IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, "Biogen" or "Plaintiffs"), by way of Complaint against Defendant Par Pharmaceutical, Inc. ("Par" or "Defendant"), 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®, 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, Par is a corporation organized under the laws of New York, having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

5. Upon information and belief, Par 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.

NATURE OF THE ACTION

6. 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 Par's filing of Abbreviated New Drug Application ("ANDA") No. 209768 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

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

8. Upon information and belief, venue and jurisdiction are proper for this proceeding.

9. Biogen believes this case belongs in Delaware, but is concurrently filing a case in New York out of an abundance of caution.

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

11. Par'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 Par in this district.

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

13. This Court also has personal jurisdiction over Par because at least one provision of 10 Del. C. § 3104(c) is satisfied. On information and belief, Par 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").

14. Par "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," on 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). Par'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, Par "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, Par will engage in marketing of its proposed ANDA products in Delaware upon approval of its ANDA.

15. Upon information and belief, Par has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 209768.

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

FIRST COUNT FOR PATENT INFRINGEMENT ('999 PATENT)

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

18. 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.

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

20. 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.

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

22. 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.

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

24. Dimethyl fumarate delayed-release capsules are marketed in the United States under the trademark Tecfidera®.

25. Upon information and belief, Par submitted ANDA No. 209768 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 ("Defendant's generic products") in the United States.

26. Biogen received a letter from Par dated May 24, 2017 ("the Notice Letter"), purporting to include a Notice of Certification for ANDA No. 209768 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '999 patent. The Notice Letter did not allege non-infringement as to any claim of the '999 patent.

27. Par thus has actual knowledge of the '999 patent.

28. Upon information and belief, Defendant's 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).

29. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Par 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. 209768 seeking approval to manufacture, use, import, offer to sell or sell Defendant's generic products before the expiration date of the '999 patent. Upon information and belief, the products described in ANDA No. 209768 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).

30. 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 Defendant's generic products upon approval.

31. Upon information and belief, upon approval, Par will take active steps to encourage the use of Defendant's generic products by physicians and/or patients with the knowledge and intent that Defendant's 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 Par. Pursuant to 21 C.F.R. § 314.94, Par is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Par will thus induce the infringement of at least one claim including at least claim 1 of the '999 patent.

32. Upon information and belief, if the FDA approves ANDA No. 209768, Par 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 Defendant's generic products are a material part of the claimed invention, wherein Par knows that physicians will prescribe and patients will use Defendant's generic products in accordance with the instructions and/or label provided by Par 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, Par will thus contribute to the infringement of at least one claim including at least claim 1 of the '999 patent.

33. Upon information and belief, Par's actions relating to Par's ANDA No. 209768 complained of herein were done by and for the benefit of Par.

34. If Par'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)

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

36. 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.

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

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

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

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

41. The Notice Letter dated May 24, 2017 purported to include a Notice of Certification for ANDA No. 209768 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '514 patent. The Notice Letter did not allege non-infringement as to any claim of the '514 patent.

42. Par thus has actual knowledge of the '514 patent.

43. Upon information and belief, Defendant's 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).

44. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Par 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. 209768 seeking approval to manufacture, use, import, offer to sell or sell Defendant's generic products before the expiration date of the '514 patent. Upon information and belief, the products described in ANDA No. 209768 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).

45. 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 Defendant's generic products upon approval.

46. Upon information and belief, upon approval, Par will take active steps to encourage the use of Defendant's generic products by physicians and/or patients with the knowledge and intent that Defendant's 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 Par. Pursuant to 21 C.F.R. § 314.94, Par is required to copy The FDA approved Tecfidera® labeling. Upon information and belief, Par will thus induce the infringement of at least one claim including at least claim 1 of the '514 patent.

47. Upon information and belief, if the FDA approves ANDA No. 209768, Par 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 Defendant's generic products are a material part of the claimed invention, wherein Par knows that physicians will prescribe and patients will

use Defendant's generic products in accordance with the instructions and/or label provided by Par 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, Par will thus contribute to the infringement of at least one claim including at least claim 1 of the '514 patent.

48. Upon information and belief, Par's actions relating to Par's ANDA No. 209768 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Par.

49. If Par'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 Defendant Par 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 Par has infringed at least one claim including at least claim 1 of the '999 patent through Par's submission of ANDA No. 209768 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendant's 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 Par's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendant's 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 Defendant's 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 Par, and all persons acting in concert with Par, from the manufacture, use, import, offer for sale and sale of Defendant's generic products until the expiration of the '999 patent, or such later date as the Court may determine;

5. enjoin Par, and all persons acting in concert with Par, from seeking, obtaining or maintaining approval of Par's ANDA No. 209768 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 Par has infringed at least one claim including at least claim 1 of the '514 patent through Par's submission of ANDA No. Par to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendant's 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 Par's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendant's 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 Defendant's 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 Par, and all persons acting in concert with Par, from the manufacture, use, import, offer for sale and sale of Defendant's generic products until the expiration of the '514 patent, or such later date as the Court may determine;

10. enjoin Par and all persons acting in concert with Par, from seeking, obtaining or maintaining approval of Par's ANDA No. 209768 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

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-188
sbalick@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiffs
Biogen International GmbH
and Biogen MA Inc.

Of Counsel:

James B. Monroe
Li Feng
Sanya Sukduang
Andrew E. Renison
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000

Dated: June 30, 2017