IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMERICAN REGENT, INC., Plaintiff, v. FRESENIUS KABI USA, LLC, Defendant.	Civil Action No. 1:24-cv-00824-MN

DEFENDANT FRESENIUS KABI USA, LLC'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Fresenius Kabi USA, LLC ("Fresenius" or "Defendant"), by and through its undersigned counsel, hereby submits the following Answer, Affirmative Defenses, and Counterclaims ("Answer") in response to the Complaint (D.I. 1) filed by Plaintiff American Regent, Inc. ("ARI" or "Plaintiff").

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Fresenius denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Fresenius denies that Plaintiff is entitled to the relief requested or any other relief. Fresenius responds to the Complaint as follows:

NATURE OF THIS ACTION[1]

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 Fresenius's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218779 ("the ANDA") which contains a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation a generic version of 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").

RESPONSE: Fresenius admits that Plaintiff's Complaint against Fresenius purports to bring a claim 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 any relief. Fresenius further admits that it submitted Abbreviated New Drug Application ("ANDA") No. 218779, which, as amended, 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 the product described therein prior to the expiration of United States Patent No. 11,998,565 ("the '565 patent"). Fresenius denies any remaining allegations in 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.

[1] For ease of reference and organization, Fresenius has adopted the section headers used in the Complaint. For clarity, Fresenius does not agree with the section headers ascribed by Plaintiff in the Complaint.

RESPONSE: Fresenius lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 2, and therefore, denies those allegations.

3. Upon information and belief, Fresenius is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

RESPONSE: Admitted.

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.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius does not object to this Court's exercise of subject matter jurisdiction for purposes of this action only. Fresenius denies any remaining allegations in paragraph 4.

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

RESPONSE: This paragraph contains conclusions of law for which no response is

required. To the extent a response is required, Fresenius does not object to this Court's exercise of personal jurisdiction for purposes of this action only. Fresenius denies any remaining allegations in paragraph 5.

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius does not object to this Court's exercise of personal jurisdiction for purposes of this action only. Fresenius denies any remaining allegations in paragraph 6.

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius does not object to this Court's exercise of personal jurisdiction for purposes of this action only. Fresenius denies any remaining allegations in paragraph 7.

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius does not object to this Court's exercise of personal jurisdiction for purposes of this action only. In further answering, Fresenius admits it filed ANDA No. 218779 with the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j), seeking approval of the product described therein. Fresenius denies any remaining allegations in paragraph 8.

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

RESPONSE: This paragraph contains a conclusion of law for which no response is

required. To the extent a response is required, Fresenius does not contest that venue is proper in this Court for purposes of this action only. Fresenius denies any remaining allegations in paragraph 9.

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

RESPONSE: This paragraph contains a conclusion of law for which no response is required. To the extent a response is required, Fresenius does not contest that venue is proper in this Court for purposes of this action only. Fresenius denies any remaining allegations in paragraph 10.

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius does not object to this Court's exercise of personal jurisdiction for purposes of this action only. Fresenius admits it filed ANDA No. 218779 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of the product described therein. Fresenius denies any remaining allegations in paragraph 11.

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius does not object to this Court's exercise of personal jurisdiction for purposes of this action only. Fresenius denies any remaining allegations in paragraph 12.

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius does not object to this Court's exercise of personal jurisdiction for purposes of this action only. Fresenius denies any remaining allegations in paragraph 13.

14. On information and belief, Fresenius derives substantial revenue from the marketing, manufacture, and/or sale of generic pharmaceutical products in the United States and Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius does not object to this Court's exercise of personal jurisdiction for purposes of this action only. Fresenius denies any remaining allegations in paragraph 14.

BACKGROUND

15. 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, and which ARI manufactures and sells in this judicial district and throughout the United States.

RESPONSE: Fresenius admits that the FDA's online publication, entitled "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (commonly known as the "Orange Book"), indicates that American Regent, Inc. is the "Applicant Holder" of New Drug Application ("NDA") No. 209379 for Selenious Acid (eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL); eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL); and eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)). According to the Orange Book, FDA initially approved NDA 209379 for Selenious Acid, eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), on April 30, 2019. Fresenius lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 15, and therefore denies those allegations.

