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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., Plaintiff, v. HIKMA PHARMACEUTICALS USA INC., Defendant.	Honorable Brian R. Martinotti, U.S.D.J. Civil Action No. 24-CV-7803 (BRM)(CLW) **DEFENDANT HIKMA PHARMACEUTICALS USA INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**

Defendant Hikma Pharmaceuticals USA Inc., ("Hikma" or "Defendant"), by and through its undersigned counsel, provide the following answers, separate defenses and counterclaims to the Complaint of patent infringement ("Complaint") (D.I. 1) of Plaintiff American Regent, Inc., ("ARI" or "Plaintiff"). This pleading is based upon Hikma's knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Hikma denies all allegations in Plaintiff's Complaint except those admitted specifically below.

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").

ANSWER: Hikma admits that it submitted ANDA No. 217680 ("the ANDA") to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of generic versions of ARI's Selenious Acid products prior to the expiration of the '565 patent). Hikma further admits that Plaintiff's Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, but denies that Plaintiff is entitled to relief. Hikma otherwise denies any remaining allegations of 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: Upon information and belief, admitted.

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.

ANSWER: Hikma admits it 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that Plaintiff's Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.* Hikma does not contest subject matter jurisdiction for the purposes of this action only, and expressly reserves the right to contest subject matter jurisdiction in any other case as to any party. Hikma otherwise denies any remaining allegations of Paragraph 4.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies any remaining allegations of Paragraph 5.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party.

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. . [sic]

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations in Paragraph 9.

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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest venue for the purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party. Hikma otherwise denies any remaining allegations of Paragraph 11.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest venue for the purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 13.

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.

ANSWER: Hikma admits that the FDA's website indicates that ARI is the holder of 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)). Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and therefore denies the same.

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

ANSWER: Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and therefore denies the same.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that on its face, the '565 patent indicates it was issued on June 4, 2024, and is entitled "Trace element compositions, methods of making and use." Hikma admits that a purported copy of the '565 patent is attached to the complaint as Exhibit 1. Hikma also admits that the patent assignment database indicates that the '565 patent is assigned to ARI. Hikma denies that the '565 patent was duly and legally issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph, and therefore denies the same.

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”).

ANSWER: Hikma admits that the ’565 patent is listed in the FDA’s Orange Book in connection with Selenious Acid products. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph, and therefore denies the same.

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

ANSWER: Hikma admits that the ’565 patent is presently listed in the FDA’s Orange Book in connection with Selenious Acid products indicating an expiration date of July 1, 2041. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph, and therefore denies the same.

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

ANSWER: Hikma admits that it prepared the ANDA No. 217680. At the time Hikma’s ANDA was filed there were no patents listed in the Orange Book for the Selenious Acid products. Hikma later amended its ANDA to include a Paragraph IV Certification to the ’565 patent after that patent was issued. Hikma otherwise denies the allegations in Paragraph 19.

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.

ANSWER: Hikma admits that Hikma sent ARI a Notice Letter which notified ARI that Hikma filed ANDA No. 217680 seeking approval to engage in the commercial manufacture, use,

offer for sale, sale, and/or importation of the ANDA Products. Hikma denies any remaining allegations of Paragraph 20.

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.

ANSWER: At the time Hikma submitted its ANDA, the '565 patent had not issued. Hikma amended its ANDA to contain a Paragraph IV Certification to the '565 patent after it issued. Hikma further states that its Notice Letter included a Detailed Statement that complied with the statutory and regulatory requirements and provided that the claims of the '565 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of Hikma's ANDA products.

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

ANSWER: Hikma admits that Hikma's Notice Letter contained the information required under 21 U.S.C. § 314.95(c)(6). Hikma further admits that Hikma's Notice Letter informed Plaintiffs that Hikma filed its ANDA with a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) that the claims of the '844 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Hikma's ANDA Product. Hikma denies any remaining allegations of Paragraph 51.

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.

ANSWER: Hikma admits that the Hikma 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. To the extent any further response is required, Hikma denies the allegations of Paragraph 23.

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.

