. On information and belief, Sun submitted ANDA No. 219852 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 Sun's ANDA ("Sun's Proposed Products"), throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

ANSWER: Sun admits that Sun India is seeking FDA approval of Sun's ANDA Product, such that it can be sold in the United States. Sun further admits that Sun's ANDA No. 219852 contains a Paragraph IV certification that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's Proposed ANDA Product. Sun denies the remaining allegations of paragraph 18.

19. On information and belief, this Judicial District is a likely destination for Sun's Proposed Products.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction for purposes of this action only. Sun denies the remaining allegations of paragraph 19.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun India is seeking FDA approval of Sun's ANDA Product, such that it can be sold in the United States. Sun denies the remaining allegations of paragraph 20.

21. On information and belief, Sun USA is a wholly owned subsidiary of Sun India organized under the laws of New Jersey with its principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

ANSWER: Sun admits that Sun USA is a wholly owned subsidiary of Sun India with a place of business at 2 Independence Way, Princeton, New Jersey, 08540. Sun denies the remaining allegations of paragraph 21.

22. On information and belief, Sun USA is the North American division of Sun India and is registered with the State of New Jersey as a drug wholesaler and manufacturer, under Registration Nos. 5003437, 5003826, and 5003941.

ANSWER: Sun admits that Sun USA is a wholly owned subsidiary of Sun India and is registered with the State of New Jersey as a drug wholesaler and manufacturer, under Registration Nos. 5003437, 5003826, and 5003941. Sun denies the remaining allegations of paragraph 22.

23. On information and belief, this Court has personal jurisdiction over Sun India because Sun India will collaborate with Sun USA for marketing and selling the Sun's Proposed Products once approved by the FDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun India is the applicant for ANDA No. 219852 and that Sun USA is the listed Authorized U.S. Agent for the ANDA. Sun India does not contest personal jurisdiction for purposes of this action only. Sun denies the remaining allegations of paragraph 23.

24. On information and belief, Sun India conducts business through and with Sun USA, its wholly owned subsidiary. Sun India has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. Sun India directly or through its

affiliates and agents, such as Sun USA, develops, formulates, synthesizes, manufactures, markets, imports, offers to sell, and/or sells pharmaceutical drug products including the Sun ANDA Products in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun India does not contest personal jurisdiction for purposes of this action only. Sun further admits that Sun India is the applicant for ANDA No. 219852 and that Sun USA is the listed Authorized U.S. Agent for the ANDA. Sun denies the remaining allegations of paragraph 24.

25. On information and belief, Sun USA maintains a regular and established physical place of business at 2 Independence Way, Princeton, New Jersey 08540. Sun USA maintains an additional place of business in New Jersey located at 1 Commerce Drive, Cranbury, New Jersey 08512.

ANSWER: Sun admits that Sun USA maintains a place of business at 2 Independence Way, Princeton, New Jersey 08540 and an additional place of business at 1 Commerce Drive, Cranbury, New Jersey, 08512. Sun denies the remaining allegations of paragraph 25.

26. On information and belief, Sun USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID Nos. 0101055400, 0100970132, and 0100954087 and is registered with the New Jersey Department of Health under Registration Nos. 5003437, 5003826, and 5003941.

ANSWER: Admitted.

27. Sun did not contest personal jurisdiction in this Court in actions arising out of its ANDA submissions. *See, e.g., TherapeuticsMD, Inc., et al. v. Sun Pharmaceutical Industries Limited, et al.*, No. 24-07974 (D.N.J.); *American Regent, Inc. f/k/a Luitpold Pharmaceuticals, Inc.*

v. Sun Pharmaceutical Industries Limited, et al., No. 24-07810 (D.N.J.); *Astellas Pharma Inc. v. Sun Pharmaceutical Industries, Inc., et al.*, 22-07357 (D.N.J.); *Orexo AB, et al. v. Sun Pharmaceutical Industries Limited, et al.*, 21-17941 (D.N.J.); *Allergan Pharmaceuticals International Ltd., et al. v. Sun Pharmaceutical Industries Limited, et al.*, 20-10176 (D.N.J); *Merck Sharp & Dohme BV, et al. v. Sun Pharmaceutical Industries, Inc., et al.*, 20-03007 (D.N.J).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction for purposes of this action only. Sun denies the remaining allegations of paragraph 27.

