R Touhey Myer
NJ Bar ID 028912009
KRATZ & BARRY LLP
800 N. West Street
Wilmington, DE 19801
(302) 527-9378
tmyer@kratzandbarry.com

Of Counsel:

Timothy H. Kratz *(Pro Hac Vice Expected)*
George J. Barry III *(Pro Hac Vice Expected)*
John Thallemer *(Pro Hac Vice Expected)*
KRATZ & BARRY LLP
1050 Crown Pointe Parkway, Suite 500
Atlanta, GA 30338
(404) 431-6600
tkratz@kratzandbarry.com
gbarry@kratzandbarry.com
jthallemer@kratzandbarry.com

Michael P. Hogan *(Pro Hac Vice Expected)*
KRATZ & BARRY LLP
P.O. Box 63765
622 S. 4th Street
Philadelphia, PA 19147
(917) 216-8585
mhogan@kratzandbarry.com

Attorneys for Defendant,
Granules India Ltd.

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

INCYTE CORP. and INCYTE HOLDINGS CORP., *Plaintiffs,* v. GRANULES INDIA LTD., *Defendant.*	C.A. No. 1:25-cv-13227-CPO-MJS (Filed Electronically)

DEFENDANT, GRANULES INDIA LTD.'S ANSWER TO COMPLAINT

Defendant, Granules India Ltd. ("Granules" or "Defendant"), by and through its undersigned attorneys, hereby respectfully responds to the Complaint filed by Plaintiffs Incyte Corp. and Incyte Holdings Corp (collectively, "Incyte" or "Plaintiffs") as follows:

RESPONSES TO ALLEGATIONS PERTAINING TO THE 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 Granules' submission of Abbreviated New Drug Application ("ANDA") No. 220521 ("Granules' 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, 15mg, 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: Granules admits Plaintiffs purport to bring this action for alleged patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*. Granules admits filing the Granules ANDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import ruxolitinib tablets in 5 mg, 10 mg, 15 mg, 20 mg and 25 mg strengths, for which the reference listed drug is Jakafi®, which, upon information and belief, is marketed by Incyte, prior to the expiration of the patents-in-suit. Granules is without knowledge or information sufficient to form a belief as to the truth regarding the ownership of the patents-in-suit and, therefore, denies all allegations pertaining to same. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO 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: Granules is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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: Granules is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

4. On information and belief, Defendant Granules India Ltd. is a corporation organized and existing under the laws of India, having a place of business at 15th Floor, Granules Tower, Botanical Garden Road, Kondapur, Hyderabad 500084, Telangana, India.

RESPONSE: Admitted.

5. On information and belief, Granules together with its subsidiaries develops, manufactures, and markets pharmaceutical products in India, the United States, Europe and internationally.

RESPONSE: Granules admits it develops and manufactures pharmaceutical products in India and the United States and markets pharmaceutical products in India, the United States, Europe and internationally. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO THE PATENTS-IN-SUIT

6. 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: Granules admits Exhibit A to the Complaint appears to be a copy of the '257 patent, which Granules admits is titled "Heteroaryl substituted pyrrolo[2,3-b]pyridines and pyrrolo[2,3-b]pyrimidines as janus kinase inhibitors." Granules admits the face of the '257 patent states the '257 patent was issued October 6, 2009. Granules denies the '257 patent was duly and

lawfully issued. Granules denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

7. 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: Granules admits Exhibit B to the Complaint appears to be a copy of the '362 patent, which Granules admits is titled "Pyrazolyl substituted pyrrolo[2,3-b]pyrimidines as Janus kinase inhibitors." Granules admits the face of the '362 patent states the '362 patent was issued April 9, 2013. Granules denies the '362 patent was duly and lawfully issued. Granules denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

8. 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: Granules admits Exhibit C of the Complaint appears to be a copy of the '693 patent, which Granules admits 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." Granules admits the face of the '693 patent states the '693 patent was issued May 13, 2014. Granules denies the '693 patent was duly and lawfully issued. Granules denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

9. 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: Granules admits Exhibit D of the Complaint appears to be a copy of the '481 patent, which Granules admits 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." Granules admits the face of the '481 patents states the '481 patent was issued September 2, 2014. Granules denies the '481 patent was duly and lawfully issued. Granules denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

