IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
CIPLA LIMITED and CIPLA USA INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Biogen International GmbH ("Biogen" or "Plaintiff"), by way of Complaint against Defendants Cipla Limited ("Cipla Ltd.") and Cipla USA Inc. ("Cipla USA") (collectively, "Cipla" 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. 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®, 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, Cipla Ltd. is a corporation organized under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, India.

4. Upon information and belief, Cipla Ltd. 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.

5. Upon information and belief, Cipla USA is a corporation organized under the laws of Delaware, having a principal place of business at 9100 S Dadeland Blvd. Ste. 1500, Miami, FL 33156.

6. Upon information and belief, Cipla USA is a subsidiary of Cipla Ltd.

7. Upon information and belief, Cipla 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 Cipla Ltd.

8. Upon information and belief, the acts of Cipla Ltd. complained of herein were done with the cooperation, participation and assistance of Cipla USA.

NATURE OF THE ACTION

9. This is an action for patent infringement of U.S. Patent No. 7,619,001 ("the '001 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 Cipla's filing of Abbreviated New Drug Application ("ANDA") No. 210305 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 containing 120 mg and 240 mg of dimethyl fumarate ("Defendants' generic products") prior to the expiration of the asserted patent.

10. Biogen International GmbH and Biogen MA Inc. filed a separate action involving the same ANDA in this Court against Cipla 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") in *Biogen International GmbH et al. v. Cipla Limited et al.*, No. 1:17-cv-00851-MN (D. Del. filed June 28, 2017) ("the First Suit"), which on February 2, 2018, was consolidated in this Court in *Biogen International GmbH et al. v. Amneal Pharmaceuticals LLC*, No. 1:17-cv-00823-MN (consolidated).

11. The First Suit was filed in response to a letter from Cipla dated May 25, 2017 ("the First Notice Letter"), which purported to include a Notice of Certification for ANDA No. 210305 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '376 patent, '999 patent, and '514 patent. The First Suit included counts for infringement of the '376 patent, '999 patent and '514 patent.

12. This complaint is filed in response to a new, second letter from Cipla dated October 18, 2019 ("the Second Notice Letter"), which purported to include a Notice of Certification for ANDA No. 210305 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '001 patent.

JURISDICTION AND VENUE

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

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

15. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because Cipla USA is incorporated in Delaware and Cipla Ltd. 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.

16. This Court has jurisdiction over Cipla Ltd. under Federal Rule of Civil Procedure 4(k)(2), because, upon information and belief, Cipla Ltd. is organized under the laws of India.

17. This court has jurisdiction over Cipla USA because Cipla USA is incorporated in Delaware.

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

19. Cipla "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," on 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). Cipla'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, Cipla "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, Cipla will engage in marketing of its proposed ANDA products in Delaware upon approval of its ANDA.

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

21. Cipla's ANDA filing, regarding the '001 patent, has a substantial connection with this district because it reliably and non-speculatively predicts activities by Cipla in this district.

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

23. This Court also has personal jurisdiction over Cipla because, *inter alia*, Cipla 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, Cipla, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Those products include, for example, generic versions of Lipitor® and Zoloft®. A list of generic products sold by Cipla can be found at http://www.ciplausa.com/content/products (accessed Nov. 11, 2019), the contents of which are incorporated herein by reference. Upon information and belief, Cipla derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business with the State of Delaware.

24. Upon information and belief, Cipla Ltd. maintains continuous and systematic contacts with Delaware through its U.S. subsidiary Cipla USA, incorporated in Delaware.

25. Upon information and belief, Cipla USA is registered to do business in Delaware (File No. 5207954). *See* https://icis.corp.delaware.gov/Ecorp/EntitySearch/NameSearch.aspx (Accessed Nov. 8, 2019).

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

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

28. Cipla has availed itself of Delaware courts through the assertion of counterclaims.

29. Upon information and belief, Cipla Ltd. and Cipla 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. Upon information and belief, Cipla is a "global pharmaceutical firm" having a "presence [in] 80+ countries . . . [t]o make healthcare more affordable globally." (https://www.cipla.com/about-us, accessed Nov. 8, 2019).

30. Upon information and belief, the effort to seek approval for ANDA No. 210305 and to manufacture, import, market, and/or sell Defendants' generic products upon approval has been a cooperative and joint enterprise and venture between Cipla Ltd. and Cipla USA.

31. Upon information and belief, Cipla Ltd. and Cipla USA have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing and maintaining ANDA No. 210305 and in commercializing Defendants' generic products in the United States, including in this judicial district, in accordance with ANDA No. 210305 upon approval.

32. Cipla did not contest subject matter jurisdiction, venue or personal jurisdiction in this Court for purposes of resolving Biogen's alleged claims in the First Suit related to Cipla's

filing of ANDA No. 210305. *See* October 16, 2017 Answer in First Suit in the Section of Jurisdiction and Venue. Biogen likewise alleges claims here related to Cipla's ANDA No. 210305. Accordingly, for at least the foregoing reasons, venue and personal jurisdiction are proper in this Court, and this Court has subject matter jurisdiction over Biogen's present claims against Cipla.

33. Upon information and belief, Cipla has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 210305.

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 Defendant.

FIRST COUNT FOR PATENT INFRINGEMENT ('001 PATENT)

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

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

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

38. The '001 patent expires on June 20, 2020, which includes 811 days of patent term extension.

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

40. The '001 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, Cipla submitted ANDA No. 210305 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 Defendants' generic products in the United States.

44. The Second Notice Letter purported to include a Notice of Certification for ANDA No. 210305 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '001 patent. The Second Notice Letter did not allege non-infringement as to at least one claim of the '001 patent.

45. Cipla thus has actual knowledge of the '001 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 '001 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), Cipla 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. 210305 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. 210305 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).

48. Upon information and belief, Cipla will manufacture, market, import, use, sell and/or offer to sell Defendants' generic products in the United States in connection with ANDA No. 210305 upon approval.

49. 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.

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

51. Upon information and belief, if the FDA approves ANDA No. 210305, Cipla 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 Cipla knows that physicians will prescribe and patients will use Defendants' generic products in accordance with the instructions and/or label provided by Cipla 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, Cipla will thus contribute to infringement of at least one claim including at least claim 1 of the '001 patent.

52. Upon information and belief, Cipla's actions relating to Cipla's ANDA No. 210305 complained of herein were done by and for the benefit of Cipla.

53. If Cipla'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.

REQUEST FOR RELIEF

WHEREFORE, Biogen respectfully requests that the Court enter judgment in its favor and against Defendants Cipla Ltd. and Cipla USA on the patent infringement claim set forth above and respectfully requests that this Court:

1. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Cipla has infringed at least one claim including at least claim 1 of the '001 patent through Cipla's submission of ANDA No. 210305 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;

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

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

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

5. enjoin Cipla, and all persons acting in concert with Cipla, from seeking, obtaining or maintaining approval of Cipla's ANDA No. 210305 until the expiration of the '001 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

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Dated: November 27, 2019