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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

AMERICAN REGENT, INC.,

Plaintiff,

v.

CIPLA USA, INC. and CIPLA LIMITED,

Defendants.

Civil Action No. 2:24-cv-07796

**DEFENDANTS CIPLA LIMITED AND CIPLA USA, INC.'S ANSWER AND
COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT**

Defendants, Cipla Limited and Cipla USA, Inc. (collectively “Cipla” or “Defendants”), by their counsel, hereby answer the allegations set forth in Plaintiff, American Regent, Inc.’s (“ARI” or “Plaintiff”), Complaint for Patent Infringement against Cipla, as follows:

NATURE OF THIS ACTION¹

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 Cipla's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 218661 ("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

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Plaintiff purports to bring this action under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* Cipla further admits that it submitted ANDA No. 218661 to the FDA with a Paragraph IV Certification directed to United States Patent No. 11,998,565 ("the '565 patent"). Cipla denies any remaining allegations in this paragraph.

THE PARTIES

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

Answer

Cipla lacks sufficient information or knowledge to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

3. On information and belief, Cipla Limited is a corporation organized and existing under the laws of India with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

¹ For convenience, certain section headings used by Plaintiff in its Complaint are repeated herein.

Answer

Cipla admits that Cipla Limited is an Indian corporation with a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

4. On information and belief, Cipla USA, Inc. is an American corporation organized and existing under the laws of Delaware with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

Answer

Cipla admits that Cipla USA, Inc. is a Delaware corporation with a place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

5. On information and belief, Cipla USA, Inc. is a wholly-owned subsidiary of InvaGen Pharmaceuticals, Inc., which is a wholly owned subsidiary of Cipla (EU Limited), which is a wholly owned subsidiary of Cipla Limited.

Answer

Admitted.

JURISDICTION AND VENUE

6. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Plaintiffs purport to bring this action under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* Furthermore, for the limited purposes of this litigation only, Cipla does not contest subject matter jurisdiction or personal jurisdiction. Cipla denies any remaining allegations in this paragraph.

7. By the letter dated June 10, 2024 (the "Notice Letter"), Cipla identified Cipla USA Inc. as U.S. Agent for Cipla Limited, whose office is at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

Answer

Admitted.

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

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Cipla USA, Inc. maintains a place of business in this District. Furthermore, for the limited purpose of this case only, Cipla does not contest personal jurisdiction over Cipla USA, Inc. in this District. Cipla denies any remaining allegations in this paragraph.

9. On information and belief, this Court has personal jurisdiction over Cipla Limited, under the New Jersey state long arm statute and consistent with due process of law because Cipla Limited has extensive contacts with the State of New Jersey, including through its subsidiary Cipla USA, Inc., and regularly does business in this judicial district, including through its subsidiary Cipla USA, Inc. Further, Cipla plans to sell the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla states that for the limited purpose of this case only it does not contest personal jurisdiction over Cipla Limited in this District. Cipla denies any remaining allegations in this paragraph.

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

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Cipla USA, Inc. maintains a place of business in this District. Furthermore, for the limited purpose of this case only Cipla does not contest personal jurisdiction over Cipla USA, Inc. in this District. Cipla denies any remaining allegations in this paragraph.

11. On information and belief, Cipla USA Inc. and Cipla Limited work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla Ltd. and Cipla USA, Inc. each perform certain tasks with respect to Cipla's ANDAs and Cipla's generic pharmaceutical products. Cipla denies any remaining allegations in this paragraph.

12. On information and belief, Cipla USA Inc. is the United States agent acting at the direction of, and for the benefit of, Cipla Limited regarding the ANDA.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla Ltd. and Cipla USA, Inc. each perform certain tasks with respect to Cipla's ANDAs and Cipla's generic pharmaceutical products. Cipla denies any remaining allegations in this paragraph.

13. This Court has personal jurisdiction over Cipla because Cipla 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, Cipla USA, 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. 0450318628, and Cipla 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 5005183. On information and belief, Cipla 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, Cipla derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Cipla USA, 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. 0450318628. Cipla further admits that Cipla USA, Inc. is registered with the New Jersey Department of Health under Registration Number 5005183. Furthermore, for the limited purpose of this litigation only Cipla does not contest personal jurisdiction over Cipla USA, Inc. or Cipla Limited in this District. Cipla denies any remaining allegations in this paragraph.

