IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. _____

BIOGEN INTERNATIONAL GMBH, a Switzerland corporation, and
BIOGEN MA INC., a Massachusetts corporation,

Plaintiffs,

v.

SANDOZ INC., a Colorado corporation,

Defendant.

BIOGEN INTERNATIONAL GMBH'S AND BIOGEN MA INC.'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, "Biogen" or "Plaintiffs"), by way of Complaint against Defendant Sandoz Inc. ("Sandoz" or "Defendant"), 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. Upon information and belief, Sandoz is a corporation organized under the laws of Colorado, having a principal place of business at 100 College Road West, Princeton, NJ 08540.

5. Upon information and belief, Sandoz is a generic pharmaceutical company that develops, manufactures, markets and distributes generic pharmaceutical products for sale in the State of Colorado and throughout the United States.

NATURE OF THE ACTION

6. This is an action for patent infringement of U.S. Patent Nos. 6,509,376 ("the '376 patent"), 7,320,999 ("the '999 patent") and 8,399,514 ("the '514 patent") 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 Sandoz's filing of Abbreviated New Drug Application ("ANDA") No. 210414 under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sell, offer to sell, and import generic dimethyl fumarate delayed-release capsules prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

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

8. Biogen believes this case belongs in Delaware, but is concurrently filing a case in this district out of an abundance of caution.

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

10. This Court has personal jurisdiction over Sandoz because Sandoz is incorporated in Colorado.

11. Upon information and belief, Sandoz has been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210414.

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

FIRST COUNT FOR PATENT INFRINGEMENT (’376 PATENT)

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

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

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

16. The ’376 patent expires on October 29, 2019, excluding any pediatric exclusivity or patent term extension.

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

18. 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.

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

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

21. Upon information and belief, Sandoz submitted ANDA No. 210414 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 dimethyl fumarate delayed-release capsules containing 120 mg and 240 mg of dimethyl fumarate (“Defendant’s generic products”) in the United States.

22. Biogen received a letter from Sandoz dated June 9, 2017 (“the Notice Letter”), purporting to include a Notice of Certification for ANDA No. 210414 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the ’376 patent. The Notice Letter did not allege non-infringement as to at least one claim of the ’376 patent.

23. Sandoz thus has actual knowledge of the ’376 patent.

24. 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).

25. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz 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. 210414 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. 210414 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).

26. Upon information and belief, Sandoz will manufacture, market, import, use, sell and/or offer to sell Defendant’s generic products in the United States in connection with ANDA No. 210414 upon approval.

27. Upon information and belief, Sandoz 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. 210414 upon approval.

28. Upon information and belief, Sandoz’s actions relating to Sandoz’s ANDA No. 210414 complained of herein were done by and for the benefit of Sandoz.

29. If Sandoz'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 adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT ('999 PATENT)

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

31. 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.

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

33. 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.

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

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

36. The Notice Letter dated June 9, 2017 purported to include a Notice of Certification for ANDA No. 210414 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.

37. Sandoz thus has actual knowledge of the ’999 patent.

38. 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).

39. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz 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. 210414 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 products described in ANDA No. 210414 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).

40. 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.

41. Upon information and belief, upon approval, Sandoz 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 Sandoz. Pursuant to 21 C.F.R. § 314.94, Sandoz is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Sandoz will thus induce the infringement of at least one claim including at least claim 1 of the ’999 patent.

42. On information and belief, if the FDA approves ANDA No. 210414, Sandoz 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 Sandoz knows that physicians will prescribe and patients will use Defendant’s generic products in accordance with the instructions and/or label provided by Sandoz 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, Sandoz will thus contribute to the infringement of at least one claim including at least claim 1 of the ’999 patent.

43. Upon information and belief, Sandoz’s actions relating to Sandoz’s ANDA No. 210414 complained of herein were done by and for the benefit of Sandoz.

44. If Sandoz’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.

THIRD COUNT FOR PATENT INFRINGEMENT ('514 PATENT)

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

46. 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 C.

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

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

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

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

51. The Notice Letter dated June 9, 2017 purported to include a Notice of Certification for ANDA No. 210414 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.

52. Sandoz thus has actual knowledge of the '514 patent.

53. 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 ’514 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

54. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz 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. 210414 seeking approval to manufacture, use, import, offer to sell or sell Defendant’s generic products before the expiration date of the ’514 patent. Upon information and belief, the products described in ANDA No. 210414 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).

55. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 of the ’514 patent by the use of Defendant’s generic products upon approval.

56. Upon information and belief, upon approval, Sandoz 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 ’514 patent, for the pecuniary benefit of Sandoz. Pursuant to 21 C.F.R. § 314.94, Sandoz is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Sandoz will thus induce the infringement of at least one claim including at least claim 1 of the ’514 patent.

57. On information and belief, if the FDA approves ANDA No. 210414, Sandoz 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 Defendant’s generic products are a material part of the claimed invention, wherein Sandoz knows that physicians will prescribe and patients will use Defendant’s generic products in accordance with the instructions and/or label provided by Sandoz 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. On information and belief, Sandoz will thus contribute to the infringement of at least one claim including at least claim 1 of the ’514 patent.

58. Upon information and belief, Sandoz’s actions relating to Sandoz’s ANDA No. 210414 complained of herein were done by and for the benefit of Sandoz.

59. If Sandoz’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 Defendant Sandoz 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 Sandoz has infringed at least one claim including at least claim 1 of the ’376 patent through Sandoz’s submission of ANDA No. 210414 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 Sandoz’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 Sandoz, and all persons acting in concert with Sandoz, 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 Sandoz, and all persons acting in concert with Sandoz, from seeking, obtaining or maintaining approval of Sandoz’s ANDA No. 210414 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 Sandoz has infringed at least one claim including at least claim 1 of the '999 patent through Sandoz's submission of ANDA No. 210414 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 Sandoz'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 Sandoz, and all persons acting in concert with Sandoz, 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 Sandoz, and all persons acting in concert with Sandoz, from seeking, obtaining or maintaining approval of Sandoz's ANDA No. 210414 until the expiration of the '999 patent, or such later date as the Court may determine;

11. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Sandoz has infringed at least one claim including at least claim 1 of the '514 patent through Sandoz's submission of ANDA No. 210414 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 '514 patent;

12. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Sandoz'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 '514 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(b) and/or (c);

13. 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 '514 patent, or such later date as the Court may determine;

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

15. enjoin Sandoz, and all persons acting in concert with Sandoz, from seeking, obtaining or maintaining approval of Sandoz's ANDA No. 210414 until the expiration of the '514 patent, or such later date as the Court may determine;

16. 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

17. award such further and other relief as this Court deems proper and just.

Dated: June 30, 2017

Respectfully submitted,

s/ *Kenzo Kawanabe*

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