IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SAWAI USA, INC. and SAWAI PHARMACEUTICAL CO., LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, "Biogen" or "Plaintiffs"), by way of Complaint against Defendants Sawai USA, Inc. ("Sawai USA") and Sawai Pharmaceutical Co., Ltd. ("Sawai Pharmaceutical") (collectively, "Sawai" 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. Upon information and belief, Sawai Pharmaceutical is a corporation organized under the laws of Japan, having a principal place of business in Osaka, Japan.

5. Upon information and belief, Sawai Pharmaceutical 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.

6. Upon information and belief, Sawai USA is a corporation organized under the laws of Delaware, having a principal place of business at 11 Morgan, Irvine, CA 92618.

7. Upon information and belief, Sawai USA is a subsidiary of Sawai Pharmaceutical.

8. Upon information and belief, Sawai USA 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 in concert with Sawai Pharmaceutical.

9. Biogen received a letter dated May 31, 2017 ("the Notice Letter"), purporting to include a Notice of Certification for ANDA No. 210285 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c). The Notice Letter states:

> Stason Pharmaceuticals, Inc., acting as the U.S. agent for Sawai USA, Inc. (collectively hereinafter "Sawai") is providing . . . notice that Sawai has submitted . . . an Abbreviated New Drug Application.

10. Biogen believes that this suit is properly placed in Delaware because Sawai USA is incorporated here. However, Biogen is concurrently filing a case in California out of an abundance of caution given the confusing language in the Notice Letter suggesting that Stason

Pharmaceuticals, Inc., which is incorporated in California, participated in the filing of the noted ANDA.

11. A press release by Sawai Pharmaceutical states that "Sawai Pharmaceutical Co., Ltd. . . . through its subsidiary Sawai USA, Inc. (Headquarters: Delaware, USA), . . . submitted Abbreviated New Drug Application (ANDA) with Paragraph IV certificate attached for the therapeutic agent 'Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg." (emphasis added).

12. Upon information and belief, Stason provided the Notice Letter to Biogen, but Sawai Pharmaceutical submitted its ANDA through its Delaware subsidiary Sawai USA, Inc.

13. Upon information and belief, the acts of Sawai Pharmaceutical complained of herein were done with the cooperation, participation and assistance of Sawai USA.

NATURE OF THE ACTION

14. This is an action for patent infringement of U.S. Patent Nos. 6,509,376 ("the '376 patent"), 7,320,999 ("the '999 patent"), 7,619,001 ("the '001 patent"), 7,803,840 ("the '840 patent"), 8,759,393 ("the '393 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 Sawai's filing of Abbreviated New Drug Application ("ANDA") No. 210285 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

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

16. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because Sawai USA is incorporated in Delaware and Sawai Pharmaceutical is incorporated in Japan and may be sued in any judicial district in the United States in which the defendant is subject to the court's personal jurisdiction.

17. This Court has personal jurisdiction over Sawai Pharmaceutical under Federal Rule of Civil Procedure 4(k)(2), because, upon information and belief, Sawai Pharmaceutical is organized under the laws of Japan.

18. This Court has personal jurisdiction over Sawai USA because Sawai USA is incorporated in Delaware.

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

20. Sawai "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). Sawai'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, Sawai "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, Sawai will engage in marketing of its proposed ANDA products in Delaware upon approval of its ANDA.

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

22. Sawai's ANDA filing regarding the '376 patent, the '999 patent, the '001 patent, the '840 patent, the '393 patent and the '514 patent, has a substantial connection with this district because it reliably and non-speculatively predicts activities by Sawai in this district.

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

24. This Court also has personal jurisdiction over Sawai because, *inter alia*, Sawai 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, Sawai, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Sawai's website https://www.sawai.co.jp/en/about/bases (accessed on June 30, 2017), the contents of which are incorporated herein by reference, identifies its two corporate bases as Japan and the United

States. Further, Sawai notes that its product line is "around 680 prescription drugs." (https://www.sawai.co.jp/en/operation/products/, accessed June 30, 2017).

25. Upon information and belief, Sawai Pharmaceutical maintains continuous and systematic contacts with Delaware through its U.S. subsidiary Sawai USA, incorporated in Delaware.

26. Upon information and belief, Sawai USA is registered to do business in Delaware (File No. 5345305). *See* https://icis.corp.delaware.gov/Ecorp/EntitySearch /NameSearch.aspx. (Accessed June 29, 2017).

