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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INCYTE CORP. and INCYTE HOLDINGS CORP.,	:	Honorable Christine P. O'Hearn, U.S.D.J.
Plaintiffs,	:	Civil Action No. 25 CV 1859 (CPO)(MJS)
v.	:	
HIKMA PHARMACEUTICALS USA INC.,	:	**DEFENDANT HIKMA PHARMACEUTICALS USA INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**
Defendant.	:	

Defendant Hikma Pharmaceuticals USA Inc. ("Hikma"), by its undersigned attorneys, hereby provides the following answers, defenses, and counterclaims to the Complaint (D.I.1) filed by Plaintiffs Incyte Corp. and Incyte Holdings Corp. ("Plaintiffs") as follows:

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 Hikma's submission of Abbreviated New Drug Application ("ANDA") No. 219768 ("Hikma'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. 7,598,257 (the "'257 patent"); 8,415,362 (the "'362 patent"); 8,722,693 (the "'693 patent"); 8,822,481 (the "'481 patent"); and 8,829,013 (the "'013 patent") (collectively, the "patents-in-suit"). The patents-in-suit are owned by Incyte Corporation and/or Incyte Holdings Corporation.

RESPONSE: Hikma admits that Plaintiffs purport to bring an action against Hikma for infringement of the '257, '362, '693, '481, and '013 patents under the patent laws of the United States, Title 35 of the United States Code. Hikma admits that it submitted an Abbreviated New Drug Application (ANDA) seeking FDA approval to market Ruxolitinib Phosphate Tablets, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg. Hikma denies the remaining allegations of 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.

RESPONSE: Hikma lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in paragraph 2, 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.

RESPONSE: Hikma lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in paragraph 3, and therefore denies the same.

4. On information and belief, Defendant Hikma is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

RESPONSE: Admitted.

The Patents-in-Suit

5. On October 6, 2009, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '257 patent, entitled, "Heteroaryl substituted pyrrolo[2,3-b]pyridines and pyrrolo[2,3-b]pyrimidines as Janus kinase inhibitors." A copy of the '257 patent is attached hereto as Exhibit A.

RESPONSE: Hikma admits that an Exhibit purporting to be a copy of the '257 patent is attached to the Complaint as Exhibit A, and is entitled "Heteroaryl substituted pyrrolo[2,3-b]pyridines and

pyrrolo[2,3-b]pyrimidines as Janus kinase inhibitors." Hikma denies the remaining allegations of paragraph 5.

6. On April 9, 2013, the USPTO duly and lawfully issued the '362 patent, entitled, "Pyrazolyl substituted pyrrolo[2,3-b]pyrimidines as Janus kinase inhibitors." A copy of the '362 patent is attached hereto as Exhibit B.

RESPONSE: Hikma admits that an Exhibit purporting to be a copy of the '362 patent is attached to the Complaint as Exhibit B, and is entitled "Pyrazolyl substituted pyrrolo[2,3-b]pyrimidines as Janus kinase inhibitors." Hikma denies the remaining allegations of paragraph 6.

7. On May 13, 2014, the 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 C.

RESPONSE: Hikma admits that an Exhibit purporting to be a copy of the '693 patent is attached to the Complaint as Exhibit C, and is entitled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile." Hikma denies the remaining allegations of paragraph 7.

8. 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 D.

RESPONSE: Hikma admits that an Exhibit purporting to be a copy of the '481 patent is attached to the Complaint as Exhibit D, and is entitled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d] pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile." Hikma denies the remaining allegations of paragraph 8.

9. 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 E.

RESPONSE: Hikma admits that an Exhibit purporting to be a copy of the '013 patent is attached to the Complaint as Exhibit E, and is entitled "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile." Hikma denies the remaining allegations of 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).

RESPONSE: Hikma lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in paragraph 10, and therefore denies the same.

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®.

RESPONSE: Hikma admits the patents-in-suit are listed in the Orange Book with respect to Jakafi®. Hikma lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in paragraph 11, and therefore denies the same.

Jurisdiction and Venue

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

RESPONSE: Paragraph 12 states a legal conclusion to which no response is required. Without waiver of rights, Hikma will not contest personal jurisdiction in this district for the purposes of this case only. Hikma lacks sufficient knowledge or information to form a belief as to the truth of the allegation that subject matter jurisdiction is present, and therefore denies the same.

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

RESPONSE: Paragraph 13 states legal conclusions to which no response is required. Without waiver of rights, Hikma will not contest personal jurisdiction in this district for the purposes of this case only. Hikma denies the remaining allegations of paragraph 13.

