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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
|---|---|
| BIOGEN INTERNATIONAL GMBH,<br><br>Plaintiff,<br><br>v.<br><br>ZYDUS PHARMACEUTICALS (USA) INC.,<br><br>Defendant. | Civil Action No.:_____ |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Biogen International GmbH ("Biogen" or "Plaintiff"), by way of Complaint against Defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus" 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. 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 New Jersey 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 previous 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. et al. v. Zydus Pharmaceuticals (USA) Inc.*, No. 3:17-cv-04857-BPM-LHG (D.N.J. filed June 30, 2017) ("the First New Jersey Suit"). The First New Jersey Suit was dismissed in favor of continued prosecution of a separate action involving the same ANDA in the District of Delaware against

Zydus for patent infringement of the '514 patent and the '999 patent, in a case captioned *Biogen MA Inc. et al. v. Zydus Pharmaceuticals (USA) Inc.*, No. 1:17-cv-00954-LPS (D. Del. filed July 14, 2017) ("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's ANDA No. 210538. *See* Notice of Voluntary Dismissal ordered in the First New Jersey Suit on October 31, 2017; *see also* October 16, 2017 Answer in the First Delaware Suit at ¶¶7-8, 10-14.

7. The First New Jersey Suit and the First Delaware 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.

8. 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. Biogen filed a complaint against Zydus in the District of Delaware on April 25, 2018 in response to the Second Notice Letter.

## JURISDICTION AND VENUE

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

10. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because Zydus is incorporated in New Jersey.

11. This Court has personal jurisdiction over Zydus because Zydus is incorporated in New Jersey.

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

13. 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)**

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

15. 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.

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

17. 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.

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

19. 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.

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

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

22. 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.

23. 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.

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

25. 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).

26. 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).

27. 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.

28. 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.

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

30. 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.

Respectfully submitted,

s/John E. Flaherty
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Dated: April 25, 2018

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**CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

Pursuant to Local Civil Rule 11.2, I hereby certify that certain of the patents-in-suit in the above captioned action are the subject of the following actions:

**A. The following case has been filed in the District of New Jersey and is hereby identified as a related case:**

1. Biogen International GmbH and Biogen MA Inc. v. Zydus Pharmaceuticals (USA) Inc., C.A. No. 17-4857-BRM-LHG (District of New Jersey) (dismissed)

**B. The following cases all have been filed in the District of Delaware and are hereby identified as related cases:**

1. Biogen International GmbH and Biogen MA Inc. v. Amneal Pharmaceuticals LLC, C.A. No. 17-823-LPS (Consolidated)

2. Biogen International GmbH and Biogen MA Inc. v. Banner Life Sciences LLC, C.A. No. 18-582-LPS

3. Biogen MA Inc. v. Caribe Holdings (Cayman) Co. Ltd. DBA Puracap Caribe, et al., C.A. No. 18-121-LPS

4. Biogen International GmbH v. Impax Laboratories, Inc., C.A. No. 18-350-LPS

5. Biogen International GmbH v. MSN Laboratories Private Ltd., et al., C.A. No. 18-337-LPS

6. Biogen International GmbH and Biogen MA Inc. v. Par Pharmaceutical, Inc., C.A. No. 17-873-LPS (dismissed)

7. Biogen International GmbH v. Zydus Pharmaceuticals (USA) Inc., C.A. No. Unassigned (filed April 25, 2018)

**C. The following cases all have been filed in other districts, and are hereby identified as related cases:**

1. Biogen International GmbH and Biogen MA Inc. v. Accord Healthcare Inc., C.A. No. 17-612-WO-LPA (Middle District of North Carolina) (dismissed)

2. Biogen International GmbH and Biogen MA Inc. v. Mylan Pharmaceuticals Inc., C.A. No. 17-116-IMK (Northern District of West Virginia)

3. Biogen International GmbH and Biogen MA Inc. v. Par Pharmaceutical, Inc., C.A. No. 17-4984-JMF (Southern District of New York) (dismissed)

4. Biogen International GmbH and Biogen MA Inc. v. Sandoz Inc., C.A. No. 17-1606-MEH (District of Colorado) (dismissed)

5. Biogen International GmbH and Biogen MA Inc. v. Stason Pharmaceuticals, Inc. and Sawai Pharmaceutical Co., Ltd., C.A. No. 17-1133-CJC-JCG (Central District of California) (dismissed)

Dated: April 25, 2018

Respectfully submitted,

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