27. Upon information and belief, Sawai USA maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Paracorp Incorporated, located at 2140 S Dupont Hwy, Camden, DE 19934.

28. Upon information and belief, Sawai USA has appointed Paracorp Incorporated, located at 2140 S Dupont Hwy, Camden, DE 19934, for receipt and service of process as its registered agent.

29. Sawai has availed itself of Delaware courts through the assertion of counterclaims.

30. Upon information and belief, Sawai Pharmaceutical and Sawai USA operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district.

31. Upon information and belief, the effort to seek approval for ANDA No. 210285 and to manufacture, import, market, and/or sell Defendants' generic products upon approval has

been a cooperative and joint enterprise and venture between Sawai Pharmaceutical and Sawai USA.

32. Upon information and belief, Sawai Pharmaceutical and Sawai USA have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing and maintaining ANDA No. 210285 and in commercializing Defendants' generic products in the United States, including in this judicial district, in accordance with ANDA No. 210285 upon approval.

33. Upon information and belief, Sawai USA and Sawai Pharmaceutical have thus been, and continue to be, the prime actors in the drafting, submission, approval and maintenance of ANDA No. 210285.

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

FIRST COUNT FOR PATENT INFRINGEMENT ('376 PATENT)

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

36. 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.

37. Biogen International GmbH is the owner of the '376 patent by virtue of assignment.

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

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

40. 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.

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

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

43. Upon information and belief, Sawai submitted ANDA No. 210285 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.

44. Biogen received a letter from Sawai dated May 31, 2017 (“the Notice Letter”), purporting to include a Notice of Certification for ANDA No. 210285 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.

45. Sawai thus has actual knowledge of the ’376 patent.

46. 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 ’376 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

47. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sawai 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. 210285 seeking approval to manufacture, use, import, offer to sell or sell Defendants’ generic products before the expiration date of the ’376 patent. Upon information and belief, the products described in ANDA No. 210285 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).

48. Upon information and belief, Sawai will manufacture, market, import, use, sell and/or offer to sell Defendants’ generic products in the United States in connection with ANDA No. 210285 upon approval.

49. Upon information and belief, Sawai 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 Defendants’ generic products in the United States in connection with ANDA No. 210285 upon approval.

50. Upon information and belief, Sawai’s actions relating to Sawai’s ANDA No. 210285 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Sawai.

51. If Sawai’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)

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

53. 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.

54. Biogen International GmbH is the owner of the ’999 patent by virtue of assignment.

55. 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.

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

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

58. The Notice Letter dated May 31, 2017, purported to include a Notice of Certification for ANDA No. 210285 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 any claim of the ’999 patent.

59. Sawai thus has actual knowledge of the ’999 patent.

60. 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).

61. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sawai 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. 210285 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. 210285 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).

62. 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.

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

64. Upon information and belief, if the FDA approves ANDA No. 210285, Sawai 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 Sawai knows that physicians will prescribe and patients

will use Defendants' generic products in accordance with the instructions and/or label provided by Sawai 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, Sawai will thus contribute to the infringement of at least one claim including at least claim 1 of the '999 patent.

65. Upon information and belief, Sawai's actions relating to Sawai's ANDA No. 210285 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Sawai.

66. If Sawai'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 ('001 PATENT)

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

68. The PTO issued the '001 patent on November 17, 2009, entitled "Utilization of Dialkylfumarates." The '001 patent identifies Rajendra Kumar Joshi and Hans-Peter Strebel as inventors of the claimed subject matter. A copy of the '001 patent is attached hereto as Exhibit C.

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

70. The '001 patent expires on April 1, 2018 excluding any pediatric exclusivity or patent term extension.

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

72. The ’001 patent is listed in the Orange Book for NDA No. 204063 for dimethyl fumarate delayed-release capsules.

73. The Notice Letter dated May 31, 2017, purported to include a Notice of Certification for ANDA No. 210285 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the ’001 patent. The Notice Letter did not allege non-infringement as to at least one claim of the ’001 patent.

74. Sawai thus has actual knowledge of the ’001 patent.

75. 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 ’001 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

76. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sawai 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, ANDA No. 210285 seeking approval to manufacture, use, import, offer to sell or sell Defendants’ generic products before the expiration date of the ’001 patent. Upon information and belief, the products described in ANDA No. 210285 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).

77. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 of the ’001 patent by the use of Defendants’ generic products upon approval.