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

RESPONSE: Paragraph 13 states legal conclusions to which no response is required. Without waiver of rights, Hikma will not contest personal jurisdiction in this district for the purposes of this case only. Hikma denies the remaining allegations of paragraph 13.

15. On information and belief, Hikma 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.

RESPONSE: Paragraph 15 states legal conclusions to which no response is required. Without waiver of rights, Hikma will not contest personal jurisdiction in this district for the purposes of this case only. Hikma denies the remaining allegations of paragraph 15.

16. On information and belief, Hikma submitted ANDA No. 219768 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 Hikma's ANDA ("Hikma'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.

RESPONSE: Paragraph 16 states legal conclusions to which no response is required. Without waiver of rights, Hikma admits it submitted ANDA No. 219768 seeking approval of Hikma's Proposed Product prior to the expiration of the patents-in-suit. Hikma denies the remaining allegations of paragraph 16.

17. On information and belief, Hikma maintains a regular and established physical place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

RESPONSE: Paragraph 17 states legal conclusions to which no response is required. Without waiver of rights, Hikma admits it has a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. Hikma denies the remaining allegations of paragraph 17.

RESPONSE:

18. On information and belief, Hikma 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 No. 0100487525 and is registered with the New Jersey Department of Health under Registration No. 5002130.

RESPONSE: Admitted.

19. Hikma did not contest personal jurisdiction in this Court in actions arising out of its ANDA submissions. *See, e.g.*, *Axsome Malta Ltd., et al. v. Hikma Pharms. USA Inc.*, No. 24-10620 (D.N.J.); *Axsome Malta Ltd., et al. v. Alkem Laboratories Ltd,. et al.*, No. 23-20354 (D.N.J.); *Celgene Corp. v. Hikma Pharms. Int'l Ltd., et al.*, No. 18-13477 (D.N.J.); *Celgene Corp. v. Hikma Pharms. USA Inc.*, No. 21-20459 (D.N.J.).

RESPONSE: Paragraph 19 states legal conclusions to which no response is required. Without waiver of rights, Hikma will not contest personal jurisdiction in this district for the purposes of this case only. Hikma denies the remaining allegations of paragraph 19.

20. Hikma has purposefully availed itself of the rights, benefits, and privileges of New Jersey, including by asserting counterclaims in this Court. *See, e.g.*, *In re Selenious Acid Litig.*, No. 24-7791 (D.N.J.); *Corcept Therapeutics, Inc. v. Hikma Pharms. USA Inc.*, No. 215034 (D.N.J.); *Celgene Corp. v. Hikma Pharms. USA Inc.*, No. 21-10398 (D.N.J.); *Janssen Pharms., Inc., et al. v. Hikma Pharms. USA, Inc., et al.*, No. 23-2942 (D.N.J.); *West-Ward Pharms. Corp., et al. v. Par Pharm. Inc.*, No. 16-5456 (D.N.J.).

RESPONSE: Paragraph 20 states legal conclusions to which no response is required. Without waiver of rights, Hikma will not contest personal jurisdiction in this district for the purposes of this case only. Hikma denies the remaining allegations of paragraph 20.

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

RESPONSE: Paragraph 21 states legal conclusions to which no response is required. Without waiver of rights, Hikma will not contest venue in this district for the purposes of this case only.

Acts Giving Rise to This Suit

22. Pursuant to Section 505 of the FFDCA, Hikma submitted ANDA No. 219768 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Hikma's Proposed Products before the patents-in-suit expire.

RESPONSE: Hikma admits it submitted ANDA No. 219768 seeking approval of Hikma's Proposed Product prior to the expiration of the patents-in-suit. Hikma denies the remaining allegations of paragraph 22.

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

RESPONSE: Hikma admits it submitted ANDA No. 219768 seeking approval of Hikma's Proposed Product prior to the expiration of the patents-in-suit. Hikma denies the remaining allegations of paragraph 23.

24. On information and belief, in connection with the submission of ANDA No. 219768 as described above, Hikma provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Hikma's ANDA.

RESPONSE: Hikma admits that ANDA No. 219768 contains Paragraph IV certifications to each of the patents in suit, alleging that each claim of the patents-in-suit is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Hikma's Proposed Products. Hikma denies the remaining allegations of paragraph 24.

25. No earlier than January 28, 2025, Hikma sent to Incyte written notice of Hikma's Paragraph IV Certification for the patents-in-suit ("Notice Letter"), alleging that the claims of those patents are invalid and/or will not be infringed by the activities described in Hikma's ANDA. Hikma's Notice Letter to Incyte conveyed that Hikma seeks approval to market Hikma's Proposed Products before the patents-in-suit expire.