28. Sun has purposefully availed itself of the rights, benefits, and privileges of New Jersey, including by asserting counterclaims in this Court. *See, e.g.*, *TherapeuticsMD, Inc., et al. v. Sun Pharmaceutical Industries Limited, et al.*, No. 24-07974 (D.N.J.); *American Regent, Inc. f/k/a Luitpold Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Limited, et al.*, No. 24-07810 (D.N.J.); *Astellas Pharma Inc. v. Sun Pharmaceutical Industries, Inc., et al.*, 22-07357 (D.N.J.); *Orexo AB, et al. v. Sun Pharmaceutical Industries Limited, et al.*, 21-17941 (D.N.J.); Allergan *Pharmaceuticals International Ltd., et al. v. Sun Pharmaceutical Industries Limited, et al.*, 20-10176 (D.N.J); *Merck Sharp & Dohme BV, et al. v. Sun Pharmaceutical Industries, Inc., et al.*, 20-03007 (D.N.J).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction for purposes of this action only. Sun denies the remaining allegations of paragraph 28.

29. For at least the foregoing reasons, venue is proper in this Judicial District for Sun pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest venue for purposes of this action only. Sun denies the remaining allegations of paragraph 29.

ACTS GIVING RISE TO THIS SUIT

30. Pursuant to Section 505 of the FFDCA, Sun submitted ANDA No. 219852 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed Products, which are proposed generic versions of Incyte's approved Jakafi® products, before the patents-in-suit expire.

ANSWER: Sun admits that Sun India is seeking FDA approval of Sun's ANDA Product, such that it can be sold in the United States, and that Sun USA is the listed Authorized U.S. Agent for the ANDA. Sun further admits that Sun's ANDA No. 219852 contains a Paragraph IV certification that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's Proposed ANDA Product. Sun denies the remaining allegations of paragraph 30.

31. On information and belief, following FDA approval of Sun's ANDA, Sun will make, use, sell, or offer to sell Sun's Proposed Products throughout the United States, and/or import such generic products into the United States.

ANSWER: Sun admits that Sun India is seeking FDA approval of Sun's ANDA Product, such that it can be sold in the United States. Sun denies the remaining allegations of paragraph 31.

32. On information and belief, following FDA approval of Sun's ANDA, Sun's Proposed Products will include prescribing information, similar to that for Jakafi®, that instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Sun's Proposed Products according to one or more of the methods claimed in the patents-in-suit.

ANSWER: Sun admits that following FDA approval of Sun's ANDA Product, Sun's Proposed Products will include FDA-approved prescribing information for intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults, polycythemia vera in adults who have had an inadequate response to or are intolerant to hydroxyurea, and steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. Sun denies the remaining allegations of paragraph 32.

33. On information and belief, in connection with the submission of ANDA No. 219852 as described above, Sun provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Sun's Paragraph IV Certifications"), alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Sun's ANDA.

ANSWER: Sun admits that Sun's ANDA No. 219852 contains a Paragraph IV certification that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's Proposed ANDA Product. Sun denies the remaining allegations of paragraph 33.

34. Sun subsequently sent to Incyte written notice of Sun's Paragraph IV Certifications for the patents-in-suit, alleging that the claims of those patents are invalid and/or will not be infringed by the activities described in Sun's ANDA. Sun's written notice to Incyte conveyed that Sun seeks approval to market Sun's Proposed Products before the patents-in-suit expire.

ANSWER: Sun admits that on May 29, 2025, Sun sent Incyte a written notice of Sun's Paragraph IV Certification that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's Proposed ANDA Product. Sun further admits

that it is seeking FDA approval of Sun's ANDA Product, such that it can be sold in the United States. Sun denies the remaining allegations of paragraph 34.

COUNT I: INFRINGEMENT OF THE '693 PATENT

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

ANSWER: Sun incorporates its responses to each of the preceding paragraphs 1 to 34 in full, as if set forth herein.

36. Sun's submission of ANDA No. 219852, 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 Sun's Proposed Products prior to the expiration of the '693 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, Sun denies the allegations of paragraph 36.

37. There is a justiciable controversy between the parties hereto as to the infringement of the '693 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that it infringes the '693 patent. Sun agrees there is a justiciable controversy between Plaintiffs and Sun as to the infringement of the '693 patent. Sun denies the remaining allegations of paragraph 37.

38. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '693 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun'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, Sun denies the allegations of paragraph 38.

39. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '693 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Products in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '693 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, Sun denies the allegations of paragraph 39.

40. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '693 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Products in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed Products are especially adapted for a use that infringes one or more claims of the '693 patent and that there is no substantial non-infringing use for Sun's Proposed Products.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of paragraph 40.

41. Incyte will be substantially and irreparably damaged and harmed if Sun's infringement of the '693 patent is not enjoined.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of paragraph 41.

