

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH)
)
)
Plaintiff,)
)
v.) C.A. No. 18-2054-LPS
)
BANNER LIFE SCIENCES LLC,)
)
Defendant.)

**DEFENDANT BANNER LIFE SCIENCES LLC'S
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Banner Life Sciences LLC (“Banner”) answers the Complaint of Plaintiff Biogen International GmbH (“Biogen GmbH”, but called “Biogen” or “Plaintiff” in the paragraphs from the Complaint) 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.

ANSWER: Upon information and belief, Banner admits that Biogen GmbH is a Swiss corporation and has a place of business at Landis + Gyr-Strasse 3, 6300 Zug, Switzerland. Banner lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 1 of the Complaint and therefore denies them.

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.

ANSWER: Upon information and belief, denied. Banner admits that Biogen Idec Inc. is listed as the New Drug Application holder for Tecfidera® and that the asserted patent in the complaint is listed for Tecfidera® in the “Approved Drug Products with Therapeutic Equivalence Evaluations” (a/k/a the “Orange Book”). Banner also states that Tecfidera® contains dimethyl fumarate as its active ingredient and that the particular usage for which it was approved is indicated in the approved label for Tecfidera®. That approved label speaks for itself. Banner is unaware, however, that Biogen GmbH (the specific company shortened to Biogen in the Complaint) has or had any involvement with the development, approval, or marketing of any drug product in the U.S.A, including the Tecfidera® product. Banner lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 2 of the Complaint and therefore denies them.

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.

ANSWER: Admitted.

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.

ANSWER: Banner admits that it is a specialty pharmaceutical company and that it intends to sell the product associated with the New Drug Application (“NDA”) that gave rise to this litigation throughout the United States upon receipt of final approval from the U.S. Food and Drug Administration (“FDA”). By way of further response Banner states that it presently has tentative approval from the FDA for its NDA.

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.

ANSWER: The allegations of paragraph 5 contain legal conclusions to which no response is required. To the extent any response is required, Banner admits that the Plaintiff purports to bring this action under the patent laws of the United States, and that this action purports to be an action for infringement of U.S. Patent No. 7,619,001 (“the ’001 patent”) based on Banner’s submission of an amendment to its NDA No. 210296. Banner also notes that its NDA presently has tentative approval from the FDA. Banner denies that there is any merit to Plaintiffs’ substantive claims of patent infringement.

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.

ANSWER: Banner admits that there was an earlier case in this Court addressing other Orange Book patents under the caption provided in the Complaint. Banner further states that that previous action filed by both Biogen GmbH and Biogen MA Inc. was dismissed pursuant to this Court’s Order on September 20, 2018, and that the dismissal applied to the ’999, ’514, and ’376 patents. Banner further states that it was not sued on the ’393 patent that was listed in the Orange Book, was included in Banner’s initial paragraph IV certification and March 2018 notice letter packet, and is now expired.

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.

ANSWER: Banner admits that it amended its NDA No. 210296 after receiving tentative approval to, among other things, include a paragraph IV certification to the ’001 and ’840 patents and to maintain its paragraph IV certification on the ’376, ’999, and ’514 patents.

Banner also amended its paragraph IV certification to reflect new expiration dates for the '376, '999, and '514 patents in the Orange Book. Upon amending its NDA, Banner admits that it also sent out a notice letter packet containing the required detailed statement and an offer of confidential access on November 19, 2018, and that that notice letter packet complied with the relevant FDA and patent law statutes and regulations.

JURISDICTION AND VENUE

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

ANSWER: The allegations of paragraph 8 contain legal conclusions to which no response is required. To the extent any response is required, Banner admits that this Court has jurisdiction over the subject matter of this action, but Banner denies any substantive patent infringement.

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.

ANSWER: The allegations of paragraph 9 contain legal conclusions to which no response is required. To the extent any response is required, Banner admits that it is incorporated in Delaware and does not contest venue in this Court solely for purposes of this action.

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

ANSWER: The allegations of paragraph 10 contain legal conclusions to which no response is required. To the extent any response is required, Banner admits that it is incorporated in Delaware and does not contest personal jurisdiction in this Court solely for purposes of this action.

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”).

ANSWER: The allegations of paragraph 11 contain legal conclusions to which no response is required. To the extent any response is required, Banner does not contest personal jurisdiction in this Court solely for purposes of this action.

