IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Avion Pharmaceuticals, LLC and RxOmeg Therapeutics, LLC, a/k/a Romeg Therapeutics, LLC, Plaintiffs, v. Granules Pharmaceuticals, Inc., Defendant.	Civil Action No. 1:20-cv-00898 (LPS)

DEFENDANT GRANULES PHARMACEUTICALS, INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO FIRST AMENDED COMPLAINT

Defendant Granules Pharmaceuticals, Inc. ("Defendant" or "Granules"), by and through its undersigned counsel, hereby submits the following Answer, Defenses, and Counterclaims ("Answer") in response to the First Amended Complaint ("Complaint") (D.I. 9) filed by Plaintiffs Avion Pharmaceuticals, LLC ("Avion") and RxOmeg Therapeutics, LLC, a/k/a Romeg Therapeutics, LLC ("RxOmeg") (collectively, "Plaintiffs").

Granules denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Granules denies that Plaintiffs are entitled to the relief requested or any other relief. Granules responds to the Complaint as follows:

RESPONSE TO "NATURE OF THE ACTION"[1]

1. This is an action by Plaintiffs for infringement of United States Patent Nos. 9,907,751 ("'751 patent"), 10,226,423 ("'423 patent"), 10,383,820 ("'820 patent"), and 10,383,821 ("'821 patent") (collectively, the "patents-in-suit"). This action arises out of the filing of Abbreviated New Drug Application ("ANDA") No. 214808 by Defendant seeking approval by the United States Food and Drug Administration ("FDA") to sell a generic version of GLOPERBA®, Plaintiffs' innovative treatment for patients with gout flares, prior to the expiration of the '751, '423, '820, and '821 patents.

ANSWER: Granules admits that the Complaint purports to be an action for infringement of the '751, '423, '820, and '821 patents arising out of the filing of ANDA No. 214808; Granules, however, denies any such infringement. Granules avers that it submitted ANDA No. 214808 to the FDA seeking approval to sell its proposed Colchicine Oral Solution, 0.6 mg/5mL prior to the expiration of the '751, '423, '820, and '821 patents. Granules otherwise denies the remaining allegations in Paragraph 1 of the Complaint.

RESPONSE TO "THE PARTIES"

2. Avion is a limited liability corporation with its principal place of business at 1880 McFarland Parkway, Suite 105, Alpharetta, Georgia 30005.

ANSWER: Upon information and belief, and based upon Avion's allegation, Granules admits the allegations of Paragraph 2 of the Complaint.

3. RxOmeg is a limited liability corporation with its principal place of business at 400 Tradecenter 128, Suite 5900, Woburn, Massachusetts 01801.

ANSWER: Upon information and belief, and based upon RxOmeg's allegation, Granules admits the allegations of Paragraph 3 of the Complaint.

4. Upon information and belief, Defendant Granules Pharmaceuticals is a corporation organized and existing under the laws of Delaware with its principal place of business at 3701 Concorde Parkway, Chantilly, VA 20151.

ANSWER: Granules admits the allegations of Paragraph 4 of the Complaint.

[1] Plaintiffs' headings are reprinted here with the same language as used in Plaintiffs' Complaint for ease of reference, and do not constitute an admission by Defendant.

RESPONSE TO "JURISDICTION"

5. This action for patent infringement arises under 35 U.S.C. § 271.

ANSWER: Granules admits that the Complaint purports to bring an action for alleged patent infringement under the patent laws of the United States of America, including 35 U.S.C. § 271. Granules denies any remaining allegations of Paragraph 5 of the Complaint.

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

ANSWER: Paragraph 6 states a legal conclusion to which no response is required. To the extent a response is required, Granules does not contest the Court's jurisdiction over the subject matter of this action.

7. Upon information and belief, this Court has personal jurisdiction over Granules Pharmaceuticals because, *inter alia*, upon information and belief, Granules Pharmaceuticals is incorporated in Delaware; has substantial, continuous, and systematic contacts with the State of Delaware that render it at home in Delaware; intends to market, sell, and/or distribute a generic colchicine product ("Defendant's Colchicine Product") to residents of the State of Delaware upon approval of ANDA No. 214808; and enjoys substantial income from sales of its pharmaceutical products in the State of Delaware.

ANSWER: Paragraph 7 states a legal conclusion to which no response is required. To the extent that a response is required, Granules does not contest personal jurisdiction in this Court solely for the purposes of this action only and reserves the right to contest personal jurisdiction in any other case.

8. Upon information and belief, Granules Pharmaceuticals has engaged in and maintained systematic and continuous business contacts within the State of Delaware and has purposefully availed itself of the benefits and protections of the laws of Delaware.

ANSWER: Paragraph 8 states a legal conclusion to which no response is required. To the extent that a response is required, Granules does not contest personal jurisdiction in this Court solely for the purposes of this action only and reserves the right to contest personal jurisdiction in any other case.

9. Upon information and belief, Granules Pharmaceuticals markets, distributes, and/or sells generic drugs throughout the United States and within the State of Delaware.

ANSWER: Granules admits that it markets, distributes, and sells generic drugs in the United States and within the State of Delaware.

10. Upon information and belief, Granules Pharmaceuticals holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy under License Nos. DM-0012454 and A4-0002432, respectively.

ANSWER: Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, Granules admits that it holds current and valid License Nos. DM-0012454 and A4-0002432, from the Delaware Board of Pharmacy. Granules denies any remaining allegations of Paragraph 10 of the Complaint.

11. Upon information and belief, Granules Pharmaceuticals consented to jurisdiction in Delaware by incorporating in Delaware and registering to conduct business with the State of Delaware and maintaining registered agent VCORP SERVICES, LLC, 1013 Centre Road Suite 403-B, Wilmington, DE.

