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

AMERICAN REGENT, INC., *Plaintiff*, v. ZYDUS PHARMACEUTICALS (USA) INC., *Defendant*.	Civil Action No. 2:24-cv-07812

ZYDUS PHARMACEUTICALS (USA) INC.'S, ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

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

All averments not expressly admitted are denied.

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Zydus's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 219322 ("the ANDA") which contain a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation of generic versions of ARI's Selenious Acid products ("the ANDA Products") prior to the expiration of United States Patent No. 11,998,565 ("the '565 Patent").

ANSWER: The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the Complaint purports to be a civil action alleging infringement of U.S. Patent No. 11,998,565 ("the '565 patent"). Zydus admits that it submitted ANDA No. 219322 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of selenious acid solution, intravenous, 12 mcg/2 mL, 60

mcg/mL, 600 mcg/10 mL ("Zydus's Proposed ANDA Product") in or into the United States and that ANDA No. 219322 identifies American Regent's selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10 mL as the Reference Listed Drug. Zydus further admits that ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) with respect to the '565 patent. Zydus denies all other allegations in paragraph 1.

THE PARTIES

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore denies them.

3. On information and belief, Zydus is an American corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534.

ANSWER: Admitted.

JURISDICTION AND VENUE

4. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: The allegations in paragraph 4 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the Complaint purports to be a civil action alleging infringement of the '565 patent. Zydus does not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiff's alleged claims against Zydus in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product described in ANDA No. 219322. Zydus denies all other allegations in paragraph 4.

5. On information and belief, this Court has personal jurisdiction over Zydus, under the New Jersey state long arm statute and consistent with due process of law, because Zydus maintains its principal place of business in New Jersey.

ANSWER: The allegations in paragraph 5 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 limited purpose of Plaintiff's alleged claims against Zydus in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product described in ANDA No. 219322. Zydus admits that it maintains its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. Zydus denies all other allegations in paragraph 5.

6. This Court has personal jurisdiction over Zydus because Zydus has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Zydus regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Zydus Inc.'s principal place of business is in Pennington, New Jersey. On information and belief, Zydus Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Entity Identification No. 0100915422. On information and belief, Zydus derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Zydus derives substantial revenue from selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

ANSWER: The allegations in paragraph 6 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 limited purpose of Plaintiff's alleged claims against Zydus in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product described in ANDA No. 219322. Zydus admits that it sells pharmaceutical products, including generic pharmaceutical products, in the United States. Zydus further admits that it is registered with the State of New Jersey's Division of Revenue and Enterprise Services under Entity Identification No. 0100915422 and that it maintains its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. Zydus denies all other allegations in paragraph 6.

7. This Court has personal jurisdiction over Zydus because, on information and belief, Zydus derives substantial revenue from directly or indirectly selling generic pharmaceutical

products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

ANSWER: The allegations in paragraph 7 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 limited purpose of Plaintiff's alleged claims against Zydus in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product described in ANDA No. 219322. Zydus admits that it sells pharmaceutical products, including generic pharmaceutical products, in the United States. Zydus denies all other allegations in paragraph 7.

8. On information and belief, Zydus is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this judicial district.

ANSWER: Zydus admits that it sells pharmaceutical products, including generic pharmaceutical products, in the United States. Zydus denies all other allegations in paragraph 8.

9. On information and belief, Zydus intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the ANDA Products.

ANSWER: The allegations in paragraph 9 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that it submitted ANDA No. 219322 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus's Proposed ANDA Product in the United States. Zydus denies all other allegations in paragraph 9.

10. On information and belief, this judicial district will be a destination for the generic drug product described in the ANDA.

ANSWER: Zydus admits that it submitted ANDA No. 219322 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus's Proposed ANDA Product in the United States. Zydus denies all other allegations in paragraph 10.

11. On information and belief, Zydus regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical 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 that it sells pharmaceutical products, including generic pharmaceutical products, in the United States. Zydus denies all other allegations in paragraph 11.

12. This Court has personal jurisdiction over Zydus because, *inter alia*, Zydus has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to ARI in New Jersey. Further, on information and belief, following approval of the ANDA, Zydus will make, use, import, sell, and/or offer for sale the ANDA Products in the United States, including in New Jersey, prior to the expiration of the '565 patent.