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.

ANSWER: The allegations of paragraph 12 contain legal conclusions to which no response is required. To the extent any response is required, Banner does not contest personal jurisdiction or venue in this Court solely for purposes of this action. By way of further response, Banner notes that the case citation is inaccurate as Banner was not a party in the cited case.

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

ANSWER: The allegations of paragraph 13 contain legal conclusions to which no response is required. To the extent any response is required, Banner does not contest personal jurisdiction in this Court solely for purposes of this action.

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.

ANSWER: The allegations of paragraph 14 contain legal conclusions to which no response is required. To the extent any response is required, Banner does not contest personal jurisdiction or venue in this Court solely for purposes of this action.

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.

ANSWER: Admitted.

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.

ANSWER: The allegations of paragraph 16 contain legal conclusions to which no response is required. To the extent any response is required, Banner does not contest personal jurisdiction in this Court solely for purposes of this action.

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.

ANSWER: Banner admits that it submitted NDA No. 210296 with the FDA, has answered FDA questions about that application and obtained tentative approval for that NDA, and continues to be responsible for seeking final approval of that NDA. To the extent any further averments in paragraph 17 are not addressed by the foregoing, Banner denies them.

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.

ANSWER: The allegations of paragraph 18 contain legal conclusions to which no response is required. To the extent any response is required, Banner does not contest personal jurisdiction in this Court solely for purposes of this action.

FIRST COUNT FOR PATENT INFRINGEMENT ('001 PATENT)

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

ANSWER: Banner incorporates its response to each preceding paragraph as if fully set forth herein.

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 Strelbel as inventors of the claimed subject matter. A copy of the '001 patent is attached hereto as Exhibit A.

ANSWER: Banner admits that the '001 patent is entitled “Utilization of Dialkylfumarates.” Banner also admits that the '001 patent indicates on its face that it was issued on November 17, 2009, and that Rajendra Kumar Joshi and Hans-Peter Strelbel are the listed inventors. Banner further admits that what purports to be a copy of the '001 patent was attached as Exhibit A to the Complaint. By way of further response, as indicated in Banner's tentative approval from the FDA, Banner is not utilizing a dialkylfumarate such as is in Tecfidera®, rather Banner's NDA product uses a monoalkylfumarate, i.e., monomethyl fumarate. A copy of the Tentative Approval Letter for NDA No 210296 is attached hereto as Exhibit 1. To the extent any further averments in paragraph 20 are not addressed by the foregoing, Banner denies them.

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

ANSWER: Banner admits that a search for patent assignments on the United States Patent and Trademark Office ("PTO") website indicates that the '001 patent is assigned to Biogen International GmbH. To the extent any further averments in paragraph 21 are not addressed by the foregoing, Banner denies them.

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.

ANSWER: Banner acknowledges that the expiration date of the '001 patent is presently listed as June 20, 2020, in the Orange Book and that the records of the PTO indicate that Biogen opted to extend the '001 patent for 811 days pursuant to 35 U.S.C. § 156. By way of further answer Banner states that the rights derived from the '001 patent are limited during the Patent Term Extension period by 35 U.S.C. § 156(b). The Patent Term Extension (PTE) Application indicates that the approved drug product that served as the basis for the extension is Tecfidera®, and its active ingredient is dimethyl fumarate. (Biogen's PTE Application for the '001 patent (copy attached hereto as Exhibit 2) at 2-4, 6-8, 11.) To the extent any further averments in paragraph 22 are not addressed by the foregoing, Banner denies them.

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

ANSWER: The text of the '001 patent speaks for itself, but the claims are directed to methods of treatment; the rights derived from those claims, however, are limited by 35 U.S.C. § 156(b) during the period of Patent Term Extension, i.e., after April 1, 2018. To the extent any further averments in paragraph 23 are not addressed by the foregoing, Banner denies them.

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.

ANSWER: Banner admits that the '001 patent is one of the patents presently listed in the Orange Book for dimethyl fumarate delayed-release capsules. To the extent any further averments in paragraph 24 are not addressed by the foregoing, Banner denies them.

