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. _____
AUROBINDO PHARMA USA, INC. and AUROBINDO PHARMA LIMITED,	)	
Defendants.	)	

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 Defendants Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited of Abbreviated New Drug Application ("ANDA") No. 217924 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 Aurobindo Pharma Limited ("Aurobindo Pharma") is a corporation domiciled and organized under the laws of India with its principal place of business at its global headquarters, Water Mark Building, Plot No. 11, Survey no.9, Kondapur, Hitech City, Hyderabad–500 084, Telangana, India, and a registered office at Plot No.2, Maitri Vihar, Ameerpet, Hyderabad–500 038, India.

6. On information and belief, Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520-1401.

7. On information and belief, Aurobindo Pharma, itself and through its subsidiaries and agents, including Aurobindo USA, manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in this judicial district.

8. On information and belief, Aurobindo USA manufactures, and/or distributes generic drugs for sale and use throughout the United States and in this judicial district at the direction, under the control, and for the direct benefit of Aurobindo Pharma.

9. On information and belief, Defendants acted collaboratively in the preparation and submission of ANDA No. 217924 for Aurobindo USA's cladribine 10 mg tablets (the "Aurobindo

ANDA Product"). On information and belief, Aurobindo USA's preparation and submission of ANDA No. 217924 was done at the direction, under the control, and for the benefit of Aurobindo Pharma.

10. On information and belief, following any FDA approval of ANDA No. 217924, Aurobindo Pharma, itself and through its subsidiaries and agents, including Aurobindo USA, will make, use, offer to sell, and/or sell the Aurobindo ANDA Product throughout the United States, including in the State of Delaware, and/or import such generic products into the United States.

11. Hereinafter, Aurobindo Pharma and Aurobindo USA are collectively referred to as "Aurobindo" or "Defendants."

JURISDICTION AND VENUE

12. 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.

13. This Court has personal jurisdiction over Aurobindo USA because it is incorporated in Delaware. Moreover, this Court has personal jurisdiction over Defendants because, on information and belief, Aurobindo USA and Aurobindo Pharma, acting in concert with one another, have engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed themselves 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.

14. Additionally, venue is proper in this Court under 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b) because Aurobindo USA is incorporated in Delaware. Aurobindo Pharma is a foreign corporation not residing in any United States district and, thus, may be sued in any judicial district. *See* 28 U.S.C. § 1391(c).

15. On information and belief, Aurobindo USA and Aurobindo Pharma, acting in concert with one another, have purposefully conducted business and/or will conduct business in the State of Delaware, and Delaware is a likely destination of Aurobindo's products, including its proposed generic version of MAVENCLAD® that is at issue in this action.

16. On information and belief, upon approval of ANDA No. 217924, Aurobindo will market and sell the Aurobindo ANDA Product in Delaware and throughout the United States and will derive substantial revenue therefrom.

17. On information and belief, upon approval of Aurobindo's ANDA No. 217924, Aurobindo will place the Aurobindo 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

18. 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.

19. 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.

20. 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.

21. 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

22. 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.

23. 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.

24. 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.

INFRINGEMENT BY AUROBINDO

25. By letter dated December 2, 2022 (the "Notice Letter"), Aurobindo notified Merck that it had submitted to the FDA ANDA No. 217924 seeking approval to market and sell the Aurobindo ANDA Product in the United States prior to the expiration of the '947, '903, and '919 patents. The '947 and '903 patents expire on October 16, 2026 and May 31, 2026, respectively. The '919 patent expires on November 23, 2038.

26. By submitting ANDA No. 217924, Aurobindo has represented to the FDA that the Aurobindo ANDA Product has the same active ingredient as MAVENCLAD®, has the same dosage forms and strengths as MAVENCLAD®, and is bioequivalent to MAVENCLAD®.

27. In the Notice Letter, Aurobindo admitted that it is seeking approval to market the Aurobindo ANDA Product for the same approved indication as MAVENCLAD®.

28. In the Notice Letter, Aurobindo stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) with respect to the '947, '903, and '919 patents, and alleged that these patents are invalid and/or will not be infringed. The Notice Letter demonstrates that Aurobindo seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Aurobindo ANDA Product before the '947, '903, and '919 patents expire.

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

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

30. Plaintiffs incorporate each of the preceding paragraphs 1-29 as if fully set forth herein.

31. Aurobindo's submission of ANDA No. 217924 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 Aurobindo 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).

32. The commercial manufacture, use, offer for sale, sale and/or importation of the Aurobindo 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 claim 36. Such infringement is imminent because, among other things, Aurobindo 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 Aurobindo ANDA Product before the expiration of the '947 patent.

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

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

35. On information and belief, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 217924.

36. On information and belief, Aurobindo will infringe and will actively induce or contribute to the infringement of the '947 patent when ANDA No. 217924 is approved, and plans and intends to, and will do so upon approval.

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

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

39. On information and belief, Aurobindo 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.

40. Unless Aurobindo 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

41. Plaintiffs incorporate each of the preceding paragraphs 1-40 as if fully set forth herein.

42. Aurobindo's submission of ANDA No. 217924 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 Aurobindo 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).

43. The commercial manufacture, use, offer for sale, sale and/or importation of the Aurobindo 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 claim 17. Such infringement is imminent because, among other things, Aurobindo 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 Aurobindo ANDA Product before the expiration of the '903 patent.

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

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

46. On information and belief, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 217924.

47. On information and belief, Aurobindo will infringe and will actively induce or contribute to the infringement of the '903 patent when ANDA No. 217924 is approved, and plans and intends to, and will do so upon approval.

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

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

50. On information and belief, Aurobindo 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.

51. Unless Aurobindo 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

52. Plaintiffs incorporate each of the preceding paragraphs 1-51 as if fully set forth herein.

53. Aurobindo's submission of ANDA No. 217924 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 Aurobindo 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).

54. The commercial manufacture, use, offer for sale, sale and/or importation of the Aurobindo 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, 14, and 27. Such infringement is imminent because, among other things, Aurobindo 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 Aurobindo ANDA Product before the expiration of the '919 patent.

55. Aurobindo had knowledge of the '919 patent prior to submitting its ANDA to the FDA, as demonstrated by Aurobindo's 21 U.S.C. § 355(j)(2)(vii)(IV) allegation with respect to the '919 patent.

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

57. On information and belief, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 217924.

58. On information and belief, Aurobindo will infringe and will actively induce or contribute to the infringement of the '919 patent when ANDA No. 217924 is approved, and plans and intends to, and will do so upon approval.

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

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

61. On information and belief, Aurobindo 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.

62. Unless Aurobindo 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 Aurobindo's submission of ANDA No. 217924 to the FDA was an act of infringement of the claims of the '947, '903, and '919 patents, and that Aurobindo's manufacture, use, offer to sell, sale, or importation of the Aurobindo 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 Aurobindo's ANDA No. 217924, 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 Aurobindo's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Aurobindo 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 Aurobindo, 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 Aurobindo 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

/s/ Jeremy A. Tigan

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