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Attorneys for Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

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

AMERICAN REGENT, INC., Plaintiff, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.

C.A. No.: 2:24-cv-07799-BRM-CLW

ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Defendants Dr. Reddy's Laboratories, Inc. ("DRL Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively, "DRL") by way of Answer, Separate Defenses and Counterclaims to the Complaint of Plaintiff American Regent, Inc. ("ARI"), upon knowledge

with respect to DRL's own acts, and upon information and belief as to other matters, state as follows:

NATURE OF THE 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 DRL's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218639 ("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 ARI's Selenious Acid products ("the ANDA Products") prior to the expiration of United States Patent No. 11,998,565 ("the '565 patent").

ANSWER: DRL admits that it filed ANDA No. 218639 ("DRL's ANDA") with the FDA seeking approval to market generic pharmaceutical products. DRL further admits based on publicly available information that the United States Patent and Trademark Office ("USPTO") lists ARI as an assignee of the '565 patent. The remaining allegations of this paragraph contain conclusions of law for which no response is required. To the extent a response is required, DRL admits that ARI's complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., but DRL denies that ARI is entitled to any relief. DRL denies the remaining allegations of paragraph 1.

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

3. On information and belief, Dr. Reddy's Laboratories, Ltd., is a corporation organized and existing under the laws of India with its principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, Telangana, Republic of India.

ANSWER: DRL admits that Dr. Reddy's Laboratories, Ltd., is a corporation organized and existing under the laws of India with a place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500034, Telangana, Republic of India. DRL denies the remaining allegations of paragraph 3.

4. On information and belief, Dr. Reddy's Laboratories, Ltd itself, and through its subsidiary and agent DRL Inc., develops, manufactures, and/or distributes generic Drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

ANSWER: Paragraph 4 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction or venue in New Jersey for purposes of this litigation only. To the extent an additional response is required, DRL admits that DRL Ltd. is in the business of developing and manufacturing pharmaceutical products. DRL denies the remaining allegations of paragraph 4.

5. On information and belief, Dr. Reddy's Laboratories, Inc., is a corporation organized and existing under the laws of New Jersey with its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

ANSWER: Admitted.

6. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories Ltd. and is controlled and/or dominated by Dr. Reddy's Laboratories, Inc.

ANSWER: Paragraph 6 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction or venue in New Jersey for purposes of this litigation only. To the extent an additional response is required, DRL admits that DRL Ltd. is the ultimate parent company of DRL Inc. DRL denies the remaining allegations of paragraph 6.

7. On information and belief, Dr. Reddy's Laboratories Ltd. established Dr. Reddy's Laboratories Inc. for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

ANSWER: Paragraph 7 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction or venue in New Jersey for purposes of this litigation only. DRL denies the remaining allegations of paragraph 7.

8. On information and belief, Dr. Reddy's Laboratories, Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

ANSWER: Paragraph 8 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction or venue in New Jersey for purposes of this litigation only. To the extent an additional response is required, DRL admits that DRL Inc. distributes generic drug products for sale in the United States. DRL denies the remaining allegations of paragraph 8.

JURISDICTION AND VENUE

9. 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 9 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest subject matter jurisdiction for purposes of this case only. DRL denies the remaining allegations of paragraph 9.

10. On information and belief, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc., under the New Jersey state long arm statute and consistent with due process of law, because Dr. Reddy's Laboratories, Inc. maintains its principal place of business in New Jersey.

ANSWER: Paragraph 10 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL denies the remaining allegations of paragraph 10.

11. On information and belief, this Court has personal jurisdiction over Dr. Reddy's Laboratories Ltd., under the New Jersey state long arm statute and consistent with due process of law because Dr. Reddy's Laboratories Ltd. has extensive contacts with the State of New Jersey,

including through its subsidiary Dr. Reddy's Laboratories, Inc., and regularly does business in this judicial district, including through its subsidiary Dr. Reddy's Laboratories, Inc. Further, Dr. Reddy's Laboratories Ltd. plans to sell the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

ANSWER: Paragraph 11 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL denies the remaining allegations of paragraph 11.

