IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK KGaA, MERCK SERONO SA, and ARES TRADING SA, Plaintiffs, v. TWI PHARMACEUTICALS, INC. and TWI PHARMACEUTICALS USA, INC., Defendants.	)	C.A. No. _____

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 TWi Pharmaceuticals, Inc. and TWi Pharmaceuticals USA, Inc. of Abbreviated New Drug Application ("ANDA") No. 217530 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 and 8,377,903 (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 TWi Pharmaceuticals, Inc. ("TWi Pharmaceuticals") is a corporation domiciled and organized under the laws of Taiwan with its principal place of business at its global headquarters, 3F., No. 41, Lane 221, Gangqian Road, Neihu District, Taipei 114, Taiwan.

6. On information and belief, Defendant TWi Pharmaceuticals USA, Inc. ("TWi USA") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 115 West Century Road, Suite 135, Paramus, NJ 07652. On information and belief, TWi USA is a wholly owned subsidiary of TWi Pharmaceuticals.

7. On information and belief, TWi Pharmaceuticals, itself and through its subsidiaries and agents, including TWi 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, TWi 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 TWi Pharmaceuticals.

9. On information and belief, Defendants acted collaboratively in the preparation and submission of ANDA No. 217530 for TWi USA's cladribine 10 mg tablets (the "TWi ANDA

Product"), and TWi Pharmaceuticals submitted ANDA No. 217530 on behalf of both TWi Pharmaceuticals and TWi USA.

10. On information and belief, following any FDA approval of ANDA No. 217530, TWi Pharmaceuticals, itself and through its subsidiaries and agents, including TWi USA, will make, use, offer to sell, and/or sell the TWi ANDA Product throughout the United States, including in the State of Delaware, and/or import such generic products into the United States.

11. Hereinafter, TWi Pharmaceuticals and TWi USA are collectively referred to as "TWi" 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 TWi USA because it is incorporated in Delaware.

14. Moreover, this Court has personal jurisdiction over Defendants because, on information and belief, TWi USA and TWi Pharmaceuticals, 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.

15. On information and belief, TWi Pharmaceuticals has previously availed itself of this forum, including by consenting to jurisdiction in *Endo Pharmaceuticals Inc., et. al. v. TWi Pharmaceuticals Inc., et. al.*, C.A. No. 12-848 (D. Del.).

16. On information and belief, TWi USA and TWi Pharmaceuticals, 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 TWi's products, including its proposed generic version of MAVENCLAD® that is at issue in this action.

17. On information and belief, upon approval of ANDA No. 217530, TWi will market and sell the TWi ANDA Product in Delaware and throughout the United States and will derive substantial revenue therefrom.

18. On information and belief, upon approval of TWi's ANDA No. 217530, TWi will place the TWi 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.

19. Alternatively, TWi Pharmaceuticals is a foreign corporation not subject to general jurisdiction in any state's courts, and thus is subject to the jurisdiction of this Court pursuant to Federal Rule of Civil Procedure 4(k)(2).

20. Additionally, venue is proper in this Court under 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b) because TWi USA is incorporated in Delaware. TWi Pharmaceuticals 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).

PATENTS-IN-SUIT

21. 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.

22. 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.

23. The '947 and '903 patents are owned by Merck Serono SA. The claims of the '947 and '903 patents are valid, enforceable, and not expired.

MERCK'S MAVENCLAD® PRODUCT

24. 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.

25. 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 C.

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

INFRINGEMENT BY TWI

27. By letter dated May 6, 2024 (the "Notice Letter"), TWi notified Merck that it had submitted to the FDA ANDA No. 217530 seeking approval to market and sell the TWi 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.

28. By submitting ANDA No. 217530, TWi has represented to the FDA that the TWi ANDA Product has the same active ingredient as MAVENCLAD®, has the same dosage forms and strengths as MAVENCLAD®, and is bioequivalent to MAVENCLAD®.

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

30. In the Notice Letter, TWi 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 TWi seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the TWi ANDA Product before the '947 and '903 patents expire.

31. 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

32. Plaintiffs incorporate each of the preceding paragraphs 1-31 as if fully set forth herein.

33. TWi's submission of ANDA No. 217530 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 TWi 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).

34. The commercial manufacture, use, offer for sale, sale and/or importation of the TWi 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, TWi 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 TWi ANDA Product before the expiration of the '947 patent.

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

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

37. On information and belief, TWi intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the TWi ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 217530.

38. On information and belief, TWi will infringe and will actively induce or contribute to the infringement of the '947 patent when ANDA No. 217530 is approved, and plans and intends to, and will do so upon approval.

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

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

41. On information and belief, TWi 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.

42. Unless TWi 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

43. Plaintiffs incorporate each of the preceding paragraphs 1-42 as if fully set forth herein.

44. TWi's submission of ANDA No. 217530 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 TWi 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).

45. The commercial manufacture, use, offer for sale, sale and/or importation of the TWi 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, TWi 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 TWi ANDA Product before the expiration of the '903 patent.

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

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

48. On information and belief, TWi intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the TWi ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 217530.

49. On information and belief, TWi will infringe and will actively induce or contribute to the infringement of the '903 patent when ANDA No. 217530 is approved, and plans and intends to, and will do so upon approval.

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

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

52. On information and belief, TWi 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.

53. Unless TWi 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.

PRAYER FOR RELIEF

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

(a) A judgment that TWi's submission of ANDA No. 217530 to the FDA was an act of infringement of the claims of the '947 and '903 patents, and that TWi's manufacture, use, offer to sell, sale, or importation of the TWi ANDA Product in or into the United States prior to the expiration of the '947 and '903 patents, will infringe and/or actively induce or contribute to the infringement of the claims of the '947, and '903 patents;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of TWi's ANDA No. 217530, shall not be earlier than the latest expiration date of the '947 and '903 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(c) A declaratory judgment that TWi's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the TWi ANDA Product prior to the expiration of the '947 and '903 patents, would infringe the claims of the '947 and '903 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 and '903 patents are not invalid or unenforceable;

(e) An Order permanently enjoining TWi, 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 TWi ANDA Product, or any product or compound that infringes the '947 and'903, patents, or inducing and/or contributing to the infringement of the '947 and '903 until after the latest expiration date of the

'947 and '903 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

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:
David B. Bassett
Mary Pheng
Gillian T. Farrell
WILMER CUTLER PICKERING
HALE & DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Vinita Ferrera
Emily R. Whelan
Deric Geng
David Mlaver
Asher S. McGuffin
WILMER CUTLER PICKERING
HALE & DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

H. Rachael Million-Perez
Phillip Takhar
WILMER CUTLER PICKERING
HALE & DORR LLP
1225 17th Street, Suite 2600
Denver, CO 80202
(720) 274-3135

Reid Whitaker
WILMER CUTLER PICKERING
HALE & DORR LLP
2100 Pennsylvania Ave., NW
Washington, DC 20037
(202) 663-6000

June 14, 2024