Marc D. Youngelson, Esq.
COSNER YOUNGELSON
197 Route 18, Ste 104 East
Brunswick, NJ 08816
Phone: (732) 937-8000
Fax: (732) 937-5439
marc@cosnerlaw.com

Of counsel:

Steven J. Moore, Esq. (*pro hac vice*)
James Nealon, Esq. (*pro hac vice*)
WITHERS BERGMAN LLP
1700 East Putnam Avenue
Greenwich, Connecticut 06830
Phone: (203) 302-4100
Fax: (203) 302-6611
Steven.moore@withersworldwide.com
James.nealon@withersworldwide.com

Attorneys for Defendants
Aurobindo Pharma USA, Inc.
and Aurobindo Pharma Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS, LTD., Plaintiff, v. AURORBINDO PHARMA USA INC. and AUROBINDO PHARMA LTD., Defendants.	Case No. 3:19-cv-15437-FLW-LHG *Document Electronically Filed*

DEFENNDANTS AUROBINDO PHARMA U.S.A., INC.'S AND AUROBINDO PHARMA LTD.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants Aurobindo Pharma USA, Inc. and Aurobindo Pharma LTD. (“Aurobindo”, and together, "Defendants"), through their undersigned counsel, hereby answers the complaint filed by Plaintiff Actelion Pharmaceuticals, Ltd. ("Plaintiff" or "Actelion") as follows:

THE PARTIES

1. Plaintiff Actelion Pharmaceuticals Ltd is a Swiss corporation having a primary place of business at Gewerbestrasse 16, CH-4123 Allschwil, and Switzerland.

ANSWER: Aurobindo admits, upon information and belief, that Actelion is organized and existing under the laws of Switzerland and has a place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland. Except as expressly so admitted, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of the remaining allegations in paragraph 1 of the Complaint and therefore denies them.

2. Upon information and belief, Defendant Aurobindo Pharma USA Inc. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401.

ANSWER: It is admitted that Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401 USA. To the extent of any remaining allegations, Aurobindo denies the same.

3. Upon information and belief, Aurobindo USA operates a distribution center at 6 Wheeling Road, Dayton, NJ 08810-1526.

ANSWER: Admitted.

4. Upon information and belief, Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100921223 and is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003120 and a manufacturer under Registration No. 5005541.

ANSWER: Admitted.

5. Upon information and belief, Defendant Aurobindo Pharma Limited is an entity organized and existing under the laws of India, having a principal place of business office at Maitri Vihar, Plot #2, Ameerpet, Hyderabad - 500038, Telangana, India.

ANSWER: Admitted.

6. Upon information and belief, Aurobindo Limited is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100904116.

ANSWER: Admitted.

7. Upon information and belief, Aurobindo Limited directly, or through its subsidiaries, agents, and/or alter egos, develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

ANSWER: Aurobindo admits that Aurobindo Limited is in the business of developing, manufacturing and selling drug products on a worldwide basis, including FDA approved versions of branded pharmaceutical drugs. Except as expressly so admitted, Aurobindo denies the remainder of paragraph 7.

8. Upon information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Limited.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required, but to the extent an answer may be deemed required, Aurobindo denies the same.

9. Upon information and belief, Aurobindo USA acts at the direction, and for the benefit, of Aurobindo Limited and is controlled and/or dominated by Aurobindo Limited.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required, but to the extent an answer may be deemed required, Aurobindo denies the same.

10. Upon information and belief, Aurobindo Limited and Aurobindo USA work in concert, either directly or indirectly, with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: Paragraph10 contains legal conclusions and allegations to which no answer is required, but to the extent an answer may be deemed required, Aurobindo denies the same.

11. Aurobindo USA sent Actelion a Notice Letter dated June 19, 2019, stating that Aurobindo USA filed Abbreviated New Drug Application ("ANDA") No. 211198, seeking approval from the United States Food and Drug Administration ("FDA") to commercially manufacture, use, market, or sell generic macitentan 10 mg oral tablets in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of United States Patent No. 7,094,781 ("the '781 patent" or "the patent-in-suit").