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

ANSWER: The Orange Book indicates that NDA No. 204063 was approved on March 27, 2013, with labeling indicating the use for which it was approved, that the active ingredient was dimethyl fumarate, and that the mechanism by which dimethyl fumarate accomplished its therapeutic effect in multiple sclerosis is unknown. (*See* FDA Approved Labeling Text dated March 27, 2013, for NDA 204063 (copy attached hereto as Exhibit 3) at Sections 11 and 12.1.) To the extent any further averments in paragraph 25 are not addressed by the foregoing, Banner denies them.

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

ANSWER: Upon information and belief, Banner admits that dimethyl fumarate delayed-release capsules are marketed in the United States under the trademark Tecfidera® by some entity. Banner does not have sufficient information to know what entity markets Tecfidera®. To the extent any further averments in paragraph 26 are not addressed by the foregoing, Banner denies them.

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.

ANSWER: Admitted. By way of further response, Banner states that it presently has tentative approval of its NDA product containing monomethyl fumarate.

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.

ANSWER: Banner admits that it sent a notice letter packet on November 19, 2018, that included a Notice of Certification for NDA 210296, pursuant to 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c) as to, amongst others, the ’001 patent. Banner admits that its earlier notice letter referenced that Banner’s NDA contained the required bioavailability and bioequivalence data, and notes that this is demonstrated by Banner’s NDA obtaining tentative approval within a year after filing. Banner also admits that its November 19, 2018, notice letter packet indicated that its NDA was not subject to a change in active ingredient, daily dosage amount or the formulation of Banner’s product. This lack of amendment is reflected in Banner’s product being approved the same year the NDA was submitted. Banner also amended its Patent Certification to include Paragraph IV certifications for the ’001 and ’840 patent. Biogen GmbH has only sued Banner on the ’001 patent in the present suit. To the extent further averments in paragraph 28 are not addressed by the foregoing, Banner denies them.

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

ANSWER: Banner admits that it is aware of the ’001 patent. To the extent further averments in paragraph 29 are not addressed by the foregoing, Banner denies them.

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).

ANSWER: Denied. By way of further response, Biogen GmbH is aware that Banner's product contains monomethyl fumarate, not dimethyl fumarate like Tecfidera®, and that Banner cannot infringe the '001 patent during the period of Patent Term Extension because of 35 U.S.C. § 156(b).

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.

ANSWER: Banner admits that it filed its NDA No. 210296 to obtain approval to engage in the manufacture, marketing, importation, use, or sale of Banner's proposed products. By way of further answer, Banner states that it presently has tentative approval and that to its best information the only thing blocking it from receiving final approval is this lawsuit.

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).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Banner admits that according to 35 U.S.C. § 271(e)(2)(A), it is a technical act of infringement that provides subject matter jurisdiction to submit an NDA under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for a drug claimed in a patent or the use of which is claimed in a patent where that submission contains a certification under 21 U.S.C. § 355(b)(2)(A)(iv). However, Biogen GmbH is aware that Banner's product contains monomethyl fumarate, not dimethyl fumarate like Tecfidera®, and that Banner cannot infringe the '001 patent during the period of Patent Term Extension because of 35 U.S.C. § 156(b). Thus, Plaintiff has no basis to bring substantive patent infringement claims against Banner. To the extent further averments in paragraph 32 are not addressed by the foregoing, Banner denies them.

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.

ANSWER: Denied. By way of further response, Biogen GmbH is aware that Banner's product contains monomethyl fumarate, not dimethyl fumarate like Tecfidera®, and that Banner cannot infringe the '001 patent during the period of Patent Term Extension because of 35 U.S.C. § 156(b).

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.

ANSWER: Denied. By way of further response, Biogen GmbH is aware that Banner's product contains monomethyl fumarate, not dimethyl fumarate like Tecfidera®, and that Banner cannot infringe the '001 patent during the period of Patent Term Extension because of 35 U.S.C. § 156(b).

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.

ANSWER: Denied. By way of further response, Biogen GmbH is aware that Banner's product contains monomethyl fumarate, not dimethyl fumarate like Tecfidera®, and that Banner cannot infringe the '001 patent during the period of Patent Term Extension because of 35 U.S.C. § 156(b).

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.

ANSWER: Banner admits that it filed and, to this point, obtained tentative approval of its NDA No. 210296 to obtain approval to engage in the manufacture, marketing, importation, use or sale of Banner's proposed products. To the extent further averments in paragraph 36 are not addressed by the foregoing, Banner denies them.

37. If Banner's marketing and sale of BAFIERTAMTM 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.

ANSWER: Denied.

