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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| AMERICAN REGENT, INC.,<br><br>*Plaintiff*,<br><br>v.<br><br>HIKMA PHARMACEUTICALS USA INC.,<br><br>*Defendant*. | Civil Action No. 24-7803<br><br>*Document Electronically Filed* |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendant Hikma Pharmaceuticals USA Inc. ("Hikma" 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 Hikma's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 217680 ("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 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").

## 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, Hikma is an American corporation organized and existing under the laws of the State of Delaware with its principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

## 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 Hikma, under the New Jersey state long arm statute and consistent with due process of law, because Hikma has extensive contacts with the State of New Jersey and regularly does business in this judicial district, including by maintaining a regular and established place of business in New Jersey. Further,

Hikma plans to sell the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

6. This Court further has personal jurisdiction over Hikma because Hikma 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, Hikma is registered to do business in New Jersey under Entity Identification No. 0100487525. On information and belief, Hikma 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, Hikma 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.

7. This Court has personal jurisdiction over Hikma because, on information and belief, Hikma 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, Hikma 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. This Court has personal jurisdiction over Hikma because, *inter alia*, Hikma 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, Hikma 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.

10. This Court also has personal jurisdiction over Hikma because it has previously availed itself of the legal protections of the State of New Jersey by, among other things, not contesting jurisdiction in this judicial district, and pursuing counterclaims in this judicial district, including in at least *Celgene Corporation v. Hikma Pharmaceuticals USA Inc.*, No. 2:21-cv-10398 (D.N.J.); and *Axsome Malta Ltd. et al v. Alkem Laboratories Ltd., et al.*, No. 2:23-cv-20354 (D.N.J).

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

12. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because, on information and belief, Hikma submitted the ANDA with a Paragraph IV Certification from its Berkeley Heights, New Jersey place of business and therefore Hikma has committed acts of infringement and has a regular and established place of business in New Jersey for the purposes of venue.

13. On information and belief, Hikma has taken steps in New Jersey, including preparing the ANDA and communicating with the FDA regarding the ANDA, that indicate its intent to market the ANDA Products. As set forth above, on information and belief, if the ANDA is approved, Hikma intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Products.

## BACKGROUND

14. 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.

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

16. 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.

17. 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").

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

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

20. By letter dated June 10, 2024 ("the Notice Letter"), Hikma notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Hikma 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.

21. On information and belief, Hikma 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.

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

23. 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)) product, as their reference listed drugs, containing the same or equivalent ingredients in the same or equivalent amounts.

24. In the Notice Letter, Hikma disclosed that the ANDA Products are: Selenious Acid Injection, USP (1) 12 mcg/2 mL (6 mcg/mL) in a single dose vial; (2) 60 mcg/mL in a single dose vial; and (3) 600 mcg/10 mL ( 60 mcg/mL) in a pharmacy bulk package.

25. On information and belief, the ANDA Products contain the same or equivalent ingredients in the same or equivalent amounts 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)).

26. 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 '565 PATENT**

27. ARI realleges paragraphs 1–26 as if fully set forth herein.

28. Hikma'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.

29. 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 Hikma 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 Hikma's specific intent and encouragement, and will constitute conduct that Hikma knows or should know will occur. On information and belief, Hikma 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.

30. On information and belief, Hikma'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, Hikma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Hikma 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.

31. ARI will be irreparably harmed if Hikma 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.

32. Hikma has had knowledge of the '565 patent since at least the date Hikma 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).

33. 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 Hikma has infringed at least one claim of the '565 patent through Hikma'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 '565 patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Hikma's 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 '565 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '565 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 '565 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 Hikma, 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 '565 patent, or inducing or contributing to the infringement of the '565 patent until after the expiration date of the '565 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 Hikma, 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 '565 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to ARI if Hikma 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 '565 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), 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: July 16, 2024
Newark, New Jersey

By: s/ Charles H. Chevalier

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