ANSWER: Hikma admits that Hikma disclosed in the Hikma Notice Letter that the ANDA Products are Selenious Acid Injection, USP, (1) 12 mcg/2 mL (6 mcg/1 mL) in a Single Dose Vial; (2) 60 mcg/1 mL in a Single Dose Vial; and (3) 600 mcg/10 mL (60 mcg/1 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)).

ANSWER: Hikma admits that the Hikma ANDA Products are generic versions of ARI's Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/1 mL), (2) eq. 60 mcg Selenium/1 mL (eq. 60 mcg Selenium/1 mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/1 mL)) product. To the extent any further response is required, Hikma denies the allegations of Paragraph 25.

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

ANSWER: Hikma admits that the Hikma ANDA Products are generic versions of ARI's Selenious Acid products. To the extent any further response is required, Hikma denies the allegations of Paragraph 26.

COUNT I: INFRINGEMENT OF THE '565 PATENT

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

ANSWER: To the extent an answer to Paragraph 27 is required, Hikma incorporates by reference its answers to the foregoing paragraphs 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations in Paragraph 28.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations in Paragraph 29.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Hikma denies the allegations in Paragraph 30.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations in Paragraph 31.

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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that it has knowledge of the '565 patent as of the filing of its Paragraph IV Certification. Hikma otherwise denies the allegations of Paragraph 32.

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

ANSWER: Denied.

RESPONSE TO PRAYER FOR RELIEF

The remainder of ARI's Complaint recites a prayer for relief for which no response is required. To the extent a response is required, Hikma denies that ARI is entitled to any remedy or relief.

SEPARATE DEFENSES

Hikma asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Hikma does not

assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Hikma reserves the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

The claims of the '565 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

THIRD DEFENSE

Hikma does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '565 patent. If the products that are the subject of ANDA No. 217680 were marketed, Hikma would not infringe any valid and enforceable claim of the patents-in-suit.

FOURTH DEFENSE

Hikma has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '565 patent. If the products that are the subject of ANDA No. 217680 were marketed, Hikma would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patents-in-suit.

FIFTH DEFENSE

The claims of the '565 patent are barred in whole or in part by the doctrine of prosecution

history estoppel, judicial estoppel, and/or other equitable doctrines.

SIXTH DEFENSE

Hikma's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against American Regent, Inc. ("Counterclaim Defendant/Plaintiff"), Counterclaim Plaintiff/Defendant Hikma Pharmaceuticals USA Inc. ("Hikma" or "Counterclaim Plaintiff/Defendant"), states as follows:

THE PARTIES

1. On information and belief and as it pled in its Complaint, 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.

2. Hikma is a corporation organized and existing under the laws of Delaware, having a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

JURISDICTION AND VENUE

3. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

4. This Court has personal jurisdiction over Counterclaim Defendant/Plaintiff on the

basis of, *inter alia*, its contacts with New Jersey relating to the subject matter of this action, including having filed suit.

5. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

6. Upon information and belief, ARI holds approved New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/1 mL), (2) eq. 60 mcg Selenium/1 mL (eq. 60 mcg Selenium/1 mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/1 mL)).

7. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

8. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

9. U.S. Patent 11,998,565 ("the '565 patent"), entitled "Trace element compositions, methods of making and use," issued on June 4, 2024.

10. Upon information and belief based upon the United States Patent Office's assignment database, ARI is the assignee of the '565 patent.

11. Hikma submitted Abbreviated New Drug Application ("ANDA") No. 217680 ("the ANDA") to obtain FDA approval to market generic versions of ARI's Selenious Acid Products ("the ANDA Products") prior to issuance of the '565 patent. At the time Hikma filed its ANDA,

there were no patents listed in the Orange Book for the Selenious Acid products.

12. Upon information and belief, after its issuance, Counterclaim Defendant/Plaintiff caused the '565 patent to be listed in the Orange Book as a drug product patent for NDA No. 209379.

13. Hikma amended its ANDA to add a Paragraph IV Certification to the '565 patent.

14. Pursuant to 21 U.S.C. § 355(j)(2)(B), Hikma notified Counterclaim Defendant/Plaintiff by letter (the "Hikma Notice Letter") that Hikma had submitted a Paragraph IV Certification for its ANDA with respect to the '565 patent. The Hikma Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Hikma Paragraph IV Certification that the claims of the '565 patent are invalid, not infringed, and/or unenforceable.