ANSWER: Admits that Aurobindo USA sent Actelion a Notice Letter dated June 19, 2019 (the "Notice Letter"), stating that Aurobindo USA filed Abbreviated New Drug Application ("ANDA") No. 211198, seeking approval from the United States Food and Drug Administration ("FDA") to commercially manufacture, use, market, or sell generic macitentan 10 mg oral tablets in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of United States Patent No. 7,094,781 ("the '781 patent" or "the patent-in-suit"), and respectfully refers the Court to the Notice Letter and the ANDA for their complete contents and applicable terms, and except as expressly so admitted, Aurobindo denies the remainder of the allegations of paragraph 11 of the Complaint.

JURISDICTION AND VENUE

12. This is a civil action for infringement of Claim 11 of the '781 patent. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo admits that Plaintiff's Complaint purports to be a civil action alleging infringement pursuant to Title 35 of the United States Code and the Declaratory Judgment Act but except as expressly so admitted, to the extent any other allegations remain, Aurobindo denies all other allegations in paragraph 12.

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, and for the limited purposes of this action only, Aurobindo does not oppose or otherwise contest the existence of subject matter jurisdiction in this Court. Otherwise, Aurobindo denies all remaining allegations of Paragraph 13.

14. Venue is proper in this Court as to Aurobindo USA under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because Aurobindo USA has a regular and established place of business in New Jersey, and has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Aurobindo admits for the purposes of this action alone that it does not contest venue. Otherwise, Defendant denies all remaining allegations of Paragraph 14.

15. This Court has personal jurisdiction, and venue is proper as to Aurobindo USA, because, inter alia, Aurobindo USA: (1) has its principal place of business in New Jersey; (2) has purposely availed itself of the privilege of doing business in New Jersey, including by, *inter alia*, registering with the State of New Jersey's Division of Revenue and Enterprise Service to do business in the State of New Jersey under entity ID No. 0100921223 and securing a New Jersey wholesale drug distributor's license under Registration No. 5003120; (3) maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of New Jersey; and (4) upon information and belief, derives substantial revenue from the sale of its products in New Jersey.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Defendant admits that it has its principal place of business in New Jersey and, for the limited purposes of this action only, Defendant does not oppose and submits to personal jurisdiction in this Court. Otherwise, Defendant denies all remaining allegations of Paragraph 15.

16. This Court also has personal jurisdiction over Aurobindo USA because, inter alia, Aurobindo USA has committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Actelion in the State of New Jersey.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Defendant admits that it has its principal place of business in New Jersey and, for the limited purposes of this action only, Defendant does not oppose and submits to personal jurisdiction in this Court. Otherwise, Defendant denies all remaining allegations of Paragraph 16.

17. This Court also has personal jurisdiction over Aurobindo USA because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously initiating litigation and consenting to personal jurisdiction in this Judicial District. *See, e.g.*, *Mylan Specialty L.P. v. Aurobindo Pharma USA Inc.*, Civil Action No. 18-15190 (D.N.J.); *Valeant Pharmaceuticals North America LLC, et al. v. Aurobindo Pharma USA Inc., et al.*, Civil Action No. 18-13693 (D.N.J.); *Celgene Corp. v. Hetero Labs Limited, et al.*, Civil Action No. 17-3387 (D.N.J.); *Aurobindo Pharma USA Inc., et al. v. Apicore US LLC*, et al., Civil Action No. 16-3358 (D.N.J.).

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Defendant admits that it has its principal place of business in New Jersey and, for the limited purposes of this action only, Defendant does not oppose and submits to personal jurisdiction in this Court. Otherwise, Defendant denies all remaining allegations of Paragraph 17.

18. Venue is proper in this Court as to Aurobindo Limited under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because, *inter alia*, Aurobindo Limited, directly or indirectly through its subsidiaries, agents, and/or alter egos, has a regular and established place of business in New Jersey, and has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, and for the limited purposes of this action only, Defendant does not oppose and submits to personal jurisdiction in this Court. Otherwise, except as expressly so admitted, Defendant denies all remaining allegations of Paragraph 18.

