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

AMERICAN REGENT, INC., *Plaintiff*, v. EUGIA PHARMA SPECIALITIES LTD. and EUGIA US LLC *Defendants*.	C.A. No. 2:24-8956-BRM-CLW

DEFENDANTS EUGIA PHARMA SPECIALITIES LTD. AND EUGIA US LLC'S ANSWER TO THE COMPLAINT

Defendants Eugia Pharma Specialities Ltd. ("Eugia Pharma") and Eugia US LLC ("Eugia US") (collectively, "Eugia"), by their counsel, hereby respond to the allegations set forth in Plaintiff American Regent, Inc.'s ("ARI" or "Plaintiff") Complaint for alleged patent infringement against Eugia purportedly arising under 35 U.S.C. § 271. This response is based on Eugia's current knowledge as to its own activities, and on information and belief as to the activities of others. If not specifically admitted herein, the allegations of the Complaint are denied. The headings in ARI's Complaint are copied herein for convenience only, and any allegations in such headings 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 Eugia's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 219756 ("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 a generic version of one of ARI's Selenious Acid products ("the ANDA Product") prior to the expiration of United States Patent No. 11,998,565 (the "'565 patent").

ANSWER: Eugia admits that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 100 et seq., and purports to seek relief for alleged patent infringement by Eugia of the '565 patent. Eugia admits that Eugia Pharma filed ANDA No. 219756 with the FDA seeking approval for a generic version of selenious acid prior to expiration of the '565 patent, and that the FDA's online Orange Book lists ARI as the "holder" of an NDA for selenious acid products. Eugia denies any remaining allegations in this paragraph.

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: Eugia is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

3. On information and belief, Eugia Pharma is a corporation organized and existing under the laws of India, with its principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, India, 500038.

ANSWER: Admitted.

4. On information and belief, Eugia Pharma has on some occasions identified itself as Eugia Pharma "Specialities," and on other occasions as Eugia Pharma "Specialties," including, for example, in Answers that Eugia Pharma filed in the following cases: *See, e.g., Pfizer Inc. et al. v. Eugia Pharma Specialties Ltd., et al.*, No. 20-cv-01528, Answer (D. Del. Dec. 4, 2020) ("Eugia Pharma Specialities Ltd."); *Amgen Inc. et al. v. Eugia Pharma Specialties Ltd., et al.*, No. 22-cv-00227, Answer (D. Del. Mar. 17, 2022) ("Eugia Pharma Specialties Limited"); and *Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 2-22-cv-03186, Answer (D.N.J. August 26, 2022) ("Eugia Pharma Specialities Limited (a.k.a. Eugia Pharma Specialties Limited)")

ANSWER: Admitted.

5. On information and belief, Eugia US is an American corporation organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER: Admitted.

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.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that this Court has subject-matter jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

7. On information and belief, this Court has personal jurisdiction over Eugia Pharma, under the New Jersey state long arm statute and consistent with due process of law because Eugia Pharma has extensive contacts with the State of New Jersey and regularly does business in this judicial district. Further, Eugia Pharma plans to sell its ANDA Product in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia Pharma does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia US does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

9. This Court has personal jurisdiction over Eugia Pharma because it 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, Eugia Pharma 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,

Eugia Pharma 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 states a legal conclusion to which no response is required. To the extent a response is required, Eugia Pharma does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

10. This Court has personal jurisdiction over Eugia US by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Eugia US's principal place of business is in East Windsor, New Jersey. On information and belief, Eugia US purposefully has conducted and continues to conduct business in this judicial district. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Eugia US.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia US does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

11. On information and belief, Eugia Pharma and Eugia US 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.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

12. On information and belief, Eugia US is the United States agent acting at the direction of, and for the benefit of, Eugia Pharma regarding the ANDA.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

13. This Court has personal jurisdiction over Eugia because Eugia 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, Eugia US is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID. No. 0400485691, and Eugia US is also registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No.

5004299. On information and belief, Eugia 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, Eugia 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 states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

14. This Court has personal jurisdiction over Eugia because, on information and belief, Eugia 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 states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

15. This Court has personal jurisdiction over Eugia Pharma because it previously availed itself of the legal protections of the State of New Jersey by, among other things, not contesting personal jurisdiction and through the assertion of counterclaims in suits brought in New Jersey, including in at least: *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd.,* No. 23-cv-06667 (D.N.J. Sept. 21, 2023); *Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 2:22-cv-03186 (D.N.J. May 26, 2022); *Celgene Corp. v. Eugia Pharma Specialties Ltd., et al.*, No. 2:21-cv-00624 (D.N.J. Jan. 12, 2021) (also filed a counterclaim); *Celgene Corp. v. Eugia Pharma Specialties Ltd. et al.*, No. 2:20-cv-00315 (D.N.J. Jan. 8, 2020) (also filed a counterclaim); *Celgene Corp. v. Eugia Pharma Specialties Ltd. et al.*, No. 2:19-cv-05799 (D.N.J. Feb. 14, 2019) (also filed a counterclaim); *Boehringer Ingelheim Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd., et al.*, No. 3:17-cv-07887 (D.N.J. Oct. 4, 2017) (also filed a counterclaim).