15. On July 16, 2024, Counterclaim Defendant/Plaintiff filed this instant lawsuit alleging infringement of the '565 patent.

COUNT I

(Declaratory Judgment of Invalidity or Unenforceability of the '565 Patent)

16. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 14 of its Counterclaims as though fully set forth herein.

17. Counterclaim Defendant/Plaintiff alleges ownership of the '565 patent and has brought claims against Hikma alleging infringement of the '565 patent.

18. One or more claims of the '565 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

19. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of

Hikma's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '565 patent.

20. Hikma is entitled to a declaration that all claims of the '565 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

COUNT II

(Declaratory Judgment of Non-Infringement of the '565 Patent)

21. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 22 of its Counterclaims as though fully set forth herein.

22. Counterclaim Defendant/Plaintiff alleges ownership of the '565 patent and has brought claims against Hikma alleging infringement of the '565 patent.

23. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '565 patent.

24. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '565 patent and is not liable for such infringement.

25. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '565 patent.

PRAYER FOR RELIEF

WHEREFORE, Hikma respectfully requests judgment in its favor and against Counterclaim Defendant/Plaintiff as follows:

a. Declaring that the filing of Hikma's ANDA No. 217680 ("the ANDA") has not

infringed and does not infringe any valid and enforceable claim of the '565 patent;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of the ANDA does not, and would not, if marketed, infringe any valid and enforceable claim of the '565 patent;

c. Declaring that each claim of the '565 patent is invalid;

d. Declaring this an exceptional case in favor of Hikma and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and reules in common law that would be appropriate;

e. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and

f. Awarding any and all such other relief as the Court determines to be just and proper.

MIDLIGE RICHTER LLC
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Hikma Pharmaceuticals USA Inc.

By: s/ James S .Richter
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DATED: September 4, 2024

OF COUNSEL:

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, the same drug and patent are at issue in the following actions currently pending in this District:

- *American Regent, Inc. v. Accord Healthcare, Inc.*, Civil Action No. 2-24-cv-07791 (D.N.J.)
- *American Regent, Inc. v. Aspiro Pharma Limited*, Civil Action No. 2-24-cv-07794 (D.N.J.)
- *American Regent, Inc. v. Cipla USA, Inc. et al.*, Civil Action No. 2-24-cv-07796 (D.N.J.)
- *American Regent, Inc. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 2-24-cv-07799 (D.N.J.)
- *American Regent, Inc. v. Fresenius Kabi USA, LLC*, Civil Action No. 2-24-cv-07801 (D.N.J.)
- *American Regent, Inc. v. Gland Pharma Limited*, Civil Action No. 2-24-cv-07802 (D.N.J.)
- *American Regent, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 2-24-cv-07803 (D.N.J.)
- *American Regent, Inc. v. Long Grove Pharmaceuticals, LLC*, Civil Action No. 2-24-cv-07804 (D.N.J.)
- *American Regent, Inc. v. RK Pharma, Inc.*, Civil Action No. 2-24-cv-07805 (D.N.J.)
- *American Regent, Inc. v. Somerset Therapeutics, LLC et al.*, Civil Action No. 2-24-cv-07807 (D.N.J.)
- *American Regent, Inc. v. Steriscience Pte Limited*, Civil Action No. 2-24-cv-07809 (D.N.J.)
- *American Regent, Inc. v. Sun Pharmaceutical Industries Limited et al.*, Civil Action No. 2-24-cv-07810 (D.N.J.)
- *American Regent, Inc. v. Xiromed, LLC et al.*, Civil Action No. 2-24-cv-07811 (D.N.J.)
- *American Regent, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 2-24-cv-07812 (D.N.J.)

Hikma is further aware of one additional action involving the same drug product and same patent pending in another court:

- *American Regent, Inc. v. Fresenius Kabi USA, LLC*, Civil Action No. 1-24-cv-00824 (D.Del.)

Hikma is not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ James S. Richter
James S. Richter

Dated: September 4, 2024

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ James S. Richter
James S. Richter

Dated: September 4, 2024

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Hikma's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on September 4, 2024.

s/ James S. Richter
James S. Richter

Dated: September 4, 2024