19. This Court has personal jurisdiction, and venue is proper as to Aurobindo Limited, because, *inter alia*, Aurobindo Limited: (1) has purposely availed itself of the privilege of doing business in New Jersey, directly or indirectly through its subsidiaries, agents, and/or alter egos, including by, inter alia, registering with the State of New Jersey's Division of Revenue and Enterprise Service to do business in the State of New Jersey; (2) maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of New Jersey, including through, directly or indirectly, its subsidiaries, agents, and/or alter egos; and (3) upon information and belief, derives substantial revenue from the sale of its products in New Jersey, including through, directly or indirectly, its subsidiaries, agents, and/or *alter egos*.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, and for the limited purposes of this action only, Defendant does not oppose and submits to personal jurisdiction in this Court. Otherwise, except as expressly so admitted, Defendant denies all remaining allegations of Paragraph 19.

20. This Court has personal jurisdiction over Aurobindo Limited because, inter alia, Aurobindo Limited, either directly or indirectly through its subsidiaries, agents and/or alter egos, has committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Actelion in the State of New Jersey.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, and for the limited purposes of this action only, Defendant does not oppose and submits to personal jurisdiction in this Court. Otherwise, except as expressly so admitted, Defendant denies all remaining allegations of Paragraph 20.

21. This Court also has personal jurisdiction over Aurobindo Limited because, inter alia, it has availed itself of the legal protections of the State of New Jersey by previously initiating litigation and consenting to personal jurisdiction in this Judicial District. *See, e.g, Valeant Pharmaceuticals North America LLC et al. v. Aurobindo Pharma USA Inc., et al.*, Civil Action No. 18-13693 (D.N.J.); *Celgene Corp. v. Hetero Labs Limited, et al.*, Civil Action No. 17-3387 (D.N.J.); *Aurobindo Pharma USA Inc. et al. v. Apicore US LLC, et al.*, Civil Action No. 16-3358 (D.N.J.); *Aurobindo Pharma Ltd., et al. v. AstraZeneca AB, et al.*, Civil Action No. 16-5079 (D.N.J.).

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, and for the limited purposes of this action only, Defendant does not oppose and submits to personal jurisdiction in this Court. Otherwise, except as expressly so admitted, Defendant denies all remaining allegations of Paragraph 20.

THE PATENTS IN SUIT

22. Actelion holds approved New Drug Application ("NDA") No. 204410, under which the FDA granted approval on October 18, 2013 for macitentan 10 mg oral once-a-day tablets, marketed in the United States under the trade name OPSUMIT®.

ANSWER: Paragraph 22 sets forth a legal conclusion based on alleged activities to which no response is required. To the extent a response is deemed required, Aurobindo admits that the Orange Book lists Actelion is the holder of NDA No. 204410 for OPSUMIT®, that the FDA approved the same on or about October 18, 2013. With respect to any remaining allegations of Paragraph 22, Aurobindo denies the same.

23. OPSUMIT® (macitentan), approved in NDA No. 204410, is indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group 1) to delay disease progression.

ANSWER: Aurobindo respectfully refers the Court to NDA No. 204410 for its complete contents and except as expressly so admitted denies the remainder of the allegations of Paragraph 23.

24. As part of the FDA approval for OPSUMIT®, Actelion received Orphan Drug exclusivity, which expires October 18, 2020.

ANSWER: Aurobindo respectfully refers the Court to NDA No. 204410 and any applicable FDA approval documents for their complete contents and except as expressly so admitted denies the remainder of the allegations of Paragraph 24.

25. Actelion owns the '781 patent titled, "Sulfamides and Their Use as Endothelin Receptor Antagonists." The '781 patent duly and legally issued on August 22, 2006. A copy of the '781 patent is attached as Exhibit A.

