UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

WEST-WARD PHARMACEUTICALS CORP. and HIKMA PHARMACEUTICALS LLC,	:	
Plaintiffs,	:	Civil Action No.:
v.	:	
GRANULES PHARMACEUTICALS, INC., USA.	:	
Defendant.	:	

COMPLAINT

Plaintiffs West-Ward Pharmaceuticals Corp. ("West-Ward") and Hikma Pharmaceuticals LLC ("Hikma") (together, "Plaintiffs"), for their Complaint against Defendant Granules Pharmaceuticals, Inc., USA ("Granules") hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. This action arises from Granules' filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Hikma's Mitigare® (colchicine) 0.6 mg capsule, before the expiration of U.S. Patent Nos. 8,927,607 (the "'607 patent," attached as Exhibit A), 9,399,036 (the "'036 patent," attached as Exhibit B), 9,555,029 (the "'029 patent," attached as Exhibit C),

9,675,613 (the "'613 patent," attached as Exhibit D), and 9,789,108 (the "'108 patent," attached as Exhibit E) throughout the United States, including in Delaware.

PARTIES

3. West-Ward Pharmaceuticals Corp. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724-2206.

4. Hikma Pharmaceuticals LLC is a company organized and existing under the laws of Jordan, having a principal place of business in Bayader Wadi Seer, P.O. Box 182400, Amman 11118, Jordan. West-Ward is the authorized U.S. agent for Hikma.

5. Upon information and belief, Granules is incorporated under the laws of Delaware, and has a principal place of business at 3701 Concorde Parkway Chantilly, VA 20151-1126, United States. Upon information and belief, Granules is registered with the State of Delaware's Division of Corporations as a business operating in Delaware, and has appointed VCORP SERVICES, LLC, 1013 Centre Road Suite 403-B, Wilmington, DE 19805, as its registered agent to accept service of process.

JURISDICTION AND VENUE

6. Hikma seeks to enforce its federal patent rights under Title 35, United States Code. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

7. This Court has personal jurisdiction over Granules because, among other reasons, Granules is incorporated in Delaware, it has substantial and continuous contacts with the state of Delaware, and because it has committed the acts of patent infringement alleged herein in Delaware.

8. Upon information and belief, Granules is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

9. This Court has personal jurisdiction over Granules by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury in Delaware to Hikma and to West-Ward. For example, upon information and belief, Granules is actively preparing to make the proposed generic copies of Mitigare® (colchicine) that are the subject of Granules' ANDA, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

THE FDA MARKETING APPROVAL PROCESS

11. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the FDA follows when considering the approval of applications for both brand-name and generic drugs.

12. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355. Alternatively, an applicant can use the 505(b)(2) "paper NDA" process for new drugs that are similar but not identical to existing ones. This process permits the applicant to rely on existing studies for a previously approved drug of the applicant's choosing while supplementing the application with new studies and data to support a safety and effectiveness determination. *Id.* § 355(b)(2).

13. An NDA or a paper NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

14. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book"). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

15. A pharmaceutical company may seek to market a generic version of the innovator's brand drug by submitting an ANDA under 21 U.S.C. § 355(j). The generic company may then rely on the studies the innovator includes in its NDA.

THE PATENTS-IN-SUIT

16. The United States Patent & Trademark Office ("USPTO") duly and legally issued the '607, '036, '029, '613, and '108 patents, all titled "Methods of colchicine administration," on January 6, 2015; July 26, 2016; January 31, 2017; June 13, 2017; and October 17, 2017, respectively. The patents list Murray Ducharme as an inventor.

17. Hikma Pharmaceuticals LLC lawfully owns all right, title, and interest in the '607, '036, '029, '613, and '108 patents, including the right to sue and to recover for past infringement.

THE MITIGARE® PRODUCT

18. Plaintiffs sell Mitigare® (colchicine) in the United States pursuant to a New Drug Application ("NDA") No. 204820 that has been approved by the FDA. Mitigare® is a colchicine 0.6 mg capsule indicated for the prophylaxis of gout.

19. In accordance with 21 U.S.C. § 355(b)(1), the '607, '036, '029, '613, and '108 patents are listed in the Orange Book in connection with NDA No. 204820 as patents "with respect

to which a claim for patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Mitigare®.

GRANULES' ANDA SUBMISSION

20. By letter dated November 28, 2017 ("Granules Notice Letter"), Granules notified Plaintiffs that it had submitted to the FDA its ANDA No. 210757 ("Granules ANDA") for Granules' colchicine capsules, a drug product that is a generic version of Mitigare® (colchicine) ("Granules' ANDA Product").

