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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD., Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC. and AMNEAL PHARMACEUTICALS LLC, Defendants.	C.A. No. 3:18-cv-01397-FLW-LHG (Filed Electronically)

DEFENDANT ZYDUS PHARMACEUTICALS (USA) INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Zydus Pharmaceuticals (USA) Inc. ("Zydus" or "Defendant") for its Answer, Affirmative Defenses, and Counterclaims to the Complaint of Actelion Pharmaceuticals Ltd. ("Actelion" or "Plaintiff") states as follows:

All averments not expressly admitted are denied.

THE PARTIES

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

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 1 and therefore denies them.

2. Upon information and belief, Defendant Zydus is an entity organized and existing under the laws of the State of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

ANSWER: Admitted.

3. Upon information and belief, Zydus 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. 0100915422 and is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003171.

ANSWER: Zydus admits that the State of New Jersey Division of Revenue and Enterprise Services Business Name Search lists the Business Name "Zydus Pharmaceuticals (USA) Inc." in connection with Entity ID No. 0100915422. Zydus further admits that the State of New Jersey Department of Health Wholesale Drug & Medical Device Registration lists the Parent Company Name "Zydus Pharmaceuticals USA Inc." in connection with Registration No. 5003171 and as being registered as "Wholesale." Zydus denies all other allegations in paragraph 3.

4. Upon information and belief, Zydus develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

ANSWER: Zydus admits that it submits Abbreviated New Drug Applications ("ANDAs") to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, or sale of pharmaceutical products and that Zydus sells pharmaceutical products, including generic pharmaceutical products, in the United States. Zydus denies all other allegations in paragraph 4.

5. Upon information and belief, Defendant Amneal is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or

information sufficient to for a belief about the truth of the allegations in paragraph 5 and therefore denies them.

6. Upon information and belief, Amneal 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. 0600211542 and is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5002991.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 6 and therefore denies them.

7. Upon information and belief, Amneal develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 7 and therefore denies them.

JURISDICTION AND VENUE

8. This is a civil action for infringement of United States Patent No. 7,094,781 ("the '781 patent" or "the patent-in-suit"). 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 8 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiff's complaint against Zydus purports to be a civil action alleging infringement of United States Patent No. 7,094,781 ("the '781 patent") pursuant to Titles 28 and 35 of the United States Code. Zydus denies that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the

macitentan oral tablets, 10 mg, that are the subject of ANDA No. 211224 would directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '781 patent.

9. 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: The allegations in paragraph 9 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies the allegations in paragraph 9.

10. Venue is proper in this Court as to Zydus under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because Zydus is incorporated in New Jersey, 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: The allegations in paragraph 10 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits only that it is an entity organized and existing under the laws of the State of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Zydus denies all other allegations in paragraph 10.

11. This Court has personal jurisdiction, and venue is proper as to Zydus, because, *inter alia*, Zydus: (1) is incorporated in New Jersey; (2) has its principal place of business in New Jersey; (3) has purposely availed itself of the privilege of doing business in New Jersey, including, *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. 0100915422 and securing a New Jersey wholesale drug distributor's license under Registration No. 5003171; (4) maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of New Jersey; and (5) upon information and belief, derives substantial revenue from the sale of its products in New Jersey.

ANSWER: The allegations in paragraph 11 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits only that it is an entity organized and existing under the laws of the State of New Jersey; that its principal place of business is at 73 Route 31 North, Pennington, New Jersey 08534; the State of New Jersey Division of Revenue and Enterprise Services Business Name Search lists the Business Name "Zydus Pharmaceuticals (USA) Inc." in connection with Entity ID No. 0100915422; and the State of New Jersey Department of Health Wholesale Drug & Medical Device Registration lists the Parent Company Name "Zydus Pharmaceuticals USA Inc." in connection with Registration No. 5003171 and as being registered as "Wholesale." Zydus denies all other allegations in paragraph 11.

12. This Court has personal jurisdiction over Zydus because, *inter alia*, Zydus 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 Plaintiff in the State of New Jersey.

ANSWER: The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies the allegations in paragraph 12.

13. Zydus sent Plaintiff a Notice Letter dated December 19, 2017, stating that Zydus filed Abbreviated New Drug Application ("ANDA") No. 211224 seeking approval from the United States Food and Drug Administration ("FDA") to commercially manufacture, use, market, or sell generic Macitentan Oral Tablets, 10 mg in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the patent-in-suit.