ANSWER: Paragraph 11 states a legal conclusion to which no response is required. To the extent that a response is required, Granules admits it is incorporated in Delaware and has VCORP SERVICES, LLC, 1013 Centre Road Suite 403-B, Wilmington, DE as a registered agent. Granules does not contest jurisdiction in this Court solely for the purposes of this action only and reserves the right to contest jurisdiction in any other case.

12. This Court also has personal jurisdiction over Defendant because it has previously been sued in this District without challenging this Court's assertion of personal jurisdiction and availed itself of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes. *See, e.g.,* Defs.' Answer, Defenses, and Countercls., *Genentech, Inc. v. Granules Pharm., Inc.*, No. 1:19-cv-00164-RGA (D. Del. Apr. 23, 2019), ECF No. 12; Def. Granules Pharmaceuticals' Answer, Defenses, Countercls., and Demand for Jury Trial, *Hikma Pharm. USA Inc. v. Granules Pharm., Inc.*, No. 1:18-cv-00085-CFC (D. Del. May 24, 2018), ECF No. 13.

ANSWER: Paragraph 12 states a legal conclusion to which no response is required. To the extent that a response is required, Granules admits that it has asserted counterclaims in

other cases unrelated to the present action. Granules does not contest personal jurisdiction in this Court solely for the purposes of this action only and reserves the right to contest personal jurisdiction in any other case. Granules denies any remaining allegations of Paragraph 12 of the Complaint.

13. Upon information and belief, this Court has personal jurisdiction over Defendant for the reasons stated herein, including, *inter alia*, Defendant's activities in the forum, activities directed at the forum, significant contacts with the forum, and consent, all of which render Defendant at home in the forum.

ANSWER: Paragraph 13 states a legal conclusion to which no response is required. To the extent that a response is required, Granules does not contest personal jurisdiction in this Court solely for the purposes of this action only and reserves the right to contest personal jurisdiction in any other case.

14. Upon information and belief, Defendant has applied for FDA approval to market and sell a generic version of GLOPERBA® throughout the United States, including in Delaware.

ANSWER: Granules avers that it filed ANDA No. 214808 for FDA approval to market and sell its proposed Colchicine Oral Solution, 0.6mg/5mL within the United States. Granules denies any remaining allegations of Paragraph 14 of the Complaint.

15. Upon information and belief, Defendant has participated in the commission of patent infringement by, *inter alia*, filing ANDA No. 214808 and intending to market, sell, and/or distribute Defendant's Colchicine Product to residents of the State of Delaware upon approval of ANDA No. 214808, that has led to foreseeable harm and injury to Plaintiffs, which manufacture GLOPERBA® for sale and use throughout the United States, including the State of Delaware.

ANSWER: Paragraph 15 states a legal conclusion to which no response is required. To the extent that a response is required, Granules admits that it filed ANDA No. 214808 for FDA approval to market and sell its proposed Colchicine Oral Solution, 0.6 mg/5mL within the United States. Granules denies it has participated in the commission of patent infringement by its actions and denies the remaining allegations of Paragraph 15 of the Complaint.

RESPONSE TO "VENUE"

16. Venue is proper in this Judicial District under 28 U.S.C. §§ 1400 and 1391. Venue is proper in this Court at least because Granules Pharmaceuticals is incorporated in the State of Delaware and therefore "resides" in Delaware under 28 U.S.C. § 1400(b).

ANSWER: Paragraph 16 states a legal conclusion to which no response is required. To the extent that a response is required, Granules does not contest venue in this Court solely for the purposes of this action and reserves the right to contest venue in any other case.

17. Venue is also proper in this Court because Defendant has previously been sued in this District without challenging that venue is proper in this Court and availed itself of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes. *See, e.g.*, Defs.' Answer, Defenses, and Countercls., *Genentech, Inc. v. Granules Pharm., Inc.*, No. 1:19-cv-00164-RGA (D. Del. Apr. 23, 2019), ECF No. 12; Def. Granules Pharmaceuticals' Answer, Defenses, Countercls., and Demand for Jury Trial, *Hikma Pharm. USA Inc. v. Granules Pharm., Inc.*, No. 1:18-cv-00085-CFC (D. Del. May 24, 2018), ECF No. 13.

ANSWER: Paragraph 17 states a legal conclusion to which no response is required. To the extent that a response is required, Granules admits that it has asserted counterclaims in other cases unrelated to the present action. Granules does not contest venue in this Court solely for the purposes of this action only and reserves the right to contest venue in any other case. Granules denies any remaining allegations of Paragraph 17 of the Complaint.

RESPONSE TO "BACKGROUND"

18. The '751 patent, entitled "Composition and Method of Use of Colchicine Oral Liquid," was duly and legally issued on March 6, 2018.

ANSWER: Paragraph 18 states a legal conclusion to which no response is required. To the extent a response is required, Granules admits that the '751 patent is titled "Composition and Method of Use of Colchicine Oral Liquid," and lists an issue date of March 6, 2018. Granules denies the remaining allegation of Paragraph 18 of the Complaint.

19. Indu Muni and Naomi Vishnupad are the named inventors of the '751 patent.

ANSWER: Granules admits that the '751 patent identifies Indu Muni and Naomi Vishnupad as inventors of the '751 patent.

20. RxOmeg is the sole owner by assignment of all rights, title and interest in the '751 patent.

ANSWER: Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 20 of the Complaint, and therefore denies the same.

21. Avion is the exclusive licensee of the '751 patent.

ANSWER: Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 21 of the Complaint, and therefore denies the same.

22. The '751 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book," with respect to GLOPERBA®.

ANSWER: Granules admits that the '751 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" for COLCHICINE (GLOPERBA) SOLUTION 0.6MG/5ML.

23. A true and correct copy of the '751 patent is attached as Exhibit A.

ANSWER: Granules admits that Exhibit A to the Complaint purports to be a copy of the '751 patent. Granules denies the remaining allegations of Paragraph 23 of the Complaint.