ANSWER: Paragraph 25 sets forth legal conclusions to which no response is required. To the extent an answer is deemed required, Aurobindo admits that, according to the face of U.S. Patent No. '781 it issued on August 22, 2006, and that a copy of the document purporting to be the '781 patent was annexed to Plaintiffs' Complaint as Exhibit A, but except as expressly so admitted Aurobindo denies the remainder of the allegations of paragraph 25.

26. Pursuant to 21 U.S.C. § 355(b)(l), the '781 patent is listed in the United States Food and Drug Administration ("FDA") publication titled, *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book"), as covering Actelion's OPSUMIT® brand macitentan tablets.

ANSWER: Admitted except Aurobindo respectfully refers the Court to the applicable portions of the Orange Book concerning the specifics of the listing therein of the '781 patent.

AUROBINDO'S ANDA AND NOTICE LETTER

27. Upon information and belief, Aurobindo submitted ANDA No. 211198 to the FDA, and that ANDA now includes a certification with respect to the '781 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of generic macitentan ("Aurobindo's ANDA Product") prior to expiration of the '781 patent.

ANSWER: Admit the allegations of paragraph 27.

28. Upon information and belief, on or about June 19, 2019, Aurobindo USA sent a Paragraph IV Certification Notice Letter to Actelion. In its Notice Letter, Aurobindo USA represented that ANDA No. 211198 included a Paragraph IV Certification with respect to the '781 patent and that Aurobindo sought approval of ANDA No. 211198 prior to the expiration of the '781 patent. On or about June 20, 2019, Actelion first received Aurobindo's Paragraph IV Certification Notice Letter.

ANSWER: Admit the allegations of paragraph 27 except refers the Court to the Paragraph IV Notice letter for its true and complete terms.

29. Actelion commenced this action within 45 days of the date of receipt of the Notice Letter, which was dated June 19, 2019.

ANSWER: Admits the allegations of paragraph 29 of the Complaint.

ACTS GIVING RISE TO THIS ACTION

ALLEGED INFRINGEMENT BY AUROBINDO

30. Actelion re-alleges paragraphs 1-29 as if fully set forth herein.

ANSWER: Aurobindo repeats and incorporates herein by reference its previous answers to paragraphs 1-29 of this Complaint.

31. In its Paragraph IV Certification Notice Letter, Aurobindo represented that "the active ingredient in the proposed drug product is Macitentan." By seeking approval of ANDA No. 211198 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Aurobindo's ANDA Product prior to the expiration of the '781 patent, Aurobindo has infringed Claim 11 of the '781 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Aurobindo respectfully refers the Court to its Paragraph IV Notice Letter for its true and complete terms, and denies the remainder of the allegations of paragraph 31.

32. Upon information and belief, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Aurobindo's ANDA Product meets or embodies all steps of Claim 11 of the '781 patent.

ANSWER: Denies paragraph 32.

33. Upon information and belief, Aurobindo intends to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Aurobindo's ANDA Product upon receipt of final FDA approval of ANDA No. 211198.

ANSWER: Due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States upon receiving FDA approval to market for same. With respect to any remaining allegations of Paragraph 33, Aurobindo denies the same.

34. If Aurobindo manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, Aurobindo's ANDA Product prior to the expiration of the '781 patent, Aurobindo will infringe Claim 11 of the '781 patent under 35 U.S.C. §§ 271(a), (b), (c) or (g).

ANSWER: Denies paragraph 34.

35. Actelion is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Aurobindo's ANDA be a date that is not earlier than the expiration date of the '781 patent, or any later expiration of any patent term extension or exclusivity for the '781 patent to which Actelion is or becomes entitled.

ANSWER: Denies paragraph 35.

36. Actelion is entitled to a declaration that, if Aurobindo commercially manufactures, uses, offers for sale, or sells Aurobindo's ANDA Product within the United States, imports Aurobindo's ANDA Product into the United States, or induces or contributes to such conduct, Aurobindo will infringe Claim 11 of the '781 patent under 35 U.S.C. §§ 271(a), (b), (c), or (g).

ANSWER: Denies paragraph 36.