ANSWER: Zydus admits that Zydus sent a letter (the "Notice Letter") dated December 19, 2017 on behalf of Zydus Worldwide DMCC ("Zydus Worldwide") to Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc. that Zydus Worldwide submitted ANDA No. 211224 to the FDA, seeking FDA approval to engage in the commercial manufacture, use, or sale of macitentan oral tablets, 10 mg, and that ANDA No. 211224 included

a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '781 patent. Zydus denies all other allegations in paragraph 13.

14. This Court also has personal jurisdiction over Zydus 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.*, *Mitsubishi Tanabe Pharma Corp., et al. v. Sandoz, et al.*, Civil Action No. 17-5319 (D.N.J.); *Takeda Pharm. Co. Ltd., et al. v. Zydus Pharms. (USA) Inc., et al.*, Civil Action No. 10-1723 (D.N.J.); *Zydus Pharms. USA, Inc. v. Eli Lilly & Co.*, Civil Action No. 10-5584 (D.N.J.).

ANSWER: The allegations in paragraph 14 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the purposes of Plaintiff's claims against Zydus in this case and solely as they apply to the proposed product described in ANDA No. 211224. Zydus denies all other allegations in paragraph 14.

15. Venue is proper in this Court as to Amneal under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because Amneal 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: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 15 and therefore denies them.

16. This Court has personal jurisdiction, and venue is proper as to Amneal, because, *inter alia*, Amneal: (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, *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. 0600211542 and securing a New Jersey wholesale drug distributor's license under Registration No. 5002991; (3) maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of New Jersey; (4) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; and (5) has committed an

act of patent infringement under 35 U.S.C. § 271(e)(2) and intends to engage in a future course of conduct that includes acts of patent infringement in New Jersey, which has led, and will lead, to foreseeable harm and injury to Plaintiff in New Jersey.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 16 and therefore denies them.

17. This Court has personal jurisdiction over Amneal because, *inter alia*, Amneal 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 Plaintiff in the State of New Jersey.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 17 and therefore denies them.

18. Amneal sent Plaintiff a Notice Letter dated December 21, 2017, stating that Amneal filed ANDA No. 211000 seeking approval from the FDA to commercially manufacture, use, market, or sell generic Macitentan Oral Tablets, 10 mg in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the patent-in-suit.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 18 and therefore denies them.

19. This Court also has personal jurisdiction over Amneal because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously asserting counterclaims and consenting to personal jurisdiction in this Judicial District. *See, e.g.*, *Sucampo AG, et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 17-2577 (D.N.J.); *Genzyme Corp., et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 16-3892 (D.N.J.); *Horizon Pharma Ireland Ltd., et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 16-646 (D.N.J.); *BTG*

International Limited, et al. v. Amneal Pharmaceuticals LLC, et al., Civil Action No. 15-5909 (D.N.J.); *Warner Chilcott Company, LLC v. Amneal Pharmaceuticals LLC*, Civil Action No. 15-3590 (D.N.J.); *Shire Development LLC, et al. v. Amneal Pharmaceuticals LLC, et al.*, Civil Action No. 15-2865 (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Amneal Pharmaceuticals LLC, et al.*, Civil Action No. 15-1585 (D.N.J.).

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 19 and therefore denies them.

THE PATENT-IN-SUIT

20. 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: Zydus admits that the FDA's Electronic Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), lists Actelion Pharmaceuticals Ltd. as the Applicant Holder for New Drug Application ("NDA") No. 204410, OPSUMIT® (macitentan) oral tablets, 10 mg. Zydus further admits that the FDA's Orange Book lists October 18, 2013 as the approval date for NDA No. 204410, OPSUMIT® (macitentan) oral tablets, 10 mg. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 20 and therefore denies them.

21. 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: Zydus admits that the prescribing information for OPSUMIT® states that OPSUMIT® is "indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression." Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 21 and therefore denies them.

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

ANSWER: Zydus admits that the FDA's Orange Book lists ODE-54 as the Exclusivity Code for NDA No. 204410, OPSUMIT® (macitentan) oral tablets, 10 mg. Zydus further admits that the FDA's Orange Book lists October 18, 2020 as the Exclusivity Expiration for Exclusivity Code ODE-54 for NDA No. 204410, OPSUMIT® (macitentan) oral tablets, 10 mg. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 22 and therefore denies them.