ANSWER: The allegations in paragraph 12 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 limited purpose of Plaintiff's alleged claims against Zydus in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product described in ANDA No. 219322. Zydus admits that it submitted ANDA No. 219322 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus's Proposed ANDA Product in the United States. Zydus further admits that ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) with respect to the '565 patent. Zydus denies all other allegations in paragraph 12.

13. On information and belief, Zydus has previously been sued in this Judicial District and have availed themselves of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey and have not challenged personal jurisdiction. *See*, *e.g.*, *Fresenius Kabi USA, LLC. v. Zydus Pharms., Inc.*, No. 22-01702, ECF No. 14 (D.N.J. Oct 28, 2022); *Aragon Pharms., Inc. et al. v. Zydus Worldwide DMCC et al.*, 22-02964, ECF No. 25 (D.N.J. Aug. 31, 2022).

ANSWER: The allegations in paragraph 13 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 limited purpose of Plaintiff's alleged claims against Zydus in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product described in ANDA No. 219322. Zydus admits that in *Fresenius Kabi USA, LLC. v. Zydus Pharms., Inc.*, No. 22-01702 (D.N.J. Oct 28, 2022), it stated that "Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Products described in ANDA No. 217066." Zydus further admits that in *Aragon Pharms., Inc. et al. v. Zydus Worldwide DMCC et al.*, 22-02964 (D.N.J. Aug. 31, 2022), it stated that "Zydus USA does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113." Zydus denies all other allegations in paragraph 13.

14. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

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 venue in this Court solely for the purpose of Plaintiff's alleged claims arising under 28 U.S.C. §§ 1391 and 1400(b) against Zydus and solely as those alleged claims apply to Zydus's Proposed ANDA Product described in ANDA No. 219322. Zydus denies all other allegations in paragraph 14.

15. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Zydus is incorporated in the State of New Jersey and therefore "resides" in this judicial district, and has committed acts of infringement in New Jersey and has a regular and established place of business in New Jersey.

ANSWER: The allegations in paragraph 15 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest venue in this judicial district

solely for the purposed of Plaintiff's alleged claims arising under 28 U.S.C. §§ 1391 and 1400(b) against Zydus and solely as those alleged claims apply to Zydus's Proposed ANDA Product described in ANDA No. 219322. Zydus admits that it maintains its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. Zydus denies all other allegations in paragraph 15.

16. On information and belief, Zydus has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting the ANDA to the FDA, by taking steps indicating its intent to market the ANDA Products in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if the ANDA receives final FDA approval.

ANSWER: Denied.

17. On information and belief, Zydus has a regular and established place of business in New Jersey under the meaning of 28 U.S.C. § 1400(b) because, *inter alia*, its principal place of business is in New Jersey. As set forth above, on information and belief, Zydus maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 73 Route 31 N., Pennington, New Jersey 08534.

ANSWER: The allegations in paragraph 17 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that it maintains its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. Zydus denies all other allegations in paragraph 17.

BACKGROUND

18. ARI holds New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)which was approved by the FDA on April 30, 2019, and which ARI manufactures and sells in this judicial district and throughout the United States.

ANSWER: Zydus admits that FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists "AMERICAN REGENT INC" as Applicant Holder, "SELENIOUS ACID" as Proprietary Name, and "EQ 12MCG SELENIUM/2ML (EQ 6MCG SELENIUM/ML)," "EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML)," and

"EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML)" as Strength in connection with NDA No. 209379. Zydus further admits that FDA's Orange Book lists "Aug. 30, 2021," "Jan. 25, 2021," and "Apr 30, 2019" as Approval Dates for the 12 mcg selenium/2 mL, 60 mcg selenium/mL, and 600 mcg selenium/10 mL strengths, respectively, in connection with NDA No. 209379. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 18 and therefore denies them.

19. ARI's Selenious Acid products are covered by one or more claims of the '565 patent.

ANSWER: The allegations in paragraph 19 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 19 and therefore denies them.

20. ARI is the owner of the '565 patent, entitled "Trace element compositions, methods of making and use," which was duly and legally issued on June 4, 2024. A copy of the '565 patent is attached as Exhibit 1.