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius denies the allegations in paragraph 16.

17. 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.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Fresenius admits that American Regent, Inc. is listed as the "Applicant" and "Assignee" on the face of the '565 patent, entitled "TRACE ELEMENT COMPOSITIONS, METHODS OF MAKING AND USE." Fresenius further admits that based on the online records of the United States Patent and Trademark Office, the '565 patent issued on

June 4, 2024. Fresenius specifically denies the '565 patent was duly or legally issued, and denies that the '565 patent is valid and/or enforceable or that Fresenius infringes any claim of the '565 patent. Fresenius further admits that what appears to be a copy of the '565 patent is attached to Plaintiff's Complaint as Exhibit 1. Fresenius denies any remaining allegations in paragraph 17.

18. 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").

RESPONSE: Fresenius admits that the '565 patent is listed in the Orange Book in connection with NDA No. 209379 for Selenious Acid. Fresenius denies any remaining allegations in paragraph 18.

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

RESPONSE: Fresenius admits that the Orange Book identifies the purported "Patent Expiration" date for the '565 patent as July 1, 2041. Fresenius denies any remaining allegations in paragraph 19.

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

RESPONSE: Fresenius admits that Fresenius submitted a Patent Amendment to ANDA No. 218779, which contained an updated patent certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4)(i). Fresenius denies any remaining allegations in paragraph 20.

21. By letter dated June 11, 2024 ("the Notice Letter"), Fresenius notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Fresenius 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 Product prior to the expiration of the '565 patent.

RESPONSE: Fresenius admits that Fresenius sent ARI, among others, a Notification of Certification, dated June 11, 2024, pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 ("Notice Letter"). Fresenius further admits that Fresenius's Notice Letter notified ARI that Fresenius submitted ANDA No. 218779 to FDA, which, as amended, included an updated patent certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4)(i). Fresenius denies any remaining allegations in paragraph 21.

22. On information and belief, Fresenius 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.

RESPONSE: Fresenius admits that Fresenius submitted a Patent Amendment to ANDA No. 218779, which contained an updated patent certification under which Fresenius certified that the '565 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the product that is the subject of that ANDA. Fresenius denies any remaining allegations in paragraph 22.

23. On information and belief, the ANDA Product is a generic version of one of ARI's Selenious Acid products (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.

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Fresenius admits that Fresenius submitted ANDA No. 218779 seeking approval for Selenious Acid Injection USP, 600 mcg/10 mL (60 mcg/mL). Fresenius denies any remaining allegations in paragraph 23.

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

RESPONSE: Fresenius admits that the Notice Letter advised that the established name of the drug product that is the subject of ANDA No. 218779 is Selenious Acid Injection USP, 600 mcg/10 mL (60 mcg/mL). Fresenius denies any remaining allegations in paragraph 24.

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

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Fresenius denies the allegations in paragraph 25.

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

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Fresenius denies the allegations in paragraph 26.

COUNT I: INFRINGEMENT OF THE '565 PATENT

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

RESPONSE: To the extent an answer to this paragraph is required, Fresenius repeats and incorporates by reference its responses to paragraphs 1-26 as if fully set forth herein.

28. Fresenius'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 Product in or into the United States, prior to the expiration of the '565 patent, constitutes direct and indirect infringement of the '565 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Fresenius denies the allegations in paragraph 28.

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

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Fresenius denies the allegations in paragraph 29.

30. On information and belief, Fresenius'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, Fresenius intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Fresenius know that the ANDA Product is especially made or adapted for use in infringing the '565 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Fresenius denies the allegations in paragraph 30.

31. ARI will be irreparably harmed if Fresenius 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.

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Fresenius denies the allegations in paragraph 31.

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

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Fresenius admits that it had knowledge of the '565 patent when

it submitted a Patent Amendment to ANDA No. 218779, which contained an updated patent certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4)(i). Fresenius denies any remaining allegations in paragraph 32.