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

ANSWER: Zydus admits on information and belief that what purports to be a copy of the '781 patent is attached to the Complaint as Exhibit A. Zydus further admits that Exhibit A is titled "Sulfamides and Their Use as Endothelin Receptor Antagonists" and lists August 22, 2006 as the Date of Patent. Zydus further admits that Exhibit A lists Actelion Pharmaceuticals Ltd. as the Assignee. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 23 and therefore denies them.

24. 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: Zydus admits that, as of January 31, 2018, the '781 patent was listed in the FDA's Orange Book for NDA No. 204410, OPSUMIT® (macitentan) oral tablets, 10 mg. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 24 and therefore denies them.

DEFENDANTS' ANDAs AND NOTICE LETTERS

25. Upon information and belief, Zydus submitted ANDA No. 211224 to the FDA, including a certification with respect to the patent-in-suit 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 ("Zydus's ANDA Product") prior to expiration of the patent-in-suit.

ANSWER: Zydus admits that Zydus Worldwide submitted ANDA No. 211224 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, or sale of macitentan oral tablets, 10 mg. Zydus further admits that ANDA No. 211224 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '781 patent. Zydus denies all other allegations in paragraph 25.

26. Upon information and belief, on or about December 19, 2017, Zydus sent a Paragraph IV Certification Notice Letter to Actelion. In its Notice Letter, Zydus represented that ANDA No. 211224 included a Paragraph IV Certification with respect to the '781 patent and that Zydus sought approval of ANDA No. 211224 prior to the expiration of the patent-in-suit. On or about December 20, 2017, Actelion first received Zydus's Paragraph IV Certification Notice Letter.

ANSWER: Zydus admits that Zydus sent the Notice Letter dated December 19, 2017 on behalf of Zydus Worldwide to Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc. that Zydus Worldwide submitted ANDA No. 211224 to the FDA, seeking FDA approval to engage in the commercial manufacture, use, or sale of macitentan oral tablets, 10 mg. Zydus further admits that ANDA No. 211224 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '781 patent. On information and belief, Zydus admits that Actelion Pharmaceuticals Ltd. received the December 19, 2017 Notice Letter on or about December 20, 2017. Zydus denies all other allegations in paragraph 26.

27. Plaintiff commenced this action within 45 days of the date of receipt of the Zydus Paragraph IV Certification Notice Letter, which was dated December 19, 2017.

ANSWER: The allegations in paragraph 27 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiff commenced this action by the filing of the Complaint on January 31, 2018, which is within forty-five days of December 20, 2017. Zydus denies all other allegations in paragraph 27.

28. Upon information and belief, Amneal submitted ANDA No. 211000 to the FDA, including a Paragraph IV Certification with respect to the patent-in-suit, 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 ("Amneal's ANDA Product") prior to expiration of the patent-in-suit.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 28 and therefore denies them.

29. Upon information and belief, on or about December 21, 2017, Amneal sent a Paragraph IV Certification Notice Letter to Actelion. In its Notice Letter, Amneal represented that ANDA No. 211000 included a Paragraph IV Certification with respect to the '781 patent and that Amneal sought approval of ANDA No. 211000 prior to the expiration of the patent-in-suit. On or about December 28, 2017, Actelion first received Amneal's Paragraph IV Certification Notice Letter.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 29 and therefore denies them.

30. Plaintiff commenced this action within 45 days of the date of receipt of the Amneal Paragraph IV Certification Notice Letter, which was dated December 21, 2017.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 30 and therefore denies them.

COUNT I – INFRINGEMENT BY ZYDUS

31. Plaintiff re-alleges paragraphs 1-30 as if fully set forth herein.

ANSWER: Zydus restates and realleges its answers to each of the preceding paragraphs 1-30, as if fully set forth herein.

32. In its Paragraph IV Certification Notice Letter, Zydus represented that its ANDA Product, as described in ANDA No. 211224, "contain[s] macitentan as the active pharmaceutical ingredient." By seeking approval of ANDA No. 211224 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Zydus's ANDA Product prior to the expiration of the patent-in-suit, Zydus has infringed one or more claims of the patent-in-suit under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Zydus admits that Zydus sent the Notice Letter dated December 19, 2017 on behalf of Zydus Worldwide to Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc. that Zydus Worldwide submitted ANDA No. 211224 to the FDA, seeking FDA approval to engage in the commercial manufacture, use, or sale of macitentan oral tablets, 10 mg. Zydus denies that the allegations in paragraph 32 accurately and completely recite the Notice Letter dated December 19, 2017 and therefore deny them. Zydus denies all other allegations in paragraph 32.