RESPONSE: Hikma admits that on January 28, 2025, Hikma provided proper and timely notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii-iv) and 21 C.F.R. § 314.95 to Incyte Corporation and Incyte Holdings Corporation, of Hikma's certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Notice Letter"). Hikma admits that its Notice Letter states that Hikma seeks approval to engage in the commercial manufacture, use or sale of Hikma's Proposed Products prior to the expiration of the patents-in-

suit. Hikma also admits that the Notice Letter states that Hikma alleges that each claim of the patents-in-suit is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Hikma's Proposed Products. Hikma denies the remaining allegations of paragraph 25.

Count I: Infringement of the '257 Patent

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

RESPONSE: Hikma repeats and realleges its responses to each of the preceding paragraphs as if fully set forth herein.

27. Hikma's submission of ANDA No. 219768, 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 Hikma's Proposed Products prior to the expiration of the '257 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Denied.

28. There is a justiciable controversy between the parties hereto as to the infringement of the '257 patent.

RESPONSE: Admitted.

29. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '257 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Products in the United States.

RESPONSE: Denied.

30. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '257 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Products in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '257 patent and knowledge that its acts are encouraging infringement.

RESPONSE: Denied.

31. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '257 patent under 35 U.S.C. § 271(c) by making,

using, offering to sell, selling, and/or importing Hikma's Proposed Products in the United States. On information and belief, Hikma has had and continues to have knowledge that Hikma's Proposed Products are especially adapted for a use that infringes one or more claims of the '257 patent and that there is no substantial non-infringing use for Hikma's Proposed Products.

RESPONSE: Denied.

32. Incyte will be substantially and irreparably damaged and harmed if Hikma's infringement of the '257 patent is not enjoined.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

Count II: Infringement of the '362 Patent

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

RESPONSE: Hikma repeats and realleges its responses to each of the preceding paragraphs as if fully set forth herein.

36. Hikma's submission of ANDA No. 219768, 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 Hikma's Proposed Products prior to the expiration of the '362 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Denied.

37. There is a justiciable controversy between the parties hereto as to the infringement of the '362 patent.

RESPONSE: Admitted.

38. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '362 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Products in the United States.

RESPONSE: Denied.

39. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '362 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Products in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '362 patent and knowledge that its acts are encouraging infringement.

RESPONSE: Denied.

40. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '362 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Products in the United States. On information and belief, Hikma has had and continues to have knowledge that Hikma's Proposed Products are especially adapted for a use that infringes one or more claims of the '362 patent and that there is no substantial non-infringing use for Hikma's Proposed Products.

RESPONSE: Denied.

41. Incyte will be substantially and irreparably damaged and harmed if Hikma's infringement of the '362 patent is not enjoined.

RESPONSE: Denied.

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

RESPONSE: Denied.

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.

RESPONSE: Denied.

Count III: Infringement of the '693 Patent

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

RESPONSE: Hikma repeats and realleges its responses to each of the preceding paragraphs as if fully set forth herein.

45. Hikma's submission of ANDA No. 219768, 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 Hikma'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).

RESPONSE: Denied.

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

RESPONSE: Admitted.

47. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States.

RESPONSE: Denied.

48. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '693 patent and knowledge that its acts are encouraging infringement.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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.

RESPONSE: Denied.

Count IV: Infringement of the '481 Patent

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

RESPONSE: Hikma repeats and realleges its responses to each of the preceding paragraphs as if fully set forth herein.

54. Hikma's submission of ANDA No. 219768, 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 Hikma'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).

RESPONSE: Denied.

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

RESPONSE: Admitted.

56. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States.

RESPONSE: Denied.

57. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '481 patent and knowledge that its acts are encouraging infringement.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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.

RESPONSE: Denied.

Count V: Infringement of the '013 Patent

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

RESPONSE: Hikma repeats and realleges its responses to each of the preceding paragraphs as if fully set forth herein.

63. Hikma's submission of ANDA No. 219768, 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 Hikma'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).

RESPONSE: Denied.

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

RESPONSE: Admitted.

65. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States.

RESPONSE: Denied.

66. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '013 patent and knowledge that its acts are encouraging infringement.

RESPONSE: Denied.

67. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States.

On information and belief, Hikma has had and continues to have knowledge that Hikma'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 Hikma's Proposed Products.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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.

RESPONSE: Denied.

PLAINTIFFS' PRAYER FOR RELIEF

WHEREFORE, Hikma denies that Plaintiffs are entitled to any of the relief sought.