24. The '423 patent, entitled "Colchicine Drug-to-Drug Interactions," was duly and legally issued on March 12, 2019.

ANSWER: Paragraph 24 states a legal conclusion to which no response is required. To the extent a response is required, Granules admits that the '423 patent is titled "Colchicine Drug-to-Drug Interactions," and lists an issue date of March 12, 2019. Granules denies the remaining allegations of Paragraph 24 of the Complaint.

25. Indu Muni and Naomi Vishnupad are the named inventors of the '423 patent.

ANSWER: Granules admits that the '423 patent identifies Indu Muni and Naomi Vishnupad as inventors of the '423 patent.

26. RxOmeg is the sole owner by assignment of all rights, title and interest in the '423 patent.

ANSWER: Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 26 of the Complaint, and therefore denies the same.

27. Avion is the exclusive licensee of the '423 patent.

ANSWER: Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 27 of the Complaint, and therefore denies the same.

28. The '423 patent is listed in the Orange Book with respect to GLOPERBA®.

ANSWER: Granules admits that the '423 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" for COLCHICINE (GLOPERBA) SOLUTION 0.6MG/5ML.

29. A true and correct copy of the '423 patent is attached as Exhibit B.

ANSWER: Granules admits that Exhibit B to the Complaint purports to be a copy of the '423 patent. Granules denies the remaining allegations of Paragraph 29 of the Complaint.

30. The '820 patent, entitled "Colchicine Drug-to-Drug Interactions," was duly and legally issued on August 20, 2019.

ANSWER: Paragraph 30 states a legal conclusion to which no response is required. To the extent a response is required, Granules admits that the '820 patent is titled "Colchicine Drug-to-Drug Interactions," and lists an issue date of August 20, 2019. Granules denies the remaining allegations of Paragraph 30 of the Complaint.

31. Indu Muni and Naomi Vishnupad are the named inventors of the '820 patent.

ANSWER: Granules admits that the '820 patent identifies Indu Muni and Naomi Vishnupad as inventors of the '820 patent.

32. RxOmeg is the sole owner by assignment of all rights, title and interest in the '820 patent.

ANSWER: Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 32 of the Complaint, and therefore denies the same.

33. Avion is the exclusive licensee of the '820 patent.

ANSWER: Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 33 of the Complaint, and therefore denies the same.

34. The '820 patent is listed in the Orange Book with respect to GLOPERBA®.

ANSWER: Granules admits that the '820 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" for COLCHICINE (GLOPERBA) SOLUTION 0.6MG/5ML.

35. A true and correct copy of the '820 patent is attached as Exhibit C.

ANSWER: Granules admits that Exhibit C to the Complaint purports to be a copy of the '820 patent. Granules denies the remaining allegations of Paragraph 35 of the Complaint.

36. The '821 patent, entitled "Colchicine Drug-to-Drug Interactions," was duly and legally issued on August 20, 2019.

ANSWER: Paragraph 36 states a legal conclusion to which no response is required. To the extent a response is required, Granules admits that the '821 patent is titled "Colchicine Drug-to-Drug Interactions," and lists an issue date of August 20, 2019. Granules denies the remaining allegations of Paragraph 36 of the Complaint.

37. Indu Muni and Naomi Vishnupad are the named inventors of the '821 patent.

ANSWER: Granules admits that the '821 patent identifies Indu Muni and Naomi Vishnupad as inventors of the '821 patent.

38. RxOmeg is the sole owner by assignment of all rights, title and interest in the '821 patent.

ANSWER: Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 38 of the Complaint, and therefore denies the same.

39. Avion is the exclusive licensee of the '821 patent.

ANSWER: Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 39 of the Complaint, and therefore denies the same.

40. The '821 patent is listed in the Orange Book with respect to GLOPERBA®.

ANSWER: Granules admits that the '821 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" for COLCHICINE (GLOPERBA) SOLUTION 0.6MG/5ML.

41. A true and correct copy of the '821 patent is attached as Exhibit D.

ANSWER: Granules admits that Exhibit D to the Complaint purports to be a copy of the '821 patent. Granules denies the remaining allegations of Paragraph 41 of the Complaint.

RESPONSE TO "PLAINTIFFS' GLOPERBA® PRODUCT"

42. Plaintiffs researched, developed, applied for, and obtained FDA approval to manufacture, sell, promote, and/or market a colchicine product that is brand named GLOPERBA®.

ANSWER: Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 42 of the Complaint, and therefore denies the same.

43. Plaintiff Avion is the holder of New Drug Application ("NDA") number 210942, approved by FDA for the use of colchicine, marketed as GLOPERBA®, for the prophylaxis of gout flares.

ANSWER: Granules admits that Gloperba is approved by FDA for the prophylaxis of gout flares. Granules lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 43 of the Complaint, and therefore denies the same.

44. The claims of the patents-in-suit cover, *inter alia*, colchicine solutions and methods of treating disorders by administering colchicine solutions.

ANSWER: Paragraph 44 states a legal conclusion to which no response is required. To the extent that a response is required, Granules denies the allegations of Paragraph 44 of the Complaint.

45. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the Orange Book with respect to GLOPERBA®.

ANSWER: Paragraph 45 states a legal conclusion to which no response is required. To the extent that a response is required, Granules admits that the ’751,’423, ’820, and ’821 patents are listed in the Orange Book for COLCHICINE (GLOPERBA) SOLUTION 0.6MG/5ML. Granules lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 45 of the Complaint, and therefore denies the same.

46. Plaintiffs’ GLOPERBA® product or its use is covered by at least one claim of each of the patents-in-suit.

ANSWER: Paragraph 46 states a legal conclusion to which no response is required. To the extent that a response is required, Granules lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 46 of the Complaint, and therefore denies the same.

