IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA U.S.A., INC., and AUROBINDO PHARMA USA LLC,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, "Biogen" or "Plaintiffs"), by way of Complaint against Defendants Aurobindo Pharma U.S.A., Inc. and Aurobindo Pharma USA LLC (collectively, "Aurobindo" or "Defendants"), allege 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. Plaintiff Biogen MA Inc. is a corporation organized and existing under the laws of the Commonwealth of Massachusetts with its principal place of business at 225 Binney Street, Cambridge, Massachusetts 02142.

3. 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.

4. Biogen received letters from Aurobindo Pharma USA Inc., purporting to include a Notice of Certification under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to Biogen's asserted patents. Upon information and belief, Aurobindo Pharma USA Inc. is the same entity as Aurobindo Pharma U.S.A., Inc. If Aurobindo Pharma USA Inc. and Aurobindo Pharma U.S.A., Inc. are not the same entity, then, upon information and belief, they operate as single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States including this judicial district.

5. Upon information and belief, Aurobindo Pharma U.S.A., Inc. is a corporation organized under the laws of Delaware, having a principal place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401.

6. Upon information and belief, Aurobindo Pharma USA LLC is a corporation organized under the laws of Delaware, having a principal place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401.

7. Upon information and belief, Aurobindo Pharma U.S.A., Inc. and Aurobindo Pharma LLC are a generic pharmaceutical companies that develop, manufacture, market and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

NATURE OF THE ACTION

8. This is an action for patent infringement of U.S. Patent Nos. 7,320,999 ("the '999 patent") and 8,399,514 ("the '514 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 Aurobindo's filing of Abbreviated New Drug Application ("ANDA") No. 21-0385 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 patents.

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 Aurobindo is incorporated in Delaware.

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

12. This Court also has personal jurisdiction over Aurobindo because at least one provision of 10 Del. C. § 3104(c) is satisfied. Upon information and belief, Aurobindo 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. Aurobindo "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). Aurobindo'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, Aurobindo "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, Aurobindo will engage in marketing of its proposed ANDA product in Delaware upon approval of its ANDA.

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

15. Aurobindo's ANDA filing, regarding the '999 patent and the '514 patent, has a substantial connection with this district because it reliably and non-speculatively predicts activities by Aurobindo in this district.

16. Exercising personal jurisdiction over Aurobindo in this district would not be unreasonable given Aurobindo'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 Aurobindo because, *inter alia*, Aurobindo 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, Aurobindo, 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 Plavix® and Prozac®. A list of generic products sold by Aurobindo can be found at http://www.aurobindousa.com/products-page/product-catalog/, the contents of which are incorporated herein by reference. Upon information and belief, Aurobindo 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, Aurobindo Pharma U.S.A., Inc. is registered with the Delaware Board of Pharmacy as "Pharmacy-Wholesale" (License No. A4-0001270) and a "Distributor/Manufacturer CSR" (License No. DM-0006550). *See* https://dpronline.delaware.gov/mylicense%20weblookup/Search.aspx?facility=Y. (Accessed June 20, 2017).

19. Upon information and belief, Aurobindo is registered to do business in Delaware (File Nos. 3769913 and 6016670). *See* https://icis.corp.delaware.gov/Ecorp/EntitySearch/NameSearch.aspx. (Accessed June 20, 2017).

20. Upon information and belief, Aurobindo maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808.

21. Upon information and belief, Aurobindo has appointed Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808 for receipt and service of process as its registered agent.

22. Aurobindo has availed itself of Delaware courts through the assertion of counterclaims.

23. Upon information and belief, Aurobindo has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 21-0385.

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 Aurobindo.

FIRST COUNT FOR PATENT INFRINGEMENT ('999 PATENT)

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

26. The U.S. Patent and Trademark Office ("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 A.

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

28. 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.

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

30. The '999 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, Aurobindo submitted ANDA No. 21-0385 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 dimethyl fumarate delayed-release capsules containing 120 mg and 240 mg of dimethyl fumarate ("Defendants' generic products") in the United States.

34. Biogen received a letter from Aurobindo dated May 24, 2017, ("the Notice Letter"), purporting to include a Notice of Certification for ANDA No. 21-0385 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '999 patent. The Notice Letter did not allege non-infringement as to at least one claim of the '999 patent.

35. Aurobindo thus has actual knowledge of the '999 patent.

36. Upon information and belief, Defendants' 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).

37. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo 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. 21-0385 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '999 patent. Upon information and belief, the products described in ANDA No. 21-0385 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).

38. Upon information and belief, Aurobindo will manufacture, market, import, use, sell and/or offer to sell Defendants' generic products in the United States in connection with ANDA No. 21-0385 upon approval.