33. Upon information and belief, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Zydus's ANDA Product meets or embodies all steps of one or more claims of the patent-in-suit.

ANSWER: Denied.

34. Upon information and belief, Zydus 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 Zydus's ANDA Product upon receipt of final FDA approval of ANDA No. 211224.

ANSWER: Zydus admits that Zydus Worldwide submitted ANDA No. 211224 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, or sale of macitentan oral tablets, 10 mg. Zydus denies all other allegations in paragraph 34.

35. If Zydus manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, Zydus's ANDA Product prior to the expiration of the patent-in-suit, Zydus will infringe one or more claims of the '781 patent under 35 U.S.C. §§ 271(a), (b), (c) or (g).

ANSWER: Denied.

36. Plaintiff 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 Zydus's ANDA be a date that is not earlier than the expiration date of the patent-in-suit, or any later expiration of any patent term extension or exclusivity for the patent-in-suit to which Plaintiff is or becomes entitled.

ANSWER: Denied.

37. Plaintiff is entitled to a declaration that, if Zydus commercially manufactures, uses, offers for sale, or sells Zydus's ANDA Product within the United States, imports Zydus's ANDA Product into the United States, or induces or contributes to such conduct, Zydus will infringe the patent-in-suit under 35 U.S.C. §§ 271(a), (b), (c), or (g).

ANSWER: Denied.

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

ANSWER: Denied.

COUNT II – INFRINGEMENT BY AMNEAL

39. Plaintiff re-alleges paragraphs 1-30 as if fully set forth herein.

ANSWER: Zydus restates and realleges its answers to each of the preceding paragraphs 1-38, as if fully set forth herein.

40. In its Paragraph IV Certification Notice Letter, Amneal represented that "the only active compound" in its ANDA Product, as described in ANDA No. 211000, "is macitentan." By seeking approval of ANDA No. 211000 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Amneal's ANDA Product prior to the expiration of the patent-in-suit, Amneal has infringed one or more claims of the patent-in-suit under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 40 and therefore denies them.

41. Upon information and belief, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Amneal's ANDA Product meets or embodies all steps of one or more claims of the patent-in-suit.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 41 and therefore denies them.

42. Upon information and belief, Amneal 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 Amneal's ANDA Product upon receipt of final FDA approval of ANDA No. 211000.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 42 and therefore denies them.

43. If Amneal manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, Amneal's ANDA Product prior to the expiration of the patent-in-suit, Amneal will infringe one or more claims of the '781 patent under 35 U.S.C. §§ 271(a), (b), (c) or (g).

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 43 and therefore denies them.

44. Plaintiff 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 Amneal's ANDA be a date that is not earlier than the expiration date of the patent-in-suit, or any later expiration of any patent term extension or exclusivity for the patent-in-suit to which Plaintiff is or becomes entitled.

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 44 and therefore denies them.

45. Plaintiff is entitled to a declaration that, if Amneal commercially manufactures, uses, offers for sale, or sells Amneal's ANDA Product within the United States, imports Amneal's ANDA Product into the United States, or induces or contributes to such conduct, Amneal will infringe the patent-in-suit under 35 U.S.C. §§ 271(a), (b), (c), or (g).

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 45 and therefore denies them.

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

ANSWER: Zydus states that this paragraph is not directed to Zydus, and as such, no response from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to for a belief about the truth of the allegations in paragraph 46 and therefore denies them.

PRAYER FOR RELIEF

Zydus specifically denies that Plaintiff is entitled to the general of specific relief requested against Zydus, or to any relief whatsoever, and prays for judgment in favor of Zydus dismissing this action with prejudice, and awarding Zydus 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.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Zydus avers and asserts the following Affirmative Defenses to Plaintiff's Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 7,094,781)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed macitentan oral tablets, 10 mg, that are the subject of ANDA No. 211224 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '781 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 7,094,781)

Upon information and belief, the claims of the '781 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

RESERVATION OF DEFENSES

Zydus hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

DATED: March 19, 2018

Respectfully submitted,

By: *s/Paul B. Sudentas*

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