RESPONSE TO “DEFENDANT’S ANDA”

47. Upon information and belief, Defendant filed an ANDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, offer for sale, sell in, and import into the United States Defendant’s Colchicine Product, prior to the expiration of the ’751,’423, ’820, and ’821 patents.

ANSWER: Paragraph 47 states a legal conclusion to which no response is required. To the extent a response is required, Granules admits that it filed ANDA No. 214808 under 21 U.S.C. § 355(j) for FDA approval of its proposed Colchicine Oral Solution, 0.6 mg/5mL within the United States prior to the expiration of the '751,'423, '820, and '821 patents. Granules denies any remaining allegations of Paragraph 47 of the Complaint.

48. Upon information and belief, FDA assigned the ANDA for Defendant's Colchicine Product number 214808.

ANSWER: Granules admits the allegations of Paragraph 48 of the Complaint.

49. Upon information and belief, FDA has not yet approved ANDA No. 214808.

ANSWER: Granules admits the allegations of Paragraph 49 of the Complaint as of the filing of this Answer.

50. Upon information and belief, Defendant intends to engage in the commercial manufacture, use, and sale of Defendant's Colchicine Product promptly upon receiving FDA approval to do so.

ANSWER: Granules is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 50 because they related to speculative future events. Granules thus denies the allegations of Paragraph 50.

51. By submitting ANDA No. 214808, Defendant has represented to FDA that Defendant's Colchicine Product has the same active ingredient as Plaintiffs' GLOPERBA® product; has the same route of administration, dosage form, use, and strength as Plaintiffs' GLOPERBA® product; and is bioequivalent to Plaintiffs' GLOPERBA® product.

ANSWER: Paragraph 51 states a legal conclusion to which no response is required. To the extent a response is required, Granules avers that ANDA No. 214808 satisfies the requirements of at least 21 U.S.C. § 355(j) as it pertains to active ingredient, route of administration, dosage form, use, strength, and bioequivalence.

52. Upon information and belief, in connection with ANDA No. 214808, Defendant filed with FDA certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the

claims of the '751,'423, '820, and '821 patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale, or offer for sale of Defendant's Colchicine Product ("Defendant's Paragraph IV Certifications").

ANSWER: Granules admits the allegations of Paragraph 52 of the Complaint.

53. By letter dated May 20, 2020, Defendant notified Plaintiffs that it had filed ANDA No. 214808 seeking approval to market Defendant's Colchicine Product prior to the expiration of the '751 and '423 patents ("Defendant's First Notice Letter").

ANSWER: Granules admits the allegations of Paragraph 53 of the Complaint.

54. Plaintiffs received Defendant's First Notice Letter no earlier than May 20, 2020.

ANSWER: On information and belief, Granules admits the allegations of Paragraph 54 of the Complaint.

55. By letter dated July 13, 2020, Defendant notified Plaintiffs that it had filed ANDA No. 214808 seeking approval to market Defendant's Colchicine Product prior to the expiration of the '820 and '821 patents ("Defendant's Second Notice Letter").

ANSWER: Granules admits the allegations of Paragraph 55 of the Complaint.

56. Plaintiffs received Defendant's Second Notice Letter no earlier than July 14, 2020.

ANSWER: On information and belief, Granules admits the allegations of Paragraph 56 of the Complaint.

57. This Action was commenced before the expiration of forty-five days from the date of receipt of Defendant's First Notice Letter.

ANSWER: Granules admits the allegations of Paragraph 57 of the Complaint.

58. This Amended Complaint is being filed before the expiration of forty-five days from the date of receipt of Defendant's Second Notice Letter.

ANSWER: Granules admits the allegations of Paragraph 58 of the Complaint.

59. Upon information and belief, Defendant prepared and submitted ANDA No. 214808.

ANSWER: Granules admits the allegations of Paragraph 59 of the Complaint.

RESPONSE TO "COUNT I: INFRINGEMENT OF THE '751 PATENT"

60. The allegations of the preceding paragraphs 1-59 are realleged and incorporated herein by reference.

ANSWER: No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 59 of the Complaint. To the extent a response is required, Granules incorporates by reference its Responses to Paragraphs 1 through 59 as if fully set forth herein.

61. Upon information and belief, Defendant's Colchicine Product is covered by one or more claims of the '751 patent.

ANSWER: Paragraph 61 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 61.

62. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's Colchicine Product would infringe one or more claims of the '751 patent.

ANSWER: Paragraph 62 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 62.

63. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to FDA of Defendant's ANDA to obtain approval for Defendant's Colchicine Product with a Paragraph IV Certification related thereto before the expiration of the '751 patent constitutes an act of infringement, and, upon information and belief, if approved, the commercial manufacture, use, offer to sell, sale, or importation of Defendant's Colchicine Product would infringe one or more claims of the '751 patent.

ANSWER: Paragraph 63 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 63.

64. Upon information and belief, Defendant was aware of the '751 patent when engaging in these knowing and purposeful activities and was aware that filing Defendant's ANDA with Defendant's Paragraph IV Certification with respect to the '751 patent constituted an act of infringement of the '751 patent.

ANSWER: Paragraph 64 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 64. Granules

further avers that it is insolubly ambiguous as to what Plaintiffs are referring to by the phrase "these knowing and purposeful activities."

65. Upon information and belief, Defendant plans to, intends to, and will infringe the '751 patent immediately and imminently upon approval of Defendant's ANDA.

ANSWER: Paragraph 65 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 65.

66. Upon information and belief, immediately and imminently upon approval of Defendant's ANDA, there will be direct infringement of the claims of the '751 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Paragraph 66 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 66.

67. Upon information and belief, Defendant's offer for sale, sale, and/or importation of Defendant's Colchicine Product will actively induce infringement of the claims of the '751 patent under 35 U.S.C. § 271(b). Upon information and belief, Defendant had knowledge of the '751 patent and know or should know that it will induce direct infringement of the claims of the '751 patent, and Defendant specifically intends that others' actions will directly infringe the claims of the '751 patent, due to at least Defendant's labeling and promotional activities for Defendant's Colchicine Product.

