IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGEN USA, INC., ALLERGAN HOLDINGS UNLIMITED COMPANY, ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED and JANSSEN PHARMACEUTICA NV,	)	
Plaintiff,	)	
v.	)	Case No. 1:19-cv-01674-RGA
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

ANSWER AND DEFENSES TO PLAINTIFF'S COMPLAINT AGAINST AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA, INC.

Defendants Aurobindo Pharma LTD. ("APL") and Aurobindo Pharma USA, Inc. ("APUI") (collectively for identification purposes only, "Aurobindo"), by and through their undersigned counsel, respectfully submit their Answer and Defenses to Plaintiff's Complaint, stating as follows:

I. RESPONSE TO ALLEGATIONS PERTAINING TO THE PARTIES

1. Plaintiff Allergan USA, Inc. is a Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the allegations in this paragraph, and therefore denies the same.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the allegations in this paragraph, and therefore denies the same.

3. Plaintiff Allergan Pharmaceuticals International Limited is an Irish corporation having a principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland (referred to herein, together with Allergan USA, Inc., and Allergan Holdings Unlimited Company, as "Allergan").

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the allegations in this paragraph, and therefore denies the same.

4. Plaintiff Janssen Pharmaceutica NV is a Belgian corporation having a principal place of business at Turnhoutseweg 30, Beerse B-2340, Belgium ("Janssen").

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the allegations in this paragraph, and therefore denies the same.

5. Upon information and belief, Defendant Aurobindo Pharma Ltd. is an Indian corporation having a principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Upon information and belief, Defendant Aurobindo Pharma Ltd. manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its wholly-owned subsidiary and agent Aurobindo Pharma USA, Inc.

RESPONSE: Aurobindo admits APL is an Indian company having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Telangana, India. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

6. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. is a Delaware corporation having a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. (referred to herein, together with Aurobindo Pharma Ltd., as "Aurobindo") is a wholly owned subsidiary of Aurobindo Pharma Ltd. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as a subsidiary and agent of Aurobindo Pharma Ltd.

RESPONSE: Aurobindo admits APUI is a Delaware corporation with a place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

II. RESPONSES PERTAINING TO THE NATURE OF THE ACTION

7. This is a civil action for the infringement by Aurobindo of United States Patent Nos. 7,741,356 ("the '356 patent"), 7,786,158 ("the '158 patent"), 8,344,011 ("the '011 patent"), 8,609,709 ("the '709 patent"), 8,772,325 ("the '325 patent"), 9,205,076 ("the '076 patent"), 9,700,542 ("the '542 patent"), and 10,213,415 ("the '415 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and arises from Aurobindo's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking to commercialize generic versions of Plaintiffs' Viberzi® brand eluxadoline tablets throughout the United States, including in this judicial district, before the expiration of Plaintiffs' applicable patents.

RESPONSE: Aurobindo admits Plaintiffs purport to bring this action pursuant to the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*. Aurobindo admits plaintiffs allege APL's ANDA infringes one or more claims of the '356, '158, '011, '709, '325, '076, '542 and '415 patents (the "patents-in-suit") but denies all such allegations. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

III. RESPONSE TO ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action

pursuant to 28 U.S.C. §§ 1331 and 1338(a).

RESPONSE: Aurobindo admits the Court has subject matter jurisdiction over claims arising under the Patent Laws of the United States. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

9. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. Each of the Defendants has participated in the preparation and/or filing 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 Plaintiffs' applicable patents expire. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not dispute personal jurisdiction. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

10. This Court has personal jurisdiction over Defendant Aurobindo Pharma Ltd. by virtue of, *inter alia*: (1) its presence in Delaware, including through its subsidiary and agent Defendant Aurobindo Pharma USA, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Defendant Aurobindo Pharma USA, Inc. Upon information and belief, Aurobindo Pharma Ltd. is amenable to litigating in this forum based on Aurobindo Pharma Ltd.'s conduct in multiple prior litigations in this District. For example, Aurobindo Pharma Ltd. did not contest jurisdiction in Civil Action No. 14-664 (D.I.12), Civil Action No. 14-872 (D.I. 16), Civil Action No. 14-909 (D.I. 10), Civil Action No. 14- 1203 (D.I. 9), Civil Action No. 14-1469 (D.I. 8), Civil Action No. 15-902 (D.I. 59), Civil Action No. 15-1032 (D.I. 8), Civil Action No. 16-451 (D.I. 8), Civil Action No. 18-932 (D.I. 9), or Civil Action No. 19-748 (D.I. 11).

