IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	Civil Action No. 1:18-cv-00623-LPS
	)	
ZYDUS PHARMACEUTICALS (USA) INC.	)	
	)	
Defendant.	)	
	)	

ZYDUS PHARMACEUTICALS (USA) INC.'S
ANSWER AND AFFIRMATIVE DEFENSES

Defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus"), for its Answer and Affirmative Defenses to the Complaint of Biogen International GmbH ("Biogen"), states as follows:

All averments not expressly admitted are denied.

The Parties

1. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 1 and therefore denies them.

2. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in the first sentence of paragraph 2 and therefore denies them. Zydus admits that U.S. Patent No. 6,509,376 ("the '376 patent") is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with New Drug Application ("NDA") No. 204063, for which the proprietary name is identified as TECFIDERA. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegation that "Tecfidera® … is marketed and sold in this judicial district and throughout the United States

for the treatment of relapsing forms of multiple sclerosis" and therefore denies that allegation. Zydus denies all other allegations of paragraph 2.

3. Admitted.

4. Zydus admits that it sells pharmaceutical products, including generic pharmaceutical products, in the United States, and that those pharmaceutical products are sold in the State of Delaware. Zydus denies all other allegations in paragraph 4.

Nature of the Action

5. The allegations in paragraph 5 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that it submitted Abbreviated New Drug Application ("ANDA") No. 210538 to the United States Food and Drug Administration ("FDA") seeking approval to import and sell dimethyl fumarate delayed-release capsules, 120 mg and 240 mg in the United States. Zydus admits that ANDA No. 210538 was amended to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '376 patent. Zydus further admits that Biogen's Complaint purports to be a civil action alleging infringement of the '376 patent under Title 35 of the United States Code. Zydus denies all other allegations in paragraph 5.

6. Zydus admits that Biogen and Biogen MA Inc. filed Civil Action No. 1:17-cv-00954-LPS ("the First Delaware Suit"), which was consolidated with Civil Action No. 1:17-cv-00823-LPS, in this Court, and in which Biogen and Biogen MA Inc. asserted claims against Zydus for alleged infringement of U.S. Patent Nos. 8,399,514 ("the '514 patent") and 7,320,999 ("the '999 patent") in connection with Zydus's submission of ANDA No. 210538. Zydus denies all other allegations in paragraph 6.

7. Zydus admits that Biogen and Biogen MA Inc. filed Civil Action No. 3:17-cv-04857-BRM-LHG ("the New Jersey Suit") in the United States District Court of the District of New Jersey, in which Biogen and Biogen MA Inc. also asserted claims against Zydus for infringement of the '514 patent and the '999 patent in connection with Zydus's submission of ANDA No. 210538. Zydus admits that, in the First Delaware Suit, it did not contest subject matter jurisdiction, personal jurisdiction, or venue in this Court solely for purposes of Biogen and Biogen MA Inc.'s alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus in the First Delaware Suit and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Zydus admits that the New Jersey Suit was dismissed. Zydus denies all other allegations in paragraph 7.

8. Zydus admits that, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and (iv), it transmitted a letter dated June 1, 2017 (the "June 1, 2017 letter") to Biogen notifying Biogen that Zydus submitted ANDA No. 210538 to FDA. Zydus further admits that the June 1, 2017 letter states that ANDA No. 210538 included a Paragraph IV certification with respect to the '514 patent and the '999 patent. Zydus further admits that the First Delaware Suit and the New Jersey Suit included counts for alleged infringement of the '514 patent and the '999 patent. Zydus denies all other allegations in paragraph 8.

9. Zydus admits that, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and (iv), it transmitted a letter dated March 12, 2018 (the "March 12, 2018 letter") to Biogen notifying Biogen that Zydus submitted ANDA No. 210538 to FDA and that ANDA No. 210538 was amended to include a Paragraph IV certification with respect to the '376 patent. Zydus denies all other allegations in paragraph 9.

Jurisdiction and Venue

10. The allegations in paragraph 10 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest subject matter jurisdiction in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the '376 patent in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Zydus denies all other allegations in paragraph 10.

11. The allegations in paragraph 11 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that it did not contest subject matter jurisdiction, personal jurisdiction, or venue in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the '514 patent and the '999 patent in the First Delaware Suit and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Further, Zydus does not contest subject matter jurisdiction, personal jurisdiction, or venue in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the '376 patent in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Zydus denies all other allegations in paragraph 11.

12. The allegations in paragraph 12 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the '376 patent in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Zydus denies all other allegations in paragraph 12.

13. The allegations in paragraph 13 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that it submitted ANDA No. 210538 to the FDA seeking approval to import and sell dimethyl fumarate delayed-release capsules, 120 mg and 240 mg in the United States. Zydus does not contest personal jurisdiction in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the '376 patent in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Zydus denies all other allegations in paragraph 13.

14. The allegations in paragraph 14 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the '376 patent in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Zydus denies all other allegations in paragraph 14.

15. The allegations in paragraph 15 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the '376 patent in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Zydus denies all other allegations in paragraph 15.

16. The allegations in paragraph 16 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against

Zydus related to the ’376 patent in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Zydus denies all other allegations in paragraph 16.

17. The allegations in paragraph 17 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that it submitted to FDA, and seeks FDA approval of, ANDA No. 210538. Zydus denies all other allegations in paragraph 17.

18. The allegations in paragraph 18 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for purposes of Biogen’s alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the ’376 patent in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 210538. Zydus denies all other allegations in paragraph 18.

