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Attorneys for Defendant
Aspiro Pharma Ltd.

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

AMERICAN REGENT, INC., Plaintiff, v. ASPIRO PHARMA LTD., Defendant.	Case No. 2:24-cv-07794-BRM-CLW

DEFENDANT ASPIRO PHARMA LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Aspiro Pharma Ltd. ("Aspiro" or "Defendant"), by and through its undersigned counsel, files this Answer, Affirmative Defenses, and Counterclaims to Plaintiff American Regent, Inc.'s ("ARI" or "Plaintiff") Complaint for Patent Infringement, and states as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Aspiro denies all allegations in Plaintiff's Complaint except those specifically admitted 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 Aspiro's submission to the United

States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 219633 ("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: Aspiro admits that Plaintiff filed an action for patent infringement alleging that Aspiro infringed U.S. Patent No. 11,998,565 ("the '565 patent") under the patent laws of the United States, Title 35, United States Code. Aspiro admits that it had filed Abbreviated New Drug Application ("ANDA") No. 219633 with the U.S. Food and Drug Administration ("FDA"). Except as expressly admitted, Aspiro is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 1, and on that basis denies these allegations.

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: Aspiro is without sufficient knowledge or information to form a belief about the truth of the allegations of Paragraph 2, and on that basis denies these allegations.

3. On information and belief, Aspiro is a corporation organized and existing under the laws of India with its principal place of business at House No. 8-3-166/7/1, 3rd Floor, Erragadda Hyderabad, Telangana, 500018 India.

ANSWER: Aspiro admits that Aspiro is a corporation organized and existing under the laws of India with its principal place of business at House No. 8-3-166/7/1, 3rd Floor, Erragadda Hyderabad, Telangana, 500018 India.

4. By the letter dated June 11, 2024 (the "Notice Letter"), Aspiro identified Somaraju Indukuri, Ph.D., U.S. Agent for Aspiro Pharma Ltd., whose office is at 121 New England Avenue Piscataway, New Jersey 08854, as the person authorized to accept service of process for any patent infringement complaint.

ANSWER: Aspiro admits that it identified Somaraju Indukuri, Ph.D., U.S. Agent for Aspiro Pharma Ltd., in its June 11, 2024 letter (the "Notice Letter") as the person authorized to accept service of process for any patent infringement complaint. Except as expressly admitted, Aspiro is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 4, and on that basis denies these allegations.

JURISDICTION AND VENUE

5. 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: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro denies the allegations of Paragraph 5.

6. On information and belief, this Court has personal jurisdiction over Aspiro, under the New Jersey state long arm statute and consistent with due process of law because Aspiro has extensive contacts with the State of New Jersey and regularly does business in this judicial district. For example, by the letter dated June 11, 2024 (the "Notice Letter"), Aspiro identified Somaraju Indukuri, Ph.D., U.S. Agent for Aspiro Pharama Ltd., whose office is at 121 New England Avenue Piscataway, New Jersey 08854, as the person authorized to accept service of process for any patent infringement complaint. Further, Aspiro plans to sell the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 6.

7. This Court has personal jurisdiction over Aspiro because Aspiro 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, Aspiro 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, Aspiro derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information

and belief, Aspiro derives substantial revenue from selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 7.

8. This Court has personal jurisdiction over Aspiro because, on information and belief, Aspiro 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: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 8.

9. On information and belief, Aspiro 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.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro denies the allegations of Paragraph 9.

10. This Court has personal jurisdiction over Aspiro because, *inter alia*, it has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its agent, Somaraju Indukuri, Ph.D., whose office located in Piscataway, New Jersey and designated by Aspiro as U.S. Agent for service in the Notice Letter.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro does not contest personal jurisdiction in

this Court for the limited purposes of this action only. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 10.

> 11. This Court has personal jurisdiction over Aspiro because, *inter alia*, Aspiro 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, Aspiro 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: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 11.

> 12. In the alternative, this Court has personal jurisdiction over Aspiro 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) Asprio is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Aspiro has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting the 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 Aspiro satisfies due process.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 12.