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

ANSWER: Denies paragraph 37.

PLAINTIFF'S PRAYER FOR RELIEF

WHEREFORE, Actelion requests that the Court grant the following relief:

A. A Judgment decreeing that Aurobindo has infringed Claim 11 of the '781 patent by submitting ANDA No. 211198;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Aurobindo, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Aurobindo, from infringing Claim 11 of the '781 patent by the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of any drug product claimed in the aforementioned patent;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 211198 be a date that is not earlier than the expiration date of the '781 patent, or any later expiration of any patent term extension or exclusivity for the aforementioned patent to which Actelion is or becomes entitled;

D. An award of monetary relief to the extent Aurobindo commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of Claim 11 of the '781 patent within the United States prior to the expiration of the aforementioned patent, including any later expiration of any patent term extension or exclusivity for the patent to which Actelion is or becomes entitled, and that any such monetary relief be awarded to Actelion with prejudgment interest; and

E. Such other and further relief as the Court may deem just and proper.

ANSWER TO PRAYER FOR RELIEF: The "WHEREFORE" paragraphs following ¶37 of the Complaint states Plaintiff's prayer for relief for which no response is required. To the extent a response is required, Defendants deny the allegations contained in the "WHEREFORE" paragraphs following ¶37 of the Complaint and deny that Plaintiff is entitled to any of the relief requested, or to any relief whatsoever. Aurobindo specifically denies that Plaintiff is entitled to the general or specific relief requested against Aurobindo, or to any relief whatsoever, and pray for judgment in favor of Aurobindo dismissing this action with prejudice, and awarding Aurobindo its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

DEFENDANTS' AFFIRMATIVE DEFENSES

The Aurobindo Defendants assert the following defenses without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's Complaint, in whole or in part, fails to state claims upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE
(INVALIDITY AND UNENFORCEABILITY)

United States Patent No. 7,094,781 ("the '781 patent" or "the Patent-in-Suit")) and each of the claims thereof, are invalid and/or unenforceable for failure to comply with one or more conditions for patentability and/or enforceability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidity and/or unenforceability, as more particularly set for in the Notice Letter ("Aurobindo's Notice Letter") sent in respect Aurobindo's Paragraph IV Certifications ("Aurobindo's Paragraph IV Certification").

THIRD AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT)

As detailed in in the Detailed Statement of the Aurobindo's Notice Letter, Defendants do not infringe literally any valid and enforceable claim of the Patent-In-Suit and thus cannot be said to literally infringe the same. As no equivalent can be found in Defendant's proposed product for the missing elements of any of the claims of the Patents-In-Suit, there can be no be no infringement under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
(NO INDIRECT INFRINGEMENT)

Defendants have not, do not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-In-Suit, and the manufacturing, marketing, sale, offer for sale, importation, and/or distribution of the Aurobindo ANDA product does not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patent-In-Suit.

FIFTH AFFIRMATIVE DEFENSE
(NO COSTS)

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SIXTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE CLAIM OF WILFULNESS)

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 §§ 271(e)(4) and 285, or otherwise.

SEVENTH AFFIRMATIVE DEFENSE
(RESERVATION OF RIGHTS)

Defendants reserve the right to assert additional defenses or counterclaims that discovery may reveal.

AUROBINDO'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. ("Aurobindo" or "Counterclaim-Plaintiffs"), through their undersigned attorneys, for their Counterclaims against Plaintiff Actelion Pharmaceuticals Ltd. ("Actelion" or the "Counterclaim-Defendant") hereby allege as follows:

1. Counterclaim-Plaintiffs repeat and incorporates by reference each of the foregoing paragraphs of Aurobindo's (Defendants') Answer and Affirmative Defenses to the Complaint.

2. This is an action for a declaratory judgment of non-infringement and invalidity of the claims of United States Patent No. 7,094,781 ("the '781 patent" or "the Patent-in-Suit") Upon information and belief, a true and correct copy of the Patent-In-Suit is attached to the Complaint as Exhibit A.

