

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH	)	
and BIOGEN MA INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
TWI PHARMACEUTICALS, INC. and TWI	)	
PHARMACEUTICALS USA, INC.,	)	
	)	
Defendants.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, “Biogen” or “Plaintiffs”), by way of Complaint against Defendants TWi Pharmaceuticals, Inc. (“TWi Pharmaceuticals”) and TWi Pharmaceuticals USA, Inc. (“TWi USA”) (collectively, “TWi” or “Defendants”), allege as follows:

**THE PARTIES**

1. Plaintiff Biogen International GmbH is a Swiss corporation with its principal place of business in Zug, Switzerland at Landis + Gyr-Strasse 3, 6300 Zug, Switzerland.
2. Plaintiff Biogen MA Inc. is a corporation organized and existing under the laws of the Commonwealth of Massachusetts with its principal place of business at 225 Binney Street, Cambridge, Massachusetts 02142.
3. Biogen is in the business of developing, manufacturing and marketing innovative therapies for patients living with serious neurological, autoimmune, and rare diseases, including therapies for multiple sclerosis. Biogen’s asserted patents cover Tecfidera<sup>®</sup>, which is marketed

and sold in this judicial district and throughout the United States for the treatment of relapsing forms of multiple sclerosis.

4. Upon information and belief, TWi Pharmaceuticals is a corporation organized under the laws of Taiwan, having a principal place of business at 3F., No. 41, Ln. 221, Gangqian Rd. Neihu District, Taipei City 114, Taiwan (R.O.C.).

5. Upon information and belief, TWi Pharmaceuticals is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

6. Upon information and belief, TWi USA is a corporation organized under the laws of Delaware, having a principal place of business at 115 West Century Road, Suite 180, Paramus, NJ 07652.

7. Upon information and belief, TWi USA is a subsidiary of TWi Pharmaceuticals.

8. Upon information and belief, TWi USA is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States in concert with TWi Pharmaceuticals.

9. Upon information and belief, the acts of TWi Pharmaceuticals complained of herein were done with the cooperation, participation, and assistance of TWi USA.

#### **NATURE OF THE ACTION**

10. This is an action for patent infringement of U.S. Patent Nos. 7,320,999 (“the ’999 patent”) and 8,399,514 (“the ’514 patent”) arising under the patent laws of the United States, Title 35, United States Code, §§ 100 *et seq.*, including 35 U.S.C. § 271. This action relates to TWi’s filing of Abbreviated New Drug Application (“ANDA”) No. 210382 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food

and Drug Administration (“FDA”) approval to manufacture, use, sell, offer to sell, and import dimethyl fumarate delayed-release capsules prior to the expiration of the asserted patents.

**JURISDICTION AND VENUE**

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because TWi USA is incorporated in Delaware and TWi Pharmaceuticals is incorporated in Taiwan and may be sued in any judicial district in the United States, in which the defendant is subject to the court’s personal jurisdiction.

13. This Court has jurisdiction over TWi Pharmaceuticals under Federal Rule of Civil Procedure 4(k)(2), because, upon information and belief, TWi Pharmaceuticals is organized under the laws of Taiwan.

14. This Court has personal jurisdiction over TWi USA because TWi USA is incorporated in Delaware.

15. This Court also has personal jurisdiction over TWi because at least one provision of 10 Del. C. § 3104(c) is satisfied. Upon information and belief, TWi satisfies at least § 3104(c)(1) (“[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) (“[c]ontracts to supply services or things in this State”), § 3104(c)(3) (“[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) “[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State”), and § 3104(c)(5) (“[h]as an interest in, uses or possesses real property in the State”).

16. TWi “has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at,” upon information and belief, the District of Delaware and elsewhere. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016), *cert. denied*, 2017 WL 69716 (U.S. Jan. 9, 2017). TWi’s “ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs.” *Id.* at 760. Upon information and belief, TWi “intends to direct sales of its drugs into Delaware, among other places, once it has the requested FDA approval to market them.” *Id.* at 758. Upon information and belief, TWi will engage in marketing of its proposed ANDA products in Delaware upon approval of its ANDA.

17. This Court also has personal jurisdiction over TWi because, *inter alia*, this action arises from activities of TWi directed toward Delaware.

18. TWi’s ANDA filing regarding the ’999 patent and the ’514 patent has a substantial connection with this district because it reliably and non-speculatively predicts activities by TWi in this district.

19. Exercising personal jurisdiction over TWi in this district would not be unreasonable given TWi’s contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

20. This Court also has personal jurisdiction over TWi because, *inter alia*, TWi has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, TWi, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Those products include, for example, generic versions of

Aricept<sup>®</sup> and Procardia<sup>®</sup> XL. A list of generic products sold by TWi can be found at [http://twipharma.com/usa/product\\_approvedProducts.aspx](http://twipharma.com/usa/product_approvedProducts.aspx) (accessed June 27, 2017), the contents of which are incorporated herein by reference. Upon information and belief, TWi derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

21. Upon information and belief, TWi Pharmaceuticals maintains continuous and systematic contacts with Delaware through its U.S. subsidiary TWi USA, incorporated in Delaware.

