IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
BANNER LIFE SCIENCES LLC,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Biogen International GmbH ("Biogen" or "Plaintiff"), by way of Complaint against Defendant Banner Life Sciences LLC ("Banner" 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, Banner is a corporation organized under the laws of Delaware, having a principal place of business at 4125 Premier Drive, High Point, North Carolina 27265.

4. Upon information and belief, Banner is a pharmaceutical company that develops, manufactures, markets and distributes 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") ("asserted patent" or "patent-in-suit") 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 Banner's filing of New Drug Application ("NDA") No. 210296 under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(b)(2), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sell, offer to sell, and import Banner's proposed BAFIERTAM™ capsules prior to the expiration of the asserted patent.

6. Biogen filed a separate action involving the same NDA in this Court against Banner for patent infringement of U.S. Patent Nos. 7,320,999 ("the '999 patent") and 8,399,514 ("the '514 patent), in *Biogen MA Inc. et al. v. Banner Life Sciences LLC*, No. 1:18-cv-00582-LPS (D. Del. filed Apr. 18, 2018) ("the First Suit"), which was dismissed pursuant to the Court's September 20, 2018, Order. The First Suit was filed in response to a letter from Banner dated March 20, 2018 ("the First Notice Letter"), which purported to include a Notice of Certification for NDA No. 210296 under 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c) as to the '999 and '514 patents and U.S. Patent Nos. 6,509,376 ("the '376 patent") and 8,759,393.

7. This complaint is filed in response to a new, second letter from Banner dated November 19, 2018 ("the Second Notice Letter"), which purported to include a Notice of Certification for NDA No. 210296 under 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c) as to the '376, '999, '001 and '514 patents and U.S. Patent No. 7,803,840.

JURISDICTION AND VENUE

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

9. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because Banner is incorporated in Delaware.

10. This Court has personal jurisdiction over Banner because Banner is incorporated in Delaware.

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

12. Banner "has taken the costly, significant step of applying to the FDA for approval to engage in future activities . . . that will be purposefully directed at," upon information and belief, the District of Delaware and elsewhere. *See Acorda Therapeutics Inc. v. Banner Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016), *cert. denied*, 2017 WL 69716 (U.S. Jan. 9, 2017). Banner's NDA filing under 505(b)(2) is similar to "ANDA filings[, which] constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Id.* at 760. Upon information and belief, Banner "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, Banner will engage in marketing of its proposed BAFIERTAM™ capsules in Delaware upon approval of its NDA.

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

14. Banner's NDA filing under § 505(b)(2) regarding the patent-in-suit has a substantial connection with this District because it reliably and non-speculatively predicts activities by Banner in this District.

15. Upon information and belief, Banner has appointed The Corporation Trust Company at Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801 for receipt and service of process as its registered agent.

16. Exercising personal jurisdiction over Banner in this District would not be unreasonable given Banner'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, Banner has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of NDA No. 210296.

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 Banner.

FIRST COUNT FOR PATENT INFRINGEMENT ('001 PATENT)

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

20. 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 A.

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

22. The '001 patent expires on June 20, 2020, which includes a term of extension for a period of 811 days pursuant to 35 U.S.C. § 156.

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

24. The '001 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for 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, Banner submitted NDA No. 210296 to the FDA, under Section 505(b)(2) of the Act, 21 U.S.C. § 355(b), seeking approval to manufacture, use, import, offer to sell and sell BAFIERTAM™ capsules ("Defendant's proposed products") in the United States.

28. The Second Notice Letter purported to include a Notice of Certification for NDA No. 210296 under 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c) as to the '001 patent. The First Notice Letter stated that Banner's NDA No. 210296 "contains the required bioavailability and/or bioequivalence data" with respect to the patents asserted in the First Suit. The Second Notice Letter stated at page 2 that the "amendment to Banner's NDA for which this notice is being sent is solely due to Banner's submission of a re-certification with regard to the

patents listed in the Orange Book in connection with Tecfidera® . . . and is not due to a change in the active ingredient, the daily dosage amount, or the formulation of Banner's product described in NDA No. 210296. Banner has also amended its Patent Certification to include [a] Paragraph IV Certification[]" for the '001 patent.

29. Banner thus has actual knowledge of the '001 patent.

30. Upon information and belief, Defendant's proposed products, which rely on the bioavailability and/or bioequivalence data for Biogen's dimethyl fumarate delayed-release capsule drug product, 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(b), and/or (c).

31. Upon information and belief, Banner will manufacture, market, import, use, sell and/or offer to sell Defendant's proposed products in the United States in connection with NDA No. 210296 upon final FDA approval.

32. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Banner 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, NDA No. 210296 seeking approval to manufacture, use, import, offer to sell or sell Defendant's proposed products before the expiration date of the '001 patent. Upon information and belief, the products described in NDA No. 210296 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).

33. Upon information and belief, physicians and/or patients will directly infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '001 patent by the use of Defendant's proposed products upon final FDA approval.

34. Upon information and belief, upon final FDA approval, Banner will take active steps to encourage the use of Defendant's proposed products by physicians and/or patients with the knowledge and intent that Defendant's proposed 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 Banner. Upon information and belief, Banner will thus induce the infringement of at least one claim including at least claim 1 of the '001 patent.

35. Upon information and belief, if NDA No. 210296 receives final FDA approval, Banner will sell or offer to sell its proposed products specifically labeled for use in practicing at least one claim including at least claim 1 of the '001 patent, wherein Defendant's proposed products are a material part of the claimed invention, wherein Banner knows that physicians will prescribe and patients will use Defendant's proposed products in accordance with the instructions and/or label provided by Banner in practicing at least one claim including at least claim 1 of the '001 patent, and wherein Defendant's proposed products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, Banner will thus contribute to the infringement of at least one claim including at least claim 1 of the '001 patent.

36. Upon information and belief, Banner's actions relating to Banner's NDA No. 210296 complained of herein were done by and for the benefit of Banner.

37. If Banner's marketing and sale of BAFIERTAM™ 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 Defendant Banner 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 Banner has infringed at least one claim including at least claim 1 of the '001 patent through Banner's submission of NDA No. 210296 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendant's proposed 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 Banner's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendant's proposed 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 proposed 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 Banner, and all persons acting in concert with Banner, from the manufacture, use, import, offer for sale and sale of Defendant's proposed products until the expiration of the '001 patent, or such later date as the Court may determine;

5. enjoin Banner, and all persons acting in concert with Banner, from seeking, obtaining or maintaining approval of Banner's NDA No. 210296 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.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiff
Biogen International GmbH

Of Counsel:

James B. Monroe
Li Feng
Sanya Sukduang
Paul W. Browning
Andrew E. Renison
John E. Nappi
Jeanette M. Roorda
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000

Dated: December 27, 2018