IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

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

3. Upon information and belief, Teva is a corporation organized under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

4. Upon information and belief, Teva 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 Nos. 6,509,376 ("the '376 patent") and 7,320,999 ("the '999 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 Teva's filing of Abbreviated New Drug Application ("ANDA") No. 210290 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 generic dimethyl fumarate delayed-release capsules prior to the expiration of the asserted patents.

6. Plaintiff Biogen International GmbH and Biogen MA. Inc. filed a separate action in this Court against Teva for patent infringement, which included counts for infringement of the '376 patent, the '999 patent and U.S. Patent No. 8,399,514 ("the '514 patent"), in *Biogen International GmbH v. Teva Pharmaceuticals USA, Inc.*, No. 1:17-cv-00829-LPS (D. Del. filed June 26, 2017) ("the First Suit"). The First Suit was filed in response to a letter from Teva dated May 23, 2017 ("the First Notice Letter"), which purported to include a Notice of Certification for ANDA No. 210290 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '376 patent, the '999 patent and the '514 patent. In addition to the counts for infringement of the '376 patent and the '999 patent, the First Suit included a count for infringement of the '514 patent.

7. This complaint is filed in response to a second letter from Teva dated August 18, 2017 ("the Second Notice Letter"), which purported to include a Notice of Certification for

ANDA No. 210290 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to only the ’376 patent and the ’999 patent.

8. This complaint does not include a count for infringement of the ’514 patent because the Second Notice Letter did not mention the ’514 patent. But based on information and belief, Teva is maintaining its certification as to the ’514 patent, as well as to the ’376 and ’999 patents, set out in the First Notice Letter. Thus, Biogen will continue to prosecute all infringement counts presented in the First Suit. Further, Biogen will request to consolidate this new action with the First Suit.

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 Teva is incorporated in Delaware.

11. This Court has personal jurisdiction over Teva because Teva is incorporated in Delaware.

12. This Court also has personal jurisdiction over Teva because at least one provision of 10 Del. C. § 3104(c) is satisfied. On information and belief, Teva 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. Teva "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," on 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). Teva's "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Id.* at 760. On information and belief, Teva "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. On information and belief, Teva will engage in marketing of its proposed ANDA products in Delaware upon approval of its ANDA.

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

15. Teva's ANDA filing, regarding the '376 patent and the '999 patent, has a substantial connection with this district because it reliably and non-speculatively predicts activities by Teva in this district.

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

17. This Court also has personal jurisdiction over Teva because, *inter alia*, Teva 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, Teva, 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

Lipitor® and Zithromax®. A list of generic products sold by Teva can be found at https://www.tevagenerics.com/products/product-search-results, the contents of which are incorporated herein by reference. Upon information and belief, Teva 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.

18. Upon information and belief, Teva is registered with the Delaware Board of Pharmacy as "Pharmacy-Wholesale" (License Nos. A4-0001468 and A4-0001447) and a "Distributor/Manufacturer CSR" (License Nos. DM-0007115 and DM-0006546). *See* https://dpronline.delaware.gov/mylicense%20weblookup/Search.aspx?facility=Y. (Accessed September 26, 2017).

19. Upon information and belief, Teva is registered to do business in Delaware. *See* https://icis.corp.delaware.gov/Ecorp/EntitySearch/NameSearch.aspx. (Accessed September 26, 2017).

20. Upon information and belief, Teva maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporate Creations Network Inc., located at 3411 Silverside Road, Tatnall Building Ste. 104, Wilmington, DE 19810.

21. Upon information and belief, Teva has appointed Corporate Creations Network Inc., located at 3411 Silverside Road, Tatnall Building Ste. 104, Wilmington, DE 19810 for receipt and service of process as its registered agent.

22. Teva has availed itself of Delaware courts by filing suits as plaintiff. Furthermore, Teva has availed itself of Delaware courts through the assertion of counterclaims.

23. Upon information and belief, Teva has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210290.

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

FIRST COUNT FOR PATENT INFRINGEMENT ('376 PATENT)

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

26. 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.

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

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

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

30. 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.

