IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED COMPANY and EDEN BIODESIGN, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 21-1065 (RGA)
SUN PHARMACEUTICAL INDUSTRIES LIMITED,	)	
Defendant.	)	

FIRST AMENDED COMPLAINT

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

THE PARTIES

1. Plaintiff Allergan USA, Inc. is a Delaware corporation with a principal place of business at 2525 Dupont Drive, Irvine, California 92612, United States. Plaintiff Allergan USA, Inc. has a registered address at 5 Giralda Farms, Madison, New Jersey 07940, United States.

2. Plaintiff Allergan Holdings Unlimited Company is an Irish corporation having a principal place of business at Clonshaugh Business & Technology Park, Coolock, Dublin 17, Ireland.

3. Plaintiff Eden Biodesign, LLC is a Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940, United States.

4. 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

5. This is a civil action for patent infringement by Sun of Allergan's United States Patent Nos. 11,007,179 (the "'179 patent") and 11,090,291 (the "'291 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 Allergan's Viberzi® brand eluxadoline tablets throughout the United States, including in this judicial district, before the expiration of the '179 and '291 patents.

JURISDICTION AND VENUE

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

7. 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 Allergan's 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 '179 and '291 patents expire.

8. 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 contest this Court's jurisdiction 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. 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.).

9. 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 PATENTS

10. On May 18, 2021, the '179 patent, titled "Opioid Receptor Modulator Dosage Formations," 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 '179 patent. A copy of the '179 patent is attached hereto as Exhibit A.

11. On August 17, 2021, the '291 patent, titled "Opioid Receptor Modulator Dosage Formulations," was duly and lawfully issued by the USPTO. Allergan Holdings Unlimited Company is the owner and assignee of the '291 patent. A copy of the '291 patent is attached hereto as Exhibit B.

12. Allergan Holdings Unlimited Company 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 '179 patent is listed in *Approved*

Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Viberzi®, along with fourteen other patents.

13. Allergan USA, Inc. is the exclusive distributor of Viberzi® in the United States.

14. Eden Biodesign, LLC is the exclusive licensee of the '179 and '291 patents.

ACTS GIVING RISE TO THIS ACTION

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 ("the Sun Generic Products").

16. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 213447 previously included certifications that the claims of U.S. Patent No. 9,675,587 (the "'587 patent") and U.S. Patent No. 10,188,632 (the "'632 patent") were invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, offer for sale, or sale of the Sun Generic Products. Allergan received written notification of ANDA No. 213447 and Sun's certifications pursuant to § 505(j)(2)(A)(vii)(IV) with respect to the '587 patent and the '632 patent on or about July 31, 2019, and timely filed suit with respect to those patents on September 13, 2019. *Allergan USA, Inc. et al. v. Sun Pharm. Indus. Ltd. et al.*, C.A. No. 19-1727-RGA (D. Del.).

17. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Sun amended ANDA No. 213447 to include certifications that the claims of U.S. Patent No. 7,741,356 (the "'356 patent") were invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, offer for sale, or sale of the Sun Generic Products. Allergan

received written notification of Sun's Amendment of ANDA No. 213447 and Sun's certifications pursuant to § 505(j)(2)(A)(vii)(IV) with respect to the '356 patent on or about October 8, 2020, and timely filed suit with respect to that patent on October 29, 2020. *See Allergan USA, Inc. et al. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-1479-RGA (D. Del.).

18. In a letter dated August 9, 2021, Sun advised Plaintiffs that it had amended ANDA No. 213447 to include certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, with respect to the '179 patent. Sun alleged that the claims of the '179 patent were invalid, unenforceable, and/or would not be infringed by the manufacture, importation, use, sale, or offer for sale of the Sun Generic Products.

19. Sun has not submitted any certifications pursuant to § 505(j)(2)(A)(vii)(IV) for the patents listed in the Orange Book for Viberzi® other than the '587, '632, '179, and '356 patents. On information and belief, Sun has submitted certifications pursuant to § 505(j)(2)(A)(vii)(III), representing to the FDA that it will not launch its proposed generic eluxadoline products prior to the expiration of U.S. Patent No. 7,786,158 ("the '158 Patent"); U.S. Patent No. 8,344,011 ("the '011 Patent"); U.S. Patent No. 8,609,709 ("the '709 Patent"); U.S. Patent No. 8,772,325 ("the '325 Patent"); U.S. Patent No. 9,205,076 ("the '076 Patent"); U.S. Patent No. 9,700,542 ("the '542 Patent"); U.S. Patent No. 10,213,415 ("the '415 Patent"); U.S. Patent No. 8,691,860 ("the '860 Patent"); U.S. Patent No. 9,115,091 ("the '091 Patent"); U.S. Patent No. 9,364,489 ("the '489 Patent"); and U.S. Patent No. 9,789,125 ("the '125 Patent"), listed in the Orange Book for Viberzi®. The unchallenged patents expire as late as July 7, 2028. As a result, under the Hatch-Waxman Act, Sun cannot manufacture, import into the United States, use, sell, or offer for sale the Sun Generic Products described in ANDA No. 213447 prior to July 7, 2028, regardless of the outcome of this action.

20. Sun's submission of ANDA No. 213447 to the FDA constitutes infringement of one or more claims of the '179 and '291 patents under 35 U.S.C. § 271(e)(2)(A). Although the '179 and '291 patents 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).

21. 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 '179 and '291 patents under 35 U.S.C. § 271(e)(2)(A).

22. Upon information and belief, if Sun commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Sun Generic Products, or induces or contributes to any such conduct, it would further infringe, *inter alia*, one or more claims of the '179 and '291 patents under 35 U.S.C. § 271(a), (b), and (c).

23. Upon information and belief, Sun has infringed, *inter alia*, one or more claims of the '179 and '291 patents 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 Sun Generic Products and the methods of using the Sun Generic Products, *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 '179 and '291 patents, either literally or under the doctrine of equivalents.

24. Upon information and belief, Sun has participated in, contributed to, aided, abetted, and/or induced infringement of the '179 and '291 patents and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '179 and '291 patents once the Sun Generic Products

are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

25. Upon information and belief, Sun has knowledge that if it were to receive approval from the FDA to market the Sun Generic Products described in ANDA No. 213447 and make the Sun Generic 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 '179 and '291 patents, 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 described in 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 '179 and '291 patents.

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

27. 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 '179 and '291 patents 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 dates of the '179 and '291 patents, 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 Sun Generic Products, and any other product that infringes or induces infringement or contributes to the infringement of the '179 or '291 patents, prior to the expiration of the '179 and '291 patents, 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:

Lisa B. Pensabene
Hassen Sayeed
Daniel O'Boyle
Carolyn Wall
James Yi Li
Mark A. Hayden
O'MELVENY & MYERS LLP
7 Times Square
New York, NY 10036
(212) 326-2000

August 17, 2021