AFFIRMATIVE DEFENSES

Without altering the burdens of proof, Hikma asserts the following affirmative defenses:

1. Hikma has not, is not, and will not infringe any valid or enforceable claim of the patents-in-suit directly, indirectly, contributorily or by inducement, either literally or under the doctrine of equivalents.

2. The '257 patent is invalid under at least one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting.

3. The '362 patent is invalid under at least one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting.

4. The '693 patent is invalid under at least one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting.

5. The '481 patent is invalid under at least one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting.

6. The '013 patent is invalid under at least one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting.

7. The Court lacks subject matter jurisdiction over all of the Plaintiffs' allegations because Plaintiffs lack standing to pursue this action.

8. Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Hikma Pharmaceuticals USA Inc. ("Hikma"), for its Counterclaims against Incyte Corporation and Incyte Holdings Corporation ("Incyte," and collectively, "Plaintiffs/Counterclaim Defendants"), alleges:

1. Hikma is a corporation existing under the laws of Delaware, having a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

2. Upon information and belief, Plaintiff/Counterclaim Defendant 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.

3. Upon information and belief, Plaintiff/Counterclaim Defendant 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.

JURISDICTION AND VENUE

4. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the United States patent laws, 35 U.S.C. §§ 1 et seq.

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

6. This Court has personal jurisdiction over Incyte Corporation and Incyte Holdings Corporation because, at the least, each of these entities subjected itself to personal jurisdiction by filing its Complaint herein.

7. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1400(b) and by Plaintiffs'/Counterclaim Defendants' choice of forum.

FACTUAL BACKGROUND

The '693, '481, and '013 Patents

8. On or about May 13, 2014, the USPTO issued 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" to James D. Rodgers and Hui-Yin Li. According to the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), the '693 patent expires on June 12, 2028, with a pediatric extension to December 12, 2028.

9. On or about September 2, 2014, the USPTO issued 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" to James D. Rodgers and Hui-Yin Li. According to the Orange Book, the '481 patent expires on June 12, 2028, with a pediatric extension to December 12, 2028.

10. On or about September 9, 2014, the USPTO issued 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" to James D. Rodgers and Hui-Yin Li. According to the Orange Book, the '013 patent expires on June 12, 2028, with a pediatric extension to December 12, 2028.

11. On information and belief, Plaintiffs/Counterclaim-Defendants purport to own, license and/or have the right to enforce the '693 patent, the '481 patent, and the '103 patent.

JAKAFI® (RUXOLITINIB)

12. On information and belief, Plaintiff/Counterclaim-Defendant Incyte Corporation purports to be the holder of approved New Drug Application ("NDA") No. 202192 for JAKAFI® ruxolitinib tablets, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg.

13. On information and belief, Plaintiffs/Counterclaim-Defendants listed and/or caused to be listed the '693 patent, the '481 patent, and the '103 patent in the FDA's Orange Book in connection with JAKAFI® ruxolitinib tablets, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg.

14. By listing the '693 patent, the '481 patent, and the '103 patent in the FDA's Orange Book in connection with JAKAFI® ruxolitinib tablets, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg, Plaintiffs/Counterclaim-Defendants maintain that an infringement action can asserted against any applicant, including Hikma, that submits an Abbreviated New Drug Application ("ANDA") seeking approval for ruxolitinib tablets, 5 mg, 10 mg, 15 mg, 20 mg, and/or 25 mg.

HIKMA'S ANDA

15. Hikma filed ANDA No. 219768 ("Hikma's ANDA") seeking FDA approval for the sale of ruxolitinib tablets, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg ("Hikma's ANDA Product"). Hikma's ANDA contained a "paragraph IV certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '693, '481, and '013 patents and two additional patents listed in the Orange Book for JAKAFI® would not be infringed by the proposed

manufacture, use, or sale of Hikma's ANDA Product, and/or that those claims are invalid or unenforceable.

16. As required by 35 U.S.C. § 355(j)(2)(B), Hikma provided notice and a detailed statement of the factual and legal bases for its paragraph IV certifications ("Hikma's Notice Letter") to Plaintiffs/Counterclaim-Defendants.

17. In response to Hikma's Notice Letter, Plaintiffs/Counterclaim-Defendants filed suit against Hikma alleging infringement of the '693, '481, and '013 patents and two additional patents listed in the Orange Book for JAKAFI®.

COUNT I

(Declaratory Judgment of Noninfringement of the '693 Patent)

18. Hikma incorporates by reference paragraphs 1-17 of its counterclaims.

19. Because Plaintiffs/Counterclaim-Defendants filed suit pursuant to 35 U.S.C. § 271(e)(2), there is an actual, substantial, continuing and justiciable controversy between Hikma and Counterclaim-Defendants as to the infringement of the '693 patent.

