IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN MA INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
PRINSTON PHARMACEUTICAL INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Biogen MA Inc. ("Biogen" or "Plaintiff"), by way of Complaint against Defendant Prinston Pharmaceutical Inc. ("Prinston" or "Defendant"), alleges as follows:

THE PARTIES

1. Biogen 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.

2. 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 patent covers Tecfidera®, which is marketed and sold this judicial district and throughout the United States for the treatment of relapsing forms of multiple sclerosis.

3. Upon information and belief, Prinston is a corporation organized under the laws of Delaware, having a principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512.

4. Upon information and belief, Prinston 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

5. This is an action for patent infringement of U.S. Patent No. 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 Prinston's filing of Abbreviated New Drug Application ("ANDA") No. 210512 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 patent.

JURISDICTION AND VENUE

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

7. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because Prinston is incorporated in Delaware.

8. This Court has personal jurisdiction over Prinston because Prinston is incorporated in Delaware.

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

10. Prinston "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). Prinston'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, Prinston "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, Prinston will engage in marketing of its proposed ANDA product in Delaware upon approval of its ANDA.

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

12. Prinston's ANDA filing, regarding the '514 patent, has a substantial connection with this district because it reliably and non-speculatively predicts activities by Prinston in this district.

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

14. This Court also has personal jurisdiction over Prinston because, *inter alia*, Prinston 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, Prinston, 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 Wellbutrin® and Requip®. A list of generic products sold by Prinston can be found at http://www.prinstonpharm.com/Products_List.html#a, the contents of which are incorporated here by reference. Upon information and belief, Prinston 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.

15. Upon information and belief, Prinston is registered to do business in Delaware (File No. 4742737). *See* https://icis.corp.delaware.gov/Ecorp/EntitySearch/NameSearch.aspx. (Accessed June 5, 2017).

16. Upon information and belief, Prinston maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, American Incorporators Ltd., located at 1013 Centre Road Suite 403-A, Wilmington, DE 19805.

17. Upon information and belief, Prinston has appointed American Incorporators Ltd., located at 1013 Centre Road Suite 403-A, Wilmington, DE 19805 for receipt and service of process as its registered agent.

18. Prinston has availed itself of Delaware courts through the assertion of counterclaims.

19. Upon information and belief, Prinston has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210512.

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

COUNT FOR PATENT INFRINGEMENT (’514 PATENT)

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

22. The U.S. Patent and Trademark Office ("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 A.

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

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

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

26. The '514 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.

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

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

29. Upon information and belief, Prinston submitted ANDA No. 210512 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 generic products containing 120 mg and 240 mg of dimethyl fumarate ("Defendant's generic products") in the United States.

30. Biogen received a letter from Prinston dated May 25, 2017 ("the Notice Letter") purporting to include a Notice of Certification for ANDA No. 210512 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 at least one claim of the '514 patent.

31. Prinston thus has actual knowledge of the ’514 patent.

32. 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).

33. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Prinston 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. 210512 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. 210512 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).

34. Upon information and belief, Prinston will manufacture, market, import, use, sell and/or offer to sell Defendant’s generic products in the United States in connection with ANDA No. 210512 upon approval.

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

36. Upon information and belief, upon approval, Prinston 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 claim 1 of the ’514 patent, for the pecuniary benefit of Prinston. Pursuant to 21 C.F.R. § 314.94, Prinston is required to copy the

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

37. On information and belief, if the FDA approves ANDA No. 210512, Prinston 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 Prinston knows that physicians will prescribe and patients will use Defendant’s generic products in accordance with the instructions and/or label provided by Prinston 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, Prinston will thus contribute to the infringement of at least one claim including at least claim 1 of the ’514 patent.

38. Upon information and belief, Prinston’s actions relating to Prinston’s ANDA No. 210512 complained of herein were done by and for the benefit of Prinston.

39. If Prinston’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 Prinston 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 Prinston has infringed at least one claim including at least claim 1 of the ’514 patent through Prinston’s submission of ANDA

No. 210512 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;

2. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Prinston'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);

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 '514 patent, or such later date as the Court may determine;

4. enjoin Prinston, and all persons acting in concert with Prinston, 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;

5. enjoin Prinston, and all persons acting in concert with Prinston, from seeking, obtaining or maintaining approval of Prinston's ANDA No. 210512 until the expiration of the '514 patent, or such later date as the Court may determine;

6. 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

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

ASHBY & GEDDES

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