ANSWER: Paragraph 67 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 67.

68. Upon information and belief, Defendant's offer for sale, sale, and/or importation of Defendant's Colchicine Product will also contributorily infringe the claims of the '751 patent under 35 U.S.C. § 271(c) because the use of Defendant's Colchicine Product constitutes a material part of the claims of the '751 patent, Defendant knows that Defendant's Colchicine Product is especially made or adapted for use in infringing the claims of the '751 patent, and Defendant's Colchicine Product is not a staple article of commerce or commodity of commerce suitable for a substantial non-infringing use.

ANSWER: Paragraph 68 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 68.

69. Plaintiffs will be substantially and irreparably harmed by Defendant's infringing activities unless the Court enjoins those activities. Plaintiffs will have no adequate remedy at law

if Defendant is not enjoined from the commercial manufacture, use, offer to sell, sale, and importation into the United States of Defendant's Colchicine Product.

ANSWER: Paragraph 69 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 69.

70. Defendant's activities render this case an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

ANSWER: Paragraph 70 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 70.

RESPONSE TO "COUNT II: INFRINGEMENT OF THE '423 PATENT"

71. The allegations of the preceding paragraphs 1-70 are realleged and incorporated herein by reference.

ANSWER: No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 70 of the Complaint. To the extent a response is required, Granules incorporates by reference its Responses to Paragraphs 1 through 70 as if fully set forth herein.

72. Upon information and belief, the use of Defendant's Colchicine Product is covered by one or more claims of the '423 patent.

ANSWER: Paragraph 72 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 72.

73. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's Colchicine Product would infringe one or more claims of the '423 patent.

ANSWER: Paragraph 73 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 73.

74. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to FDA of Defendant's ANDA to obtain approval for Defendant's Colchicine Product with a Paragraph IV Certification related thereto before the expiration of the '423 patent constitutes an act of infringement, and, upon information and belief, if approved, the commercial manufacture, use, offer to sell, sale, or

importation of Defendant's Colchicine Product would infringe one or more claims of the '423 patent.

ANSWER: Paragraph 74 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 74.

75. Upon information and belief, Defendant was aware of the '423 patent when engaging in these knowing and purposeful activities and were aware that filing Defendant's ANDA with Defendant's Paragraph IV Certification with respect to the '423 patent constituted an act of infringement of the '423 patent.

ANSWER: Paragraph 75 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 75. Granules further avers that it is insolubly ambiguous as to what Plaintiffs are referring to by the phrase "these knowing and purposeful activities."

76. Upon information and belief, Defendant plans to, intends to, and will, infringe the '423 patent immediately and imminently upon approval of Defendant's ANDA.

ANSWER: Paragraph 76 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 76.

77. Upon information and belief, immediately and imminently upon approval of Defendant's ANDA, there will be direct infringement of the claims of the '423 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Paragraph 77 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 77.

78. Upon information and belief, Defendant's offer for sale, sale, and/or importation of Defendant's Colchicine Product will actively induce infringement of the claims of the '423 patent under 35 U.S.C. § 271(b). Upon information and belief, Defendant had knowledge of the '423 patent and know or should know that it will induce direct infringement of the claims of the '423 patent, and Defendant specifically intends that others' actions will directly infringe the claims of the '423 patent, due to at least Defendant's labeling and promotional activities for Defendant's Colchicine Product.

ANSWER: Paragraph 78 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 78.

79. Upon information and belief, Defendant's offer for sale, sale, and/or importation of Defendant's Colchicine Product will also contributorily infringe the claims of the '423 patent under 35 U.S.C. § 271(c) because the use of Defendant's Colchicine Product constitutes a material part of the claims of the '423 patent, Defendant knows that Defendant's Colchicine Product is especially made or adapted for use in infringing the claims of the '423 patent, and Defendant's Colchicine Product is not a staple article of commerce or commodity of commerce suitable for a substantial non-infringing use.

ANSWER: Paragraph 79 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 79.

80. Plaintiffs will be substantially and irreparably harmed by Defendant's infringing activities unless the Court enjoins those activities. Plaintiffs will have no adequate remedy at law if Defendant is not enjoined from the commercial manufacture, use, offer to sell, sale, and importation into the United States of Defendant's Colchicine Product.

ANSWER: Paragraph 80 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 80.

81. Defendant's activities render this case an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

ANSWER: Paragraph 81 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 81.

RESPONSE TO "COUNT III: INFRINGEMENT OF THE '820 PATENT"

82. The allegations of the preceding paragraphs 1-81 are realleged and incorporated herein by reference.

ANSWER: No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 81 of the Complaint. To the extent a response is required, Granules incorporate by reference its Responses to Paragraphs 1 through 81 as if fully set forth herein.

83. Upon information and belief, the use of Defendant's Colchicine Product is covered by one or more claims of the '820 patent.

ANSWER: Paragraph 83 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 83.

84. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's Colchicine Product would infringe one or more claims of the '820 patent.

ANSWER: Paragraph 84 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 84.

85. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to FDA of Defendant's ANDA to obtain approval for Defendant's Colchicine Product with a Paragraph IV Certification related thereto before the expiration of the '820 patent constitutes an act of infringement, and, upon information and belief, if approved, the commercial manufacture, use, offer to sell, sale, or importation of Defendant's Colchicine Product would infringe one or more claims of the '820 patent.

ANSWER: Paragraph 85 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 85.

86. Upon information and belief, Defendant was aware of the '820 patent when engaging in these knowing and purposeful activities and was aware that filing Defendant's ANDA with Defendant's Paragraph IV Certification with respect to the '820 patent constituted an act of infringement of the '820 patent.