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.

RESPONSE TO PRAYER FOR RELIEF BY DEFENDANT

Banner denies that Plaintiff is entitled to any of the relief requested by the Complaint, or any other relief whatsoever.

AFFIRMATIVE DEFENSES OF DEFENDANT

Banner asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Banner does not assume the burden of proof of any such defenses, except as required by the applicable law with respect to the particular defense asserted. Banner reserves the right to assert other defenses and/or to otherwise supplement or amend its Answer and Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST AFFIRMATIVE DEFENSE

(Non-Infringement of the '001 Patent)

Plaintiff has failed to aver any facts that support its allegations of infringement by Banner's proposed NDA product. Banner's proposed NDA product, which may be marketed if and when the NDA obtains approval, would not directly or indirectly infringe any valid claim of the '001 patent, either literally or under the doctrine of equivalents. The manufacture, use, sale, offer for sale, and/or importation by Banner of Banner's proposed NDA product, which may be marketed if and when the NDA obtains approval, would not directly or indirectly infringe any valid claim of the '001 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

(Invalidity of the '001 Patent)

The '001 patent is invalid for failing to satisfy the requirements of 35 U.S.C. §§ 1 *et seq.*

THIRD AFFIRMATIVE DEFENSE

(Failure to State a Claim)

The complaint should be dismissed under Federal Rule of Civil Procedure Rule 12(b)(6) for failure to state a claim. More specifically, Plaintiff has failed to explain how it can assert the '001 patent during the Patent Term Extension period against a product that does not contain dimethyl fumarate as the active ingredient.

FOURTH AFFIRMATIVE DEFENSE

(No Exceptional Case)

Plaintiff has failed to aver any facts supporting that this is an exceptional case and that it should be granted an award of attorneys' fees under 35 U.S.C. § 285.

COUNTERCLAIMS

For its counterclaims against Counterclaim-Defendant Biogen International GmbH (“Biogen GmbH” or “Counterclaim-Defendant”), Counterclaim-Plaintiff Banner Life Sciences LLC (“Banner” or Counterclaim-Plaintiff”), states as follows:

THE PARTIES

1. Banner is a corporation organized and existing under the laws of Delaware, having a principal place of business at 4125 Premier Drive, High Point, North Carolina 27265.
2. On information and belief and as pled in the Complaint, Biogen GmbH is a Swiss corporation with its principal place of business in Zug, Switzerland at Landis + Gyr-Strasse 3, 6300 Zug, Switzerland.

JURISDICTION AND VENUE

3. These counterclaims arise under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

4. This Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

5. This Court has personal jurisdiction over Counterclaim-Defendant because Counterclaim-Defendant has availed itself of the rights and privileges of this forum by bringing this civil action in this judicial district and because, upon information and belief, Counterclaim-Defendant conducts substantial business in, and has regular and systematic contact with, this judicial district.

6. Venue for these counterclaims is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

PATENT-IN-SUIT AND OTHER ORANGE BOOK PATENTS

7. On or about November 17, 2009, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent 7,619,001 (“the ’001 patent” or the “counterclaim patent-in-suit”), entitled “Utilization of Dialkylfumarates.”

8. Upon information and belief and as pled in the complaint, Biogen GmbH is the assignee of the ’001 patent. Upon information and belief, Biogen GmbH, however, is not the NDA holder for Tecfidera®, nor did it conduct any clinical studies relating to, or seek, approval from the FDA of the delayed-release dimethyl fumarate product that became Tecfidera®.

9. Upon information and belief, Biogen GmbH caused another Biogen entity to list the ’001 patent in the FDA’s on-line website containing *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) in connection with the Tecfidera® drug product. Upon information and belief, Biogen GmbH is also the assignee of U.S. Patent

Nos. 6,509,376; 7,320,999; and 7,803,840 (collectively, “the other Orange Book patents”); and it caused another Biogen entity to list those patents in the Orange Book in connection with the Tecfidera® drug product as well.

THE PATENT TERM EXTENSION APPLICATION

10. Biogen GmbH also applied for Patent Term Extensions for each of the counterclaim patent-in-suit and the other Orange Book patents, and while that request was pending it received one-year interim patent term extensions on the counterclaim patent-in-suit and the other Orange Book patents. A copy of Biogen’s PTE Application for the ’001 patent is attached hereto as Exhibit 2.