21. Upon information and belief, the purpose of the Granules ANDA was to obtain marketing approval from FDA to engage in the commercial manufacture, use, and/or sale of Granules' ANDA Product prior to the expiration of the '607, '036, '029, '613, and '108 patents.

22. In the Granules Notice Letter, Granules notified Plaintiffs that, as part of its ANDA, Granules included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that, in its opinion and to the best of its knowledge, the '607, '036, '029, '613, and '108 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of Granules' ANDA Product.

23. The use of Granules' ANDA Product is covered by one or more claims of the '607, '036, '029, '613, and '108 patents.

24. Granules had knowledge of the '607, '036, '029, '613, and '108 patents when it submitted the Granules ANDA.

25. This action was commenced before the expiration of forty-five days from the date Plaintiffs received the Granules Notice Letter, which Plaintiffs received on or about November, 29, 2017. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Granules Notice Letter.

COUNT 1: INFRINGEMENT OF THE '607 PATENT

26. Paragraphs 1 to 25 are incorporated as if fully set forth herein.

27. The use of Granules' ANDA Product is covered by one or more claims of the '607 patent.

28. The submission of Granules' ANDA No. 210757 with a Paragraph IV certification regarding the '607 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Granules' ANDA Product before the expiration of the '607 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '607 patent under 35 U.S.C. § 271(e)(2).

29. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules' ANDA Product before the expiration of the '607 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '607 patent under 35 U.S.C. § 271.

30. Unless enjoined by this Court, Granules intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules' ANDA Product immediately and imminently upon approval of the Granules ANDA.

31. Unless enjoined by this Court, Granules intends to, and will, actively induce infringement of the '607 patent when the Granules ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

32. The foregoing actions by Granules prior to the expiration of the '607 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b) or (c).

33. Unless Granules is enjoined from infringing the ’607 patent, actively inducing infringement of the ’607 patent, and/or contributing to the infringement of the ’607 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

34. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Granules’ ANDA No. 210757 to be a date which is not earlier than the date on which the ’607 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

COUNT 2: INFRINGEMENT OF THE ’036 PATENT

35. Paragraphs 1 to 34 are incorporated as if fully set forth herein.

36. The use of Granules’ ANDA Product is covered by one or more claims of the ’036 patent.

37. The submission of Granules’ ANDA No. 210757 with a Paragraph IV certification regarding the ’036 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Granules’ ANDA Product before the expiration of the ’036 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the ’036 patent under 35 U.S.C. § 271(e)(2).

38. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules’ ANDA Product before the expiration of the ’036 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the ’036 patent under 35 U.S.C. § 271.

39. Unless enjoined by this Court, Granules intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules' ANDA Product immediately and imminently upon approval of the Granules ANDA.

40. Unless enjoined by this Court, Granules intends to, and will, actively induce infringement of the '036 patent when the Granules ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

41. The foregoing actions by Granules prior to the expiration of the '036 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b) or (c).

42. Unless Granules is enjoined from infringing the '036 patent, actively inducing infringement of the '036 patent, and/or contributing to the infringement of the '036 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

43. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Granules' ANDA No. 210757 to be a date which is not earlier than the date on which the '036 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

COUNT 3: INFRINGEMENT OF THE '029 PATENT

44. Paragraphs 1 to 43 are incorporated as if fully set forth herein.

45. The use of Granules' ANDA Product is covered by one or more claims of the '029 patent.

46. The submission of Granules' ANDA No. 210757 with a Paragraph IV certification regarding the '029 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Granules' ANDA Product before the expiration of the '029 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '029 patent under 35 U.S.C. § 271(e)(2).

47. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules' ANDA Product before the expiration of the '029 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '029 patent under 35 U.S.C. § 271.

48. Unless enjoined by this Court, Granules intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules' ANDA Product immediately and imminently upon approval of the Granules ANDA.

49. Unless enjoined by this Court, Granules intends to, and will, actively induce infringement of the '029 patent when the Granules ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

50. The foregoing actions by Granules prior to the expiration of the '029 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b) or (c).

