

4. Upon information and belief, Windlas 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 No. 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 Windlas’s filing of Abbreviated New Drug Application (“ANDA”) No. 210284 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.

6. Biogen MA Inc. filed a separate action involving the same ANDA in this Court against Windlas for patent infringement of U.S. Patent No. 8,399,514 (“the ’514 patent”), in *Biogen MA Inc. v. Windlas Healthcare, Pvt. Ltd.*, No. 1:17-cv-00849-LPS (D. Del. filed June 28, 2017) (“the First Suit”), which is now consolidated in *Biogen International GmbH et al. 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 Windlas dated May 30, 2017 (“the First Notice Letter”), which purported to include a Notice of Certification for ANDA No. 210284 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 Windlas dated July 20, 2018 (“the Second Notice Letter”), which purported to include a Notice of Certification

for ANDA No. 210284 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 Windlas is incorporated in India and may be sued in any judicial district in the United States, in which the defendant is subject to the court's personal jurisdiction.

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

11. Windlas “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). Windlas’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, Windlas “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, Windlas will engage in marketing of its proposed ANDA products in Delaware upon approval of its ANDA.

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

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

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

15. This Court also has personal jurisdiction over Windlas because, *inter alia*, Windlas 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, Windlas, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. According to its website, Windlas is “focused primarily on developed markets, and USA is the highest priority market.” (<http://www.windlashealthcare.com/countries-products-dossiers.html>, accessed August 23, 2018). Moreover, Windlas has “filed 4 ANDAs in USA in 2014 and aim to file 5-7 ANDAs each year.” (*Id.*) Upon information and belief, Windlas derives substantial revenue from the sale of those products in Delaware and have availed itself of the privilege of conducting business within the State of Delaware.

16. Alternatively, this Court has jurisdiction over Windlas under Federal Rule of Civil Procedure 4(k)(2), because, upon information and believe, Windlas is organized under the laws of India.

17. Upon information and belief, Windlas has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210284.

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

COUNT FOR PATENT INFRINGEMENT ('376 PATENT)

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

20. 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.

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

22. The ’376 patent expires on April 1, 2019, which includes an interim patent term extension for a period of one year, excluding any pediatric exclusivity or patent term extension.

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

24. 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.

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

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

27. Upon information and belief, Windlas submitted ANDA No. 210284 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.

28. The Second Notice Letter purported to include a Notice of Certification for ANDA No. 210284 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.

29. Windlas thus has actual knowledge of the ’376 patent.

30. 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).

31. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Windlas 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. 210284 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. 210284 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).

32. Upon information and belief, Windlas will manufacture, market, import, use, sell and/or offer to sell Defendant's generic products in the United States in connection with ANDA No. 210284 upon approval.

33. Upon information and belief, Windlas 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. 210284 upon approval.

34. Upon information and belief, Windlas's actions relating to Windlas's ANDA No. 210284 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Windlas.

35. If Windlas'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)

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

37. 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.

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

39. The '999 patent expires on October 20, 2019, which includes 202 dates of Patent Term Adjustment under 35 U.S.C. § 154(b), excluding any pediatric exclusivity or patent term extension.

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

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

42. The Second Notice Letter purported to include a Notice of Certification for ANDA No. 210284 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.

43. Windlas thus has actual knowledge of the '999 patent.

44. 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).

45. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Windlas 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. 210284 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. 210284 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).

46. 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.

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

48. Upon information and belief, if the FDA approves ANDA No 210284, Windlas 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 Windlas knows that physicians will prescribe and patients will use Defendant's generic products in accordance with the instructions and/or label provided by Windlas 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, Windlas will thus contribute to the infringement of at least one claim, including at least claim 1 of the '999 patent.

49. Upon information and belief, Windlas's actions relating to Windlas's ANDA No. 210284 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Windlas.

50. If Windlas'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.

REQUEST FOR RELIEF

WHEREFORE, Biogen respectfully requests that the Court enter judgment in its favor and against Defendant Windlas 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 Windlas has infringed at least one claim including at least claim 1 of the '376 patent through Windlas's submission of ANDA No. 210284 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 Windlas'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 Windlas, and all persons acting in concert with Windlas, 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 Windlas and all persons acting in concert with Windlas, from seeking, obtaining or maintaining approval of Windlas's ANDA No. 210284 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 Windlas has infringed at least one claim including at least claim 1 of the '999 patent through Windlas's submission of ANDA No. 210284 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 Windlas'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 Windlas, and all persons acting in concert with Windlas, 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 Windlas and all persons acting in concert with Windlas, from seeking, obtaining or maintaining approval of Windlas's ANDA No. 210284 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

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-188
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

*Attorneys for Plaintiff
Biogen International GmbH*

Of Counsel:

James B. Monroe
Li Feng
Sanya Sukduang
Paul W. Browning
Andrew E. Renison
Jeanette M. Roorda
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000

Dated: August 31, 2018