11. But for the interim patent term extensions, the ’001 patent would have expired on April 1, 2018, and the other Orange Book patents all would have expired in 2018.

12. The Patent Term Extension Applications for the counterclaim patent-in-suit and the other Orange Book patents were based on the regulatory review period for Tecfidera®. The NDA associated with Tecfidera®, and the one that the Patent Term Extension Applications relied on, was NDA No. 204063. A copy of the Federal Register Notice for the Determination of Regulatory Review Period for Purposes of Patent Extension; TECFIDERA, 82 Fed. Reg. 46,502 (Oct. 5, 2017) is attached hereto as Exhibit 4.

13. The Orange Book indicates that the Active Ingredient of Tecfidera® is dimethyl fumarate. A copy of the listing for Tecfidera® from FDA’s Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (available at https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm, search Tecfidera, last accessed January 4, 2019) is attached hereto as Exhibit 5.

14. Each Patent Term Extension Application identifies the active ingredient of Tecfidera® as dimethyl fumarate.

15. None of the drug products used in the clinical studies reviewed by the FDA during its review of NDA No. 204063 contained monomethyl fumarate as the active ingredient.

16. On October 22, 2018, Biogen GmbH chose to extend the '001 patent under 35 U.S.C. § 156. Simultaneously, Biogen GmbH chose not to extend the other Orange Book patents. A copy of the PTO's Notice of Final Determination and Requirement for Election is attached hereto as Exhibit 6. A copy of Biogen's Election of Patent for Patent Term Extension is attached hereto as Exhibit 7.

17. The Patent Term Extension Certification for the '001 patent was issued on December 4, 2018. A copy of the Patent Term Extension Certification for the '001 patent is attached hereto as Exhibit 8.

18. As such, as of at least December 4, 2018, U.S. Patent Nos. 6,509,376; 7,320,999; and 7,803,840 have expired.

19. Upon information and belief, Biogen GmbH has not caused the Orange Book to be updated to indicate that the other Orange Book patents have expired.

20. The '001 patent has only 1 independent claim, i.e., claim 1, and that independent claim is a method of treatment claim.

BANNER'S NDA

21. Banner submitted New Drug Application ("NDA") No. 210296 to the FDA, under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), seeking approval to market BAFIERTAM™ capsules ("Banner's Proposed NDA Product"). That NDA as filed contained a certification under 21 U.S.C. § 355(b)(2)(A)(iv) ("Paragraph IV certification") indicating that, among others, U.S. Patent Nos. 6,509,376; 7,320,999; and 8,399,514 are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of Banner's Proposed NDA Product.

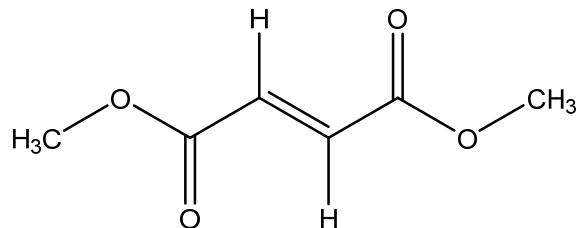
22. After Banner provided notice in March 2018 with regard to its Paragraph IV certification, Biogen GmbH and Biogen MA Inc. sued Banner in this district in Civil Action No. 1:18-cv-00582-LPS. After outside counsel for the two Biogen entities had the opportunity to review Banner's NDA, Biogen and Banner dismissed the claims and counterclaims relating to the '376, '999, and '514 patents.

23. Banner has been provided a covenant not to sue on the '376, '999, and '514 patents absent specific changes to its NDA.

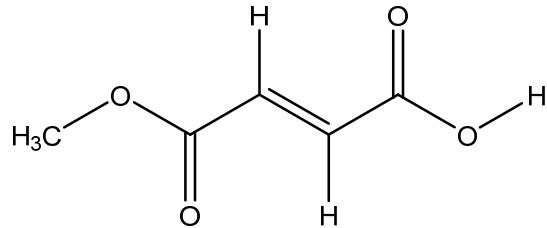
24. On November 16, 2018, the FDA granted tentative approval to Banner's NDA No. 210296. A copy of the Tentative Approval Letter for NDA No 210296 is attached hereto as Exhibit 1. A copy of the FDA Approved Drug Products list for November 2018 showing (on page 13) the approval of Banner's NDA No. 210296 is attached hereto as Exhibit 9 (available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=reportsSearch.process>, search November 2018, last accessed January 4, 2019). The FDA indicated that Banner's active ingredient was monomethyl fumarate.