51. Unless Granules is enjoined from infringing the '029 patent, actively inducing infringement of the '029 patent, and/or contributing to the infringement of the '029 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35

U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

52. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Granules' ANDA No. 210757 to be a date which is not earlier than the date on which the '029 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

COUNT 4: INFRINGEMENT OF THE '613 PATENT

53. Paragraphs 1 to 52 are incorporated as if fully set forth herein.

54. The use of Granules' ANDA Product is covered by one or more claims of the '613 patent.

55. The submission of Granules' ANDA No. 210757 with a Paragraph IV certification regarding the '613 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Granules' ANDA Product before the expiration of the '613 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '613 patent under 35 U.S.C. § 271(e)(2).

56. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules' ANDA Product before the expiration of the '613 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '613 patent under 35 U.S.C. § 271.

57. Unless enjoined by this Court, Granules intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules' ANDA Product immediately and imminently upon approval of the Granules ANDA.

58. Unless enjoined by this Court, Granules intends to, and will, actively induce infringement of the ’613 patent when the Granules ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

59. The foregoing actions by Granules prior to the expiration of the ’613 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b) or (c).

60. Unless Granules is enjoined from infringing the ’613 patent, actively inducing infringement of the ’613 patent, and/or contributing to the infringement of the ’613 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

61. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Granules’ ANDA No. 210757 to be a date which is not earlier than the date on which the ’613 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

COUNT 5: INFRINGEMENT OF THE ’108 PATENT

62. Paragraphs 1 to 61 are incorporated as if fully set forth herein.

63. The use of Granules’ ANDA Product is covered by one or more claims of the ’108 patent.

64. The submission of Granules’ ANDA No. 210757 with a Paragraph IV certification regarding the ’108 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Granules’ ANDA Product before the expiration of the ’108 patent

constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '108 patent under 35 U.S.C. § 271(e)(2).

65. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules' ANDA Product before the expiration of the '108 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '108 patent under 35 U.S.C. § 271.

66. Unless enjoined by this Court, Granules intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Granules' ANDA Product immediately and imminently upon approval of the Granules ANDA.

67. Unless enjoined by this Court, Granules intends to, and will, actively induce infringement of the '108 patent when the Granules ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

68. The foregoing actions by Granules prior to the expiration of the '108 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b) or (c).

69. Unless Granules is enjoined from infringing the '108 patent, actively inducing infringement of the '108 patent, and/or contributing to the infringement of the '108 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

70. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Granules' ANDA No.

210757 to be a date which is not earlier than the date on which the ’108 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

a. Judgment in favor of Plaintiffs and against Defendant;

b. Judgment that the ’607, ’036, ’029, ’613, and ’108 patents are valid and enforceable;

c. Judgment that Granules has infringed, literally and/or by the doctrine of equivalents, one or more claims of the ’607, ’036, ’029, ’613, and ’108 patents by submitting ANDA No. 210757, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Granules’ ANDA Product in the United States will constitute infringement, contributory infringement, or actively induced infringement of the ’607, ’036, ’029, ’613, and ’108 patents;

d. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 210757 relating to Granules’ ANDA Product shall be not earlier than the date of expiration of the ’607, ’036, ’029, ’613, and ’108 patents, or any later date of exclusivity to which Hikma is or becomes entitled;

e. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., restraining and enjoining Granules and its officers, partners, agents, attorneys, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in privity or concert with it, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or

importation within the United States Granules' ANDA Product, and any product that is similar to or only colorably different from that product, and from infringing, contributorily infringing, or inducing others to infringe the '607, '036, '029, '613, and '108 patents, before the expiration of the '607, '036, '029, '613, and '108 patents or any later date of exclusivity to which Hikma is or becomes entitled;

f. Damages or other monetary relief, including pre-judgment and post-judgment interest, to the extent that Granules engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation within the United States Granules' ANDA Product, or any product that infringes the '607, '036, '029, '613, and '108 patents, or contributes to or actively induces infringement of the '607, '036, '029, '613, and '108 patents, before the expiration of the '607, '036, '029, '613, and '108 patents or any later date of exclusivity to which Hikma is or becomes entitled;

g. A declaration that this is an exceptional case and an award of reasonable attorney's fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

h. Plaintiffs reasonable costs and expenses incurred in bringing and prosecuting this action; and

i. Such other and further relief as the Court deems just and appropriate.

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (# 3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

Attorneys for Defendants West-Ward Pharmaceutical Corp. and Hikma Pharmaceuticals, LLC

OF COUNSEL:

Samuel S. Park
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, Illinois 60601-9703
(312) 558-5600
spark@winston.com

Charles B. Klein
Ilan Wurman
WINSTON & STRAWN LLP
1700 K Street, N.W.
Washington, DC 20006
(202) 282-5000
cklein@winston.com
iwurman@winston.com

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