ANSWER: Zydus admits on information and belief that what purports to be a copy of the '565 patent is attached to Plaintiff's Complaint as Exhibit 1. Zydus further admits that Exhibit 1 is titled "Trace Element Compositions, Methods of Making and Use" and lists June 4, 2024, as the date of the patent. Zydus further admits that the United States Patent and Trademark Office ("USPTO") lists "American Regent, Inc." as the assignee of the '565 patent under Reel/Frame no. 067520/0290. Zydus denies all other allegations in paragraph 20.

21. The '565 patent has been listed in connection with ARI's Selenious Acid products in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

ANSWER: Zydus admits that FDA's Orange Book lists the '565 patent under "Patent and Exclusivity" in connection with NDA No. 209379. Zydus denies all other allegations in paragraph 21.

22. As indicated in the Orange Book, the expiration date for the '565 patent is July 1, 2041.

ANSWER: Zydus admits that FDA's Orange Book lists July 1, 2041, as the expiration date for the '565 patent. Zydus denies all other allegation in paragraph 22.

23. On information and belief, Zydus was responsible for preparing the ANDA which contained a Paragraph IV Certification.

ANSWER: Zydus admits that it submitted ANDA No. 219322 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus's Proposed ANDA Product in the United States. Zydus further admits that ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) with respect to the '565 patent. Zydus denies all other allegations in paragraph 23.

24. By letter dated June 10, 2024, ("the Notice Letter"), Zydus notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Zydus had submitted the ANDA with a Paragraph IV Certification to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the '565 patent.

ANSWER: Zydus admits that it sent a letter dated June 10, 2024 ("Zydus's Notice Letter") to Plaintiff pursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act notifying Plaintiff that Zydus submitted ANDA No. 219322 to FDA seeking approval to engage in the commercial importation, manufacture, use, or sale of Zydus's Proposed ANDA Product and that ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) with respect to the '565 patent. Zydus denies all other allegations in paragraph 24.

25. On information and belief, Zydus submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the '565 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Products, or alternatively, that the '565 patent is invalid.

ANSWER: Zydus admits that it submitted ANDA No. 219322 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus's Proposed ANDA Product in the United States. Zydus further admits that ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) with respect to the '565 patent and that Zydus's Notice Letter states that, in Zydus's opinion, no valid and enforceable claim of the '565 patent will be infringed by the importation, manufacture, use, sale of, or offer to sell Zydus's Proposed ANDA Product in the United States. Zydus denies all other allegations in paragraph 25.

26. The Notice Letter contained no non-infringement defenses for any claim of the '565 patent.

ANSWER: The allegations in paragraph 26 do not completely an accurately set forth Zydus's Notice Letter and therefore, Zydus denies them. Zydus's Notice Letter states that "Zydus reserves the right to allege the same, similar, different, or new theories of noninfringement, invalidity, and/or unenforceability, and nothing in the notice letter or detailed statement shall be construed as to limit Zydus's rights to make any allegation in any subsequent litigation regarding any issue." Zydus denies all other allegations in paragraph 26.

27. On information and belief, the ANDA Products are generic versions of ARI's Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), as their reference listed drugs, containing the same or equivalent ingredients in the same or equivalent amounts.

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 ANDA No. 219322 identifies American Regent's selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10

mL as the Reference Listed Drug and that ANDA No. 219322 complies with applicable law. Zydus denies all other allegations in paragraph 27.

28. In the Notice Letter, Zydus disclosed that the ANDA Products are: selenious acid solutions, intravenous, (1) 12 mcg/2 mL; (2) 60 mcg/mL; and (3) 600 mcg/10 mL.

ANSWER: Admitted.

29. On information and belief, the ANDA Products consist of the same or equivalent formulations as ARI's Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)).

ANSWER: The allegations in paragraph 29 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that ANDA No. 219322 identifies American Regent's selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10 mL as the Reference Listed Drug and that ANDA No. 219322 complies with applicable law. Zydus denies all other allegations in paragraph 29.

30. On information and belief, the ANDA Products will feature the same or equivalent chemical and therapeutic properties as ARI's Selenious Acid products.