10. 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: Granules admits Exhibit E of the Complaint appears to be a copy of the '013 patent, which Granules admits 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." Granules admits the face of the '013 patent states the '013 patent was issued September 9, 2014. Granules denies the '013 patent was duly and lawfully issued. Granules denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO THE JAFAKI® DRUG PRODUCT

11. 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: Granules is without knowledge or information sufficient to form a belief as to the ownership of approved New Drug Application No. 202192 and therefore, denies all allegations pertaining to the same. Granules denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

12. 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: Granules admits the patents-in-suit are listed in the Orange Book with respect to Jakafi®. Granules denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

13. 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.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

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

RESPONSE: Granules admits the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). Granules denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Solely for the purpose of this litigation, Granules does not contest personal jurisdiction in this District. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Solely for the purpose of this litigation, Granules does not contest personal jurisdiction in this District. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

17. On information and belief, Granules 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: Granules admits and avers it develops, manufactures, markets, imports, offers for sale, and sells pharmaceutical products in the United States following approval by the U.S. Food & Drug Administration ("FDA"). Solely for the purpose of this litigation, Granules does not contest personal jurisdiction in this District. Granules denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Solely for the purpose of this litigation, Granules does not contest personal jurisdiction in this District. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

19. On information and belief, Granules submitted ANDA No. 220521 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 Granules' ANDA ("Granules' 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: Granules admits it submitted ANDA No. 220521 seeking approval to manufacture, use, import, offer to sell, and/or sell the pharmaceutical product that is the subject of Granules' ANDA. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

20. On information and belief, this Judicial District is a likely destination for Granules' Proposed Products.

RESPONSE: Solely for the purpose of this litigation, Granules does not contest personal jurisdiction in this District. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: This paragraph contains allegations that are hypothetical or speculative in nature, and Granules denies the same for that reason. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

22. On information and belief, Granules USA, Inc. ("Granules USA") is a wholly owned subsidiary of Granules organized under the laws of New Jersey with its principal place of business at 35 Waterview Blvd, Parsippany, NJ 07054.

RESPONSE: Denied.

23. On information and belief, Granules USA is the North American division of Granules and is registered with the State of New Jersey as a drug wholesaler, under Registration No. 5003061.

RESPONSE: Denied.

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

RESPONSE: Denied.

25. On information and belief, Granules conducts business through and with Granules USA, its wholly owned subsidiary. Granules has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. Granules directly or through its affiliates and agents, such as Granules USA, develops, formulates, synthesizes, manufactures, markets, imports, offers to sell, and/or sells pharmaceutical drug products including the Granules ANDA Products in New Jersey.

RESPONSE: Denied.

26. On information and belief, Granules maintains a regular and established physical place of business through its wholly owned subsidiary Granules USA at 35 Waterview Blvd, 3rd Floor, Parsippany, NJ 07054.

RESPONSE: Denied.

27. On information and belief, Granules through its subsidiaries and various agents 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. 0100902434 and is registered with the New Jersey Department of Health under Registration Nos. 5003061, 5005086, and 5006297.

RESPONSE: Denied.

28. Venue is proper in this Judicial District for Granules pursuant to 28 U.S.C. §§ 1391

and/or 1400(b), including, for example, because Granules is a company organized and existing under the laws of India and may be sued in any judicial district.

RESPONSE: Solely for the purpose of this litigation, Granules does not contest venue in this District. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO ACTS GIVING RISE TO THIS SUIT

29. Pursuant to Section 505 of the FFDCA, Granules submitted ANDA No. 220521 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Granules' Proposed Products, which are proposed generic versions of Incyte's approved Jakafi® products, before the patents-in-suit expire.

RESPONSE: Granules admits submitting ANDA No. 220521 to the FDA under section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking regulatory approval for the pharmaceutical product that is the subject of Granules' ANDA. Granules admits Incyte's product Jakafi® is the reference listed drug relied upon in Granules' ANDA. Granules denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: This paragraph contains allegations of a hypothetical and speculative nature pertaining to uncertain future events, and, on that basis, Granules denies all allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

32. On information and belief, in connection with the submission of ANDA No. 220521 as described above, Granules provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Granules' 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 Granules' ANDA.

