

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BIOGEN MA INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
SHILPA MEDICARE LIMITED,	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Biogen MA Inc. (“Biogen” or “Plaintiff”), by way of Complaint against Defendant Shilpa Medicare Limited (“Shilpa” or “Defendant”), alleges as follows:

**THE PARTIES**

1. Biogen 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.

2. Biogen is in the business of developing, manufacturing and marketing innovative therapies for patients living with serious neurological, autoimmune, and rare diseases, including therapies for multiple sclerosis. Biogen’s asserted patent covers Tecfidera<sup>®</sup>, which is marketed and sold in this judicial district and throughout the United States for the treatment of relapsing forms of multiple sclerosis.

3. Upon information and belief, Shilpa is a corporation organized under the laws of India, having a principal place of business at 12-6-214/A1, Hyderabad Road, Raichur, 584135, Karnataka, India.

4. Upon information and belief, Shilpa 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. 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 Shilpa’s filing of Abbreviated New Drug Application (“ANDA”) No. 210291 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to manufacture, use, sell, offer to sell, and import dimethyl fumarate delayed-release capsules prior to the expiration of the asserted patent.

#### **JURISDICTION AND VENUE**

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

7. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because Shilpa 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.

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

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

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

11. Shilpa’s ANDA filing regarding the ’514 patent has a substantial connection with this district because it reliably and non-speculatively predicts activities by Shilpa in this district.

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

13. This Court also has personal jurisdiction over Shilpa because, *inter alia*, Shilpa 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, Shilpa, either directly or through affiliates, currently sells significant quantities of generic drug products in the

United States and in the State of Delaware. These products include, for example, generic versions of Viagra®. A list of generic products sold by Shilpa can be found at [http://www.vbshilpa.com/products\\_oncology\\_otherpharma.html](http://www.vbshilpa.com/products_oncology_otherpharma.html) (accessed June 28, 2017). Further, Shilpa's 2015-2016 Annual Report states that "[i]n FY 15-16, Shilpa filed two ANDA with paragraph IV certifications" and that its "future plan 16-17" is to "file 3 ANDA with paragraph IV certification with US FDA." ([http://www.vbshilpa.com/pdf/Shilpa\\_Annual\\_Report\\_2015-2016.pdf](http://www.vbshilpa.com/pdf/Shilpa_Annual_Report_2015-2016.pdf), accessed June 27, 2017). Upon information and belief, Shilpa 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.

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

15. Upon information and belief, Shilpa has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210291.

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

**COUNT FOR PATENT INFRINGEMENT ('514 PATENT)**

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

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

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

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

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

22. The '514 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.

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

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

25. Upon information and belief, Shilpa submitted ANDA No. 210291 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.

26. Biogen received a letter from Shipla dated June 8, 2017 (“the Notice Letter”), purporting to include a Notice of Certification for ANDA No. 210291 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.

27. Shilpa thus has actual knowledge of the '514 patent.

28. 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).

29. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Shilpa 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. 210291 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. 210291 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).

30. 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 Defendant's generic products upon approval.

31. Upon information and belief, upon approval, Shilpa 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 Shilpa. Pursuant to 21 C.F.R. § 314.94, Shilpa is required to copy the FDA approved Tecfidera<sup>®</sup> labeling. Upon information and belief, Shilpa will thus induce the infringement of at least one claim including at least claim 1 of the '514 patent.

32. Upon information and belief, if the FDA approves ANDA No. 210291, Shilpa 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 Shilpa knows that physicians will prescribe and patients will use Defendant's generic products in accordance with the instructions and/or label provided by Shilpa 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, Shilpa will thus contribute to the infringement of at least one claim including at least claim 1 of the '514 patent.

33. Upon information and belief, Shilpa's actions relating to Shilpa's ANDA No. 210291 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Shilpa.

34. If Shilpa'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 Shilpa 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 Shilpa has infringed at least one claim including at least claim 1 of the '514 patent through Shilpa's submission of ANDA No. 210291 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;

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

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

4. enjoin Shilpa, and all persons acting in concert with Shilpa, 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;

5. enjoin Shilpa and all persons acting in concert with Shilpa, from seeking, obtaining or maintaining approval of Shilpa's ANDA No. 210291 until the expiration of the '514 patent, or such later date as the Court may determine;

6. 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

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

ASHBY & GEDDES

*/s/ Steven J. Balick*

*Of Counsel:*

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

---

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

*Attorneys for Plaintiff  
Biogen MA Inc.*

Dated: June 28, 2017