12. This Court has personal jurisdiction over DRL because DRL 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, Dr. Reddy's Laboratories, Inc. 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. 0100518911, and Dr. Reddy's Laboratories, Inc. is also licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey under Registration Number 5002312. On information and belief, DRL 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, DRL 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: Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL denies the remaining allegations of paragraph 12.

13. This Court has personal jurisdiction over DRL because, on information and belief, DRL 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 13 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL denies the remaining allegations of paragraph 13.

14. Dr. Reddy's Laboratories Ltd. has previously availed itself of the legal protections of the State of New Jersey by, among other things, selecting the State of New Jersey as the place of incorporation and principal place of business for Dr. Reddy's Laboratories, Inc., not contesting personal jurisdiction in this judicial district, and asserting counterclaims in this judicial district,

in the related litigation, *Intra-Cellular Therapies, Inc. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 24-4314 (D.N.J.).

ANSWER: Paragraph 14 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL denies the remaining allegations of paragraph 14.

15. Dr. Reddy's Laboratories Ltd has also not contested personal jurisdiction in this judicial district, and asserted counterclaims in other cases in this judicial district, including at least *Novo Nordisk Inc. et al. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 23-22112 (D.N.J.); *Bausch & Lomb Inc. et al., v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 23-03463 (D.N.J.); *Eisai R&D Mgmt Co., Ltd. et al. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 22-05950 (D.N.J.); *Celgene Corp. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 21-02111 (D.N.J.); *Merck Sharp & Dohme BV et al. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 20-02909 (D.N.J.); *Mitsubishi Tanabe Pharma Corp. et al. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 19-18764 (D.N.J.); *AstraZeneca LP et al. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 19-15739 (D.N.J.); *Supernus Pharm., Inc. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 22-04705 (D.N.J.); *Bausch & Lomb Inc. et al. v. Slayback Pharma LLC et al.*, C.A. No. 21-16766 (D.N.J.).

ANSWER: Paragraph 15 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL denies the remaining allegations in paragraph 15.

16. This Court has personal jurisdiction over DRL because, *inter alia*, DRL 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, DRL 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 16 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL admits it filed DRL's ANDA seeking FDA approval for Selenious acid Injection, USP 600 mcg/10 mL (60 mcg/mL) and 60 mcg/mL of Selenium (DRL's Proposed ANDA Products"). DRL denies the remaining allegations of paragraph 16.

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

ANSWER: Paragraph 17 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. The remaining allegations of paragraph 17 are denied or contain conclusions of law for which no response is required.

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

ANSWER: Paragraph 18 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest venue for purposes of this case only. DRL denies the remaining allegations of paragraph 18.

19. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Dr. Reddy's Laboratories, Inc. is organized under the laws of the State of New Jersey and therefore "resides" in this judicial district and has committed acts of infringement in New Jersey and has a regular and established place of business in New Jersey. Dr. Reddy's Laboratories Ltd. 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 19 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest venue for purposes of this case only. The remaining allegations of paragraph 19 are denied or contain conclusions of law for which no response is required.

20. On information and belief, DRL 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: Paragraph 20 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest venue for purposes of this case only. DRL denies the remaining allegations of paragraph 20.

21. On information and belief, Dr. Reddy's Laboratories, Inc. 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, Dr. Reddy's Laboratories, Inc. maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 107 College Road East, Princeton, New Jersey, 08540.

ANSWER: Paragraph 21 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest venue for purposes of this case only. DRL admits that DRL Inc. is a corporation organized and existing under the laws of New Jersey with its principal place of business at 107 College Road East, Princeton, New Jersey 08540. The remaining allegations of paragraph 21 are denied or contain conclusions of law for which no response is required.

22. On information and belief, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. have taken steps in New Jersey, including preparing the ANDA and communicating with the FDA regarding the ANDA, that indicate their intent to market the ANDA Product. As set forth above, on information and belief, if the ANDA is approved, DRL intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Product.

ANSWER: Paragraph 22 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest venue for purposes of this case only. DRL admits that it filed DRL's ANDA seeking FDA approval of DRL's Proposed ANDA Products. The remaining allegations of paragraph 22 are denied or contain conclusions of law for which no response is required.

