IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HIKMA PHARMACEUTICALS USA INC. and HIKMA INTERNATIONAL PHARMACEUTICALS LLC (EXEMPT), *Plaintiffs*, v. ANNORA PHARMA PRIVATE LIMITED *Defendant.*	C.A. No.

COMPLAINT

Plaintiffs Hikma Pharmaceuticals USA Inc. and Hikma International Pharmaceuticals LLC (Exempt) (together, "Plaintiffs" or "Hikma") for their Complaint against Defendant Annora Pharma Private Limited ("Annora") 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 Annora's 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) (collectively, the "patents-in-suit") throughout the United States, including in Delaware.

PARTIES

3. Hikma Pharmaceuticals USA Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 200 Connell Drive, Suite 4100, Berkeley Heights, New Jersey 07922.

4. Hikma International Pharmaceuticals LLC (Exempt) is a company organized and existing under the laws of Jordan, having a principal place of business at King Abdullah II Street, Adjacent Ahli Club, P.O. Box 182400, Amman 11118, Jordan. Hikma Pharmaceuticals USA Inc. is the authorized U.S. agent for Hikma International Pharmaceuticals LLC (Exempt).

5. Upon information and belief, Defendant Annora is an Indian corporation having a principal place of business at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy Dist. Telangana State, 502313. India. Upon information and belief, Defendant Annora manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

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 Annora because, among other reasons, it maintains an adequate presence in Delaware; it has substantial and continuous contacts with Delaware; and it has committed the acts of patent infringement alleged herein in Delaware.

8. Upon information and belief, Annora 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 Annora 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 it 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. For example, upon information and belief, Annora is actively preparing to make the proposed generic copies of Mitigare® (colchicine) that are the subject of Annora's 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 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 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, 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 International Pharmaceuticals LLC (Exempt) 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 of 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®.

ANNORA'S ANDA SUBMISSION

20. By letter dated January 17, 2023 ("Notice Letter"), Annora notified Plaintiffs that it had submitted to FDA its ANDA No. 217620 ("ANDA") for Annora's colchicine capsules, a drug product that is a generic version of Mitigare® (colchicine) ("Annora's ANDA Product").

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

22. In the Notice Letter, Annora notified Plaintiffs that, as part of its ANDA, Annora 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 Annora's ANDA Product.

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

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

25. This action was commenced before the expiration of forty-five days from the date Plaintiffs received the Notice Letter, which Plaintiffs received on or about January 17, 2023.

COUNT 1: INFRINGEMENT OF THE '607 PATENT

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

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

28. The submission of ANDA No. 217620 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 Annora's 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 Annora's 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, Annora intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Annora's ANDA Product immediately and imminently upon approval of the ANDA.

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

32. The foregoing actions by Annora before 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 Annora 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 Fed. R. Civ. P. 65, 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 FDA set the effective date of approval for ANDA No. 217620 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 Annora's ANDA Product is covered by one or more claims of the '036 patent.

37. The submission of ANDA No. 217620 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 Annora's 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 Annora's 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, Annora intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Annora's ANDA Product immediately and imminently upon approval of the ANDA.

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

41. The foregoing actions by Annora before 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 Annora 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 Fed. R. Civ. P. 65, 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 FDA set the effective date of approval for ANDA No. 217620 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 Annora’s ANDA Product is covered by one or more claims of the ’029 patent.

46. The submission of ANDA No. 217620 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 Annora’s 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 Annora’s 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, Annora intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Annora's ANDA Product immediately and imminently upon approval of the ANDA.

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

50. The foregoing actions by Annora before 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 Annora 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 Fed. R. Civ. P. 65, 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 FDA set the effective date of approval for ANDA No. 217620 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 Annora's ANDA Product is covered by one or more claims of the '613 patent.

55. The submission of ANDA No. 217620 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 Annora's 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 Annora's 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, Annora intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Annora's ANDA Product immediately and imminently upon approval of the ANDA.

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

59. The foregoing actions by Annora before 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 Annora 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 Fed. R. Civ. P. 65, 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 FDA set the effective date of approval for ANDA No. 217620 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 Annora's ANDA Product is covered by one or more claims of the '108 patent.

64. The submission of ANDA No. 217620 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 Annora's 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 Annora's 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, Annora intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Annora's ANDA Product immediately and imminently upon approval of the ANDA.

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

68. The foregoing actions by Annora before 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 Annora 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 Fed. R. Civ. P. 65, 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 FDA set the effective date of approval for ANDA No. 217620 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 Annora 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. 217620, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Annora's 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. 217620 relating to Annora's 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 Fed. R. Civ. P. 65, restraining and enjoining Annora 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 Annora's 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 Annora engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation within the United States

Annora's 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.

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