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

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Fresenius denies the allegations in paragraph 33.

PRAYER FOR RELIEF

Fresenius denies all allegations of infringement and that ARI is entitled to any of the relief requested in its Prayer for Relief or to any relief whatsoever.

GENERAL DENIAL

Fresenius denies all remaining allegations not specifically admitted herein. Fresenius further denies that ARI is entitled to any judgment or relief requested in the Complaint, or to any relief whatsoever. Fresenius respectfully requests that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of Fresenius; (c) award Fresenius its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and (d) award Fresenius such further relief as the Court deems just and appropriate.

FRESENIUS'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Fresenius asserts the following defenses in response to the allegations in the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Fresenius reserves the right to amend its Answer with additional defenses as further information is obtained in discovery.

Fresenius asserts the following defenses without prejudice to the denials in its Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE

(Invalidity or Unenforceability of the '565 Patent)

The '565 patent and each of the claims thereof are invalid or unenforceable for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101,102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE

(No Direct Infringement of the '565 Patent)

Fresenius does not infringe, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '565 patent.

THIRD AFFIRMATIVE DEFENSE

(No Indirect Infringement of the '565 Patent)

Fresenius has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and/or enforceable claim of the '565 patent.

FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Fresenius.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Fresenius for exceptional case under 35 U.S.C. § 285.

SIXTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Fresenius respectfully requests that ARI takes nothing by way of its Complaint, that judgment be entered in favor of Fresenius, that Fresenius be awarded its attorneys'

fees and costs, and all other just and proper relief.

FRESENIUS KABI USA, LLC'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Defendant/Counterclaim-Plaintiff Fresenius Kabi USA, LLC ("Counterclaim Plaintiff" or "Fresenius"), by and through its counsel, brings the following Counterclaims against Plaintiff/Counterclaim-Defendant American Regent, Inc. ("Counterclaim Defendant" or "ARI") for a declaratory judgment that U.S. Patent No. 11,998,565 ("the '565 patent") is invalid and/or not infringed by Fresenius's Selenious Acid Injection, USP 600 mcg/10 mL (60 mcg/mL) product that is the subject of Abbreviated New Drug Application ("ANDA") No. 218779 ("Fresenius' Proposed ANDA Product").

THE PARTIES

1. Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of Delaware, with a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

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. 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 on the basis of, *inter alia*, its contacts with Delaware relating to the subject matter of this action, including having

filed this litigation against Fresenius.

5. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400 and by the Counterclaim Defendant's choice of forum.

BACKGROUND

6. Upon information and belief, and based on paragraph 15 of ARI's Complaint, ARI holds New Drug Application ("NDA") No. 209379, which was approved by the U.S. Food and Drug Administration ("FDA") for Selenious Acid (eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL); eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL); and eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)).

7. An NDA must include, among other things, the number of any patent that purportedly 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 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. Based on the online records of the United States Patent and Trademark Office, the '565 patent, entitled "TRACE ELEMENT COMPOSITIONS, METHODS OF MAKING AND USE," issued on June 4, 2024.

10. Upon information and belief, and based on paragraph 17 of ARI's Complaint, ARI is the current purported owner and assignee of the '565 patent.

11. Upon information and belief, and based on paragraph 18 of ARI's Complaint, ARI caused the '565 patent to be listed in the Orange Book in connection with NDA No. 209379.

12. Fresenius submitted a Patent Amendment to ANDA No. 218779, which contained an updated patent certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4)(i).

13. Under the updated patent certification, Fresenius certified that the '565 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Fresenius' Proposed ANDA Product.

14. Pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Fresenius sent to, among others, ARI a Notification of Certification, dated June 11, 2024, via FEDEX® notifying ARI that Fresenius submitted ANDA No. 218779 to FDA, which, as amended, included an updated patent certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Notice Letter").

15. The Notice Letter included a Detailed Statement pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) of the factual and legal bases for Fresenius's opinion that the '565 patent is invalid, unenforceable, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, or sale of Fresenius' Proposed ANDA Product.