BACKGROUND

23. ARI holds New Drug Application ("NDA") No. 209379 for Selenious Acid (eq 12 mcg selenium/2 mL ((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)selenium/2 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.

ANSWER: DRL admits and avers that the FDA's website indicates that ARI holds NDA No. 209379 for 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), and that the FDA website indicates ARI's NDA received FDA approval on April 30, 2019. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 23 and, therefore, denies the same.

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

ANSWER: Paragraph 24 contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the FDA's website indicates that the '565 patent is listed in the Orange Book in connection with NDA No. 209379. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 24 and, therefore, denies the same.

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: DRL admits that a purported copy of the '565 patent is attached as Exhibit 1. DRL admits that, on its face, the '565 patent is entitled "Trace element compositions, methods of making and use," identifies ARI as an assignee, and bears an issuance date of June 4, 2024. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 25, and therefore denies the same.

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: DRL admits that the FDA's website indicates that the '565 patent is listed in the Orange Book in connection with NDA No. 209379. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 26 and, therefore, denies the same.

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

ANSWER: DRL admits that the FDA's website indicates that the '565 patent is listed in the Orange Book in connection with NDA No. 209379, and lists a patent expiration of July 1, 2041. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 27 and, therefore, denies the same.

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

ANSWER: Paragraph 28 contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA 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"). DRL denies the remaining allegations of paragraph 28.

29. By the letter dated June 10, 2024 ("the Notice Letter"), DRL notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, DRL had submitted the ANDA with a Paragraph IV Certification to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the '565 patent.

ANSWER: DRL admits that it sent a letter to ARI on dates including at least June 10, 2024, and June 11, 2024, that notified ARI that DRL's ANDA contains a Paragraph IV Certification against the '565 patent ("DRL's Notice Letter"). DRL admits that its Notice Letter informed ARI that DRL had submitted an ANDA "seeking approval" for DRL's Proposed ANDA Products prior to the expiration of the '565 patent. DRL denies the remaining allegations of paragraph 29.

30. On information and belief, DRL 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: DRL admits that it filed DRL's ANDA seeking FDA approval of DRL's Proposed ANDA Products before the expiration of the '565 patent, and that DRL's ANDA contains a Paragraph IV Certification against the '565 patent. The remaining allegations of paragraph 30 are denied or contain conclusions of law for which no response is required.

31. The Notice Letter did not assert defenses of non-infringement for claims 1-2, 4-11, 13-17, 19-20, 22-26, 28-29 of the '565 patent.

ANSWER: DRL admits that DRL's Notice Letter did not include allegations of non-infringement of some claims of the '565 patent. DRL denies the remaining allegations of paragraph 31, including without limitation any implication DRL infringes any claim of the '565 patent or that DRL was required to include any basis for such non-infringement in its Notice Letter.

32. 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/mL) and (2) eq. 60 mcg selenium/mL (eq. 60 mcg/mL), as their reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

ANSWER: Paragraph 32 contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that it filed DRL's ANDA seeking

FDA approval of DRL's Proposed ANDA Products. DRL denies the remaining allegations of paragraph 32.

33. In the Notice Letter, DRL disclosed that the ANDA Products are: selenious acid, intravenous solution, EQ 600 mcg Selenium/10 mL and EQ 60 mcg Selenium/mL.

ANSWER: DRL admits that DRL's Notice Letter disclosed DRL's Proposed ANDA Products. DRL denies the remaining allegations of paragraph 33.

34. On information and belief, the ANDA Products contains [sic] 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/mL) and (2) eq. 60 mcg selenium/mL (eq. 60 mcg/mL)).

ANSWER: Paragraph 34 contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that it filed DRL's ANDA seeking FDA approval of DRL's Proposed ANDA Products. DRL denies the remaining allegations of paragraph 34.

35. 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 35 contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that it filed DRL's ANDA seeking FDA approval of DRL's Proposed ANDA Products. DRL denies the remaining allegations of paragraph 35.

COUNT I: INFRINGEMENT OF THE '565 PATENT

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

ANSWER: DRL incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

37. DRL'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: Denied.

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

39. On information and belief, DRL'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, DRL intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, DRL 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: Denied.