20. Hikma's manufacture, use, sale, offer for sale, and/or importation of Hikma's ANDA Product does not and will not literally infringe any valid and enforceable claim of the '693 patent, either directly or indirectly.

21. Hikma is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Hikma's ANDA Product does not and will not literally infringe, directly

or indirectly, any valid and enforceable claim of the '693 patent, either literally or under the doctrine of equivalents.

COUNT II

(Declaration of Invalidity of the '693 Patent)

22. Hikma incorporates by reference paragraphs 1-21 of its counterclaims.

23. Because Plaintiffs/Counterclaim-Defendants filed suit pursuant to 35 U.S.C. § 271(e)(2), there is an actual, substantial, continuing and justiciable controversy between Hikma and Counterclaim-Defendants as to the validity of the '693 patent.

24. The '693 patent is invalid under at least one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting ("OTDP").

25. For example, and without limitation, the claims of the '693 patent are invalid for OTDP over the claims of commonly owned U.S. Patent No. 7,598,257 ("the '257 patent," attached as Exhibit 1).

26. The '257 patent expires on December 24, 2027, with a pediatric extension to June 24, 2028. The '693 patent expires on June 12, 2028, with a pediatric extension to December 12, 2028. Therefore, the '257 patent is a proper reference patent to the '693 patent with respect to OTDP.

27. Claim 2 of the '257 reference patent claims "a compound which is [ruxolitinib] or a pharmaceutically acceptable salt thereof." The '257 patent defines a "pharmaceutically

acceptable salt" as "derivatives of the disclosed compounds wherein the parent compound is modified by converting an existing acid or base moiety to its salt form." (Exhibit 1 at 32:44-48.)

28. Comparing claim 2 of the '257 patent to claim 1 of the '693 patent, claim 2 of the '257 patent claims a genus of pharmaceutically acceptable salts of ruxolitinib, which includes the phosphoric acid salt, while claim 1 of the '693 patent claims the specific phosphoric acid salt species.

29. This difference does not render claim 1 of the '693 patent patentably distinct from claim 2 of the reference '257 patent, because claim 1 of the '693 patent would have been obvious over claim 2 of the '257 reference patent in view of (1) the common knowledge of a POSA, as evidenced by prior art references Berge, J. Pharm. Sci., 66(1):1-16 (1977) ("Berge"), Bastin et al., Organic Process Research and Development 4:427-435 (2000), Gould, Int. J. Pharmaceutics, 33:201-217 (1986) ("Gould"), and Bighley, the Encyclopedia of Pharmaceutical Technology (1996) ("Bighley"), (2) the inherent properties of ruxolitinib free base, and (3) U.S. Patent No. 6,627,754, which reissued as Reissue Patent No. RE41,783 ("RE'783").

30. Claim 2 of the reference '257 patent claims both ruxolitinib free base, and its pharmaceutically acceptable salts. Thus, based on the claim alone, a POSA would be motivated to make pharmaceutically acceptable salts of ruxolitinib.

31. Further, a POSA would have been motivated to make a salt form of ruxolitinib to potentially increase aqueous solubility, bioavailability, manufacturability, and/or stability. (See, e.g., Bastin at 427-429.) In this regard, a POSA who had made ruxolitinib free base would have tested it for aqueous solubility as a matter of routine, and would have discovered that its aqueous

solubility ranged from 38 mg/250 ml at pH 7.5 to greater than 130 mg/250 ml at pH 3.3 or lower, which is low. (FDA Clinical/Pharmacology Review for NDA No. 202192 at 37.)

32. The POSA would then conduct a routine salt screen to identify advantageous ruxolitinib salts. Prior to conducting the screen, the POSA would determine the pKa of ruxolitinib free base and discover that it is 5.9. (Bastin at 427; Shi et al., Clin. Pharmacol. Ther., 97(2):177-185 (2014).) Since ruxolitinib free base is obviously a base, the POSA would use the decision tree outlined in Bighley for the salt screen, first starting with hydrochloric acid, because it is a strong acid and very common, and next turning to inorganic acids, as they are also strong acids. (Bighley at 34-35.) The group of inorganic acids other than hydrochloric acid is small, and includes only four other acids, hydrobromic acid, sulfuric acid, nitric acid, and phosphoric acid. (Bastin at 428.)