42. 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, Sun denies the allegations of paragraph 42.

43. 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, Sun denies the allegations of paragraph 43.

COUNT II: INFRINGEMENT OF THE '481 PATENT

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

ANSWER: Sun incorporates its responses to each of the preceding paragraphs 1 to 43 in full, as if set forth herein.

45. Sun's submission of ANDA No. 219852, 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 Sun's Proposed Products prior to the expiration of the '481 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, Sun denies the allegations of paragraph 45.

46. There is a justiciable controversy between the parties hereto as to the infringement of the '481 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that it infringes the '481 patent. Sun agrees there is a justiciable controversy between Plaintiffs and Sun as to the infringement of the '481 patent. Sun denies the remaining allegations of paragraph 46.

47. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '481 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun'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, Sun denies the allegations of paragraph 47.

48. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '481 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Products in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '481 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, Sun denies the allegations of paragraph 48.

49. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '481 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Products in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed Products are especially adapted for a use that infringes one or more claims of the '481 patent and that there is no substantial non-infringing use for Sun's Proposed Products.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of paragraph 49.

50. Incyte will be substantially and irreparably damaged and harmed if Sun's infringement of the '481 patent is not enjoined.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of paragraph 50.

51. 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, Sun denies the allegations of paragraph 51.

52. 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, Sun denies the allegations of paragraph 52.

COUNT III: INFRINGEMENT OF THE '013 PATENT

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

ANSWER: Sun incorporates its responses to each of the preceding paragraphs 1 to 52 in full, as if set forth herein.

54. Sun's submission of ANDA No. 219852, 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 Sun's Proposed Products prior to the expiration of the '013 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, Sun denies the allegations of paragraph 54.

55. There is a justiciable controversy between the parties hereto as to the infringement of the '013 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that it infringes the '013 patent. Sun agrees there is a justiciable controversy between Plaintiffs and Sun as to the infringement of the '013 patent. Sun denies the remaining allegations of paragraph 55.

56. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '013 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun'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, Sun denies the allegations of paragraph 56.

57. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '013 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Products in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '013 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, Sun denies the allegations of paragraph 57.

58. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '013 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Products in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed Products are especially adapted for a use that infringes one or more claims of the '013 patent and that there is no substantial non-infringing use for Sun's Proposed Products.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of paragraph 58.

59. Incyte will be substantially and irreparably damaged and harmed if Sun's infringement of the '013 patent is not enjoined.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of paragraph 59.

60. 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, Sun denies the allegations of paragraph 60.

61. 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, Sun denies the allegations of paragraph 61.

COUNT IV: INFRINGEMENT OF THE '429 PATENT

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

ANSWER: Sun incorporates its responses to each of the preceding paragraphs 1 to 61 in full, as if set forth herein.

63. Sun's submission of ANDA No. 219852, 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 Sun's Proposed Products prior to the expiration of the '429 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, Sun denies the allegations of paragraph 63.

64. There is a justiciable controversy between the parties hereto as to the infringement of the '429 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that it infringes the '429 patent. Sun agrees there is a justiciable controversy between Plaintiffs and Sun as to the infringement of the '429 patent. Sun denies the remaining allegations of paragraph 64.

65. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '429 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun'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, Sun denies the allegations of paragraph 65.

66. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '429 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Products in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '429 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, Sun denies the allegations of paragraph 66.

67. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '429 patent under 35 U.S.C. § 271(c) by making,

using, offering to sell, selling, and/or importing Sun's Proposed Products in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed Products are especially adapted for a use that infringes one or more claims of the '429 patent and that there is no substantial non-infringing use for Sun's Proposed Products.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of paragraph 67.

68. Incyte will be substantially and irreparably damaged and harmed if Sun's infringement of the '429 patent is not enjoined.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of paragraph 68.

69. 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, Sun denies the allegations of paragraph 69.

70. 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, Sun denies the allegations of paragraph 70.

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, Sun denies that Plaintiffs are entitled to any remedy or relief.

SEPARATE DEFENSES

Sun asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Sun does not assume

the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Sun 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 patents-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

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

THIRD DEFENSE

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

FOURTH DEFENSE

Claims of the patents-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, Sun'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 Plaintiffs/Defendants Sun Pharmaceuticals Industries, Inc. ("Sun USA") and Sun Pharmaceutical Industries Ltd. ("Sun India") (collectively, "Sun") 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. Sun Pharmaceutical Industries Limited is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063.

4. Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

5. 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.

6. 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.

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

8. There is an actual and justiciable controversy between Sun and Counterclaim Defendants/Plaintiffs as to the infringement of the patents-in-suit.