39. 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 Defendants' generic products upon approval.

40. Upon information and belief, upon approval, Aurobindo will take active steps to encourage the use of Defendants' generic products by physicians and/or patients with the knowledge and intent that Defendants' 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 Aurobindo. Pursuant to 21 C.F.R. § 314.94, Aurobindo is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Aurobindo will thus induce infringement of at least one claim including at least claim 1 of the '999 patent.

41. On information and belief, if the FDA approves ANDA No. 21-0385, Aurobindo 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 Defendants' generic products are a material part of the claimed invention, wherein Aurobindo knows that physicians will prescribe and patients will use Defendants' generic products in accordance with the instructions and/or label provided by Aurobindo 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. Upon information and belief, Aurobindo will thus contribute to the infringement of at least one claim including at least claim 1 of the '999 patent.

42. Upon information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 210385 complained of herein were done by and for the benefit of Aurobindo.

43. If Aurobindo'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.

SECOND COUNT FOR PATENT INFRINGEMENT ('514 PATENT)

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

45. The PTO issued the '514 patent on March 19, 2013, entitled "Treatment for Multiple Sclerosis." The '514 patent identifies Matvey E. Lukashev and Gilmore O'Neill as inventors of the claimed subject matter. A copy of the '514 patent is attached hereto as Exhibit B.

46. Biogen MA Inc. is the owner of the '514 patent by virtue of assignment.

47. The '514 patent expires on February 7, 2028, excluding any pediatric exclusivity.

48. The '514 patent is directed to and claims, *inter alia*, methods of treating multiple sclerosis.

49. The '514 patent is listed in the Orange Book for NDA No. 204063 for dimethyl fumarate delayed-release capsules.

50. The Notice Letter dated May 24, 2017 purported to include a Notice of Certification for ANDA No. 21-0385 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '514 patent. The Notice Letter did not allege non-infringement as to at least one claim of the '514 patent. Biogen received a second letter dated May 24, 2017 purporting to include a Notice of Certification for ANDA No. 21-0385 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '514 patent. The second letter also did not allege non-infringement to at least one claim of the '514 patent.

51. Aurobindo thus has actual knowledge of the '514 patent.

52. Upon information and belief, Defendants' 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 '514 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

53. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim including at least claim 1 of the '514 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 21-0385 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '514 patent. Upon information and belief, the products described in ANDA No. 21-0385 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '514 patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, physicians and/or patients will directly infringe the '514 patent by the use of Defendants' generic products upon approval.

55. Upon information and belief, upon approval, Aurobindo will take active steps to encourage the use of Defendants' generic products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients, in a manner that infringes at least one claim including claim 1 of the '514 patent, for the pecuniary benefit of Aurobindo. Pursuant to 21 C.F.R. § 314.94, Aurobindo is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Aurobindo will thus induce the infringement of at least one claim including at least claim 1 of the '514 patent.

56. On information and belief, if the FDA approves ANDA No. 21-0385, Aurobindo 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 '514 patent, wherein Defendants' generic products are a

material part of the claimed invention, wherein Aurobindo knows that physicians will prescribe and patients will use Defendants' generic products in accordance with the instructions and/or label provided by Aurobindo in practicing at least one claim including at least claim 1 of the '514 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, Aurobindo will thus contribute to the infringement of at least one claim including at least claim 1 of the '514 patent.

57. Upon information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 21-0385 complained of herein were done by and for the benefit of Aurobindo.

58. If Aurobindo's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '514 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 Defendants Aurobindo 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 Aurobindo has infringed at least one claim including at least claim 1 of the '999 patent through Aurobindo's submission of ANDA No. 21-0385 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '999 patent;

2. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United

States of Defendants' 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);

3. order that the effective date of any approval by the FDA of Defendants' 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;

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

5. enjoin Aurobindo, and all persons acting in concert with Aurobindo, from seeking, obtaining or maintaining approval of Aurobindo's ANDA No. 21-0385 until the expiration of the '999 patent, or such later date as the Court may determine;

6. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim including at least claim 1 of the '514 patent through Aurobindo's submission of ANDA No. 21-0385 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '514 patent;

7. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' generic products prior to the expiration of the '514 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 Defendants' generic products be a date that is not earlier than the expiration date of the '514 patent, or such later date as the Court may determine;

9. enjoin Aurobindo, and all persons acting in concert with Aurobindo, from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '514 patent, or such later date as the Court may determine;

10. enjoin Aurobindo, and all persons acting in concert with Aurobindo, from seeking, obtaining or maintaining approval of Aurobindo's ANDA No. 21-0385 until the expiration of the '514 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.

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