40. ARI will be irreparably harmed if DRL 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: Denied.

41. DRL has had knowledge of the '565 patent since at least the date DRL 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 41 contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that it submitted DRL's ANDA, and that DRL's ANDA contains a Paragraph IV Certification against the '565 patent. DRL denies the remaining allegations of paragraph 41.

42. 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 AND ARI'S JURY DEMAND

The remainder of ARI's complaint recites a prayer for relief and jury demand for which no response is required. To the extent any response is required, DRL denies that ARI is entitled to any remedy or relief, including entitlement to a jury.

SEPARATE DEFENSES

Without any admissions as to the burden of proof, burden of persuasion, or the truth of any allegations in ARI's complaint, DRL states the following defenses:

First Separate Defense

The filing of DRL's ANDA has not infringed, does not infringe and will not infringe, any valid and enforceable claim of the '565 patent.

Second Separate Defense

The manufacture, use, sale, offer for sale, or importation of DRL's Proposed ANDA Products have not infringed, and do not and would not infringe, directly or indirectly, any valid and enforceable claim of the '565 patent, either literally or under the doctrine of equivalents.

Third Separate Defense

The claims of the '565 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, 112, 115, 116, and/or improper inventorship, or other judicially-created bases for invalidity.

Fourth Separate Defense

ARI's complaint fails to state a claim upon which relief may be granted.

Fifth Separate Defense

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

Sixth Separate Defense

DRL has not willfully infringed any claim of the '565 patent.

Seventh Separate Defense

ARI is estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

Eighth Separate Defense

The allegations in ARI's complaint do not entitle ARI to relief under 35 U.S.C. § 271(e).

Ninth Separate Defense

Any additional defenses or counterclaims that discovery may reveal.

WHEREFORE, DRL requests that ARI's complaint be dismissed with prejudice and that DRL be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

COUNTERCLAIMS

Defendants, Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively, "DRL") by way of Counterclaims against Plaintiff, American Regent, Inc. ("ARI"), state as follows:

PARTIES

1. 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.

2. DRL Ltd. is a company organized and existing under the laws of India, having a place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India 500034.

3. DRL Inc. is a company organized and existing under the laws of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey, 08540.

NATURE OF THE ACTION

4. DRL seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent No. 11,998,565 ("the '565 patent") is invalid and/or not infringed.

JURISDICTION AND VENUE

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over ARI because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its complaint here.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by ARI's choice of forum.

8. ARI alleged in its complaint that there is an actual and justiciable controversy between the parties as to the noninfringement and invalidity of the '565 patent.

BACKGROUND

A. FDA Approval of New Brand Name Drugs

9. The Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

11. An NDA must include, among other things, the number of any patent that allegedly 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 unauthorized party. *See* 21 U.S.C. §§ 355(b)(1)(A)(viii), (b)(2), (c)(2); 21 C.F.R. §§ 314.53(a), (b)(1), (c)(2).

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

13. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. §§ 355(b)(1)(A)(viii), (c)(2); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure either that it is accurate or

that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

16. Among other things, an ANDA must contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

17. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

18. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

C. DRL's ANDA and ARI's Complaint

19. DRL submitted ANDA No. 218639 ("DRL's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of Selenious acid Injection, USP 600 mcg/10 mL (60 mcg/mL) and 60 mcg/mL of Selenium ("DRL's Proposed ANDA Products").

20. On information and belief, ARI is the holder of NDA No. 209379 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of 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) selenium/2 mL), under Section 505(b) of the FFDCA.

21. Selenious acid products have been on the market since as early as 1990. For example, on information and belief, ARI has marketed an unapproved Selenium Injection product for over thirty years. In particular, the Multi-Discipline Review for NDA No. 209379 represents that ARI has marketed the unapproved product Selenium Injection (65.4 mcg/mL selenious acid equivalent to 40 mcg/mL selenium) available in 10-mL and 30-mL vials since 1990 as an additive to parenteral nutrition. *See* NDA No. 209379, Multi-Discipline Review at 25.