THE PARTIES

3. Counterclaim-Plaintiff Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401 USA.

4. Counterclaim-Plaintiff Aurobindo Pharma Limited is an Indian corporation having a principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andra Pradesh, India.

5. On information and belief, based on the Complaint filed by the Plaintiff/Counterclaim-Defendant in this case, Counterclaim-Defendant Actelion is a Swiss corporation having a primary place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

JURISDICTION

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Counterclaim-Plaintiff, on the one hand, and the Counterclaim-Defendants on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

7. This Court has personal jurisdiction over Counterclaim-Defendant based, *inter alia,* on the filing by Counterclaim-Defendant of this lawsuit in this jurisdiction and because Counterclaim-Defendant is doing business in this jurisdiction.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

ORANGE BOOK LISTING OF THE PATENTS

9. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

10. On information and belief, on August 22, 2006, the U.S. Patent and Trademark Office ("PTO") issued the '781 patent. On information and belief, a true and correct copy of the '781 Patent is attached to the Complaint as Exhibit A.

11. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(l), the Counterclaim-Defendant caused the FDA to list the Patents-In-Suit in the Orange Book in connection with NDA No. 204410 (in respect of the brand name product OPSUMIT®) (the "OPSUMIT NDA").

12. By maintaining the listings of the Patents-in-Suit in the Orange Book, Counterclaim-Defendant represents to the world that the Patent-In-Suit could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale (21 U.S.C. § 355(b)(l)) of the respective brand name product before the expiration of the Patents-in-Suit.

AUROBINDO'S ABBREVIATED NEW DRUG APPLICATION (ANDA)

13. Aurobindo filed ANDA No. 211198 ("ANDA") with the FDA seeking approval to market a generic macitentan, intended to be a generic version of OPSUMIT®. Aurobindo's Paragraph IV Certification Letter concerning the Patent-in-Suit dated June 19, 2019, certified that to the best of Aurobindo's knowledge that all of the claims of the Patent-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the product described in Aurobindo's ANDA, and that Aurobindo was seeking approval of its ANDA prior to the expiration of the '781 patent.

THE PRESENCE OF A CASE OR CONTROVERSY

14. By maintaining the Orange Book listing of the Patent-in-Suit in connection with the Julbia®, Counterclaim-Defendant represents that the Patent-in-Suit could reasonably be asserted against anyone making, using or selling generic macitentan, intended to be generic version of Julbia®, without a license from the Counterclaim-Defendants prior to the expiration of the Patent-in-Suit.

15. Counterclaim-Defendant has filed an infringement action under Title 35, United States Code, Sections 100 *et seq*., asserting the Patent-In-Suit against Counterclaim-Plaintiffs and seeking a declaration of infringement regarding the Patent-In-Suit. There has been, and is now, an actual and justiciable controversy between Aurobindo on the one hand, and Counterclaim-Defendant, on the other hand, as to whether the products disclosed in Aurobindo's ANDA infringe the Patent-in-Suit, and whether any valid, enforceable claim in the Patent-in-Suit exists.

16. Aurobindo seeks to market its generic macitentan product that is the subject of Aurobindo's ANDA in the United States prior to the expiration of the Patent-In-Suit.

17. If Aurobindo succeeds in proving that its macitentan product that is the subject of Aurobindo's ANDA does not infringe the Patent-in-Suit or are otherwise invalid or unenforceable, such a judgment will remove any uncertainty that may exist by virtue of Counterclaim-Defendant's maintenance of the Patent-In-Suit in the Orange Book in connection with the Jublia® NDA.

18. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim-Defendant and Counterclaim-Plaintiffs as to whether the claims of the Patent-in-Suit are invalid and/or not infringed by Counterclaim-Plaintiffs.

COUNT I
(DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE PATENT-IN-SUIT)

19. Counterclaim-Plaintiffs repeat and incorporate by reference Paragraphs 1-28 of their Counterclaims, above, as if fully set forth herein.

20. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning the claims of the Patent-in-Suit.