RESPONSE: Granules admits ANDA No. 220521 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the patents-in-suit are invalid, unenforceable and/or will not be infringed by the product that is the subject of Granules' ANDA. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

33. Granules subsequently sent to Incyte written notice of Granules' 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 Granules' ANDA. Granules' written notice to Incyte conveyed that Granules seeks approval to market Granules' Proposed Products before the patents-in-suit expire.

RESPONSE: Granules admits it sent Incyte written notice of its Paragraph IV Certifications for the patents-in-suit alleging that the claims of those patents are invalid, unenforceable and/or will not be infringed by the product that is the subject of Granules' ANDA. Granules

denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT I: ALLEGED INFRINGEMENT OF THE '257 PATENT

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

RESPONSE: Granules restates and incorporates by reference each response to each preceding paragraph of the Complaint as if fully set forth herein.

35. Granules' submission of ANDA No. 220521, 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 Granules' 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.

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

RESPONSE: Granules denies infringement of the '257 patent. Granules admits there is a dispute between the parties as to whether Granules' ANDA and the product that is the subject of Granules' ANDA infringes the '257 patent. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

37. Unless enjoined by this Court, upon FDA approval of Granules' ANDA, Granules 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 Granules' Proposed Products in the United States.

RESPONSE: Denied.

38. Unless enjoined by this Court, upon FDA approval of Granules' ANDA, Granules 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 Granules' Proposed Products in the United States. On information and belief, upon FDA approval of Granules' ANDA, Granules will intentionally encourage acts of direct infringement with knowledge of the '257 patent and knowledge that its acts are encouraging infringement.

RESPONSE: Denied.

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

RESPONSE: Denied.

40. Incyte will be substantially and irreparably damaged and harmed if Granules' infringement of the '257 patent is not enjoined.

RESPONSE: Denied.

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

RESPONSE: Denied.

42. 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.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT II: ALLEGED INFRINGEMENT OF THE '362 PATENT

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

RESPONSE: Granules objects to Incyte's incorporation of all previous allegations, which is improper shotgun pleading and renders Count II vague and ambiguous. Granules nonetheless restates and incorporates by reference each response to each preceding paragraph of the Complaint as if fully set forth herein.

44. Granules' submission of ANDA No. 220521, 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 Granules' 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.

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

RESPONSE: Granules denies infringement of the '362 patent. Granules admits there is a dispute between the parties as to whether Granules' ANDA and the product that is the subject of Granules' ANDA infringes the '362 patent. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

46. Unless enjoined by this Court, upon FDA approval of Granules' ANDA, Granules 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 Granules' Proposed Products in the United States.

RESPONSE: Denied.

47. Unless enjoined by this Court, upon FDA approval of Granules' ANDA, Granules 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 Granules' Proposed Products in the United States. On information and belief, upon FDA approval of Granules' ANDA, Granules will intentionally encourage acts of direct infringement with knowledge of the '362 patent and knowledge that its acts are encouraging infringement.

RESPONSE: Denied.

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

RESPONSE: Denied.

49. Incyte will be substantially and irreparably damaged and harmed if Granules' infringement of the '362 patent is not enjoined.

RESPONSE: Denied.

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

RESPONSE: Denied.

51. 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.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT III: ALLEGED INFRINGEMENT OF THE '693 PATENT

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

RESPONSE: Granules objects to Incyte's incorporation of all previous allegations, which is improper shotgun pleading and renders Count III vague and ambiguous. Granules nonetheless restates and incorporates by reference each response to each preceding paragraph of the Complaint as if fully set forth herein.

53. Granules' submission of ANDA No. 220521, 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 Granules' 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.

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

RESPONSE: Granules denies infringement of the '693 patent. Granules admits there is a dispute between the parties as to whether Granules' ANDA and the product that is the subject of Granules' ANDA infringes the '693 patent. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

55. Unless enjoined by this Court, upon FDA approval of Granules' ANDA, Granules 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 Granules' Proposed Products in the United States.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

58. Incyte will be substantially and irreparably damaged and harmed if Granules' infringement of the '693 patent is not enjoined.

RESPONSE: Denied.

