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. _____

COMPLAINT

Plaintiffs Avion Pharmaceuticals, LLC ("Avion") and R_xOmeg Therapeutics, LLC, a/k/a Romeg Therapeutics, LLC ("R_xOmeg") (collectively "Plaintiffs") bring this action for patent infringement against Granules Pharmaceuticals, Inc. ("Defendant" or "Granules Pharmaceuticals").

NATURE OF THE ACTION

1. This is an action by Plaintiffs for infringement of United States Patent Nos. 9,907,751 ("'751 patent") and 10,226,423 ("'423 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 and '423 patents.

THE PARTIES

Plaintiffs

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

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

Defendant

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.

JURISDICTION

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

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

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.

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.

9. Upon information and belief, Granules Pharmaceuticals markets, distributes, and/or sells generic drugs throughout 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.

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.

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.

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.

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.

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.

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).

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.

BACKGROUND

The '751 Patent

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

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

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

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

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®.

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

The '423 Patent

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

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

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

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

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

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

Plaintiffs' GLOPERBA® Product

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

31. 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.

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

33. 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®.

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

Defendant's ANDA

35. 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 and '423 patents.

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

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

38. 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.

39. 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.

40. Upon information and belief, in connection with ANDA No. 214808, Defendant filed with FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the claims of the '751 and '423 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 Certification").

41. 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 Notice Letter").

42. Plaintiffs received the Defendant's Notice Letter no earlier than May 20, 2020.

43. This Action is being commenced before the expiration of forty-five days from the date of receipt of Defendant's Notice Letter.

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

COUNT I: INFRINGEMENT OF THE '751 PATENT

45. The allegations of the preceding paragraphs 1-44 are realleged and incorporated herein by reference.

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

47. 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.

48. 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.

49. 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.

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

51. 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.

52. 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.

53. 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.

54. 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.

55. 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.

COUNT II: INFRINGEMENT OF THE ’423 PATENT

56. The allegations of the preceding paragraphs 1-55 are realleged and incorporated herein by reference.

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

58. 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.

59. 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.

60. 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.

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

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) a finding that the '751 and '423 patents are valid and enforceable;

(b) a judgment that Defendant's submission of ANDA No. 214808 was an act of infringement of one or more claims of the '751 and '423 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendant's Colchicine Product prior to the expiration of the '751 and '423 patents will infringe, actively induce infringement of, and/or contribute to the infringement of one or more claims of the '751 and '423 patents;

(c) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Defendant's ANDA No. 214808 or any product the use of which

infringes the ’751 and ’423 patents, shall be a date that is not earlier than the expiration of the ’751 and ’423 patents;

(d) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendant and all persons acting in concert with Defendant from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendant’s Colchicine Product, or any product the use of which infringes the ’751 and ’423 patents, or induces or contributes to the infringement of the ’751 and ’423 patents, until after the expiration of the ’751 and ’423 patents;

(e) an Order enjoining Defendant and all persons acting in concert with Defendant from seeking, obtaining, or maintaining approval of the Defendant’s ANDA No. 214808 before the expiration of the ’751 and ’423 patents;

(f) an award of Plaintiffs’ damages or other monetary relief to compensate Plaintiffs if Defendant engages in the commercial manufacture, use, offer to sell, sale, or marketing or distribution in, or importation into the United States of Defendant’s Colchicine Product, or any product or compound the use of which infringes the ’751 and ’423 patents, or induces or contributes to the foregoing, prior to the expiration of the ’751 and ’423 patents in accordance with 35 U.S.C. § 271(e)(4)(C);

(g) a judgment that this is an exceptional case and awarding Plaintiffs their attorneys’ fees under 35 U.S.C. § 285;

(h) an award of Plaintiffs’ reasonable costs and expenses in this action; and

(i) an award of any further and additional relief to Plaintiffs as this Court deems just and proper.

DATED: July 1, 2020

By: */s/ Stamatios Stamoulis*

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