21. Counterclaim-Defendant alleges that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiffs' generic macitentan that is the subject of Aurobindo's ANDA infringes one or more claims of the Patent-In-Suit.

22. Counterclaim-Plaintiffs assert that no valid claim of the Patent-in-Suit is infringed by the manufacture, use, offer for sale, sale, and/or importation of generic macitentan that is the subject of Aurobindo's ANDA.

23. Counterclaim-Plaintiffs are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of the Counterclaim-Plaintiff's macitentan that is the subject of Aurobindo's ANDA, does not infringe any valid claim of the Patent-in-Suit.

COUNT II
(DECLARATORY JUDGMENT OF INVALIDITY OF THE PATENT-IN-SUIT)

24. Counterclaim-Plaintiffs repeat and incorporate by reference Paragraphs 1-23 of Counterclaim-Plaintiffs' Counterclaims, above, as if fully set forth herein.

25. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.,* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiffs and Counterclaim-Defendant concerning the claims of the Patent-in-Suit.

26. Counterclaim Defendant alleges that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiffs' macitentan product that is the subject of Aurobindo's ANDA, infringes one or more claims of the Patent-in-Suit.

27. Counterclaim-Plaintiffs assert that the manufacture, use, offer-for-sale, sale, and/or importation of Counterclaim-Plaintiffs' macitentan product that is the subject of Aurobindo's ANDA does not infringe any valid claim of the Patent-in-Suit, and that the claims of the Patents-in-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

28. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the Patent-in-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs respectfully requests that the Court enter judgment in their favor and against Counterclaim-Defendant as follows:

a. Denying Counterclaim-Defendant's claims and dismissing Plaintiffs' Complaint with prejudice.

b. For a declaration that the claims of the Patent-in-Suit are invalid;

c. For a declaration that the claims of the Patent-in-Suit are not, and will not be, infringed by Counterclaim-Plaintiffs' manufacture, use, sale, offer for sale, or importation of the macitentan that is the subject of Aurobindo's ANDA;

d. Preliminarily and permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from utilizing the Patent-in-Suit to block, hamper, hinder or obstruct FDA approval of Counterclaim-Plaintiffs' proposed product;

e. Permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from asserting or otherwise seeking to enforce the Patent-in-Suit against Counterclaim-Plaintiffs or anyone in privity with Counterclaim-Plaintiffs;

f. Declaring this case exceptional and awarding Counterclaim-Plaintiffs their attorneys' fees pursuant to 35 U.S.C. § 285, the inherent power of this Court, or otherwise;

g. Awarding costs to Counterclaim-Plaintiffs; and

h. Awarding any other such and further relief as is just and proper.

Dated: August 26, 2019

Marc D. Youngelson, Esq.
COSNER YOUNGELSON
197 Route 18, Ste 104
East Brunswick, NJ 08816
(732) 937-8000
(732) 937-5439
marc@cosnerlaw.com

Of counsel:
Steven J. Moore, Esq. (*pro hac vice*)
James Nealon (*pro hac vice*)
WITHERS BERGMAN LLP
1700 East Putnam Avenue
Greenwich, Connecticut 06830
Phone: (203) 302-4100
Fax: (203) 302-6611
Steven.moore@withersworldwide.com
James.nealon@withersworldwide.com

Attorneys for Defendant/Counterclaim-Plaintiffs Aurobindo Pharma USA, Inc. and Aurobindo Pharma LTD.

CERTIFICATE OF SERVICE

I certify that, on August 26, 2019, I caused the foregoing Answer and Counterclaims of Defendants/Counterclaim-Plaintiffs Aurobindo Pharma USA, Inc. and Aurobindo Pharma LTD. to be served upon plaintiffs' counsel of record by email, who shall also receive a copy simultaneously through the Court's ECF system.

Dated: August 26, 2019

Marc D. Youngelson, Esq
COSNER YOUNGELSON
197 Route 18, Ste 104
East Brunswick, NJ 08816
(732) 937-8000
(732) 937-5439 (f)
marc@cosnerlaw.com