

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK KGaA, MERCK SERONO SA,)
and ARES TRADING SA,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
HOPEWELL PHARMA VENTURES, INC.,)
)
Defendant.)

COMPLAINT

Plaintiffs Merck KGaA, Merck Serono SA, and Ares Trading SA (collectively, “Merck” or “Plaintiffs”), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Defendant Hopewell Pharma Ventures, Inc. of Abbreviated New Drug Application (“ANDA”) No. 215547 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Merck’s MAVENCLAD[®] product prior to the expiration of U.S. Patent Nos. 7,713,947, 8,377,903, and 10,849,919 (the “Patents-in-Suit”).

PARTIES

2. Plaintiff Merck KGaA is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Hessen, Germany.¹

¹ In the United States, Plaintiff Merck KGaA conducts business under the name “Merck KGaA, Darmstadt, Germany.”

3. Plaintiff Merck Serono SA is a Swiss corporation having a principal place of business at Rue de l'Ouriette, 151, Zone industrielle de l'Ouriettaz, Aubonne 1170, Switzerland. Merck Serono SA is a wholly owned subsidiary of Plaintiff Merck KGaA.

4. Plaintiff Ares Trading SA is a Swiss corporation having a principal place of business at Rue de l'Ouriette, 151, Zone industrielle de l'Ouriettaz, Aubonne 1170, Switzerland. Ares Trading SA is a wholly owned subsidiary of Plaintiff Merck KGaA.

5. On information and belief, Defendant Hopewell Pharma Ventures, Inc. ("Hopewell") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1201 North Orange Street, Suite 717, Wilmington, Delaware, 19899.

6. On information and belief, Hopewell's business includes at least marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Hopewell submits ANDAs to the FDA seeking approval to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic versions of drug products covered by United States patents.

7. On information and belief, Hopewell prepared and submitted ANDA No. 215547 seeking FDA approval to market Hopewell's cladribine 10 mg tablets (the "Hopewell ANDA Product") in the United States prior to the expiration of the Patents-in-Suit.

8. On information and belief, following any FDA approval of ANDA No. 215547, Hopewell will market, distribute, offer for sale, and/or sell the Hopewell ANDA Product throughout the United States including in Delaware.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Hopewell because it is incorporated and has its principal place of business in Delaware. Additionally, on information and belief, Hopewell has engaged and/or will engage in continuous and systematic contacts with the State of Delaware and/or purposefully has availed and/or will avail itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in Delaware, and deriving substantial revenue from such activities. Additionally, venue is proper in this Court under 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b) because Hopewell is incorporated and has its principal place of business in Delaware.

11. On information and belief, Hopewell has purposefully conducted business and/or will conduct business in the State of Delaware, and Delaware is a likely destination of Hopewell's products, including its proposed generic version of MAVENCLAD[®] that is at issue in this action.

12. On information and belief, upon approval of ANDA No. 215547, Hopewell will market and sell the Hopewell ANDA Product in Delaware and throughout the United States and will derive substantial revenue therefrom.

13. On information and belief, upon approval of Hopewell's ANDA No. 215547, Hopewell will place the Hopewell ANDA Product into the stream of commerce with the expectation or knowledge and the intent that such product will be purchased and used by consumers in Delaware and throughout the United States.

PATENTS-IN-SUIT

14. United States Patent No. 7,713,947 (“the ’947 patent”), entitled “Cladribine Regimen for Treating Multiple Sclerosis” (attached as Exhibit A), was duly and legally issued on May 11, 2010.

15. United States Patent No. 8,377,903 (“the ’903 patent”), entitled “Cladribine Regimen for Treating Multiple Sclerosis” (attached as Exhibit B), was duly and legally issued on February 19, 2013.

16. United States Patent No. 10,849,919 (“the ’919 patent”), entitled “Cladribine Regimen for Treating Progressive Forms of Multiple Sclerosis” (attached as Exhibit C), was duly and legally issued on December 1, 2020.

17. The ’947 and ’903 patents are owned by Merck Serono SA. The ’919 patent is owned by Ares Trading SA. The claims of the ’947, ’903, and ’919 patents are valid, enforceable, and not expired.

MERCK’S MAVENCLAD® PRODUCT

18. EMD Serono, Inc. holds New Drug Application (“NDA”) No. 022561, which the FDA approved on March 29, 2019 for the marketing and sale of 10 mg strength cladribine tablets. EMD Serono, Inc. markets 10 mg strength cladribine tablets in the United States under the trade name “MAVENCLAD®.” EMD Serono, Inc. is a wholly owned subsidiary of Merck KGaA.

19. MAVENCLAD® is a purine antimetabolite. It is approved by the FDA for the treatment of relapsing forms of multiple sclerosis, including relapsing-remitting disease and active secondary progressive disease, in adults. A copy of the complete prescribing information for MAVENCLAD® is attached as Exhibit D.