ANSWER: Paragraph 86 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 86. Granules further avers that it is insolubly ambiguous as to what Plaintiffs are referring to by the phrase "these knowing and purposeful activities."

87. Upon information and belief, Defendant plans to, intends to, and will, infringe the '820 patent immediately and imminently upon approval of Defendant's ANDA.

ANSWER: Paragraph 87 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 87.

88. Upon information and belief, immediately and imminently upon approval of Defendant's ANDA, there will be direct infringement of the claims of the '820 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Paragraph 88 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 88.

89. Upon information and belief, Defendant's offer for sale, sale, and/or importation of Defendant's Colchicine Product will actively induce infringement of the claims of the '820 patent under 35 U.S.C. § 271(b). Upon information and belief, Defendant had knowledge of the '820 patent and knows or should know that it will induce direct infringement of the claims of the '820 patent, and Defendant specifically intends that others' actions will directly infringe the claims of the '820 patent, due to at least Defendant's labeling and promotional activities for Defendant's Colchicine Product.

ANSWER: Paragraph 89 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 89.

90. Upon information and belief, Defendant's offer for sale, sale, and/or importation of Defendant's Colchicine Product will also contributorily infringe the claims of the '820 patent under 35 U.S.C. § 271(c) because the use of Defendant's Colchicine Product constitutes a material part of the claims of the '820 patent, Defendant knows that Defendant's Colchicine Product is especially made or adapted for use in infringing the claims of the '820 patent, and Defendant's Colchicine Product is not a staple article of commerce or commodity of commerce suitable for a substantial non-infringing use.

ANSWER: Paragraph 90 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 90.

91. Plaintiffs will be substantially and irreparably harmed by Defendant's infringing activities unless the Court enjoins those activities. Plaintiffs will have no adequate remedy at law if Defendant is not enjoined from the commercial manufacture, use, offer to sell, sale, and importation into the United States of Defendant's Colchicine Product.

ANSWER: Paragraph 91 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 91.

92. Defendant's activities render this case an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

ANSWER: Paragraph 92 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 92.

RESPONSE TO "COUNT IV: INFRINGEMENT OF THE '821 PATENT"

93. The allegations of the preceding paragraphs 1-92 are realleged and incorporated herein by reference.

ANSWER: No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 92 of the Complaint. To the extent a response is required, Granules incorporate by reference its Responses to Paragraphs 1 through 92 as if fully set forth herein.

94. Upon information and belief, the use of Defendant's Colchicine Product is covered by one or more claims of the '821 patent.

ANSWER: Paragraph 94 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 94.

95. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's Colchicine Product would infringe one or more claims of the '821 patent.

ANSWER: Paragraph 95 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 95.

96. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission to FDA of Defendant's ANDA to obtain approval for Defendant's Colchicine Product with a Paragraph IV Certification related thereto before the expiration of the '821 patent constitutes an act of infringement, and, upon information and belief, if approved, the commercial manufacture, use, offer to sell, sale, or importation of Defendant's Colchicine Product would infringe one or more claims of the '821 patent.

ANSWER: Paragraph 96 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 96.

97. Upon information and belief, Defendant was aware of the '821 patent when engaging in these knowing and purposeful activities and was aware that filing Defendant's ANDA with Defendant's Paragraph IV Certification with respect to the '821 patent constituted an act of infringement of the '821 patent.

ANSWER: Paragraph 97 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 97. Granules further avers that it is insolubly ambiguous as to what Plaintiffs are referring to by the phrase "these knowing and purposeful activities."

98. Upon information and belief, Defendant plans to, intends to, and will, infringe the '821 patent immediately and imminently upon approval of Defendant's ANDA.

ANSWER: Paragraph 98 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 98.

99. Upon information and belief, immediately and imminently upon approval of Defendant's ANDA, there will be direct infringement of the claims of the '821 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Paragraph 99 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 99.

100. Upon information and belief, Defendant's offer for sale, sale, and/or importation of Defendant's Colchicine Product will actively induce infringement of the claims of the '821 patent under 35 U.S.C. § 271(b). Upon information and belief, Defendant had knowledge of the '821 patent and knows or should know that it will induce direct infringement of the claims of the '821 patent, and Defendant specifically intends that others' actions will directly infringe the claims of the '821 patent, due to at least Defendant's labeling and promotional activities for Defendant's Colchicine Product.

ANSWER: Paragraph 100 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 100.

101. Upon information and belief, Defendant's offer for sale, sale, and/or importation of Defendant's Colchicine Product will also contributorily infringe the claims of the '821 patent under 35 U.S.C. § 271(c) because the use of Defendant's Colchicine Product constitutes a material part of the claims of the '821 patent, Defendant knows that Defendant's Colchicine Product is especially made or adapted for use in infringing the claims of the '821 patent, and Defendant's Colchicine Product is not a staple article of commerce or commodity of commerce suitable for a substantial non-infringing use.

ANSWER: Paragraph 101 states a legal conclusion to which no response is required.

To the extent a response is required, Granules denies the allegations of Paragraph 101.

102. Plaintiffs will be substantially and irreparably harmed by Defendant's infringing activities unless the Court enjoins those activities. Plaintiffs will have no adequate remedy at law if Defendant is not enjoined from the commercial manufacture, use, offer to sell, sale, and importation into the United States of Defendant's Colchicine Product.

ANSWER: Paragraph 102 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 102.

103. Defendant's activities render this case an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

ANSWER: Paragraph 103 states a legal conclusion to which no response is required. To the extent a response is required, Granules denies the allegations of Paragraph 103.

RESPONSE TO "PRAYER FOR RELIEF"

With respect to Plaintiffs' request for relief, Defendant denies that Plaintiffs are entitled to any relief for the allegations and claims made in the Complaint, including the relief requested in subsections (a) through (i).