33. A POSA would also know that for the formation of a stable salt, it is widely accepted that there should be a minimum difference of about 3 pKa units between the pKa of the base and that of the acid used to form the salt. Here, as noted above, the pKa of ruxolitinib free base is 5.9, and phosphoric acid has a pKa of 2.15, which are different by 3.75 pKa units. (Gould at 216.)

34. A POSA would also know that phosphate salts are one of the most common forms of pharmaceutically acceptable salts used in FDA-approved drug products. (Berge at 2.)

35. RE'783 discloses and claims tofacitinib and its pharmaceutically acceptable salts. Tofacitinib is a prior art JAK inhibitor having a pyrrolopyrimidine scaffold and a CN group like ruxolitinib. RE'783 also teaches that the pharmaceutically acceptable salts can be selected from a

limited group including the phosphate salt. (RE'783 at 4:1-11.) This would further motivate a POSA to prepare the phosphoric acid salt of ruxolitinib, making it at least "obvious to try."

36. A POSA would also have a reasonable expectation of success in preparing the phosphoric acid salt of ruxolitinib. As of the priority date of the '693 patent, methods for forming pharmaceutically acceptable salts of drug substances were well known. For example, RE'783 discloses methods for forming acid addition salts from base compounds, and Bastin discloses methods for making and screening a number of salts at once. (RE'783 at 13:50-59; Bastin at 428.)

37. Claim 2 of the '693 patent claims a drug product comprising ruxolitinib phosphoric acid salt and a pharmaceutically acceptable carrier, while claim 3 requires that the drug product of claim 2 be suitable for oral administration.

38. Claims 4 and 5 of the '257 patent claim the same additional limitations of claims 2 and 3 of the '693 patent, respectively.

39. Claim 4 of the '693 patent requires that the drug product of claim 2 be in tablet form.

40. Claim 5 of the '257 patent claims a composition comprising ruxolitinib free base or a pharmaceutically acceptable salt thereof, where the composition is suitable for oral administration. A POSA would understand that tablets are a common form of oral drug compositions.

41. Claim 5 of the '693 patent requires that the ruxolitinib phosphoric acid salt is crystalline. This is an inherent property of ruxolitinib phosphate salt. Further, a POSA would

understand that in making a selection of potential salts, the quality of crystallization is important. (Gould at 201.)

42. Claim 6 of the ’693 patent depends from claim 5 and is directed to the crystalline salt being a 1:1 ruxolitinib:phosphoric acid salt. This is an inherent property of ruxolitinib phosphate salt.

43. Claim 7 of the ’693 patent is directed to a drug product comprising a crystalline ruxolitinib phosphoric acid salt and a pharmaceutically acceptable carrier. Claim 8 recites the crystalline salt being a 1:1 ruxolitinib:phosphoric acid salt. Claims 9 and 10 also depend from claim 7 and are directed to the drug product being suitable for oral administration and in tablet form, respectively.

44. The limitations of claims 7-10 of the ’693 patent are found in one or more of the claims of the reference ’257 patent or are obvious therefrom.

45. Hikma is entitled to a judicial declaration that the ’693 patent is invalid for failure to comply with one of more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for OTDP.

COUNT III

(Declaratory Judgment of Noninfringement of the ’481 Patent)

46. Hikma incorporates by reference paragraphs 1-45 of its counterclaims.

47. Because Plaintiffs/Counterclaim-Defendants filed suit pursuant to 35 U.S.C. § 271(e)(2), there is an actual, substantial, continuing and justiciable controversy between Hikma and Counterclaim-Defendants as to the infringement of the '481 patent.

48. Hikma's manufacture, use, sale, offer for sale, and/or importation of Hikma's ANDA Product does not and will not literally infringe any valid and enforceable claim of the '481 patent, either directly or indirectly.

49. Hikma is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Hikma's ANDA Product does not and will not literally infringe, directly or indirectly, any valid and enforceable claim of the '481 patent, either literally or under the doctrine of equivalents.

COUNT IV

(Declaratory Judgment of Invalidity of the '481 Patent)

50. Hikma incorporates by reference paragraphs 1-49 of its counterclaims.

51. Because Plaintiffs/Counterclaim-Defendants filed suit pursuant to 35 U.S.C. § 271(e)(2), there is an actual, substantial, continuing and justiciable controversy between Hikma and Counterclaim-Defendants as to the validity of the '481 patent.

52. The '481 patent is invalid under at least one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting ("OTDP").

53. For example, and without limitation, the claims of the ’481 patent are invalid for OTDP over the claims of commonly owned U.S. Patent No. 9,079,912 (“the ’912 patent,” attached as Exhibit 2).