20. The FDA's official publication of approved drugs (the "Orange Book") includes MAVENCLAD[®]. The Orange Book lists the '947, '903, and '919 patents as patents covering MAVENCLAD[®] and its use.²

INFRINGEMENT BY HOPEWELL

21. By letter dated September 13, 2022 (the "Notice Letter"), Hopewell notified Merck that it had submitted to the FDA ANDA No. 215547 seeking approval to market and sell the Hopewell ANDA Product in the United States prior to the expiration of the '947 and '903 patents. The '947 and '903 patents expire on October 16, 2026 and May 31, 2026, respectively. The '919 patent expires on November 23, 2038. Therefore, Hopewell is necessarily seeking approval of the Hopewell ANDA Product before the '919 patent's later expiration.

22. By submitting ANDA No. 215547, Hopewell has represented to the FDA that the Hopewell ANDA Product has the same active ingredient as MAVENCLAD[®], has the same dosage forms and strengths as MAVENCLAD[®], and is bioequivalent to MAVENCLAD[®].

23. In the Notice Letter, Hopewell admitted that it is seeking approval to market the Hopewell ANDA Product for the same approved indication as MAVENCLAD[®].

24. In the Notice Letter, Hopewell stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) with respect to the '947 and '903 patents, and alleged that these patents are invalid and/or will not be infringed. The Notice Letter demonstrates that Hopewell seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Hopewell ANDA Product before the '947 and '903 patents expire.

25. This action is being commenced before the expiration of forty-five days from the date of Merck's receipt of the Notice Letter.

² The '919 patent was listed in the Orange Book on September 12, 2022.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 7,713,947

26. Plaintiffs incorporate each of the preceding paragraphs 1-25 as if fully set forth herein.

27. Hopewell's submission of ANDA No. 215547 to the FDA for the purpose of obtaining approval to engage in the commercial importation, manufacture, use, offer for sale, and/or sale of the Hopewell ANDA Product in the United States before the expiration of the '947 patent was an act of infringement of the '947 patent under 35 U.S.C. § 271(e)(2).

28. The commercial manufacture, use, offer for sale, sale and/or importation of the Hopewell ANDA Product in the United States would infringe one or more claims of the '947 patent under 35 U.S.C. § 271(a), (b) and/or (c), either literally or under the doctrine of equivalents. The infringed claims of the '947 patent include at least claims 36, 38, 39, and 41-46. Such infringement is imminent because, among other things, Hopewell has notified Merck of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Hopewell ANDA Product before the expiration of the '947 patent.

29. Hopewell had knowledge of the '947 patent prior to submitting its ANDA to the FDA, as demonstrated by Hopewell's 21 U.S.C. § 355(j)(2)(vii)(IV) allegation with respect to the '947 patent.

30. On information and belief, use of the Hopewell ANDA Product in accordance with and as directed by Hopewell's proposed labeling for that product would infringe one or more claims of the '947 patent.

31. On information and belief, Hopewell intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Hopewell ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 215547.

32. On information and belief, Hopewell will infringe and will actively induce or contribute to the infringement of the '947 patent when ANDA No. 215547 is approved, and plans and intends to, and will do so upon approval.

33. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '947 patent.

34. Pursuant to 28 U.S.C. § 2201, Merck is entitled to a declaratory judgment that Hopewell's making, using, offering to sell, selling, and/or importing the Hopewell ANDA Product, and inducement thereof or contribution thereto, will infringe the '947 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

35. On information and belief, Hopewell acted without a reasonable basis for believing that it would not be liable for infringing the '947 patent and/or actively inducing or contributing to the infringement of the '947 patent.

36. Unless Hopewell is enjoined from infringing the '947 patent and/or actively inducing or contributing to the infringement of the '947 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 8,377,903

37. Plaintiffs incorporate each of the preceding paragraphs 1-36 as if fully set forth herein.

38. Hopewell's submission of ANDA No. 215547 to the FDA for the purpose of obtaining approval to engage in the commercial importation, manufacture, use, offer for sale, and/or sale of the Hopewell ANDA Product in the United States before the expiration of the '903 patent was an act of infringement of the '903 patent under 35 U.S.C. § 271(e)(2).

39. The commercial manufacture, use, offer for sale, sale and/or importation of the Hopewell ANDA Product in the United States would infringe one or more claims of the '903 patent under 35 U.S.C. § 271(a), (b) and/or (c), either literally or under the doctrine of equivalents. The infringed claims of the '903 patent include at least claims 17, 19, 20, and 22-27. Such infringement is imminent because, among other things, Hopewell has notified Merck of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Hopewell ANDA Product before the expiration of the '903 patent.

40. Hopewell had knowledge of the '903 patent prior to submitting its ANDA to the FDA, as demonstrated by Hopewell's 21 U.S.C. § 355(j)(2)(vii)(IV) allegation with respect to the '903 patent.