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

RESPONSE: Denied.

60. 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.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT IV: ALLEGED INFRINGEMENT OF THE '481 PATENT

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

RESPONSE: Granules objects to Incyte's incorporation of all previous allegations, which is improper shotgun pleading and renders Count IV vague and ambiguous. Granules nonetheless restates and incorporates by reference each response to each preceding paragraph of the Complaint as if fully set forth herein.

62. Granules' submission of ANDA No. 220521, 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 Granules' 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.

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

RESPONSE: Granules denies infringement of the '481 patent. Granules admits there is a dispute between the parties as to whether Granules' ANDA and the product that is the subject of Granules' ANDA infringes the '481 patent. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

64. Unless enjoined by this Court, upon FDA approval of Granules' ANDA, Granules 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 Granules' Proposed Products in the United States.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

67. Incyte will be substantially and irreparably damaged and harmed if Granules' infringement of the '481 patent is not enjoined.

RESPONSE: Denied.

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

RESPONSE: Denied.

69. 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.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT V: ALLEGED INFRINGEMENT OF THE '013 PATENT

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

RESPONSE: Granules objects to Incyte's incorporation of all previous allegations, which is improper shotgun pleading and renders Count V vague and ambiguous. Granules nonetheless restates and incorporates by reference each response to each preceding paragraph of the Complaint as if fully set forth herein.

71. Granules' submission of ANDA No. 220521, 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 Granules' 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.

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

RESPONSE: Granules denies infringement of the '013 patent. Granules admits there is a dispute between the parties as to whether Granules' ANDA and the product that is the subject of Granules' ANDA infringes the '013 patent. Granules denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

73. Unless enjoined by this Court, upon FDA approval of Granules' ANDA, Granules 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 Granules' Proposed Products in the United States.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

76. Incyte will be substantially and irreparably damaged and harmed if Granules' infringement of the '013 patent is not enjoined.

RESPONSE: Denied.

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

RESPONSE: Denied.

78. 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.

GENERAL DENIAL AND RESPONSE TO PLAINTIFF'S REQUEST FOR RELIEF

All allegations in Plaintiffs' Complaint not expressly admitted by Granules are hereby denied. Having answered Plaintiffs' Complaint, Granules denies Plaintiffs are entitled to any of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Granules asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiffs.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the product(s) that is the subject of Granules' ANDA has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the Asserted Patents.

SECOND SEPARATE DEFENSE

Each of claim of the patents-in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102 or 103, respectively, for example, for at least the reasons set forth in Granules' Paragraph IV notice to Plaintiffs.

THIRD SEPARATE DEFENSE

Each of claim of the patents asserted in this action is invalid, pursuant to 35 U.S.C. § 112, as, for example, indefinite, not enabled and/or failing to provide adequate written description.

FOURTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the patents asserted in this Action, and specifically prosecution history estoppel, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the Asserted Patents is infringed by the product that is the subject of Granules' ANDA.

FIFTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

SIXTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Granules hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patents asserted in this Action, an award of all costs and fees incurred in defense of this Action, including, without limitation reasonable attorneys' fees under 35 U.S.C. § 285, and for such other relief as the Court may deem just and proper.

Dated: October 28, 2025

KRATZ & BARRY LLP

/s/ R Touhey Myer
R Touhey Myer
NJ Bar ID 028912009
800 N. West Street
Wilmington, DE 19801
(302) 527-9378
tmyer@kratzandbarry.com

Of Counsel:

Timothy H. Kratz *(Pro Hac Vice Expected)*
George J. Barry III *(Pro Hac Vice Expected)*
John Thallemer *(Pro Hac Vice Expected)*
KRATZ & BARRY, LLP
1050 Crown Pointe Parkway, Suite 500
Atlanta, GA 30338
(404) 431-6600
tkratz@kratzandbarry.com
gbarry@kratzandbarry.com
jthallemer@kratzandbarry.com

Michael P. Hogan *(Pro Hac Vice Expected)*
KRATZ & BARRY LLP
P.O. Box 63765
622 S. 4th Street
Philadelphia, PA 19147
(917) 216-8585
mhogan@kratzandbarry.com

Attorneys for Defendant,
Granules India Ltd.