> 13. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b) at least because, on information and belief, Aspiro 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: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro does not contest venue in this Court for the

limited purposes of this action only. Except as expressly admitted, Aspiro denies the remaining 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 originally approved by the FDA on April 30, 2019, which ARI manufactures and sells in this judicial district and throughout the United States.

ANSWER: Aspiro admits that the FDA publication, the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), lists ARI as the holder of 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)). Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 14.

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

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro denies the allegations of Paragraph 15.

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: Aspiro admits that the '565 patent is titled "Trace element compositions, methods of making and use," and that the '565 patent was issued by the United States Patent and Trademark Office ("USPTO") on or about June 4, 2024. Aspiro admits that ARI appears as the assignee on the face page of the '565 patent. What appears to be an uncertified copy of the '565 patent was attached to Plaintiff's Complaint as Exhibit 1. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 16.

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: Aspiro admits that the Orange Book lists the ’565 patent in connection with ARI’s Selenious Acid products. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 17.

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

ANSWER: Aspiro admits that the Orange Book lists the expiration date of the ’565 patent as July 1, 2041. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 18.

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

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. Aspiro admits that it was responsible for preparing the ANDA which contained a Paragraph IV Certification. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 19.

20. By the letter dated June 11, 2024 (“the Notice Letter”), Aspiro notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Aspiro had submitted the ANDA with a Paragraph IV Certification to the FDA seeking 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: Paragraph 20 contains legal conclusions and allegations to which no answer is required. Aspiro admits that it sent a notice letter to Plaintiff. The contents of Aspiro’s Notice Letter speaks for itself. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 20.

21. On information and belief, Aspiro 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: Paragraph 21 contains legal conclusions and allegations to which no answer is required. Aspiro admits that it submitted its ANDA to the FDA, which contained a Paragraph IV Certification. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 21.

22. The Notice Letter does not contain any specific non-infringement positions for claims 1–25 and 28–29 of the '565 patent.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. Aspiro admits that it sent a notice letter to Plaintiff. The contents of Aspiro's Notice Letter speaks for itself. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 22.

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) and (2) eq. 12 mcg/2mL (eq. 6 mcg selenium/mL)), as their reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro denies the allegations of Paragraph 23.

24. In the Notice Letter, Aspiro disclosed that the ANDA Products are: Selenious Acid Injection USP, eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL).

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. Aspiro admits that it sent a notice letter to Plaintiff. The contents of Aspiro's Notice Letter speaks for itself. Except as expressly admitted, Aspiro denies the remaining allegations of Paragraph 24.

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) and (2) eq. 12 mcg/2mL (eq. 6 mcg selenium/mL)).

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro 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: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro 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: Aspiro incorporates by reference each of its responses to paragraphs 1–26 as if fully set forth herein.

28. Aspiro's submissions 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: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro denies the allegations of 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 Aspiro 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 Aspiro's specific intent and encouragement, and will constitute conduct that Aspiro knows or should know will occur. On information and belief, Aspiro 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: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro denies the allegations of Paragraph 29.

30. On information and belief, Aspiro'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, Aspiro intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Aspiro 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: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro denies the allegations of Paragraph 30.

31. ARI will be irreparably harmed if Aspiro 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: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro denies the allegations of Paragraph 31.

32. Aspiro has had knowledge of the '565 patent since at least the date Aspiro 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: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro 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: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aspiro denies the allegations of Paragraph 33.

PLAINTIFF'S PRAYER FOR RELIEF

All allegations in Plaintiff's Complaint that are not expressly admitted by Aspiro are denied. Aspiro denies that Plaintiff is entitled to any of the relief sought in its Prayer for Relief.

ASPIRO'S AFFIRMATIVE DEFENSES

Without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not expressly admitted, Aspiro asserts the following Affirmative Defenses to Plaintiff's Complaint without assuming the burden of proof on any defense that would otherwise rest on Plaintiff. Aspiro reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Aspiro's ANDA No. 219633 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '565 patent.

SECOND DEFENSE

Each of the claims of each of the '565 patent is invalid for failure to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, or for failure to satisfy other judicially created bases for invalidation or unenforceability.