SEPARATE DEFENSES

Without prejudice to the denials set forth in this Answer, Granules further responds to the Complaint with the defenses set forth below. Granules expressly reserves the right to supplement this Answer, including the right to assert additional defenses as more information is learned through discovery and further factual investigation in this case. Granules does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

FIRST AFFIRMATIVE DEFENSE
(Non-Infringement of the '751 Patent)

Granules has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '751 patent.

SECOND AFFIRMATIVE DEFENSE
(Non-Infringement of the '423 Patent)

Granules has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '423 patent.

THIRD AFFIRMATIVE DEFENSE
(Non-Infringement of the '820 Patent)

Granules has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '820 patent.

FOURTH AFFIRMATIVE DEFENSE
(Non-Infringement of the '821 Patent)

Granules has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '821 patent.

FIFTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiffs fail to state a claim upon which relief may be granted.

SIXTH AFFIRMATIVE DEFENSE
(Equitable Defenses)

Any claim of relief by Plaintiffs is barred, in whole or in part, by the equitable doctrines of unclean hands, estoppel, or patent misuse.

SEVENTH AFFIRMATIVE DEFENSE
(Not An Exceptional Case)

Granules's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

COUNTERCLAIMS

Granules Pharmaceuticals, Inc. ("Granules"), by and through its undersigned counsel, asserts the following Counterclaims against Avion Pharmaceuticals, LLC ("Avion") and RxOmeg Therapeutics, LLC, a/k/a Romeg Therapeutics, LLC ("RxOmeg") (collectively, "Avion and RxOmeg" or "Plaintiffs"): United States Patent Nos. 9,907,751 ("'751 patent"), 10,226,423 ("'423 patent"), 10,383,820 ("'820 patent"), and 10,383,821 ("'821 patent") are not infringed by the products described in Abbreviated New Drug Application ("ANDA") No. 214808.

PARTIES

1. Granules Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware having a place of business at 3701 Concorde Parkway, Chantilly, VA 20151.

2. On information and belief and based on allegations in Plaintiffs' Complaint, Avion Pharmaceuticals, LLC is a limited liability corporation with its principal place of business at 1880 McFarland Parkway, Suite 105, Alpharetta, Georgia 30005.

3. On information and belief and based on allegations in Plaintiffs' Complaint, RxOmeg Therapeutics, LLC, a/k/a Romeg Therapeutics, LLC is a limited liability corporation with its principal place of business at 400 Tradecenter 128, Suite 5900, Woburn, Massachusetts 01801.

NATURE OF THE ACTION

4. These Counterclaims seek a declaratory judgment that Granules's submission of ANDA No. 214808 does not infringe any valid and enforceable claim of the '751 patent, the '423 patent, the '820 patent, and the '821 patent.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy among the parties as demonstrated by, *inter alia*, Plaintiffs' filing of the Complaint, arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, as well as 21 U.S.C. § 355(c)(3)(D).

6. Plaintiffs have submitted to personal jurisdiction in this Court by, *inter alia*, suing Granules in this judicial district. On information and belief, and based on Plaintiffs' allegations,

Plaintiffs, either directly or indirectly through agents, conduct substantial business, have regular and systematic contacts, and derive substantial revenues within this District, including from selling products in this District such as Gloperba. On information and belief, both Avion and RxOmeg are corporations organized and existing under the laws of the State of Delaware.

7. Venue is proper in this District under 28 U.S.C. §§ 1400(b), 1391(b) (c) and (d) and because Plaintiffs have consented to venue in this Court by filing the instant action in this jurisdiction.

BACKGROUND

8. The ’751 patent, on its face, is entitled “Composition and Method of Use of Colchicine Oral Liquid,” and states its date of issue as March 6, 2018.

9. The ’423 patent, on its face, is entitled “Colchicine Drug-to-Drug Interactions,” and states its date of issue as March 12, 2019.

10. The ’820 patent, on its face, is entitled “Colchicine Drug-to-Drug Interactions,” and states its date of issue as August 20, 2019.

11. The ’821 patent, on its face, is entitled “Colchicine Drug-to-Drug Interactions,” and states its date of issue as August 20, 2019.

12. On information and belief, and based on Plaintiffs’ allegations, Avion is the holder of New Drug Application (“NDA”) No. 210942.

13. On information and belief, and based on Plaintiffs’ allegations, RxOmeg is the owner of the ’751,’423, ’820, and ’821 patents.

14. On information and belief, and based on Plaintiffs’ allegations, Avion is the exclusive licensee of the ’751,’423, ’820, and ’821 patents.

15. The ’751,’423, ’820, and ’821 patents are listed in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the “Orange Book”) for Gloperba.

16. Granules submitted ANDA No. 214808 to the Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, or sales of its proposed Colchicine Oral Solution 0.6 mg/5 mL (the “Granules ANDA Product” or “Granules’s ANDA Product”).

17. Granules sent both Avion and RxOmeg each a confidential letter dated May 20, 2020 (the “First Notice Letter” or “First Notice Letters”), notifying Plaintiffs that the FDA had received Granules’s ANDA No. 214808 containing a Paragraph IV certification that the claims of ’751 and ’423 patents are invalid and/or will not be infringed by the Granules ANDA Products that are the subject of ANDA No. 214808.

18. The First Notice Letter to Avion contained an offer of confidential access (“OCA”) to review Granules ANDA No. 214808, and the First Notice Letter to RxOmeg contained an OCA to review Granules’s ANDA No. 214808.

19. Neither Avion nor RxOmeg executed the OCA to review ANDA No. 214808.

20. Avion engaged in negotiations with Granules regarding modification of various provisions in the OCA. As of the filing of the original complaint on July 1, 2020, those negotiations were still ongoing.

21. RxOmeg did not attempt to negotiate any revisions to the OCA with Granules.

22. As such, Avion and RxOmeg remained willfully blind as to the contents of ANDA No. 214808 and filed a baseless complaint against Granules.