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not dispute personal

jurisdiction. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

11. This Court has personal jurisdiction over Defendant Aurobindo Pharma USA, Inc. by virtue of, *inter alia*, the fact that Aurobindo Pharma USA, Inc. is a Delaware corporation.

RESPONSE: APUI admits the Court has personal jurisdiction over APUI. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

12. Venue is proper in this judicial district as to Aurobindo pursuant to 28 U.S.C. §§ 1391 and 1400(b).

RESPONSE: Solely for purposes of this litigation, Aurobindo does not challenge venue in this District. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

IV. RESPONSE TO ALLEGATIONS PERTAINING TO THE PATENTS-IN-SUIT

13. On June 22, 2010, the '356 patent, titled "Compounds As Opioid Receptor Modulators," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). The USPTO issued a certificate of correction for the '356 patent on September 23, 2014. Janssen is the sole owner of the '356 patent. Allergan is the exclusive licensee of the '356 patent with respect to manufacturing and commercializing therapeutic products containing eluxadoline worldwide, including in the United States. A copy of the '356 patent, including its certificate of correction, is attached hereto as Exhibit A.

RESPONSE: Denied.

14. On August 31, 2010, the '158 patent, titled "Compounds As Opioid Receptor Modulators," was duly and lawfully issued by the USPTO. The USPTO issued a certificate of correction for the '158 patent on January 14, 2014. Janssen is the sole owner of the '158 patent. Allergan is the exclusive licensee

of the '158 patent with respect to manufacturing and commercializing therapeutic products containing eluxadoline worldwide, including in the United States. A copy of the '158 patent, including its certificate of correction, is attached hereto as Exhibit B.

RESPONSE: Denied.

15. On January 1, 2013, the '011 patent, titled "Compounds As Opioid Receptor Modulators," was duly and lawfully issued by the USPTO. Janssen is the sole owner of the '011 patent. Allergan is the exclusive licensee of the '011 patent with respect to manufacturing and commercializing therapeutic products containing eluxadoline worldwide, including in the United States. A copy of the '011 patent is attached hereto as Exhibit C.

RESPONSE: Denied.

16. On December 17, 2013, the '709 patent, titled "Compounds As Opioid Receptor Modulators," was duly and lawfully issued by the USPTO. Janssen is the sole owner of the '709 patent. Allergan is the exclusive licensee of the '709 patent with respect to manufacturing and commercializing therapeutic products containing eluxadoline worldwide, including in the United States. A copy of the '709 patent is attached hereto as Exhibit D.

RESPONSE: Denied.

17. On July 8, 2014, the '325 patent, titled "Compounds As Opioid Receptor Modulators," was duly and lawfully issued by the USPTO. Janssen is the sole owner of the '325 patent. Allergan is the exclusive licensee of the '325 patent with respect to manufacturing and commercializing therapeutic products containing eluxadoline worldwide, including in the United States. A copy of the '325 patent is attached hereto as Exhibit E.

RESPONSE: Denied.

18. On December 8, 2015, the '076 patent, titled "Compounds As Opioid Receptor Modulators," was duly and lawfully issued by the USPTO. Janssen is the sole owner of the '076 patent. Allergan is the exclusive licensee of the '076

patent with respect to manufacturing and commercializing therapeutic products containing eluxadoline worldwide, including in the United States. A copy of the '076 patent is attached hereto as Exhibit F.

RESPONSE: Denied.

19. On July 11, 2017, the '542 patent, titled "Compounds As Opioid Receptor Modulators," was duly and lawfully issued by the USPTO. Janssen is the sole owner of the '542 patent. Allergan is the exclusive licensee of the '542 patent with respect to manufacturing and commercializing therapeutic products containing eluxadoline worldwide, including in the United States. A copy of the '542 patent is attached hereto as Exhibit G.

RESPONSE: Denied.

20. On February 26, 2019, the '415 patent, titled "Compounds As Opioid Receptor Modulators," was duly and lawfully issued by the USPTO. Janssen is the sole owner of the '415 patent. Allergan is the exclusive licensee of the '415 patent with respect to manufacturing and commercializing therapeutic products containing eluxadoline worldwide, including in the United States. A copy of the '415 patent is attached hereto as Exhibit H.

RESPONSE: Denied.

21. 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 '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent are all listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Viberzi®.

RESPONSE: Aurobindo admits the patents-in-suit are listed in the Orange Book for the drug product Viberzi®. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the allegations in this paragraph, and therefore denies the same.