16. The Notice Letter contained an Offer of Confidential Access to ANDA No. 218779 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8).

17. On information and belief, the Notice Letter was received by all recipients, including ARI, on or about June 12, 2024.

18. On July 16, 2024, ARI filed this instant lawsuit alleging infringement of the '565 patent.

COUNT I

(Declaratory Judgment of Noninfringement of the '565 Patent)

19. Fresenius re-alleges and incorporates by reference the allegations set forth in paragraphs 1-18 of its Counterclaims as if fully set forth herein.

20. ARI alleges ownership of the '565 patent, and ARI has brought claims against Fresenius alleging infringement of the '565 patent.

21. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, continuing and justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between the parties concerning the infringement of the '565 patent.

22. The manufacture, use, offer for sale, sale, and/or importation of Fresenius' Proposed ANDA Product has not infringed, does not infringe, and would not directly or indirectly infringe any valid and/or enforceable claim of the '565 patent, either literally or under the doctrine of equivalents, for at least the reasons Fresenius presented in the Notice Letter, which is incorporated by reference.

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

24. Fresenius is entitled to a declaration that the manufacture, use, offer to sell, sale and/or importation of Fresenius' Proposed ANDA Product have not infringed, do not infringe, and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the '565 patent.

COUNT II

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

25. Fresenius re-alleges and incorporates by reference the allegations set forth in paragraphs 1-25 of its Counterclaims as if fully set forth herein.

26. ARI alleges ownership of the '565 patent, and ARI has brought claims against Fresenius alleging infringement of the '565 patent.

27. There is an actual, substantial, continuing and justiciable controversy between the parties regarding, *inter alia*, the invalidity of the '565 patent.

28. The claims of the '565 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements for patentability as specified in 35 U.S.C. § 1 *et seq*., including, without limitation, under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112 and /or in view of defenses recognized in 35 U.S.C. § 282(b), and/or any other judicially-created basis for invalidation or unenforceability.

29. For example, the subject matter claimed in the '565 patent fails to comply with at least 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

30. As sufficient example, as described in the Notice Letter, all claims of the '565 patent are at least invalid as obvious under § 103 in light of at least the following prior art: Selenious Acid Injection Prescribing Information; International PCT Publication No. WO 95/28937; Chinese Patent Publication No. 103340895; G. Cappelli et al., *Water Quality for On-line Haemodiafiltration*¸13 [Suppl 5] NEPHROLOGY DIALYSIS TRANSPLANTATION 12 (1998);

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, Guideline for Elemental Impurities Q3D(R1) (Mar. 22, 2019); and J. Zhao et al., *Glass Delamination: a Comparison of the Inner Surface Performance of Vials and Pre-filled Syringes*, 15 AAPS PHARMSCITECH 1398 (2014). Additionally, the claims are invalid for lack of written description at least with respect to the fluoride and iodine limitations, and not enabled at least with respect to the amounts of fluoride and iodine in an injectable composition. Additional contentions will be provided consistent with the rules and orders of this Court.

31. Fresenius is entitled to a declaration that all claims of the '565 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Fresenius requests judgment in its favor and against Counterclaim Defendant as follows:

a. A declaration that all claims of the '565 patent are invalid;

b. A declaration that the filing of Fresenius's ANDA No. 218779 has not infringed and does not infringe any valid and/or enforceable claim of the '565 patent;

c. A declaration that the manufacture, use, offer to sell, sale, and/or importation into the United States of Fresenius' Proposed ANDA Product does not, and would not, infringe any valid and/or enforceable claim of the '565 patent;

d. A declaration that Counterclaim Defendant is entitled to no damages, interest, costs, or other relief from or against Fresenius;

e. A declaration that this an exceptional case in favor of Fresenius and awarding its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

f. A declaration that Counterclaim Defendant is not entitled to injunctive relief;

g. Awarding costs and expenses; and

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

Dated: August 20, 2024

Respectfully submitted,

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