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

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

33. Upon information and belief, Teva submitted ANDA No. 210290 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 dimethyl fumarate delayed-release capsules containing 120 mg and 240 mg of dimethyl fumarate ("Defendant's generic products") in the United States.

34. The Second Notice Letter purported to include a Notice of Certification for ANDA No. 210290 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 alleged non-infringement of all claims of the '376 patent, but Teva has not yet provided materials supporting this allegation.

35. Teva thus has actual knowledge of the '376 patent.

36. 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).

37. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva 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. 210290 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. 210290 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).

38. Upon information and belief, Teva will manufacture, market, import, use, sell and/or offer to sell Defendant's generic products in the United States in connection with ANDA No. 210290 upon approval.

39. Upon information and belief, Teva 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. 210290 upon approval.

40. Upon information and belief, Teva's actions relating to Teva's ANDA No. 210290 complained of herein were done by and for the benefit of Teva.

41. If Teva'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)

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

43. 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.

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

45. The '999 patent expires on May 18, 2020, which includes 202 days of Patent Term Adjustment under 35 U.S.C. § 154(b), excluding any pediatric exclusivity or patent term extension.

46. The '999 patent is directed to and claims, *inter alia*, methods of treating multiple sclerosis.

47. The '999 patent is listed in the Orange Book for NDA No. 204063 for dimethyl fumarate delayed-release capsules.

48. The Second Notice Letter purported to include a Notice of Certification for ANDA No. 210290 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '999 patent. The Second Notice Letter did not allege non-infringement as to at least one claim of the '999 patent.

49. Teva thus has actual knowledge of the '999 patent.

50. 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 '999 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

51. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim including at least claim 1 of the '999 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 210290 seeking approval to manufacture, use, import, offer to sell or sell Defendant's generic products before the expiration date of the '999 patent. Upon information and belief, the products described in ANDA No. 210290 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '999 patent under 35 U.S.C. § 271(e)(2)(A).

52. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 of the '999 patent by the use of Defendant's generic products upon approval.

53. Upon information and belief, upon approval, Teva 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 at least claim 1 of the '999 patent,

for the pecuniary benefit of Teva. Pursuant to 21 C.F.R. § 314.94, Teva is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Teva will thus induce the infringement of at least one claim including at least claim 1 of the '999 patent.

54. On information and belief, if the FDA approves ANDA No. 21290, Teva 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 '999 patent, wherein Defendant's generic products are a material part of the claimed invention, wherein Teva knows that physicians will prescribe and patients will use Defendant's generic products in accordance with the instructions and/or label provided by Teva in practicing at least one claim including at least claim 1 of the '999 patent, and wherein dimethyl fumarate delayed-release capsules are not staple articles or commodities of commerce suitable for substantial non-infringing use. On information and belief, Teva will thus contribute to the infringement of at least one claim including at least claim 1 of the '999 patent.

55. Upon information and belief, Teva's actions relating to Teva's ANDA No. 210290 complained of herein were done by and for the benefit of Teva.

56. If Teva's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '999 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 Teva 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 Teva has infringed at least one claim including at least claim 1 of the '376 patent through Teva's submission of ANDA No.

210290 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 Teva'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 '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 Teva, and all persons acting in concert with Teva, 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 Teva, and all persons acting in concert with Teva, from seeking, obtaining or maintaining approval of Teva's ANDA No. 210290 until the expiration of the '376 patent, or such later date as the Court may determine;

6. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim including at least claim 1 of the '999 patent through Teva's submission of ANDA No. 210290 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 '999 patent;

7. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Teva'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 '999 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271 (b) and/or (c);

8. 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 '999 patent, or such later date as the Court may determine;

9. enjoin Teva, and all persons acting in concert with Teva, from the manufacture, use, import, offer for sale and sale of Defendant's generic products until the expiration of the '999 patent, or such later date as the Court may determine;

10. enjoin Teva, and all persons acting in concert with Teva, from seeking, obtaining or maintaining approval of Teva's ANDA No. 210290 until the expiration of the '999 patent, or such later date as the Court may determine;

11. 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

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

ASHBY & GEDDES

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