22. ARI has represented that it has marketed selenious acid under NDA 209379 since July 1, 2019. Specifically, the FDA National Drug Code ("NDC") Directory lists a "Start Marketing Date" of "07/01/2019" for "selenious acid" having a "Product NDC" of 0517-6560. FDA represents that the "[m]arketing start date is the date the labeler reports that the product has entered commercial distribution." *See* https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.

23. On information and belief, ARI caused the '565 patent to be listed in the Orange Book, as a patent that purportedly claims the drug listed in, and/or purportedly claims a method of using the drug for which ARI submitted, NDA No. 209379.

24. The '565 patent, entitled "Trace element compositions, methods of making and use" was issued on June 4, 2024.

25. On information and belief, ARI is the assignee of the '565 patent.

26. On July 16, 2024, ARI filed the present lawsuit alleging infringement of the '565 patent.

27. On the basis of ARI's suit alleging that DRL infringes the '565 patent, there has been and now is an actual, substantial, continuing and justiciable controversy between ARI and DRL as to whether the claims of the '565 patent are invalid and/or infringed, and whether any injunctive remedy is available to ARI, which are of sufficient immediacy and reality to warrant the issuance of declaratory judgment.

COUNT I: DECLARATORY JUDGMENT OF INVALIDITY OF THE '565 PATENT

28. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

29. The claims of the '565 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

30. DRL is entitled to a declaration that all claims of the '565 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, 112, 115, 116, and/or improper inventorship, or other judicially-created bases for invalidity.

COUNT II: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '565 PATENT

31. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

32. ARI claims to be the owner of all legal rights, title, and interests in the '565 patent, including the right to enforce the '565 patent.

33. DRL's Proposed ANDA Products have not infringed, will not infringe, and are not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '565 patent.

34. Unless ARI is enjoined, DRL believes that ARI will continue to assert that DRL's Proposed ANDA Products infringe the claims of the '565 patent and will continue to interfere with DRL's business with respect to DRL's Proposed ANDA Products.

35. DRL will be irreparably harmed if ARI is not enjoined from continuing to assert the '565 patent and from interfering with DRL's business.

36. DRL is entitled to a declaratory judgment that DRL's Proposed ANDA Products have not infringed, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '565 patent.

COUNT III: DECLARATORY JUDGMENT OF NO INJUNCTIVE REMEDY FOR THE '565 PATENT

37. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

38. Neither the patent holder nor any exclusive licensee will in fact experience any harm from any DRL sales of DRL's Proposed ANDA Products that have nexus to the claims of the '565 patent.

39. ARI cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages even if infringement of a valid and enforceable patent were presumed.

40. ARI is not entitled to any injunctive remedy of any kind.

PRAYER FOR RELIEF

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

a. Dismissing the Complaint with prejudice and denying each and every prayer for relief contained therein;

b. Declaring that the claims of the '565 patent are invalid and/or unenforceable;

c. Declaring that DRL's Proposed ANDA Products do not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '565 patent;

d. Declaring that ARI is not entitled to any injunctive remedy for the '565 patent;

e. Enjoining ARI and its officers, employees, agents, representatives, attorneys and others acting on their behalf, from representing to anyone, either directly or indirectly, that DRL's Proposed ANDA Products have infringed, are infringing or will infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '565 patent;

f. Awarding DRL its costs and expenses in this action;

g. Declaring this an exceptional case in favor of DRL and awarding DRL its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

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

Dated: August 27, 2024

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LOCAL CIVIL RULE 11.2 and 40.1 CERTIFICATION

Pursuant to Local Civil Rule 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. I further certify that the matter in controversy is related to the actions pending before the Judicial Panel on Multidistrict Litigation in *In re Selenious Acid Litigation*, Case MDL No. 3129.

Dated: August 27, 2024

s/ Gregory D. Miller
Gregory D. Miller

LOCAL CIVIL RULE 201.1 CERTIFICATION

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

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

Dated: August 27, 2024

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

I hereby certify that, on August 27, 2024, the foregoing document described as **DEFENDANTS' ANSWER TO COMPLAINT, SEPARATE DEFENSES AND COUNTERCLAIMS** was served on all counsel of record indicated below via electronic mail.

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