IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
ZYDUS PHARMACEUTICALS (USA) INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Biogen International GmbH ("Biogen" or "Plaintiff"), by way of Complaint against Defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus" or "Defendant"), alleges as follows:

THE PARTIES

1. Biogen is a Swiss corporation with its principal place of business in Zug, Switzerland at Landis + Gyr-Strasse 3, 6300 Zug, Switzerland.

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

3. Upon information and belief, Zydus is a corporation organized under the laws of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

4. Upon information and belief, Zydus 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. 6,509,376 ("the '376 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 Zydus' filing of Abbreviated New Drug Application ("ANDA") No. 210538 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.

6. Biogen MA Inc. and Biogen International GmbH filed a separate action involving the same ANDA in this Court against Zydus for patent infringement of U.S. Patent Nos. 8,399,514 ("the '514 patent") and 7,320,999 ("the '999 patent"), in *Biogen MA Inc. v. Zydus Pharmaceuticals (USA) Inc.*, No. 1:17-cv-00954-LPS (D. Del. filed July 14, 2017) ("the First Delaware Suit"), which on February 2, 2018 was consolidated with numerous related actions in this Court in *Biogen International GmbH v. Amneal Pharmaceuticals LLC*, No. 1:17-cv-00823-LPS (consolidated).

7. Biogen International GmbH and Biogen MA Inc. also filed an action against Zydus involving the same ANDA in the District of New Jersey for patent infringement of the '514 patent and the '999 patent, in a case captioned *Biogen International GmbH and Biogen MA Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 3:17-cv-4857-BRM-LHG ("the New Jersey Suit"). The New Jersey Suit was dismissed in favor of continued prosecution of the First

Delaware Suit after Zydus answered that it would not contest subject matter jurisdiction, venue or personal jurisdiction in Delaware for the alleged claims arising under 35 U.S.C. § 271(e)(2) related to Zydus' ANDA No. 210538. *See* Notice of Voluntary Dismissal ordered in the New Jersey Suit on October 31, 2017; *see also* October 16, 2017 Answer in the First Delaware Suit at ¶¶ 7-8, 10-14.

8. The First Delaware Suit and the New Jersey Suit were filed in response to a letter from Zydus dated June 1, 2017 ("the First Notice Letter"), which purported to include a Notice of Certification for ANDA No. 210538 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '514 patent and the '999 patent. The First Delaware Suit and the New Jersey Suit included counts for infringement of the '514 patent and the '999 patent.

9. This complaint is filed in response to a new, second letter from Zydus dated March 12, 2018 ("the Second Notice Letter"), which purported to include a Notice of Certification for ANDA No. 210538 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '376 patent.

JURISDICTION AND VENUE

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

11. Zydus did not contest subject matter jurisdiction, venue or personal jurisdiction in this Court for purposes of resolving Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) in the First Delaware Suit directed to Zydus's filing of ANDA No. 210538. *See* October 16, 2017 Answer in First Delaware Suit at ¶¶ 7-8, 10-14. Biogen likewise alleges claims arising under 35 U.S.C. § 271(e)(2) here related to Zydus's ANDA No. 210538. Accordingly, for at least the foregoing reasons, venue and personal jurisdiction are proper in this Court, and this Court has subject matter jurisdiction over Biogen's present claims against Zydus.

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

13. Zydus "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). Zydus' "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, Zydus "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, Zydus will engage in marketing of its proposed ANDA products in Delaware upon approval of its ANDA.

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

15. Zydus' ANDA filing regarding the '376 patent has a substantial connection with this district because it reliably and non-speculatively predicts activities by Zydus in this district.

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

17. Upon information and belief, Zydus has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210538.

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

FIRST COUNT FOR PATENT INFRINGEMENT ('376 PATENT)

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

20. 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.

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

22. The '376 patent expires on April 1, 2019, which includes an interim patent term extension for a period of one year, excluding any pediatric exclusivity or patent term extension.

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

24. 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.

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

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

27. Upon information and belief, Zydus submitted ANDA No. 210538 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.

28. The Second Notice Letter purported to include a Notice of Certification for ANDA No. 210538 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '376 patent. The Second Notice Letter did not allege non-infringement as to at least one claim of the '376 patent.

29. Zydus thus has actual knowledge of the '376 patent.

30. 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).

31. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus 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. 210538 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. 210538 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).

32. Upon information and belief, Zydus will manufacture, market, import, use, sell and/or offer to sell Defendant's generic products in the United States in connection with ANDA No. 210538 upon approval.

33. Upon information and belief, Zydus 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. 210538 upon approval.

34. Upon information and belief, Zydus' actions relating to Zydus' ANDA No. 210538 complained of herein were done by and for the benefit of Zydus.

35. If Zydus' 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 remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Biogen respectfully requests that the Court enter judgment in its favor and against Defendant Zydus 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 Zydus has infringed at least one claim, including at least claim 1 of the '376 patent, through Zydus' submission of ANDA No. 210538 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 '376 patent;

2. enter judgment under 35 U.S.C. § 271(a) that Zydus' 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 '376 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(a);

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

4. enjoin Zydus, and all persons acting in concert with Zydus, from the manufacture, use, import, offer for sale and sale of Defendant's generic products until the expiration of the '376 patent, or such later date as the Court may determine;

5. enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus' ANDA No. 210538 until the expiration of the '376 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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