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia Pharma does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

16. This Court has personal jurisdiction over Eugia because, *inter alia*, Eugia 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, Eugia 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 states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

17. In the alternative, this Court has personal jurisdiction over Eugia Pharma 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) Eugia Pharma is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Eugia Pharma 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 Eugia Pharma satisfies due process.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia Pharma does not contest that this Court has personal jurisdiction for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that venue is proper in this Court for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

19. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Eugia US has committed acts of infringement in New Jersey and has a regular and established place of business in New Jersey. Eugia Pharma 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).

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that venue is proper in this Court for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

20. On information and belief, Eugia 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: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that venue is proper in this Court for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

21. On information and belief, Eugia US 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, Eugia US maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that venue is proper in this Court for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

22. On information and belief, Eugia has taken steps in New Jersey, including preparing the ANDA and communicating with the FDA regarding the ANDA, that indicates its intent to market the ANDA Products. As set forth above, on information and belief, if the ANDA is approved, Eugia 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 states a legal conclusion to which no response is required. To the extent a response is required, Eugia does not contest that venue is proper in this Court for the limited purpose of this action only. Eugia denies any remaining allegations in this paragraph.

BACKGROUND

23. 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) 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), which was originally approved by the FDA on April 30, 2019. Under NDA No 209379, ARI manufactures and sells Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)) in this judicial district and throughout the United States.

ANSWER: Eugia admits that the FDA's online Orange Book indicates that ARI holds NDA No. 209379 for selenious acid "EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML)," "EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML)," and "EQ 12MCG

SELENIUM/2ML (EQ 6MCG SELENIUM/ML),” with an approval date of April 30, 2019, for “EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML)” only. Eugia is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

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

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia admits that the FDA’s online Orange Book lists the ’565 patent in connection with NDA No. 209379. Eugia is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

25. 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: Eugia admits that Exhibit 1 contains a copy of what purports to be the ’565 patent and that bears the title “Trace element compositions, methods of making and use,” an issue date of June 4, 2024, and an assignee of “American Regent, Inc.” Eugia denies that the ’565 patent was “duly and legally issued.” Eugia denies any remaining allegations in this paragraph.

26. 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: Eugia admits that the FDA’s online Orange Book lists the ’565 patent in connection with NDA No. 209379. Eugia is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

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

ANSWER: Eugia admits that the FDA's online Orange Book lists the '565 patent in connection with NDA No. 209379 and provides a patent-expiration date of July 1, 2041. Eugia is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

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

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia admits that Eugia Pharma's ANDA No. 219756 contains a certification pursuant to Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification"). Eugia denies any remaining allegations in this paragraph.

29. In a letter dated August 5, 2024 ("the Notice Letter"), Eugia notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Eugia had submitted the ANDA to the FDA with a Paragraph IV Certification to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product prior to the expiration of the '565 patent.

ANSWER: Eugia admits it sent a letter to ARI dated August 5, 2024 ("Eugia's Notice Letter"), that notified ARI that Eugia Pharma submitted ANDA No. 219756 to the FDA, that such ANDA contains a Paragraph IV Certification against the '565 patent, and that, through such ANDA, Eugia Pharma seeks approval for the ANDA products proposed therein prior to expiration of the '565 patent. Eugia denies any remaining allegations in this paragraph.

30. On information and belief, Eugia 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 Product, or alternatively, that the '565 patent is invalid.

ANSWER: Eugia admits that Eugia Pharma submitted ANDA No. 219756 to the FDA, that such ANDA contains a Paragraph IV Certification against the '565 patent, and that Eugia's Notice Letter asserts that the '565 patent will not be infringed by the manufacture, use, importation, sale, or offer for sale of Eugia's proposed ANDA product and/or is invalid. Eugia denies any remaining allegations in this paragraph.

31. On information and belief, 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.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia admits that Eugia Pharma submitted ANDA No. 219756 to the FDA seeking approval of Eugia's proposed ANDA product described therein. Eugia denies any remaining allegations in this paragraph.

32. In the Notice Letter, Eugia disclosed that the ANDA Product is selenious acid injection USP, 600 mcg base/10 mL (60 mcg selenium/mL) of selenium.