22. Upon information and belief, TWi USA is registered to do business in Delaware (File No. 5433345). *See* <https://icis.corp.delaware.gov/Ecorp/EntitySearch/NameSearch.aspx>. (Accessed June 27, 2017).

23. Upon information and belief, TWi USA maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Harvard Business Services, Inc., located at 16192 Coastal Hwy, Lewes, DE 19958.

24. Upon information and belief, TWi USA has appointed Harvard Business Services, Inc., located at 16192 Coastal Hwy, Lewes, DE 19958 for receipt and service of process as its registered agent.

25. Upon information and belief, TWi Pharmaceuticals and TWi USA operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district. Upon information and belief, TWi “integrate[s] various kinds of expertise from R&D all the way to commercial production.” (*See* [http://twipharma.com/aboutUs\\_introduction.aspx](http://twipharma.com/aboutUs_introduction.aspx), accessed June 27, 2017.)

26. Upon information and belief, the effort to seek approval for ANDA No. 210382 and to manufacture, import, market, and/or sell Defendants' generic products upon approval has been a cooperative and joint enterprise and venture between TWi Pharmaceuticals and TWi USA.

27. Upon information and belief, TWi Pharmaceuticals and TWi USA have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing and maintaining ANDA No. 210382 and in commercializing Defendants' generic products in the United States, including in this judicial district, in accordance with ANDA 210382 upon approval.

28. Upon information and belief, TWi Pharmaceuticals and TWi USA have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 210382.

29. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Defendants.

**FIRST COUNT FOR PATENT INFRINGEMENT ('999 PATENT)**

30. Biogen realleges, and incorporates in full herein, each preceding paragraph.

31. The U.S. Patent and Trademark Office ("PTO") issued the '999 patent on January 22, 2008, entitled "Dimethyl Fumarate for the Treatment of Multiple Sclerosis." The '999 patent identifies Rajendra Kumar Joshi and Hans-Peter Strebel as inventors of the claimed subject matter. A copy of the '999 patent is attached hereto as Exhibit A.

32. Biogen International GmbH is the owner of the '999 patent by virtue of assignment.

33. The '999 patent expires on May 18, 2020, which includes 202 days of Patent Term Adjustment under 35 U.S.C. § 154(b), excluding any pediatric exclusivity or patent term extension.

34. The '999 patent is directed to and claims, *inter alia*, methods of treating multiple sclerosis.

35. The '999 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for New Drug Application (“NDA”) No. 204063 for dimethyl fumarate delayed-release capsules.

36. The FDA approved NDA No. 204063 on March 27, 2013, for the treatment of relapsing forms of multiple sclerosis.

37. Dimethyl fumarate delayed-release capsules are marketed in the United States under the trademark Tecfidera<sup>®</sup>.

38. Upon information and belief, TWi submitted ANDA No. 210382 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell dimethyl fumarate delayed-release capsules containing 120 mg and 240 mg of dimethyl fumarate (“Defendants’ generic products”) in the United States.

39. Biogen received a letter from TWi dated May 23, 2017 (“the Notice Letter”), purporting to include a Notice of Certification for ANDA No. 210382 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '999 patent.

40. TWi thus has actual knowledge of the '999 patent.

41. Upon information and belief, Defendants’ generic products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim

including at least claim 1 of the '999 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

42. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), TWi has infringed at least one claim including at least claim 1 of the '999 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 210382 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '999 patent. Upon information and belief, the products described in ANDA No. 210382 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '999 patent under 35 U.S.C. § 271(e)(2)(A).

43. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 of the '999 patent by the use of Defendants' generic products upon approval.

44. Upon information and belief, upon approval, TWi will take active steps to encourage the use of Defendants' generic products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients, in a manner that infringes at least one claim including at least claim 1 of the '999 patent, for the pecuniary benefit of TWi. Pursuant to 21 C.F.R. § 314.94, TWi is required to copy the FDA approved Tecfidera<sup>®</sup> labeling. Upon information and belief, TWi will thus induce the infringement of at least one claim including at least claim 1 of the '999 patent.

45. Upon information and belief, if the FDA approves ANDA No. 210382, TWi will sell or offer to sell its generic products specifically labeled for use in practicing at least one claim including at least claim 1 of the '999 patent, wherein Defendants' generic products are a material part of the claimed invention, wherein TWi knows that physicians will prescribe and patients



will use Defendants' generic products in accordance with the instructions and/or label provided by TWi in practicing at least one claim including at least claim 1 of the '999 patent, and wherein dimethyl fumarate delayed-release capsules are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, TWi will thus contribute to the infringement of at least one claim including at least claim 1 of the '999 patent.