BACKGROUND

9. Upon information and belief, Incyte Corporation is the holder of New Drug Application ("NDA") No. 202192.

10. 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).

11. 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).

12. U.S. Patent No. 8,722,693 ("the '693 patent"), titled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile" issued on May 13, 2014.

13. U.S. Patent No. 8,822,481 ("the '481 patent"), titled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile" issued on September 2, 2014.

14. U.S. Patent No. 8,829,013 ("the '013 patent"), titled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile" issued on September 9, 2014.

15. U.S. Patent No. 10,016,429 ("the '429 patent"), titled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile" issued on July 10, 2018.

16. Upon information and belief, Incyte Holdings Corporation and Incyte Corporation are the assignees of the '693, '481, '013, and '429 patents.

17. Upon information and belief, Counterclaim Defendants/Plaintiffs caused the '693, '481, '013, and '429 patents ("the patents-in-suit") to be listed in the Orange Book as patents that claim such a drug for which Incyte Corporation submitted NDA No. 202192.

18. On March 31, 2025, Sun India submitted Abbreviated New Drug Application ("ANDA") No. 219852 ("Sun's ANDA") with a Paragraph IV certification stating that the patents-in-suit are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Sun's ruxolitinib tablet (EQ 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg), that is the subject of ANDA No. 219852 ("Sun's ANDA Product"). Sun USA is the listed Authorized U.S. Agent for the ANDA.

19. By letter dated May 29, 2025 ("Sun's Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Sun notified Counterclaim Defendants/Plaintiffs that ANDA No. 219852 includes an amended Paragraph IV certification with respect to the patents-in-suit. Sun's Notice Letter,

which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Sun's amended Paragraph IV certification that the claims of the patents-in-suit are invalid, not infringed, and/or unenforceable.

20. On July 11, 2025, Counterclaim Defendants/Plaintiffs filed this instant lawsuit alleging infringement of the patents-in-suit.

COUNT I

(Declaratory Judgment of Non-Infringement of the '693 Patent)

21. Sun re-alleges and incorporates by reference the allegations in paragraphs 1 through 20 of its Counterclaims as though fully set forth herein.

22. Counterclaim Defendants/Plaintiffs allege ownership of the '693 patent and have brought claims against Sun alleging infringement of the '693 patent.

23. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sun's ANDA and/or the commercial marketing of Sun's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '693 patent.

24. Sun has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '693 patent and is not liable for such infringement.

25. Sun is entitled to a declaration that the manufacture, use, or sale of Sun's ANDA Product would not infringe any valid or enforceable claim of the '693 patent.

COUNT II

(Declaratory Judgment of Invalidity of the '693 Patent)

26. Sun re-alleges and incorporates by reference the allegations in paragraphs 1 through 25 of its Counterclaims as though fully set forth herein.

27. Counterclaim Defendants/Plaintiffs allege ownership of the ’693 patent and have brought claims against Sun alleging infringement of the ’693 patent.

28. One or more claims of the ’693 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.

29. The ’693 patent describes and claims salt forms of (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile, and use in the treatment of disorders related to Janus kinase activity.

30. The alleged invention of the ’693 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 ’693 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 ’693 patent and would have had a reasonable expectation of success in doing so.

31. The subject matter claimed in the ’693 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.

32. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sun’s ANDA No. 219852 and/or the commercial marketing of Sun’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’693 patent.

33. Sun is entitled to a declaration that all claims of the ’693 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity or unenforceability.

COUNT III

(Declaratory Judgment of Non-Infringement of the ’481 Patent)

34. Sun re-alleges and incorporates by reference the allegations in paragraphs 1 through 33 of its Counterclaims as though fully set forth herein.

35. Counterclaim Defendants/Plaintiffs allege ownership of the ’481 patent and have brought claims against Sun alleging infringement of the ’481 patent.

36. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sun’s ANDA and/or the commercial marketing of Sun’s ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the ’481 patent.

37. Sun has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’481 patent and is not liable for such infringement.

38. Sun is entitled to a declaration that the manufacture, use, or sale of Sun’s ANDA Product would not infringe any valid or enforceable claim of the ’481 patent.

COUNT IV

(Declaratory Judgment of Invalidity of the ’481 Patent)

39. Sun re-alleges and incorporates by reference the allegations in paragraphs 1 through 38 of its Counterclaims as though fully set forth herein.

40. Counterclaim Defendants/Plaintiffs allege ownership of the ’481 patent and have brought claims against Sun alleging infringement of the ’481 patent.