54. The ’912 patent expires on December 12, 2026, with a pediatric extension to June 12, 2027. The ’481 patent expires on June 12, 2028, with a pediatric extension to December 12, 2028. Therefore, the ’912 patent is a proper reference patent to the ’481 patent with respect to OTDP.

55. Claim 1 of the reference ‘912 patent claims “[a] method of inhibiting JAK1 and/or JAK2 in a patient in need thereof, comprising administering to said patient an effective amount of a compound that is [ruxolitinib], or a pharmaceutically acceptable salt thereof.” The ’912 patent defines a “pharmaceutically acceptable salt” as “derivatives of the disclosed compounds wherein the parent compound is modified by converting an existing acid or base moiety to its salt form.” (Exhibit 2 at 32:54-57.)

56. Comparing claim 1 of the ’912 patent to claim 1 of the ’481 patent, claim 1 of the ’912 patent claims a genus of pharmaceutically acceptable salts of ruxolitinib, which includes the phosphoric acid salt, while claim 1 of the ’481 patent claims the specific phosphoric acid salt species.

57. This difference does not render claim 1 of the ’481 patent patentably distinct from claim 1 of the reference ’912 patent. Claim 1 of the ’481 patent is obvious over claim 1 of the ’912 patent for the same reasons that claim 1 of the ’693 patent is obvious over claim 2 of the ’257 patent.

58. Claims 2 and 3 of the ’481 patent claim the method of claim 1, where JAK1 or JAK2 is inhibited, respectively. Inhibition of JAK1 and/or JAK2 is claimed in claim 1 of the reference ’912 patent.

59. Claim 4 of the ’481 patent requires that the ruxolitinib phosphoric acid salt is crystalline. This is an inherent property of ruxolitinib phosphate salt. Further, a POSA would understand that in making a selection of potential salts, the quality of crystallization is important. (Gould at 201.)

60. Claims 5 and 6 of the ’481 patent claim the method of claim 4, where JAK1 or JAK2 is inhibited, respectively. Inhibition of JAK1 and/or JAK2 is claimed in claim 1 of the reference ’912 patent.

61. Claim 7 of the ’481 patent depends from claim 4 and is directed to the crystalline salt being a 1:1 ruxolitinib:phosphoric acid salt. This is an inherent property of ruxolitinib phosphate salt.

62. Claims 8-14 of the ’481 patent mirror claims 1-7, with the exception that they claim use of a pharmaceutical composition that includes a carrier. A POSA would have understood that active pharmaceutical compositions are always developed as pharmaceutical compositions that include at least one pharmaceutically acceptable carrier.

63. Claims 15-28 of the ’481 patent mirror claims 1-14, with the exception that they claim modulating an activity of JAK1 and/or JAK2 in a patient, instead of “inhibiting JAK1 and/or JAK2.”

64. According to the ’481 patent specification, “the term modulate is meant to refer to an ability to increase or decrease the activity of one or more members of JAK family of kinases.” (’481 patent at 3:31-33.) Decreasing the activity of a member of the JAK family of kinases is the same thing as inhibiting them, as claimed in claim 1 of the reference ’912 patent.

65. Hikma is entitled to a judicial declaration that the ’481 patent is invalid for failure to comply with one of more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for OTDP.

COUNT V

(Declaratory Judgment of Noninfringement of the ’013 Patent)

66. Hikma incorporates by reference paragraphs 1-65 of its counterclaims.

67. Because Plaintiffs/Counterclaim-Defendants filed suit pursuant to 35 U.S.C. § 271(e)(2), there is an actual, substantial, continuing and justiciable controversy between Hikma and Counterclaim-Defendants as to the validity infringement of the ’013 patent.

68. Hikma’s manufacture, use, sale, offer for sale, and/or importation of Hikma’s ANDA Product does not and will not literally infringe any valid and enforceable claim of the ’’013 patent, either directly or indirectly.

69. Hikma is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Hikma’s ANDA Product does not and will not literally infringe, directly or indirectly, any valid and enforceable claim of the ’013 patent, either literally or under the doctrine of equivalents

COUNT VI

(Declaratory Judgment of Invalidity of the '013 Patent)

70. Hikma incorporates by reference paragraphs 1-69 of its counterclaims.

71. Because Plaintiffs/Counterclaim-Defendants filed suit pursuant to 35 U.S.C. § 271(e)(2), there is an actual, substantial, continuing and justiciable controversy between Hikma and Counterclaim-Defendants as to the validity of the '013 patent.

72. The '013 patent is invalid under at least one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting ("OTDP").

73. For example, and without limitation, the claims of the '013 patent are invalid for OTDP over the claims of commonly owned '257 patent.