V. RESPONSE TO ALLEGED ACTS GIVING RISE TO THIS ACTION

23. Upon information and belief, on or before July 30, 2019, Aurobindo submitted ANDA No. 213511 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 213511 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 Aurobindo Generic Products"). ANDA No. 213511 specifically seeks FDA approval to market the Aurobindo Generic Products prior to the expiration of, *inter alia*, the '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent.

RESPONSE: Admitted.

24. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Aurobindo alleges in ANDA No. 213511 that the claims of the '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Aurobindo Generic Products. On or after July 31, 2019, Janssen received a letter from Aurobindo's counsel notifying Janssen of ANDA No. 213511, including its § 505(j)(2)(A)(vii)(IV) allegations.

RESPONSE: Admitted.

25. Aurobindo's submission of ANDA No. 213511 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of, *inter alia*, claims 1-43 of the '356 patent, claims 1-29 of the '158 patent, claims 1-78 of the '011 patent, claims 1-8 of the '709 patent, claims 1-23 of the '325 patent, claims 1-24 of the '076 patent, claims 1-19 of the '542 patent, and claims 1-2 of the '415 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Aurobindo commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Aurobindo Generic Products, or induces or contributes to any such conduct, it would further infringe, *inter alia*, these claims of the '356 patent, the '158 patent, the '011 patent, the '709 patent,

the '325 patent, the '076 patent, the '542 patent, and the '415 patent under 35 U.S.C. § 271(a), (b), and/or (c).

RESPONSE: Denied.

26. Aurobindo has infringed the identified claims under 35 U.S.C. § 271(e)(2)(A), and will further infringe one or more of these claims under 35 U.S.C. § 271(a), (b), and/or (c), because, *inter alia*, the Aurobindo Generic Products and the methods of using the Aurobindo 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 '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent, either literally or under the doctrine of equivalents.

RESPONSE: Denied.

27. Upon information and belief, Aurobindo has participated in, contributed to, aided, abetted, and/or induced infringement of the '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent once the Aurobindo Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

RESPONSE: Denied.

28. Upon information and belief, Aurobindo has knowledge that if it were to receive approval from the FDA to market the Aurobindo Generic Products described in ANDA No. 213511 and make the Aurobindo 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 '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Aurobindo has knowledge of such infringing use and also knows that the products described in ANDA No. 213511 are not a staple article or commodity of commerce suitable for substantial non-infringing use,

but rather are especially made and/or adapted for use in the direct infringement of the '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent.

RESPONSE: Denied.

29. Upon information and belief, Aurobindo was aware of the '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent prior to the submission of ANDA No. 213511, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents. Upon information and belief, the proposed label and prescribing information for the Aurobindo Generic Products will induce others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe the '356 patent, the '158 patent, the '011 patent, the '709 patent, the '325 patent, the '076 patent, the '542 patent, and the '415 patent, and, based on Aurobindo's § 505(j)(2)(A)(vii)(IV) allegations, Aurobindo possesses the specific intent to encourage others to infringe.

RESPONSE: Denied.

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

RESPONSE: Denied.

31. Plaintiffs will be irreparably harmed by Aurobindo's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

RESPONSE: Denied.

VI. GENERAL DENIAL AND RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

All allegation in Plaintiffs' Complaint not expressly admitted by Aurobindo are hereby denied. Having answered Plaintiffs' complaint, Aurobindo denies Plaintiffs are entitled to any

of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Aurobindo asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiffs.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of APL's ANDA No. 206940 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the patents-in-suit.

SECOND SEPARATE DEFENSE

Each of the claims of each of the patents-in-suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or for satisfying other bases (including judicially-created bases) for invalidation or unenforceability, for example, for at least the reasons set forth in APL's Notice Letter dated July 30, 2019.

THIRD SEPARATE DEFENSE

Each of the claims of each of the patents-in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102, 103, for example, for at least the reasons set forth in APL's Notice Letter dated July 30, 2019.

FOURTH SEPARATE DEFENSE

Each of the claims of each of the patents-in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. § 112, for example, indefiniteness, lack of enablement and/or written

description, for example, for least the reasons set forth in APL's Notice Letter dated July 30, 2019.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the patents-in-suit, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the patents-in-suit is infringed by the product that is the subject of APL's ANDA No. 206940.

SIXTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

SEVENTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Aurobindo hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patents-in-suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: December 2, 2019

/s/ Kenneth L. Dorsney

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