46. Upon information and belief, TWi's actions relating to TWi's ANDA No. 210382 complained of herein were done with the cooperation, participation, assistance, and for the benefit of TWi.

47. If TWi's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '999 patent and all other relevant activities are not enjoined, Biogen will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**SECOND COUNT FOR PATENT INFRINGEMENT ('514 PATENT)**

48. Biogen realleges, and incorporates in full herein, each preceding paragraph.

49. The PTO issued the '514 patent on March 19, 2013, entitled "Treatment for Multiple Sclerosis." The '514 patent identifies Matvey E. Lukashev and Gilmore O'Neill as inventors of the claimed subject matter. A copy of the '514 patent is attached hereto as Exhibit B.

50. Biogen MA Inc. is the owner of the '514 patent by virtue of assignment.

51. The '514 patent expires on February 7, 2028 excluding any pediatric exclusivity.

52. The '514 patent is directed to and claims, *inter alia*, methods of treating multiple sclerosis.

53. The '514 patent is listed in the Orange Book for NDA No. 204063 for dimethyl fumarate delayed-release capsules.

54. The Notice Letter dated May 23, 2017 purported to include a Notice of Certification for ANDA No. 210382 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '514 patent.

55. TWi thus has actual knowledge of the '514 patent.

56. Upon information and belief, Defendants' generic products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '514 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

57. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), TWi has infringed at least one claim including at least claim 1 of the '514 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 210382 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '514 patent. Upon information and belief, the products described in ANDA No. 210382 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '514 patent under 35 U.S.C. § 271(e)(2)(A).

58. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 the '514 patent by the use of Defendants' generic products upon approval.

59. Upon information and belief, upon approval, TWi will take active steps to encourage the use of Defendants' generic products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients, in a manner that infringes at least one claim including at least claim 1 of the '514 patent, for the pecuniary benefit of TWi. Pursuant to 21 C.F.R. § 314.94, TWi is required to copy The

FDA approved Tecfidera® labeling. Upon information and belief, TWi will thus induce the infringement of at least one claim including at least claim 1 of the '514 patent.

60. Upon information and belief, if the FDA approves ANDA No. 210382, TWi will sell or offer to sell its generic products specifically labeled for use in practicing at least one claim including at least claim 1 of the '514 patent, wherein Defendants' generic products are a material part of the claimed invention, wherein TWi knows that physicians will prescribe and patients will use Defendants' generic products in accordance with the instructions and/or label provided by TWi in practicing at least one claim including at least claim 1 of the '514 patent, and wherein dimethyl fumarate delayed-release capsules are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, TWi will thus contribute to the infringement of at least one claim including at least claim 1 of the '514 patent.

61. Upon information and belief, TWi's actions relating to TWi's ANDA No. 210382 complained of herein were done with the cooperation, participation, assistance, and for the benefit of TWi.

62. If TWi's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '514 patent and all other relevant activities are not enjoined, Biogen will suffer substantial and irreparable harm for which there is no adequate remedy at law.

### **REQUEST FOR RELIEF**

**WHEREFORE**, Biogen respectfully requests that the Court enter judgment in its favor and against Defendants TWi Pharmaceuticals and TWi USA on the patent infringement claims set forth above and respectfully requests that this Court:

1. enter judgment under 35 U.S.C. § 271(e)(2)(A) that TWi has infringed at least one claim including at least claim 1 of the '999 patent through TWi's submission of ANDA No.

210382 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '999 patent;

2. enter judgment under 35 U.S.C. § 271(b) and/or (c) that TWi's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' generic products prior to the expiration of the '999 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(b) and/or (c);

3. order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration date of the '999 patent, or such later date as the Court may determine;

4. enjoin TWi, and all persons acting in concert with TWi, from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '999 patent, or such later date as the Court may determine;

5. enjoin TWi, and all persons acting in concert with TWi, from seeking, obtaining or maintaining approval of TWi's ANDA No. 210382 until the expiration of the '999 patent, or such later date as the Court may determine;

6. enter judgment under 35 U.S.C. § 271(e)(2)(A) that TWi has infringed at least one claim including at least claim 1 of the '514 patent through TWi's submission of ANDA No. TWi to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '514 patent;

7. enter judgment under 35 U.S.C. § 271(b) and/or (c) that TWi's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' generic products prior to the expiration of the '514 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(b) and/or (c);

8. order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration date of the '514 patent, or such later date as the Court may determine;

9. enjoin TWi, and all persons acting in concert with TWi, from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '514 patent, or such later date as the Court may determine;

10. enjoin TWi and all persons acting in concert with TWi, from seeking, obtaining or maintaining approval of TWi's ANDA No. 210382 until the expiration of the '514 patent, or such later date as the Court may determine;

11. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Biogen costs, expenses and disbursements in this action, including reasonable attorney fees; and

12. award such further and other relief as this Court deems proper and just.

ASHBY & GEDDES

*/s/ Steven J. Balick*

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