23. Plaintiffs filed this action against Granules on July 1, 2020, identifying and alleging infringement of the ’751 and ’423 patents.

24. After Plaintiff late-listed the ’820 and ’821 patents in the Orange Book, Granules sent both Avion and RxOmeg each a confidential letter dated July 13, 2020 (the “Second Notice Letter” or “Second Notice Letters”), notifying Plaintiffs that the FDA had received Granules’s ANDA No. 214808 containing a Paragraph IV certification that the claims of ’820 and ’821 patents are invalid and/or will not be infringed by the Granules ANDA Products that are the subject of ANDA No. 214808.

25. Plaintiffs filed an amended complaint in this action against Granules on August 10, 2020, identifying and alleging infringement of the ’820 and ’821 patents.

26. As a consequence of the foregoing, there is an actual and justiciable controversy between Granules, on the one hand, and Plaintiffs, on the other, as to whether the Orange Book Patents are invalid and/or will not be infringed.

FIRST COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the ’751 Patent)

27. Granules re-alleges and incorporates the allegations of Counterclaim Paragraphs 1-26 as if fully set forth herein.

28. The manufacture, use, sale, offer for sale, and/or importation into the United States of Granules’s ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the ’751 patent.

29. The manufacture, use, sale, offer for sale, and/or importation into the United States of Granules’s ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the ’751 patent under the doctrine of equivalents.

30. Plaintiffs are barred, by the doctrine of prosecution history estoppel, from asserting that Granules's ANDA Product infringes any claim of the '751 patent under the doctrine of equivalents.

31. A definite and concrete, real and substantial, justiciable controversy exists between Granules and Plaintiffs concerning the alleged infringement by Granules's ANDA Product of the '751 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

32. Granules is entitled to a judicial declaration that its ANDA Product will not infringe any valid or enforceable claim of the '751 patent.

SECOND COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '423 Patent)

33. Granules re-alleges and incorporates the allegations of Counterclaim Paragraphs 1-32 as if fully set forth herein.

34. The manufacture, use, sale, offer for sale, and/or importation into the United States of Granules's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '423 patent.

35. The manufacture, use, sale, offer for sale, and/or importation into the United States of Granules's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '423 patent under the doctrine of equivalents.

36. Plaintiffs are barred, by the doctrine of prosecution history estoppel, from asserting that Granules's ANDA Product infringes any claim of the '423 patent under the doctrine of equivalents.

37. A definite and concrete, real and substantial, justiciable controversy exists between Granules and Plaintiffs concerning the alleged infringement by Granules's ANDA Product of the '423 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

38. Granules is entitled to a judicial declaration that its ANDA Product will not infringe any valid or enforceable claim of the '423 patent.

THIRD COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '820 Patent)

39. Granules re-alleges and incorporates the allegations of Counterclaim Paragraphs 1-38 as if fully set forth herein.

40. The manufacture, use, sale, offer for sale, and/or importation into the United States of Granules's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '820 patent.

41. The manufacture, use, sale, offer for sale, and/or importation into the United States of Granules's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '820 patent under the doctrine of equivalents.

42. Plaintiffs are barred, by the doctrine of prosecution history estoppel, from asserting that Granules's ANDA Product infringes any claim of the '820 patent under the doctrine of equivalents.

43. A definite and concrete, real and substantial, justiciable controversy exists between Granules and Plaintiffs concerning the alleged infringement by Granules's ANDA Product of the '820 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

44. Granules is entitled to a judicial declaration that its ANDA Product will not infringe any valid or enforceable claim of the ’820 patent.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the ’821 Patent)

45. Granules re-alleges and incorporates the allegations of Counterclaim Paragraphs 1-44 as if fully set forth herein.

46. The manufacture, use, sale, offer for sale, and/or importation into the United States of Granules’s ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the ’821 patent.

47. The manufacture, use, sale, offer for sale, and/or importation into the United States of Granules’s ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the ’821 patent under the doctrine of equivalents.

48. Plaintiffs are barred, by the doctrine of prosecution history estoppel, from asserting that Granules’s ANDA Product infringes any claim of the ’821 patent under the doctrine of equivalents.

49. A definite and concrete, real and substantial, justiciable controversy exists between Granules and Plaintiffs concerning the alleged infringement by Granules’s ANDA Product of the ’821 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

50. Granules is entitled to a judicial declaration that its ANDA Product will not infringe any valid or enforceable claim of the ’821 patent.

FIFTH COUNTERCLAIM
(Exceptional Case)

51. Granules re-alleges and incorporates the allegations of Counterclaim Paragraphs 1-50 as if fully set forth herein.

52. This case is exceptional under 35 U.S.C. § 285 and Granules is entitled to receive its reasonable costs and attorneys' fees incurred in connection with this action.

PRAYER FOR RELIEF

WHEREFORE, Granules respectfully requests the following relief:

A. A judgment dismissing the Complaint with prejudice;

B. A judgment denying Plaintiffs of the relief requested in the Complaint;

C. A judgment declaring that the manufacture, use, sale, offer for sale, or importation of Granules's proposed ANDA Products described in ANDA No. 214808 would not infringe any valid and enforceable claim of the '751, '423, '820, and '821 patents;

D. A judgment that this is an exceptional case under 35 U.S.C. § 285 and awarding Counterclaim Plaintiff its attorneys' fees, costs, and expenses in defending this action; and

E. Such other further and additional relief as the Court may deem just and proper.

DATED: September 15, 2020

YOUNG CONAWAY STARGATT & TAYLOR,LLP

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on September 15, 2020, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF (which will send notification that such filing is available for viewing and downloading to all registered counsel), and in addition caused true and correct copies of the foregoing document to be served upon the following counsel in the manner indicated:

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/s/ Karen L. Pascale

September 15, 2020

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