ANSWER: The allegations in paragraph 30 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that ANDA No. 219322 identifies American Regent's selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10 mL as the Reference Listed Drug and that ANDA No. 219322 complies with applicable law. Zydus denies all other allegations in paragraph 30.

COUNT I: INFRINGEMENT OF THE '565 PATENT

31. ARI realleges paragraphs 1–30 as if fully set forth herein.

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

32. Zydus's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of

the ANDA Products in or into the United States, prior to the expiration of the '565 patent, constitutes direct and indirect infringement of the '565 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

33. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Defendants or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '565 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Zydus's specific intent and encouragement, and will constitute conduct that Zydus knows or should know will occur. On information and belief, Zydus will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '565 patent.

ANSWER: Denied.

34. On information and belief, Zydus's manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and/or contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '565 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Zydus knows that the ANDA Products are especially made or adapted for use in infringing the '565 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Denied.

35. ARI will be irreparably harmed if Zydus is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '565 patent, or any later expiration of exclusivity for the '565 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: Denied.

36. Zydus has had knowledge of the '565 patent since at least the date Zydus submitted the ANDA with a Paragraph IV Certification, and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Zydus admits that ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and that Zydus's Notice Letter states that, in Zydus's opinion, no valid and enforceable claim of the '565 patent will be infringed by the importation, manufacture, use, sale of, or offer to sell Zydus's Proposed ANDA Product in the United States. Zydus denies all other allegations in paragraph 36.

37. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

PRAYER FOR RELIEF

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

JURY DEMAND

Zydus denies that Plaintiff is entitled to a trial by jury any issues.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of Plaintiff's 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. 11,998,565)

Plaintiff will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus's Proposed ANDA Product described in ANDA No. 219322 will directly or

indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '565 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,998,565)

Upon information and belief, the claims of the '565 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, and/or obviousness-type double patenting.

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.

COUNTERCLAIMS

Zydus Pharmaceuticals (USA) Inc. ("Zydus" or "Counterclaimant") by its attorneys, allege the following counterclaims against Plaintiff/Counterclaim Defendant American Regent, Inc. ("American Regent" or "Counterclaim Defendant").

PARTIES

1. Zydus is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534.

2. Upon information and belief, American Regent is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 5 Ramsey Road, Shirley, New York 11967.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 et seq., 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

4. This Court has personal jurisdiction over American Regent because American Regent commenced and continues to maintain this action against Zydus in this judicial district.

5. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II) and because American Regent commenced and continues to maintain this action against Zydus in this judicial district.

REGULATORY FRAMEWORK

6. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD.

7. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the

manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA lists the patent number(s) and expiration date(s) in its publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

ORANGE BOOK LISTED PATENT FOR SELENIOUS ACID

8. Upon information and belief, American Regent is the holder of NDA No. 209379 for selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10 mL.

9. United States Patent No. 11,998,565 ("the '565 patent"), titled "Trace Element Compositions, Methods of Making and Use"— a copy of which American Regent purported to attach to its Complaint as Exhibit 1—was issued on June 4, 2024. According to the United States Patent and Trademark Office's ("USPTO") Patent Assignment Search database, Reel/Frame No. 067520/0290, the '565 patent is assigned to American Regent. FDA's Orange Book lists the expiration date of the '565 patent as July 1, 2041.

10. Upon information and belief, the '565 patent is owned by American Regent.

11. Upon information and belief, American Regent submitted the '565 patent to FDA for listing in the Orange Book concerning NDA No. 209379 for selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10 mL, on June 7, 2024. Accordingly, American Regent maintains and has affirmatively represented that the '565 patent claims the approved drug selenious acid solution or a method of using that drug. Therefore, any ANDA applicant, including Zydus, attempting to sell selenious acid solution before the expiration of the '565 patent has a reasonable apprehension of suit with respect to the '565 patent.

ZYDUS'S ANDA

12. On May 1, 2024, Zydus submitted ANDA No. 219322 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, or sale of selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10 mL.

13. Because Zydus seeks FDA approval to engage in the commercial importation, manufacture, use, or sale of the proposed product described in ANDA No. 219322 before the expiration of the '565 patent, ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '565 patent.

