IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
ACCORD HEALTHCARE INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Biogen International GmbH ("Biogen" or "Plaintiff"), by way of Complaint against Defendant Accord Healthcare Inc. ("Accord" 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 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, Accord is a corporation organized under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210B, Durham, NC 27703.

4. Upon information and belief, Accord 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. 7,619,001 ("the '001 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 Accord's filing of Abbreviated New Drug Application ("ANDA") No. 210499 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 containing 120 mg and 240 mg of dimethyl fumarate ("Defendant's generic products") prior to the expiration of the asserted patent.

6. Biogen International GmbH and Biogen MA Inc. filed a separate action involving the same ANDA in this Court against Accord for patent infringement of U.S. Patent Nos. 6,509,376 ("the '376 patent"), 7,320,999 ("the '999 patent"), and 8,399,514 ("the '514 patent") in *Biogen International GmbH, et al. v. Accord Healthcare Inc.*, No. 1:17-cv-00872-LPS (D. Del. filed June 30, 2017) ("the First Delaware Suit"), which on February 2, 2018 was consolidated in this Court in *Biogen International GmbH, et al. v. Amneal Pharmaceuticals LLC*, No. 1:17-cv-00823-LPS (consolidated).

7. Biogen International GmbH and Biogen MA Inc. also filed an action against Accord involving the same ANDA in the Middle District of North Carolina for patent infringement of the '376 patent, the '999 patent, and the '514 patent in a case captioned *Biogen International GmbH, et al. v. Accord Healthcare Inc.*, C.A. No. 1:17-cv-00612-WO-LPA (M.D.N.C. filed June 30, 2017) ("the First North Carolina Suit"). The First North Carolina Suit was dismissed in favor of continued prosecution of the First Delaware Suit after Accord answered that it would not contest subject matter jurisdiction, venue, or personal jurisdiction in Delaware for the alleged claims

related to Accord's ANDA No. 210499. *See* Notice of Voluntary Dismissal ordered in the First North Carolina Suit on October 27, 2017; *see also* October 16, 2017 Answer in the First Delaware Suit in the of Section Jurisdiction and Venue.

8. The First Delaware Suit and the First North Carolina Suit were filed in response to a letter from Accord dated May 30, 2017 ("the First Notice Letter"), which purported to include a Notice of Certification for ANDA No. 210499 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '376 patent, '999 patent, and '514 patent. The First Delaware Suit and the First North Carolina Suit included counts for infringement of the '376 patent, '999 patent, and '514 patent.

9. This complaint is filed in response to a new, second letter from Accord dated December 29, 2018 ("the Second Notice Letter"), which purported to include a Notice of Certification for ANDA No. 210499 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '001 patent.

JURISDICTION AND VENUE

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

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

12. Upon information and belief, venue and jurisdiction are proper for this proceeding. Accord has agreed to not contest venue or personal jurisdiction in this Court for this matter. See Stipulated Order Regarding Personal Jurisdiction, Venue, Consolidation of Actions, and Stay of Action, which has been filed concurrently herewith, and a copy of which is attached hereto as Exhibit A.

13. Accord did not contest subject matter jurisdiction, venue or personal jurisdiction in this Court for purposes of resolving Biogen's alleged claims in the First Delaware Suit related to Accord's filing of ANDA No. 210499. *See* October 16, 2017 Answer in First Delaware Suit in

the Section of Jurisdiction and Venue. Biogen likewise alleges claims here related to Accord's ANDA No. 210499. 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 Accord.

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

15. Accord's ANDA filing, regarding the '001 patent, has a substantial connection with this district because it reliably and non-speculatively predicts activities by Accord in this district.

16. Exercising personal jurisdiction over Accord in this district would not be unreasonable given Accord's 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, Accord has been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210499.

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

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

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 Defendant.

FIRST COUNT FOR PATENT INFRINGEMENT ('001 PATENT)

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

22. The U.S. Patent and Trademark Office ("PTO") issued the '001 patent on November 17, 2009, entitled "Utilization of Dialkylfumarates." The '001 patent identifies Rajendra Kumar Joshi and Hans-Peter Strebel as inventors of the claimed subject matter. A copy of the '001 patent is attached hereto as Exhibit B.

23. Biogen International GmbH is the owner of the '001 patent by virtue of assignment.

24. The '001 patent expires on June 20, 2020, which includes 811 days of patent term extension.

25. The '001 patent is directed to and claims, *inter alia*, methods of treating multiple sclerosis.

26. The ’001 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, Accord submitted ANDA No. 210499 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 Defendant’s generic products in the United States.

30. The Second Notice Letter purported to include a Notice of Certification for ANDA No. 210499 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the ’001 patent. The Second Notice Letter did not allege non-infringement as to at least one claim of the ’001 patent.

31. Accord thus has actual knowledge of the ’001 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 ’001 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), Accord has infringed at least one claim including at least claim 1 of the ’001 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 210499 seeking approval to manufacture, use, import, offer to sell or sell Defendant’s generic products before the expiration date of the ’001 patent. Upon

information and belief, the products described in ANDA No. 210499 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '001 patent under 35 U.S.C. § 271(e)(2)(A).

34. Upon information and belief, Accord will manufacture, market, import, use, sell and/or offer to sell Defendant's generic products in the United States in connection with ANDA No. 210499 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 '001 patent by the use of Defendant's generic products upon approval.

36. Upon information and belief, upon approval, Accord 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 '001 patent, for the pecuniary benefit of Accord. Pursuant to 21 C.F.R. § 314.94, Accord is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Accord will thus induce infringement of at least one claim including at least claim 1 of the '001 patent.

37. Upon information and belief, if the FDA approves ANDA No. 210499, Accord 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 '001 patent, wherein Defendant's generic products are a material part of the claimed invention, wherein Accord knows that physicians will prescribe and patients will use Defendant's generic products in accordance with the instructions and/or label provided by Accord in practicing at least one claim including at least claim 1 of the '001 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, Accord will thus contribute to infringement of at least one claim including at least claim 1 of the '001 patent.

38. Upon information and belief, Accord's actions relating to Accord's ANDA No. 210499 complained of herein were done by and for the benefit of Accord.

39. If Accord's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '001 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 Accord on the patent infringement claim set forth above and respectfully requests that this Court:

1. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Accord has infringed at least one claim including at least claim 1 of the '001 patent through Accord's submission of ANDA No. 210499 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 '001 patent;

2. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Accord'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 '001 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 '001 patent, or such later date as the Court may determine;

4. enjoin Accord, and all persons acting in concert with Accord, from the manufacture, use, import, offer for sale and sale of Defendant's generic products until the expiration of the '001 patent, or such later date as the Court may determine;

5. enjoin Accord, and all persons acting in concert with Accord, from seeking, obtaining or maintaining approval of Accord's ANDA No. 210499 until the expiration of the '001 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.

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