41. On information and belief, use of the Hopewell ANDA Product in accordance with and as directed by Hopewell's proposed labeling for that product would infringe one or more claims of the '903 patent.

42. On information and belief, Hopewell intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Hopewell ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 215547.

43. On information and belief, Hopewell will infringe and will actively induce or contribute to the infringement of the '903 patent when ANDA No. 215547 is approved, and plans and intends to, and will do so upon approval.

44. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '903 patent.

45. Pursuant to 28 U.S.C. § 2201, Merck is entitled to a declaratory judgment that Hopewell's making, using, offering to sell, selling, and/or importing the Hopewell ANDA Product,

and inducement thereof or contribution thereto, will infringe the '903 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

46. On information and belief, Hopewell acted without a reasonable basis for believing that it would not be liable for infringing the '903 patent and/or actively inducing or contributing to the infringement of the '903 patent.

47. Unless Hopewell is enjoined from infringing the '903 patent and/or actively inducing or contributing to the infringement of the '903 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 10,849,919

48. Plaintiffs incorporate each of the preceding paragraphs 1-47 as if fully set forth herein.

49. Hopewell's submission of ANDA No. 215547 to the FDA for the purpose of obtaining approval to engage in the commercial importation, manufacture, use, offer for sale, and/or sale of the Hopewell ANDA Product in the United States before the expiration of the '919 patent was an act of infringement of the '919 patent under 35 U.S.C. § 271(e)(2).

50. The commercial manufacture, use, offer for sale, sale and/or importation of the Hopewell ANDA Product in the United States would infringe one or more claims of the '919 patent under 35 U.S.C. § 271(a), (b) and/or (c), either literally or under the doctrine of equivalents. The infringed claims of the '919 patent include at least claims 1-6, 8, 9, 11, 12, 14-16, 18-20, 23-27, 30, 33, and 34. Upon information and belief, Hopewell has made and will continue to make substantial and meaningful preparations to practice, induce and/or contribute to practicing of one or more of the claims of the '919 patent and/or import, offer to sell, sell, make, and/or use within the United States the Hopewell ANDA Product prior to the expiration of the '919 patent. For

example, infringement of the '919 patent is imminent because, among other things, Hopewell has notified Merck of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Hopewell ANDA Product before the expiration of the '947 and '903 patents, which is before the expiration of the '919 patent.

51. Hopewell knew or should have known of the '919 patent no later than September 12, 2022, when the '919 patent was listed in the Orange Book for MAVENCLAD®.

52. On information and belief, use of the Hopewell ANDA Product in accordance with and as directed by Hopewell's proposed labeling for that product would infringe one or more claims of the '919 patent.

53. On information and belief, Hopewell intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Hopewell ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 215547.

54. On information and belief, Hopewell will infringe and will actively induce or contribute to the infringement of the '919 patent when ANDA No. 215547 is approved, and plans and intends to, and will do so upon approval.

55. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '919 patent.

56. Pursuant to 28 U.S.C. § 2201, Merck is entitled to a declaratory judgment that Hopewell's making, using, offering to sell, selling, and/or importing the Hopewell ANDA Product, and inducement thereof or contribution thereto, will infringe the '919 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

57. On information and belief, Hopewell acted without a reasonable basis for believing that it would not be liable for infringing the '919 patent and/or actively inducing or contributing to the infringement of the '919 patent.

58. Unless Hopewell is enjoined from infringing the '919 patent and/or actively inducing or contributing to the infringement of the '919 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

(a) A judgment that Hopewell's submission of ANDA No. 215547 to the FDA was an act of infringement of the claims of the '947, '903, and '919 patents, and that Hopewell's manufacture, use, offer to sell, sale, or importation of the Hopewell ANDA Product in or into the United States prior to the expiration of the '947, '903, and '919 patents, will infringe and/or actively induce or contribute to the infringement of the claims of the '947, '903, and '919 patents;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Hopewell's ANDA No. 215547, shall not be earlier than the latest expiration date of the '947, '903, and '919 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(c) A declaratory judgment that Hopewell's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Hopewell ANDA Product prior to the expiration of the '947, '903, and '919 patents, would infringe the claims of the '947, '903, and '919 patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

(d) A judgment declaring that the claims of the '947, '903, and '919 patents are not invalid or unenforceable;

(e) An Order permanently enjoining Hopewell, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, or importing in or into the United States the Hopewell ANDA Product, or any product or compound that infringes the '947, '903, and '919 patents, or inducing and/or contributing to the infringement of the '947, '903, and '919 patents until after the latest expiration date of the '947, '903, and '919 patents, including any extension and/or additional periods of exclusivity to which Merck is or becomes entitled.

(f) A declaration that this is an exceptional case and an award of attorneys' fees to Plaintiffs pursuant to 35 U.S.C. §§ 285 and 271(e)(4), together with reasonable costs; and

(g) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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October 17, 2022