25. The active ingredient in Banner's proposed product that was granted tentative approval by the FDA under NDA No. 210296 is monomethyl fumarate.

26. Dimethyl fumarate has the following structure:



27. Monomethyl fumarate has the following structure:



28. Monomethyl fumarate is not a dialkylfumarate.
29. Monomethyl fumarate is not the same chemical compound as dimethyl fumarate.
30. Monomethyl fumarate is not an ester of dimethyl fumarate.
31. Monomethyl fumarate is not a salt of dimethyl fumarate.
32. On November 19, 2018, Banner amended its NDA No. 210296 to, among other things, add a certification under 21 U.S.C. § 355(b)(2)(A)(iv) indicating that the '001 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of Banner's Proposed NDA Product.
33. Also, on November 19, 2018, Banner sent out a Notice Letter and Detailed Statement package to Biogen GmbH. In its November 19, 2018, letter, Banner made an Offer of Confidential Access ("OCA") to its NDA No. 210296 pursuant to 21 U.S.C. § 355(c)(3)(D)(i)(III) that was based on the earlier protective order entered by this Court in Civil Action No. 1:18-cv-00582-LPS (D. Del., filed Apr. 18, 2018).
34. Biogen GmbH's outside counsel responded to Banner's OCA, and the parties negotiated a revised OCA based on the provisions of Delaware Local Rule 26.2. Biogen GmbH's outside counsel accepted the revised OCA terms on December 21, 2018.
35. On December 27, 2018, Counterclaim-Defendants initiated this civil action, CA No. 1:18-cv-02054-LPS against Banner in this judicial district alleging infringement of only the '001 patent.

36. Banner seeks a declaratory judgment that the '001 patent is not infringed during the period of Patent Term Extension based on the limitations of 35 U.S.C. § 156(b).

COUNT I

(Declaratory Judgment of Non-Infringement of the '001 Patent)

37. Banner restates and re-alleges each of the foregoing paragraphs 1-36 of the Counterclaims as if fully set forth herein.

38. Counterclaim-Defendant has alleged that Banner's amendment of NDA No. 210296 infringes the '001 patent.

39. As evidenced by Counterclaim-Defendant's Complaint and Banner's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Banner and Counterclaim-Defendant regarding the infringement of the '001 patent under 21 U.S.C. § 355(c)(3)(D)(ii) and 28 U.S.C. §§ 2201 and 2202.

40. The manufacture, use, sale, offer for sale, and/or importation by Banner of Banner's Proposed NDA Product pursuant to NDA No. 210296 will not directly infringe, either literally or under the doctrine of equivalents, any valid claim of the '001 patent under any provision of 35 U.S.C. § 271 as limited by 35 U.S.C. § 156.

41. Banner's Proposed NDA Product, which may be marketed upon approval of NDA No. 210296, would not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '001 patent during the period of Patent Term Extension (*i.e.*, from April 1, 2018 to June 20, 2020).

42. Banner is entitled to a judicial determination that Banner's Proposed NDA Product, which is the subject of NDA No. 210296, has not infringed, does not infringe, and would not if marketed infringe, any valid claim of the '001 patent during the period of Patent Term Extension.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff respectfully requests that this Court enter a judgment in its favor and against Counterclaim-Defendants as follows:

- (a) Dismissing the Complaint with prejudice and entering judgment for Counterclaim-Plaintiff;
- (b) Declaring that no valid claim of the '001 patent would be infringed by the manufacture, use, sale, offer for sale, and/or importation of Banner's Proposed Product pursuant to NDA No. 210296 during the period of Patent Term Extension;
- (c) Enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendant from threatening to assert or otherwise attempting to enforce the '001 patent against Banner, its customers, suppliers, or anyone in privity with Banner;
- (d) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Banner its reasonable attorneys' fees and costs incurred in this action;
- (e) Awarding Banner its costs and expenses incurred in this action; and
- (f) Awarding Banner such other and further relief as this Court may deem proper.

/s/ Karen E. Keller

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David M. Fry (No. 5486)

Nathan R. Hoeschen (No. 6232)

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Dated: January 4, 2019