First Count for Patent Infringement (’376 Patent)

19. Zydus realleges, and incorporates in full herein, its answers to each preceding paragraph.

20. Zydus admits on information and belief that Exhibit A to the Complaint purports to be a copy of the ’376 patent and that the ’376 patent was issued by the United States Patent and Trademark Office. Zydus further admits that Exhibit A is titled “Utilization of dialkyfumarates” and indicates on its face a January 21, 2003 issue date. Zydus further admits that Exhibit A identifies Rajendra Kumar Joshi and Hans-Peter Strebel as inventors. Zydus denies all other allegations in paragraph 20.

21. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 21 and therefore denies them.

22. Zydus admits that the Orange Book lists April 1, 2019 as the expiration date for the ’376 patent. Zydus denies all other allegations in paragraph 22.

23. The allegations in paragraph 23 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 23 accurately and completely recite the limitations of the claims in the ’376 patent and therefore denies the allegations in paragraph 23.

24. Zydus admits that the ’376 patent is listed in the Orange Book in connection with NDA No. 204063. Zydus denies all other allegations in paragraph 24.

25. Zydus admits that FDA’s website, www.accessdata.fda.gov/scripts/cder/daf/index.cfm, indicates that NDA No. 204063 was approved on March 27, 2013, and that the Drug Name listed for NDA No. 204063 is Tecfidera®. Zydus further admits that the 2013 prescribing information for Tecfidera® found at https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204063lbl.pdf states that “TECFIDERA is indicated for the treatment of patients with relapsing forms of multiple sclerosis.” Zydus denies all other allegations in paragraph 25.

26. Zydus admits that FDA’s website, www.accessdata.fda.gov/scripts/cder/daf/index.cfm, indicates that the Drug Name listed for NDA No. 204063 is Tecfidera®, that the “Active Ingredients” listed for NDA No. 204063 is dimethyl fumarate, and that the “Dosage Form/Route” listed for NDA No. 204063 is “capsule,

delayed release; oral." Zydus lacks knowledge or information sufficient to form a belief about the other allegations in paragraph 26 and therefore denies them.

27. Zydus admits that it submitted ANDA No. 210538 to FDA seeking approval to import into, and sell within, the United States the dimethyl fumarate delayed-release capsules, 120 mg and 240 mg described in ANDA No. 210538. Zydus denies all other allegations in paragraph 27.

28. Zydus admits that, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and (iv), it transmitted the March 12, 2018 letter to Biogen notifying Biogen that Zydus submitted ANDA No. 210538 to FDA. Zydus further admits that the March 12, 2018 letter states that ANDA No. 210538 was amended to include a Paragraph IV certification with respect to the '376 patent. Zydus denies that the allegations accurately and completely recite the March 12, 2018 letter and therefore denies them. Zydus does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '376 patent in this or any ensuing litigation or other proceeding. *See Abbott Labs, Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 727 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because ANDA filers are "not limited to the invalidity and noninfringement theories raised in its paragraph IV notice letters"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, at *4 (S.D.N.Y. Mar. 6, 2000) ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Zydus denies all other allegations in paragraph 28.

29. Zydus admits that the March 12, 2018 letter states that ANDA No. 210538 was amended to include a Paragraph IV certification with respect to the '376 patent. Zydus denies

that it has infringed any valid and enforceable claim of the '376 patent. Zydus denies all other allegations in paragraph 29.

30. Denied.

31. Denied.

32. Zydus admits that it submitted ANDA No. 210538 to the FDA seeking approval to import into, and sell within, the United States the dimethyl fumarate delayed-release capsules, 120 mg and 240 mg described in ANDA No. 210538. Zydus denies all other allegations in paragraph 32.

33. Denied.

34. Zydus admits that it submitted ANDA No. 210538 to the FDA to obtain approval to import into, and sell within, the United States the dimethyl fumarate delayed-release capsules, 120 mg and 240 mg described in ANDA No. 201538. Zydus denies all other allegations in paragraph 34.

35. Denied.

Prayer for Relief

Zydus denies that Biogen is entitled to the general or specific relief requested against Zydus, or to any relief whatsoever, and prays for judgment in favor of Zydus dismissing this action with prejudice and awarding Zydus its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Zydus avers and asserts the following Affirmative Defenses to Biogen's Complaint.

First Affirmative Defense:
Noninfringement of U.S. Patent No. 6,509,376

Biogen will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed products described in ANDA No. 210538 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '376 patent.

Second Affirmative Defense:
Invalidity of U.S. Patent No. 6,509,376

Upon information and belief, the claims of the '376 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

Reservation of Defenses

Zydus hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

Respectfully submitted,

Dated: June 1, 2018

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (No. 110)
David A. Bilson (No. 4986)
PHILLIPS GOLDMAN MCLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, Delaware 19806-4204
Phone: (302) 655-4200

Fax: (302) 655-4210
jcp@pgmhlaw.com
dab@pgmhlaw.com

Of counsel
Michael J. Gaertner (*to be admitted pro hac*)
Andy J. Miller (*to be admitted pro hac*)
Timothy F. Peterson (*to be admitted pro hac*)
Jonathan B. Turpin (*to be admitted pro hac*)
LOCKE LORD LLP
111 S. Wacker Drive
Chicago, IL 60606
(312) 443-0700

Attorneys for Defendant
Zydus Pharmaceuticals (USA) Inc.