IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 1:17-CV-116

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, "Biogen" or "Plaintiffs"), by way of Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan" 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, Mylan is a corporation organized under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

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

NATURE OF THE ACTION

6. This is an action for patent infringement of U.S. Patent Nos. 6,509,376 ("the '376 patent"), 7,320,999 ("the '999 patent"), 7,619,001 ("the '001 patent"), 7,803,840 ("the '840 patent"), 8,759,393 ("the '393 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 Mylan's filing of Abbreviated New Drug Application ("ANDA") No. 210531 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. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because Mylan is incorporated in West Virginia.

9. This Court has personal jurisdiction over Mylan because Mylan is incorporated in West Virginia.

10. Upon information and belief, Mylan has been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210531.

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

FIRST COUNT FOR PATENT INFRINGEMENT ('376 PATENT)

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

13. The U.S. Patent and Trademark Office ("PTO") issued the '376 patent on January 21, 2003, entitled "Utilization of Dialkyfumarates." The '376 patent identifies Rajendra Kumar Joshi and Hans-Peter Strebel as inventors of the claimed subject matter. A copy of the '376 patent is attached hereto as Exhibit A.

14. Biogen International GmbH is the owner of the '376 patent by virtue of assignment.

15. The '376 patent expires on October 29, 2019, excluding any pediatric exclusivity or patent term extension.

16. The '376 patent is directed to and claims, *inter alia*, pharmaceutical preparations and compositions.

17. The '376 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.

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

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

20. Upon information and belief, Mylan submitted ANDA No. 210531 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.

21. Biogen received a letter from Mylan dated June 1, 2017 ("the Notice Letter"), purporting to include a Notice of Certification for ANDA No. 210531 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '376 patent. The Notice Letter did not allege non-infringement as to at least one claim of the '376 patent.

22. Mylan thus has actual knowledge of the '376 patent.

23. 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 '376 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

24. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim including at least claim 1 of the '376 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 210531 seeking approval to manufacture, use, import, offer to sell or sell Defendant's generic products before the expiration date of the '376 patent. Upon information and belief, the products described in ANDA No. 210531 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '376 patent under 35 U.S.C. § 271(e)(2)(A).

25. Upon information and belief, Mylan will manufacture, market, import, use, sell and/or offer to sell Defendant's generic products in the United States in connection with ANDA No. 210531 upon approval.

26. Upon information and belief, Mylan will directly infringe at least one claim including at least claim 1 of the '376 patent when it proceeds to manufacture, market, import, use, sell and/or offer to sell Defendant's generic products in the United States in connection with ANDA No. 210531 upon approval.

27. Upon information and belief, Mylan's actions relating to Mylan's ANDA No. 210531 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Mylan.

28. If Mylan's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '376 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 ('999 PATENT)

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

30. The 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 B.

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

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