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**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. 24-11133

(Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT TO ZYDUS

Plaintiff American Regent, Inc. (“ARI” or “Plaintiff”), by its undersigned attorneys, for its Complaint against Zydus Pharmaceuticals (USA) Inc. (“Zydus” or “Defendant”) alleges as follows:

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. 12,150,957 ("the '957 patent" or the "Asserted Patent"). As discussed below, this case involves the same ANDA No. 219322 and thus is a related case to *American Regent, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 24-7812 (D.N.J.) (the "Related Action").

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.

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.

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.

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.

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.

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.

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.

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.

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

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.

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 Asserted Patent.

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).

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

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.

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.

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.

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.

19. The use of ARI’s Selenious Acid products is covered by one or more claims of the Asserted Patent.

20. ARI is the owner of the ’957 patent, entitled “Trace element compositions, methods of making and use,” which was duly and legally issued on November 26, 2024. A copy of the ’957 patent is attached as Exhibit A.

21. The ’957 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”).

22. As indicated in the Orange Book, the patent expiration date for the '957 patent is July 1, 2041.

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

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 U.S. Patent No. 11,998,565 ("the '565 patent"), which is at issue in the Related Action.

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.

26. Since ARI received the Notice Letter and filed its complaint against Zydus in the Related Action, the '957 patent has been listed in connection with ARI's Selenious Acid products in the Orange Book.

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.

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.

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)).

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

COUNT I: INFRINGEMENT OF THE '957 PATENT

31. ARI realleges 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 Product in or into the United States, prior to the expiration of the '957 patent, constitutes direct and indirect infringement of the '957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

33. On information and belief, the ANDA Product, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Zydus 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 '957 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 Product 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 '957 patent.

34. On information and belief, Zydus's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, 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 '957 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Zydus knows that the ANDA Product is especially made or adapted for use in infringing the '957 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

35. ARI will be irreparably harmed if Zydus is permitted to make, use, sell, offer to sell, and/or import the ANDA Product 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 '957 patent, or any later expiration of exclusivity for the '957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

36. Zydus has had knowledge of the '957 patent since at least October 11, 2024, when ARI emailed all defendants in the Related Action to inform them that the '957 patent would issue in due course.

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

PRAYER FOR RELIEF

WHEREFORE, ARI prays that this Court grant the following relief:

- (a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Zydus has infringed at least

one claim of the Asserted Patent through Zydus's submission of the ANDA with a Paragraph IV Certification to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States the ANDA Products before the expiration of the Asserted Patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the ANDA Products before the expiration of the Asserted Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the Asserted Patent;

(c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the ANDA, shall not be earlier than the latest expiration date of the Asserted Patent, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(d) The entry of a permanent and/or preliminary injunction enjoining Zydus, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, and importing in or into the United States the ANDA Products, or any product that infringes the Asserted Patent, or inducing or contributing to the infringement of the Asserted Patent until after the expiration date of the Asserted Patent, including any extension and/or additional periods of exclusivity to which ARI is or becomes entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(e) The entry of a permanent and/or preliminary injunction enjoining Zydus, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Asserted

Patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

- (f) Damages or other monetary relief to ARI if Zydus engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Products prior to the expiration of the Asserted Patent, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;
- (g) A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding ARI its attorneys' fees incurred in this action; and
- (h) Such further relief as this Court deems proper and just.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues triable to a jury. Specifically, Plaintiffs demand a jury trial in the event that there is a launch at risk and damages are in issue.

Dated: December 13, 2024

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