ANSWER: Eugia admits that Eugia's Notice Letter disclosed Eugia's proposed ANDA product. Eugia denies any remaining allegations in this paragraph.

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)).

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia admits that Eugia Pharma submitted ANDA No. 219756 to the FDA seeking approval of Eugia's proposed ANDA product described therein. Eugia denies any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Eugia admits that Eugia Pharma submitted ANDA No. 219756 to the FDA seeking approval of Eugia's proposed ANDA product described therein. Eugia denies any remaining allegations in this paragraph.

COUNT I: INFRINGEMENT OF THE '565 PATENT

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

ANSWER: Eugia realleges paragraphs 1-34 as if fully set forth herein.

36. Eugia'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.

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

38. On information and belief, Eugia'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 '565 patent, either literally or under the doctrine of equivalents. On information and belief, Eugia intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Eugia knowa 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.

ANSWER: Denied.

39. ARI will be irreparably harmed if Eugia 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 '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.

40. Eugia has had knowledge of the '565 patent since at least the date Eugia 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 states a legal conclusion to which no response is required. To the extent a response is required, Eugia admits that it was aware of the '565 patent when it provided its factual and legal bases that the patent is invalid and non-infringed by Eugia's proposed ANDA product. Eugia denies any remaining allegations in this paragraph.

41. 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

Eugia denies all allegations of infringement and that ARI is entitled to any of the relief sought in its Prayer for Relief.

JURY DEMAND

Eugia denies that ARI is entitled to a jury.

AFFIRMATIVE DEFENSES

An allegation of any defense below is not an admission that Eugie bears the burden of proof or persuasion on any claim or issue.

FIRST AFFIRMATIVE DEFENSE
Invalidity and/or Unenforceability of the Claims of the '565 Patent

The claims of the '565 patent are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code and/or judicially created bases for invalidity and unenforceability, including, without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and 116 and/or for double patenting.

SECOND AFFIRMATIVE DEFENSE
Non-Infringement of the Claims of the '565 Patent

Eugia did not, does not, and will not infringe, induce to infringe, or contribute to infringement of any valid and enforceable claim of the '565 patent, literally or under the doctrine of equivalents.

THIRD AFFIRMATIVE DEFENSE
Estoppel

ARI's claims are barred, in whole or in part, by estoppel, including prosecution history estoppel and/or other equitable doctrines.

FOURTH AFFIRMATIVE DEFENSE
Failure to State a Claim

ARI's Complaint fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL DEFENSES AND DAMAGES

Eugia reserves the right to assert such other additional defenses and damages including additional defenses and/or damages discovered during the course of this litigation.

PRAYER FOR RELIEF

WHEREFORE, Eugia respectfully prays that this Court enter judgment in Eugia's favor and grant the following relief:

A. Dismiss Plaintiff's Complaint with prejudice and deny each and every prayer for relief contained therein;

B. A declaration that Eugia does not infringe the claims of the '565 patent;

C. A declaration that the claims of the '565 patent are invalid or unenforceable;

D. Award the costs of this action against Plaintiff;

E. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Eugia is entitled to recover reasonable attorney fees and costs upon prevailing in this action;

F. A declaration that the effective date of any FDA approval of Eugia's proposed ANDA product shall not be stayed thirty months from the date of its Notice Letters, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii);

G. An award to Eugia of such further and other relief as this Court deems necessary, just, and proper.

Dated: September 11, 2024

/s/ Dmitry Shelhoff

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that, upon information and belief, the matter in controversy is not the subject of any other action pending against Eugia in any other court, or any pending arbitration or administrative proceeding. The patent at issue in this proceeding, U.S. Patent No. 11,998,565, appears at the time of this certification to be involved in various other actions involving Plaintiff (but not Eugia) in the District of New Jersey and the District of Delaware, and Plaintiff's Certification Pursuant to Local Civil Rule 11.2 purports to provide a list of such cases. In addition, although not referenced in Plaintiff's certification, it appears that, as of the time of this certification, patent at issue is the subject of a pending MDL, *IN RE: American Regent, Inc., Selenious Acid Injection ('565) Patent Litigation*, MDL 3129.

Dated: September 11, 2024

/s/ Dmitry Shelhoff

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CERTIFICATE OF SERVICE

I, Dmitry V. Shelhoff, certify that on September 11, 2024, I caused a true and correct copy of DEFENDANTS EUGIA PHARMA SPECIALITIES LTD. AND EUGIA US LLC'S ANSWER TO THE COMPLAINT and CERTIFICATION PURSUANT TO L. CIV. R. 11.2 to be served via ECF to the following counsel of record:

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