IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMERICAN REGENT, INC., *Plaintiff,* v. MEITHEAL PHARMACEUTICALS, INC. and KINDOS PHARMACEUTICALS CO., LTD, *Defendant.*	Civil Action No. _____ (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Meitheal Pharmaceuticals, Inc. ("Meitheal") and Kindos Pharmaceuticals Co., LTD ("Kindos") (collectively, "Defendants") 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 Defendants' submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 219472 ("the ANDA") which contains 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 a generic version of ARI's Selenious Acid products ("the ANDA Product") prior to the expiration of United States Patent No. 11,998,565 ("the '565 patent") and 12,150,957 ("the '957 patent") (collectively, the "Asserted Patents").

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, Meitheal is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 8700 W. Bryn Mawr Avenue, Suite 600S, Chicago, Illinois 60631.

4. On information and belief, Kindos is a corporation organized and existing under the laws of China having a principal place of business at No. 8-9 Kexin Road, Chengdu Hi-Tech Comprehensive Bonded Zone, China.

5. On information and belief, Meitheal is the U.S. Agent for Kindos for the ANDA.

JURISDICTION AND VENUE

6. 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.

7. This Court has personal jurisdiction over Meitheal because, on information and belief, Meitheal is a corporation organized and existing under the laws of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, Meitheal has purposefully availed itself to the privileges of conducting business in Delaware and consented to general jurisdiction in Delaware. This Court has personal jurisdiction over Meitheal because Meitheal derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

8. This Court has personal jurisdiction over Meitheal because, *inter alia*, Meitheal either directly or through its subsidiaries, agents, and/or affiliates, has purposefully availed itself

of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hauled into court here. On information and belief, Meitheal either directly or through its subsidiaries, agents, and/or affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to ARI's claims, and/or has engaged in systematic and continuous business contacts within Delaware.

9. This Court has personal jurisdiction over Kindos because, *inter alia*, Kindos either directly or through its subsidiaries, agents, and/or affiliates, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hauled into court here. On information and belief, Kindos either directly or through its subsidiaries, agents, and/or affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to ARI's claims, and/or has engaged in systematic and continuous business contacts within Delaware.

10. On information and belief, Meitheal and Kindos work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

11. On information and belief, Meitheal is the United States agent acting at the direction of, and for the benefit of, Kindos regarding the ANDA.

12. Upon information and belief, Defendants are in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, either directly or through various operating subsidiaries, agents, and/or affiliates throughout the United States, including in Delaware.

13. In addition, this Court has personal jurisdiction over Defendants because, among other things, on information and belief: (1) Defendants developed the ANDA Product that is the subject of the ANDA and filed the ANDA for the purpose of seeking approval to engage in, either directly or through subsidiaries, agents, affiliates, and/or alter egos, the commercial manufacture, use, sale or offer for sale of the ANDA Product in the United States, including in Delaware; (2) upon approval of the ANDA, Defendants intend to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or import the ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Product in Delaware; and (3) upon approval of the ANDA, the ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware. By filing the ANDA, Defendants have made clear that they intend to use its distribution channel to direct sales of the ANDA Product into Delaware.

14. In the alternative, this Court has personal jurisdiction over Kindos because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as: (a) ARI's claims arise under federal law; (b) Kindos is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Kindos has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Kindos satisfies due process.

15. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and 1391(c), and § 1400(b).

16. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because, upon information and belief, Meitheal is organized under the laws of the State of Delaware.

17. On information and belief, venue is further proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Kindos is a foreign company not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

18. On information and belief, Defendants filed the ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product in the United States, including in Delaware.

19. On information and belief, if Defendants receive approval for the ANDA, Defendants will market, distribute, offer for sale, and/or sell the ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Product in the State of Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016).

20. On information and belief, if the ANDA is approved, the ANDA Product would, among other things, be manufactured, marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

21. On information and belief, Defendants derive substantial revenue from the marketing, manufacture, and/or sale of generic pharmaceutical products in the United States and Delaware.

BACKGROUND

22. 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 originally approved by the FDA on April 30, 2019, which ARI manufactures and sells in this Judicial District and throughout the United States.

23. ARI's Selenious Acid products or the use of ARI's Selenious Acid products are covered by one or more claims of the Asserted Patents.

24. 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 A.

25. 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").

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

27. 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 B.

28. The '957 patent has been listed in connection with ARI's Selenious Acid products in the Orange Book.

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

30. By letter dated December 30, 2024 (the "Notice Letter"), Defendants notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Defendants 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 a generic version of ARI's Selenious Acid product (eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)), prior to the expiration of the Asserted Patents.

31. On information and belief, as indicated in the Notice Letter, the ANDA Product is a generic version of ARI's Selenious Acid product (eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)), as its reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts and will be indicated for use in the same or equivalent manner.

32. In the Notice Letter, Defendants disclosed that the ANDA Product is Selenious Acid Injection, USP, (600 mcg Selenium/10 mL (60 mcg/mL)).

33. On information and belief, the ANDA Product contains the same or equivalent ingredients in the same or equivalent amounts as ARI's Selenious Acid product (eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)).

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

COUNT I: INFRINGEMENT OF THE '565 PATENT

35. ARI realleges paragraphs 1–34 as if fully set forth herein.

36. Defendants' 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 '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.

37. 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 Defendants or on their 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 Product will occur with Defendants' specific intent and encouragement, and will constitute conduct that Defendants know or should know will occur. On information and belief, Defendants 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.

38. On information and belief, Defendants' 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 '565 patent, either literally or under the doctrine of equivalents. On information and belief, Defendants intend that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Defendants know that the ANDA Product is especially made or adapted for use in infringing the '565 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

39. ARI will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and are 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.

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

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

COUNT II: INFRINGEMENT OF THE '957 PATENT

42. ARI realleges paragraphs 1–41 as if fully set forth herein.

43. Defendants' 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.

44. 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 Defendants or on their 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 Defendants'

specific intent and encouragement, and will constitute conduct that Defendants know or should know will occur. On information and belief, Defendants 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.

45. On information and belief, Defendants' 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, Defendants intend that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Defendants know 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.

46. ARI will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and are 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.

47. 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 Defendants have infringed at least one claim of the Asserted Patents through Defendants' 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 Product before the expiration of the Asserted Patents;

(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 Product before the expiration of the Asserted Patents will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the Asserted Patents;

(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 Patents, 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 Defendants, and their 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 Product, or any product that infringes the Asserted Patents, or inducing or contributing to the infringement of the Asserted Patents until after the expiration date of the Asserted Patents, 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

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

(f) Damages or other monetary relief to ARI if Defendants engage in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Product prior to the expiration of the Asserted Patents, 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 attorney's 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), Plaintiff hereby demands a trial by jury on all issues triable to a jury. Specifically, Plaintiff demands a jury trial in the event that there is a launch at risk and damages are in issue.

Dated: February 14, 2025

By: s/ Christopher Viceconte

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