78. Upon information and belief, upon approval, Sawai 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 '001 patent, for the pecuniary benefit of Sawai. Pursuant to 21 C.F.R. § 314.94, Sawai is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Sawai will thus induce the infringement of at least one claim including at least claim 1 of the '001 patent.

79. Upon information and belief, if the FDA approves ANDA No. 210285, Sawai 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 '001 patent, wherein Defendants' generic products are a material part of the claimed invention, wherein Sawai knows that physicians will prescribe and patients will use Defendants' generic products in accordance with the instructions and/or label provided by Sawai in practicing at least one claim including at least claim 1 of the '001 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, Sawai will thus contribute to the infringement of at least one claim including at least claim 1 of the '001 patent.

80. Upon information and belief, Sawai's actions relating to Sawai's ANDA No. 210285 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Sawai.

81. If Sawai's marketing and sale of generic dimethyl fumarate delayed-release 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.

FOURTH COUNT FOR PATENT INFRINGEMENT (’840 PATENT)

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

83. The PTO issued the ’840 patent on September 28, 2010, entitled “Utilization of Dialkylfumarates.” The ’840 patent identifies Rajendra Kumar Joshi and Hans-Peter Strebel as inventors of the claimed subject matter. A copy of the ’840 patent is attached hereto as Exhibit D.

84. Biogen International GmbH is the owner of the ’840 patent by virtue of assignment.

85. The ’840 patent expires on April 1, 2018 excluding any pediatric exclusivity or patent term extension.

86. The ’840 patent is directed to and claims, *inter alia*, methods of treating multiple sclerosis.

87. The ’840 patent is listed in the Orange Book for NDA No. 204063 for dimethyl fumarate delayed-release capsules.

88. The Notice Letter dated May 31, 2017, purported to include a Notice of Certification for ANDA No. 210285 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the ’840 patent. The Notice Letter did not allege non-infringement as to any claim of the ’840 patent.

89. Sawai thus has actual knowledge of the ’840 patent.

90. 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 ’840 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

91. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sawai has infringed at least one claim including at least claim 1 of the '840 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 210285 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '840 patent. Upon information and belief, the products described in ANDA No. 210285 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '840 patent under 35 U.S.C. § 271(e)(2)(A).

92. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 of the '840 patent by the use of Defendants' generic products upon approval.

93. Upon information and belief, upon approval, Sawai 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 '840 patent, for the pecuniary benefit of Sawai. Pursuant to 21 C.F.R. § 314.94, Sawai is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Sawai will thus induce the infringement of at least one claim including at least claim 1 of the '840 patent.

94. Upon information and belief, if the FDA approves ANDA No. 210285, Sawai 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 '840 patent, wherein Defendants' generic products are a material part of the claimed invention, wherein Sawai knows that physicians will prescribe and patients will use Defendants' generic products in accordance with the instructions and/or label provided by Sawai in practicing at least one claim including at least claim 1 of the '840 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, Sawai will thus contribute to the infringement of at least one claim including at least claim 1 of the '840 patent.

95. Upon information and belief, Sawai's actions relating to Sawai's ANDA No. 210285 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Sawai.

96. If Sawai's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '840 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.

FIFTH COUNT FOR PATENT INFRINGEMENT ('393 PATENT)

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

98. The PTO issued the '393 patent on June 24, 2014, entitled "Utilization of Dialkylfumarates." The '393 patent identifies Rajendra Kumar Joshi and Hans-Peter Strebel as inventors of the claimed subject matter. A copy of the '393 patent is attached hereto as Exhibit E.

99. Biogen International GmbH is the owner of the '393 patent by virtue of assignment.

100. The '393 patent expires on October 29, 2019 excluding any pediatric exclusivity.

101. The '393 patent is directed to and claims, *inter alia*, pharmaceutical preparations.

102. The '393 patent is listed in the Orange Book for NDA No. 204063 for dimethyl fumarate delayed-release capsules.

103. The Notice Letter dated May 31, 2017, purported to include a Notice of Certification for ANDA No. 210285 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '393 patent. The Notice Letter did not allege non-infringement as to any claim of the '393 patent.

104. Sawai thus has actual knowledge of the '393 patent.

105. 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 '393 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

106. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sawai has infringed at least one claim including at least claim 1 of the '393 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 210285 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '393 patent. Upon information and belief, the products described in ANDA No. 210285 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '393 patent under 35 U.S.C. § 271(e)(2)(A).

107. Upon information and belief, Sawai will directly infringe at least one claim including at least claim 1 of the '393 patent when it proceeds to manufacture, market, import, use, sell and/or offer to sell Defendants' generic products in the United States in connection with ANDA No. 210285 upon approval.