THIRD DEFENSE

Plaintiff's Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or willful infringement. Aspiro's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

RESERVATION OF DEFENSES

Aspiro reserves any and all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

ASPIRO'S COUNTERCLAIMS

Defendant/Counterclaim Plaintiff Aspiro Pharma Ltd. ("Aspiro"), by and through its undersigned counsel, pleads the following counterclaims against Plaintiff/Counterclaim Defendant American Regent, Inc.'s ("ARI"):

PARTIES

1. Aspiro is a corporation organized and existing under the laws of India with its principal place of business at House No. 8-3-166/7/1, 3rd Floor, Erragadda Hyderabad, Telangana, 500018 India.

2. On information and belief, 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.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; based on an actual controversy between Aspiro, on the one hand, and ARI on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

4. This Court has personal jurisdiction over ARI because, *inter alia*, ARI subjected itself to the jurisdiction of this Court by filing its Complaint here.

5. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b), and/or by ARI's choice of forum.

FACTUAL BACKGROUND

6. On information and belief, and based on the allegations in the Complaint, ARI is the holder of the 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)).

7. On information and belief, and based on the allegations in the Complaint, ARI caused the Food and Drug Administration ("FDA") to list U.S. Patent No. 11,998,565 ("the '565 patent") in the FDA publication, the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with NDA No. 209379.

8. The '565 patent lists the title as "Trace Element Compositions, Methods of Making and Use," and the issue date as June 4, 2024.

9. ARI purports and claims to be the owner of, and to have the right to enforce, the '565 patent.

10. Aspiro submitted Abbreviated New Drug Application ("ANDA") No. 219633 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Aspiro's proposed drug product containing 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)). ("Aspiro's ANDA product"). For ANDA No. 219633, Aspiro submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA with respect to the '565 patent.

11. Aspiro sent notice of the certification with respect to the '565 patent to ARI on or about June 11, 2024 (the "Notice Letter"). On information and belief, and as ARI alleges in its Complaint, ARI received the Notice Letter.

12. On July 16, 2024, ARI filed suit in this Judicial District against Aspiro in connection with ANDA No. 219633 alleging infringement of the '565 patent.

13. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Aspiro and ARI having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the '565 patent, and as to Aspiro's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Aspiro's ANDA product.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,998,565)

14. Aspiro incorporates by reference and re-alleges each of the foregoing paragraphs of Aspiro's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

15. Aspiro has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '565 patent.

16. A present, genuine, and justiciable controversy exists between Aspiro, on the one hand, and ARI, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aspiro's ANDA Product would infringe any valid or enforceable claim of the '565 patent.

17. The Court should declare that Aspiro has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '565 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,998,565)

18. Aspiro incorporates by reference and re-alleges each of the foregoing paragraphs of Aspiro's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

19. Upon information and belief, the claims of the '565 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

20. There is a real, substantial, and justiciable controversy between Aspiro and ARI concerning whether the claims of the '565 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

21. The Court should declare that the claims of the '565 patent are invalid and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Aspiro prays that the Court enter judgment in its favor and against ARI as follows:

A. Declaring that the filing of Aspiro's ANDA No. 219633 has not and does not directly or indirectly infringe any valid claim of any of the '565 patent;

B. Declaring that the commercial manufacture, use, offer to sell, sale within the United States, and/or importation into the United States of Aspiro's ANDA product described in ANDA No. 219633 does not, and would not, if marketed, directly or indirectly infringe any valid claim of the '565 patent;

C. Declaring that the claims of the '565 patent are invalid;

D. Ordering that judgment be entered in favor of Aspiro and that ARI's Complaint be dismissed with prejudice;

E. Declaring this case exceptional and awarding Aspiro its reasonable attorney fees and costs of defending this action and prosecuting its counterclaims under 35 U.S.C. § 285; and

F. Awarding Aspiro such other and further relief as this Court deems just and proper.

Dated: August 27, 2024

Respectfully submitted,

s/ Kaan Ekiner

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: August 27, 2024

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1 Defendants/Counterclaim Plaintiffs Aspiro Pharma Ltd., by its undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: August 27, 2024

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATE OF SERVICE

I, Kaan Ekiner, hereby certify that on August 27, 2024, a true and correct copy of the foregoing **DEFENDANT ASPIRO PHARMA LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS** was filed electronically with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

s/ Kaan Ekiner
Kaan Ekiner