

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN HOLDINGS UNLIMITED)
COMPANY, ABBVIE INC., ABBVIE US LLC,)
and EDEN BIODESIGN, LLC,)
Plaintiffs,)
v.) C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES)
LIMITED,)
Defendant.)

COMPLAINT

Allergan Holdings Unlimited Company, AbbVie Inc., AbbVie US LLC, and Eden Biodesign, LLC (collectively, “Plaintiffs”), for their Complaint against Defendant Sun Pharmaceutical Industries Limited (“Sun”), hereby allege as follows.

THE PARTIES

1. Plaintiff Allergan Holdings Unlimited Company is an Irish unlimited liability company having a registered address at Clonshaugh Business & Technology Park, Coolock, Dublin 17, Ireland D17 E400.
2. Plaintiff AbbVie Inc. is a Delaware corporation with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064, United States.
3. Plaintiff AbbVie US LLC is a Delaware limited liability company having a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064, United States.
4. Plaintiff Eden Biodesign, LLC is a Delaware limited liability company having a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064, United

States.

5. Upon information and belief, Defendant Sun is a corporation organized and existing under the laws of India, having a place of business at Sun House, Plot. No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063. Upon information and belief, Defendant Sun manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action for patent infringement by Sun of Plaintiffs' U.S. Patent No. 12,097,187 (the "'187 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and arises from Sun's submission of Abbreviated New Drug Application ("ANDA") ANDA No. 213447 to the United States Food and Drug Administration ("FDA") seeking to commercialize a generic version of Plaintiffs' Viberzi® brand eluxadoline tablets throughout the United States, including in this judicial district, before the expiration of the '187 patent.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Sun because, *inter alia*, it has maintained continuous and systematic contacts with this judicial district and availed itself of the privilege of doing business in this judicial district. On information and belief, Sun has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of a tortious act of patent infringement that will lead to foreseeable harm and injury to Plaintiffs in Delaware. Sun has participated in the preparation, filing, and/or amendment of an ANDA seeking approval to market

and sell a generic version of Plaintiffs' branded product, Viberzi®, and has distribution channels and plans to market and sell its generic product throughout the United States, including in this judicial district, before the '187 patent expires.

9. This Court also has personal jurisdiction over Sun by virtue of, *inter alia*, its systematic and continuous contacts with Delaware. Upon information and belief, Sun is amenable to litigating in this forum based on Sun's conduct in multiple prior litigations in this judicial district. For example, Sun did not previously contest this Court's jurisdiction in this action, or in Plaintiffs' related, previously-filed civil actions regarding Sun's ANDA No. 213447, Civil Action Nos. 19-1727-RGA and 20-1479-RGA. *See Allergan USA, Inc. et al. v. Sun Pharm. Indus. Ltd. et al.*, C.A. No. 19-1727-RGA, D.I. 27 at ¶¶ 15, 23; D.I. 266 at ¶¶ 7-8; D.I. 346 at ¶¶ 7-8 (D. Del.); *Allergan USA, Inc. et al. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-1479-RGA, D.I. 8 at ¶¶ 8-9 (D. Del.).

10. Venue is proper in this judicial district for Sun pursuant to 28 U.S.C. § 1391 because Sun is organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this District.

THE PATENT

11. On September 24, 2024, the '187 patent, titled "Opioid Receptor Modulator Dosage Formulations," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Allergan Holdings Unlimited Company is the owner and assignee of the '187 patent. A copy of the '187 patent is attached hereto as Exhibit A.

12. AbbVie Inc. holds New Drug Application ("NDA") No. 206940 for Viberzi® brand eluxadoline tablets. Viberzi® is approved for the treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults. The '187 patent will be listed in

Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for Viberzi®.

13. AbbVie US LLC is the exclusive distributor of Viberzi® in the United States.
14. Eden Biodesign, LLC is the exclusive licensee of the ’187 patent.

ACTS GIVING RISE TO THIS ACTION

Count 1 – Patent Infringement by Sun

15. Upon information and belief, on or before July 31, 2019, Sun submitted ANDA No. 213447 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 213447 seeks FDA approval for the commercial manufacture, use, and sale of generic oral tablet products containing 75 mg and 100 mg of eluxadoline as the active ingredient.

16. Sun’s submission of ANDA No. 213447 to the FDA constitutes infringement of one or more claims of the ’187 patent under 35 U.S.C. § 271(e)(2)(A). Although the ’187 patent did not issue until after ANDA No. 213447 was filed, this does not preclude Sun from infringement liability under 35 U.S.C. § 271(e)(2). *Vanda Pharms. Inc. v. W.-Ward Pharms. Int’l Ltd.*, 887 F.3d 1117, 1127 (Fed. Cir. 2018).

17. Sun’s participation in, contribution to, inducement of, aiding, or abetting the submission of ANDA No. 213447 constitutes direct, contributory, or induced infringement of one or more claims of the ’187 patent under 35 U.S.C. § 271(e)(2)(A).

18. Upon information and belief, if Sun commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, products under ANDA No. 213447, or induces or contributes to any such conduct, it would further infringe, *inter alia*, one or more claims of the ’187 patent under 35 U.S.C. § 271(a), (b), and (c).

19. Upon information and belief, Sun has infringed, *inter alia*, one or more claims of

the '187 patent under 35 U.S.C. § 271(e)(2)(A), and, upon information and belief, will further infringe, *inter alia*, one or more of these claims under 35 U.S.C. § 271(a), (b), and (c), because, *inter alia*, the products under ANDA No. 213447 and the methods of using the products under ANDA No. 213447, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert and prescribing information will meet each and every claim element of one or more claims of the '187 patent, either literally or under the doctrine of equivalents.

20. Upon information and belief, Sun has participated in, contributed to, aided, abetted, and/or induced infringement of the '187 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '187 patent once the products under ANDA No. 213447 are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

21. Upon information and belief, Sun has knowledge that if it were to receive approval from the FDA to market the products under ANDA No. 213447 and make the products available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '187 patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, Sun has knowledge of such infringement and/or such infringing use and also knows that the products under ANDA No. 213447 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but rather are especially made to infringe and/or are especially adapted for use in the direct infringement of the '187 patent.

22. Sun's actions render this an exceptional case under 35 U.S.C. § 285.

23. Plaintiffs will be irreparably harmed by Sun's infringing activities unless those

activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

- a) That Sun's submission of ANDA No. 213447 is an act of infringement of one or more claims of the '187 patent under 35 U.S.C. § 271(e)(2);
- b) That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sun's ANDA No. 213447 shall not be earlier than the expiration date of the '187 patent, including any extensions or exclusivities;
- c) That Sun, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the products under ANDA No. 213447, and any other product that infringes or induces infringement or contributes to the infringement of the '187 patent, prior to the expiration of the '187 patent, including any extensions or exclusivities;
- d) That this is an exceptional case under 35 U.S.C. § 285 and that Plaintiffs be awarded the attorneys' fees, costs, and expenses that they incur prosecuting this action; and
- e) That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

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