74. The '257 patent expires on December 24, 2027, with a pediatric extension to June 24, 2028. The '013 patent expires on June 12, 2028, with a pediatric extension to December 12, 2028. Therefore, the '257 patent is a proper reference patent to the '013 patent with respect to OTDP.

75. Claims 6-8 of the '257 patent claim a method of treating myeloid metaplasia with myelofibrosis ("MMM"), polycythemia vera ("PV"), or essential thrombocythemia ("ET"), respectively, comprising administering to a patient an effective amount of the compounds of any of claims 1-3.

76. Claim 2 of the ’257 reference patent claims “a compound which is [ruxolitinib] or a pharmaceutically acceptable salt thereof.” The ’257 patent defines a “pharmaceutically acceptable salt” as “derivatives of the disclosed compounds wherein the parent compound is modified by converting an existing acid or base moiety to its salt form.” (Exhibit 1 at 32:44-48.)

77. Comparing one or more of claims 6-8 of the ’257 patent to claims one or more of claims 1-4 of the ’013 patent, claims 6-8 of the reference ’257 patent claim a genus of pharmaceutically acceptable salts of ruxolitinib, which includes the phosphoric acid salt, while claims 1-4 of the ’013 patent claim the specific phosphoric acid salt species.

78. This difference does not render claims 1-4 of the ’013 patent patentably distinct from claims 6-8 of the reference ’257 patent. Claims 1-4 of the ’013 patent are obvious over claims 6-8 of the ’257 patent for the same reasons as expressed above with respect to the claims of the ’693 patent.

79. Claim 5 of the ’013 patent requires that the ruxolitinib phosphoric acid salt is crystalline. This is an inherent property of ruxolitinib phosphate salt. Further, a POSA would understand that in making a selection of potential salts, the quality of crystallization is important. (Gould at 201.)

80. Claim 6 of the ’013 patent depends from claim 5 and is directed to the crystalline salt being a 1:1 ruxolitinib:phosphoric acid salt. This is an inherent property of ruxolitinib phosphate salt.

81. Claims 7-10 and 13-14 of the ’013 patent mirror claims 1-6, except that they claim use of a pharmaceutical composition that includes a carrier. A POSA would have understood that active pharmaceutical compositions are always developed as pharmaceutical compositions that include at least one pharmaceutically acceptable carrier.

82. Further, claim 4 of the reference ’257 patent claims a composition comprising the compound of any of claims 1-3 or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable carrier.

83. Claims 11 and 12 of the ’013 patent claim the method of claim 7, and additionally require that the composition be suitable for oral administration, and that it be in the form of a tablet, respectively.

84. Claim 5 of the reference ’257 patent claims the composition of claim 4 which is suitable for oral administration. A POSA would understand that tablets are a common form of oral drug compositions.

85. Hikma is entitled to a judicial declaration that the ’013 patent is invalid for failure to comply with one of more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for OTDP.

PRAYER FOR RELIEF

WHEREFORE, Hikma prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants as follows:

A. Judgment that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '693 patent;

B. Judgment that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '481 patent;

C. Judgment that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '013 patent;

D. Judgment that the claims of the '693 patent are invalid;

E. Judgment that the claims of the '481 patent are invalid;

F. Judgment that the claims of the '013 patent are invalid;

G. Judgment that Plaintiffs are not entitled to injunctive relief;

H. Judgment that Plaintiffs take nothing by this action;

I. Judgment that this be declared an exceptional case under 35 U.S.C. § 285, and that Hikma be awarded its costs, including reasonable attorneys' fees; and

J. For such other relief as the Court deems just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendant,
Hikma Pharmaceuticals USA, Inc.

By: *s/ James S. Richter*
James S. Richter
jrichter@midlige-richter.com

Dated: June 16, 2025

OF COUNSEL:

Jeffrey S. Ward (*pro hac vice* pending)
Emer Simic (*pro hac vice* pending)
NEAL GERBER & EISENBERG LLP
Two North LaSalle Street, Suite 1700
Chicago, Illinois 60602

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, the same drug and patents are at issue in the following action currently pending in this District:

- *Incyte Corp., et al. v. Apotex Inc., No. 24-4366 (CPO)(MJS) (D.N.J.)*

Hikma is not aware of any other action in any court or any pending arbitration or administrative proceeding related to this matter

s/ James S. Richter
James S. Richter

Dated: June 16, 2025

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*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ James S. Richter
James S. Richter

Dated: June 16, 2025

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Hikma's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on June 16, 2025.

s/James S. Richter
James S. Richter

Dated: June 16, 2025