41. One or more claims of the ’481 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.

42. The ’481 patent describes and claims salt forms of (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile, and use in the treatment of disorders related to Janus kinase activity.

43. The alleged invention of the ’481 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 ’481 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 ’481 patent and would have had a reasonable expectation of success in doing so.

44. The subject matter claimed in the ’481 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.

45. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sun’s ANDA No. 219852 and/or the commercial marketing of Sun’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’481 patent.

46. Sun is entitled to a declaration that all claims of the ’481 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity or

unenforceability.

COUNT V

(Declaratory Judgment of Non-Infringement of the ’013 Patent)

47. Sun re-alleges and incorporates by reference the allegations in paragraphs 1 through 46 of its Counterclaims as though fully set forth herein.

48. Counterclaim Defendants/Plaintiffs allege ownership of the ’013 patent and have brought claims against Sun alleging infringement of the ’013 patent.

49. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sun’s ANDA and/or the commercial marketing of Sun’s ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the ’013 patent.

50. Sun has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’013 patent and is not liable for such infringement.

51. Sun is entitled to a declaration that the manufacture, use, or sale of Sun’s ANDA Product would not infringe any valid or enforceable claim of the ’013 patent.

COUNT VI

(Declaratory Judgment of Invalidity of the ’013 Patent)

52. Sun re-alleges and incorporates by reference the allegations in paragraphs 1 through 51 of its Counterclaims as though fully set forth herein.

53. Counterclaim Defendants/Plaintiffs allege ownership of the ’013 patent and have brought claims against Sun alleging infringement of the ’013 patent.

54. One or more claims of the ’013 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.

55. The ’013 patent describes and claims salt forms of (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile, and use in the treatment of disorders related to Janus kinase activity.

56. The alleged invention of the ’013 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 ’013 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 ’013 patent and would have had a reasonable expectation of success in doing so.

57. The subject matter claimed in the ’013 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.

58. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sun’s ANDA No. 219852 and/or the commercial marketing of Sun’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’013 patent.

59. Sun is entitled to a declaration that all claims of the ’013 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity or unenforceability.

COUNT VII

(Declaratory Judgment of Non-Infringement of the ’429 Patent)

60. Sun re-alleges and incorporates by reference the allegations in paragraphs 1 through 59 of its Counterclaims as though fully set forth herein.

61. Counterclaim Defendants/Plaintiffs allege ownership of the ’429 patent and have brought claims against Sun alleging infringement of the ’429 patent.

62. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sun’s ANDA and/or the commercial marketing of Sun’s ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the ’429 patent.

63. Sun has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’429 patent and is not liable for such infringement.

64. Sun is entitled to a declaration that the manufacture, use, or sale of Sun’s ANDA Product would not infringe any valid or enforceable claim of the ’429 patent.

COUNT VIII

(Declaratory Judgment of Invalidity of the ’429 Patent)

65. Sun re-alleges and incorporates by reference the allegations in paragraphs 1 through 64 of its Counterclaims as though fully set forth herein.

66. Counterclaim Defendants/Plaintiffs allege ownership of the ’429 patent and have brought claims against Sun alleging infringement of the ’429 patent.

67. One or more claims of the ’429 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.

68. The ’429 patent describes and claims salt forms of (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1- yl)-3-cyclopentylpropanenitrile, and use in the treatment of

disorders related to Janus kinase activity.

69. The alleged invention of the ’429 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 ’429 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 ’429 patent and would have had a reasonable expectation of success in doing so.

70. The subject matter claimed in the ’429 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.

71. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sun’s ANDA No. 219852 and/or the commercial marketing of Sun’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’429 patent.

72. Sun is entitled to a declaration that all claims of the ’429 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, Sun respectfully requests judgment in its favor and against Counterclaim Defendants/Plaintiffs as follows:

a. Declaring that the filing of Sun’s ANDA No. 219852 has not infringed and does not infringe any valid and enforceable claim of the ’693, ’481, ’013, or ’429 patents;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Sun's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '693, '481, '013, or '429 patents;

c. Declaring that the claims of the '693, '481, '013, and '429 patents are invalid;

d. Declaring this an exceptional case in favor of Sun 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: September 29, 2025

RIVKIN RADLER LLP

s/ Gregory D. Miller

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 29, 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: September 29, 2025

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

I hereby certify that, on September 29, 2025, the foregoing document described as **DEFENDANT SUN'S ANSWER TO COMPLAINT, SEPARATE DEFENSES AND COUNTERCLAIMS** was served on all counsel of record indicated below via electronic mail.

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s/ Gregory D. Miller
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