

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH, )  
 )  
 Plaintiff, )  
 )  
 v. ) C.A. No. \_\_\_\_\_  
 )  
 IMPAX LABORATORIES, INC., )  
 )  
 Defendant. )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Biogen International GmbH (“Biogen” or “Plaintiff”), by way of Complaint against Defendant Impax Laboratories, Inc. (“Impax” or “Defendant”), alleges as follows:

**THE PARTIES**

1. Biogen 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<sup>®</sup>, 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, Impax is a corporation organized under the laws of Delaware, having a principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

4. Upon information and belief, Impax 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 Impax’s filing of Abbreviated New Drug Application (“ANDA”) No. 210286 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 dimethyl fumarate delayed-release capsules prior to the expiration of the asserted patent.

6. Biogen MA Inc. filed a separate action involving the same ANDA in this Court against Impax for patent infringement of U.S. Patent No. 8,399,514 (“the ’514 patent”), in *Biogen MA Inc. v. Impax Laboratories, Inc.*, No. 1:17-cv-00826-LPS (D. Del. filed June 26, 2017) (“the First Suit”), which is now consolidated in *Biogen International GmbH v. Amneal Pharmaceuticals LLC*, No. 1:17-cv-00823-LPS (D. Del. consolidated Feb. 2, 2018). The First Suit was filed in response to a letter from Impax dated June 5, 2017 (“the First Notice Letter”), which purported to include a Notice of Certification for ANDA No. 210286 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the ’514 patent. The First Suit included a count for infringement of the ’514 patent.

7. This complaint is filed in response to a new, second letter from Impax dated January 22, 2018 (“the Second Notice Letter”), which purported to include a Notice of

Certification for ANDA No. 210286 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '376 and '999 patents.

**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 Impax is incorporated in Delaware.

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

11. This Court also has personal jurisdiction over Impax because at least one provision of 10 Del. C. § 3104(c) is satisfied. Upon information and belief, Impax 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. Impax “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,” upon 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). Impax’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, Impax “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, Impax will engage in marketing of its proposed ANDA products in Delaware upon approval of its ANDA.

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

14. Impax’s ANDA filing regarding the ’376 and the ’999 patents has a substantial connection with this district because it reliably and non-speculatively predicts activities by Impax in this district.

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

16. This Court also has personal jurisdiction over Impax because, *inter alia*, Impax 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, Impax, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Upon information and belief, Impax 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.

17. Upon information and belief, Impax is registered to do business in Delaware (File No. 2492482). *See* <https://icis.corp.delaware.gov/Ecorp/EntitySearch/NameSearch.aspx>. (Accessed January 25, 2018).

18. Upon information and belief, Impax maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, The Corporation Trust Company, located at Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

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

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

21. Upon information and belief, Impax has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210286.

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

**FIRST COUNT FOR PATENT INFRINGEMENT ('376 PATENT)**

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

24. The U.S. Patent and Trademark Office (“PTO”) issued the ’376 patent on January 21, 2003, entitled “Utilization of Dialkylfumarates.” 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.

25. Biogen International GmbH is the owner of the ’376 patent by virtue of assignment.

26. The ’376 patent expires on April 1, 2018, excluding any pediatric exclusivity or patent term extension.

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

28. 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.

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

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

31. Upon information and belief, Impax submitted ANDA No. 210286 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 products containing 120 mg and 240 mg of dimethyl fumarate (“Defendant’s generic products”) in the United States.

32. The Second Notice Letter purported to include a Notice of Certification for ANDA No. 210286 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 did not allege non-infringement as to at least one claim of the '376 patent.

33. Impax thus has actual knowledge of the '376 patent.

34. 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).

35. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Impax 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. 210286 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. 210286 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).

36. Upon information and belief, Impax will manufacture, market, import, use, sell and/or offer to sell Defendant's generic products in the United States in connection with ANDA No. 210286 upon approval.

37. Upon information and belief, Impax 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. 210286 upon approval.

38. Upon information and belief, Impax's actions relating to Impax's ANDA No. 210286 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Impax.

39. If Impax'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 remedy at law.

**SECOND COUNT FOR PATENT INFRINGEMENT ('999 PATENT)**

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

41. 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.

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

43. The '999 patent expires on October 20, 2018, which includes 202 days of Patent Term Adjustment under 35 U.S.C. § 154(b), excluding any pediatric exclusivity or patent term extension.

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

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

46. The Second Notice Letter purported to include a Notice of Certification for ANDA No. 210286 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.

47. Impax thus has actual knowledge of the '999 patent.

48. 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).

49. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Impax 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. 210286 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 product described in ANDA No. 210286 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).

50. 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.

51. Upon information and belief, Impax 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 Impax. Pursuant to 21 C.F.R. § 314.94, Impax is required to copy Biogen's FDA approved package insert. Upon information and belief, Impax will thus induce the infringement of at least one claim, including at least claim 1, of the '999 patent.

52. On information and belief, if the FDA approves ANDA No. 210286, Impax 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 Impax knows that physicians will prescribe and patients will use Defendant's generic products in accordance with the instructions and/or label provided by Impax 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, Impax will thus contribute to the infringement of at least one claim, including at least claim 1 of the '999 patent.

53. Upon information and belief, Impax's actions relating to Impax's ANDA No. 210286 complained of herein were done by and for the benefit of Impax.

54. If Impax'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 remedy at law.

#### **REQUEST FOR RELIEF**

**WHEREFORE**, Biogen respectfully requests that the Court enter judgment in its favor and against Defendant Impax 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 Impax has infringed at least one claim, including at least claim 1 of the '376 patent, through Impax's submission of ANDA No. 210286 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 Impax'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 Impax, and all persons acting in concert with Impax, 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 Impax and all persons acting in concert with Impax, from seeking, obtaining or maintaining approval of Impax's ANDA No. 210286 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 Impax has infringed at least one claim, including at least claim 1 of the '999 patent, through Impax's submission of ANDA No. 210286 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 Impax'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 Impax, and all persons acting in concert with Impax, 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 Impax and all persons acting in concert with Impax, from seeking, obtaining or maintaining approval of Impax's ANDA No. 210286 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

*/s/ Steven J. Balick*

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