108. Upon information and belief, Sawai's actions relating to Sawai's ANDA No. 210285 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Sawai.

109. If Sawai's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '393 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.

SIXTH COUNT FOR PATENT INFRINGEMENT ('514 PATENT)

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

111. 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 F.

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

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

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

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

116. The Notice Letter dated May 31, 2017, purported to include a Notice of Certification for ANDA No. 210285 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.

117. Sawai thus has actual knowledge of the '514 patent.

118. 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).

119. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sawai 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. 210285 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. 210285 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).

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

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

122. Upon information and belief, if the FDA approves ANDA No. 210285, Sawai 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 Sawai knows that physicians will prescribe and patients

will use Defendants' generic products in accordance with the instructions and/or label provided by Sawai 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, Sawai will thus contribute to the infringement of at least one claim including at least claim 1 of the '514 patent.

123. Upon information and belief, Sawai's actions relating to Sawai's ANDA No. 210285 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Sawai.

124. If Sawai'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 Sawai Pharmaceutical and Sawai USA 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 Sawai has infringed at least one claim including at least claim 1 of the '376 patent through Sawai's submission of ANDA No. 210285 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 '376 patent;

2. enter judgment under 35 U.S.C. § 271(a) that Sawai'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 '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 Defendants' 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 Sawai, and all persons acting in concert with Sawai, from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '376 patent, or such later date as the Court may determine;

5. enjoin Sawai, and all persons acting in concert with Sawai, from seeking, obtaining or maintaining approval of Sawai's ANDA No. 210285 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 Sawai has infringed at least one claim including at least claim 1 of the '999 patent through Sawai's submission of ANDA No. 210285 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;

7. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Sawai'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);

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 '999 patent, or such later date as the Court may determine;

9. enjoin Sawai, and all persons acting in concert with Sawai, 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;

10. enjoin Sawai, and all persons acting in concert with Sawai, from seeking, obtaining or maintaining approval of Sawai's ANDA No. 210285 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 Sawai has infringed at least one claim including at least claim 1 of the '001 patent through Sawai's submission of ANDA No. 210285 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 '001 patent;

12. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Sawai'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 '001 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 Defendants' generic 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;

14. enjoin Sawai, and all persons acting in concert with Sawai, from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '001 patent, or such later date as the Court may determine;

15. enjoin Sawai, and all persons acting in concert with Sawai, from seeking, obtaining or maintaining approval of Sawai's ANDA No. 210285 until the expiration of the '001 patent, or such later date as the Court may determine;

16. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Sawai has infringed at least one claim including at least claim 1 of the ’840 patent through Sawai’s submission of ANDA No. 210285 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 ’840 patent;

17. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Sawai’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 ’840 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(b) and/or (c);

18. 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 ’840 patent, or such later date as the Court may determine;

19. enjoin Sawai, and all persons acting in concert with Sawai, from the manufacture, use, import, offer for sale and sale of Defendants’ generic products until the expiration of the ’840 patent, or such later date as the Court may determine;

20. enjoin Sawai, and all persons acting in concert with Sawai, from seeking, obtaining or maintaining approval of Sawai’s ANDA No. 210285 until the expiration of the ’840 patent, or such later date as the Court may determine;

21. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Sawai has infringed at least one claim including at least claim 1 of the ’393 patent through Sawai’s submission of ANDA No. 210285 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 ’393 patent;

22. enter judgment under 35 U.S.C. § 271(a) that Sawai’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 '393 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(a);

23. 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 '393 patent, or such later date as the Court may determine;

24. enjoin Sawai, and all persons acting in concert with Sawai, from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '393 patent, or such later date as the Court may determine;

25. enjoin Sawai, and all persons acting in concert with Sawai, from seeking, obtaining or maintaining approval of Sawai's ANDA No. 210285 until the expiration of the '393 patent, or such later date as the Court may determine;

26. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Sawai has infringed at least one claim including at least claim 1 of the '514 patent through Sawai's submission of ANDA No. 210285 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;

27. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Sawai'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);

28. 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;

29. enjoin Sawai, and all persons acting in concert with Sawai, 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;

30. enjoin Sawai and all persons acting in concert with Sawai, from seeking, obtaining or maintaining approval of Sawai's ANDA No. 210285 until the expiration of the '514 patent, or such later date as the Court may determine;

31. 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

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

ASHBY & GEDDES

/s/ Steven J. Balick

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