14. Zydus sent a letter dated June 10, 2024, notifying American Regent that Zydus submitted ANDA No. 219322 to FDA seeking approval to engage in the commercial importation, manufacture, use, or sale of Zydus's Proposed ANDA Product and that ANDA No. 219322 includes a Paragraph IV Certification with respect to the '565 patent ("Zydus's Notice Letter").

15. Zydus's Notice Letter includes a statement of the factual and legal bases in support of Zydus's Paragraph IV Certification for the '565 patent.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,998,565)

16. Zydus repeats and realleges the allegations in paragraphs 1-15 above as though fully set forth herein.

17. By asserting its claim against Zydus for infringement of the '565 patent, American Regent has created a case or controversy regarding the noninfringement of the '565 patent.

18. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of the proposed selenious acid solution that is the subject of ANDA No. 219322 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '565 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,998,565)

19. Zydus repeats and realleges the allegations in paragraphs 1-18 above as though fully set forth herein.

20. By asserting its claim against Zydus for infringement of the '565 patent, American Regent has created a case or controversy regarding the validity of the '565 patent 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, and/or obviousness-type double patenting.

21. The claims of the '565 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.

PRAYER FOR RELIEF

WHEREFORE, Zydus respectfully requests that the Court enter judgment against American Regent as follows:

A. A declaration that Zydus has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '565 patent;

B. A declaration that the claims of the '565 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 et seq., including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

C. A declaration that American Regent takes nothing by its Complaint;

D. A dismissal of American Regent's Complaint with prejudice;

E. An award to Zydus of its reasonable costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

F. An award of any other and further relief that this Court may deem just and proper.

Dated: August 15, 2024

Respectfully submitted,

/s/ Zhibin Li

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Attorneys for Defendant Zydus Pharmaceuticals (USA) Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Defendant Zydus Pharmaceuticals (USA) Inc. certifies that, to the best of his knowledge, the matters in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, except that the same plaintiff has asserted the patent in this case in the following pending matters in this judicial district: *American Regent, Inc. v. Accord Healthcare Inc.*, Civil Action No. 2:24-cv-07791-BRM-CLW; *American Regent, Inc. v. Aspiro Pharma LTD.*, Civil Action No. 2:24-cv-07794-BRM-CLW; *American Regent, Inc. v. Cipla USA, Inc. et al.*, Civil Action No. 2:24-cv-07796-BRM-CLW; *American Regent, Inc. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 2:24-cv-07799-BRM-CLW; *American Regent, Inc. v. Fresenius Kabi USA, LLC*, Civil Action No. 2:24-cv-07801-BRM-CLW; *American Regent, Inc. v. Gland Pharma Limited*, Civil Action No. 2:24-cv-07802-BRM-CLW; *American Regent, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 2:24-cv-07803-BRM-CLW; *American Regent, Inc. v. Long Grove Pharmaceuticals, LLC*, Civil Action No. 2:24-cv-07804-BRM-CLW; *American Regent, Inc. v. RK Pharma, Inc.*, Civil Action No. 2:24-cv-07805-BRM-CLW; *American Regent, Inc. v. Somerset Therapeutics, LLC et al.*, Civil Action No. 2:24-cv-07807-BRM-CLW; *American Regent, Inc. v. Steriscience Pte. LTD*, Civil Action No. 2:24-cv-07809-BRM-CLW; *American Regent, Inc. v. Sun Pharmaceuticals Industries Limited et al.*, Civil Action No. 2:24-cv-07810-BRM-CLW; *American Regent, Inc. v. Xiromed, LLC et al.*, Civil Action No. 2:24-cv-07811-BRM-CLW.

By: s/ *Zhibin Li*
Zhibin Li

Dated: August 15, 2024

CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendant Zydus Pharmaceuticals (USA) Inc. hereby certifies that Defendant seeks declaratory relief, and, therefore, the above captioned matter is not appropriate for compulsory arbitration.

By: s/ *Zhibin Li*
Zhibin Li

Dated: August 15, 2024

CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2024, a copy of ZYDUS PHARMACEUTICALS (USA) INC.'S, ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT was served to counsel of record via electronic means.

By: s/ *Zhibin Li*
Zhibin Li

Dated: August 15, 2024