14. This Court has personal jurisdiction over Cipla because, on information and belief, Cipla derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this litigation only Cipla states that it does not contest personal jurisdiction over Cipla USA, Inc. or Cipla Limited in this District. Cipla denies any remaining allegations in this paragraph.

15. Cipla Limited 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 Cipla USA, Inc., not contesting personal jurisdiction in this judicial district, and asserting counterclaims in this judicial district, including in at least *Par Pharmaceutical, Inc. et al. v. Cipla Limited et al.*, C.A. No. 22-02814, Dkt. No. 10 (D.N.J. July 7, 2022); *Teva Branded*

Pharmaceutical Products R&D, Inc. et al. v. Cipla Limited, C.A. No. 20-10172, Dkt. No. 7 (D.N.J. Feb. 3, 2021); *Celgene Corp. v. Cipla Limited*, C.A. No. 17-06163, Dkt. No. 10 (D.N.J. Oct. 13, 2017); *AstraZeneca AB et al. v. Cipla Limited et al.*, C.A. No. 16-09583, Dkt. No. 8 (D.N.J. Feb. 3, 2017).

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this litigation only Cipla states that it does not contest personal jurisdiction over Cipla Limited in this District, and that it has previously asserted counterclaims and declined to challenge personal jurisdiction in the litigations listed in this paragraph. Cipla denies any remaining allegations in this paragraph.

16. This Court has personal jurisdiction over Cipla because, *inter alia*, Cipla 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, Cipla will make, use, import, sell, and/or offer for sale the ANDA Products in the United States, including in New Jersey, prior to the expiration of the '565 patent.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this litigation only Cipla states that it does not contest personal jurisdiction over Cipla USA, Inc. or Cipla Limited in this District. Cipla denies any remaining allegations in this paragraph.

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

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Cipla Limited is a foreign corporation. Cipla further states that for the limited purpose of this litigation only it does not contest personal jurisdiction over Cipla Limited in this District. Cipla denies any remaining allegations in this paragraph.

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

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla states that for the limited purpose of this litigation only it does not contest venue in this District. Cipla denies any remaining allegations in this paragraph.

19. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Cipla USA, 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. Cipla Limited is a foreign company not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that Cipla USA, Inc. is organized under the laws of the State of New Jersey, and admits that Cipla USA, Inc. has a place of business in New Jersey. Cipla further admits that Cipla Limited is a foreign company. For the limited purpose of this litigation only, Cipla states that it does not contest venue in this District. Cipla denies any remaining allegations in this paragraph.

20. On information and belief, Cipla has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting the ANDA to the FDA, by taking steps indicating its intent to market the ANDA Products in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if the ANDA receives final FDA approval.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that it has committed acts of infringement of any valid claims of the ‘565 Patent. Cipla admits that it has submitted the ANDA to the FDA. Cipla states that for the limited purpose of this litigation only it does not contest venue in this District. Cipla denies any remaining allegations in this paragraph.

21. On information and belief, Cipla USA, 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, Cipla USA, Inc. maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Cipla USA, Inc. maintains an office at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. For the limited purpose of this litigation only Cipla states that it does not contest venue in this District. Cipla denies any remaining allegations in this paragraph.

22. On information and belief, Cipla Limited and Cipla USA, 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 Products. As set forth above, on information and belief, if the ANDA is approved, Cipla intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Products.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that it intends to commit any acts that infringe any valid claim of the ‘565 Patent. Cipla admits that it has prepared an ANDA and communicated with the FDA regarding the ANDA. Cipla denies any remaining allegations in this paragraph.

BACKGROUND

23. ARI holds New Drug Application (“NDA”) No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) 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

Cipla admits that FDA’s electronic *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) lists ARI as the holder for NDA No. 209379 and that a product containing eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) was approved on April 30, 2019. Cipla further admits that the Orange Book lists two other strengths for NDA No. 209379, eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL) and eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), but denies that these were approved on April 30, 2019. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in this paragraph and therefore denies them.

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

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

25. ARI is the owner of the ’565 patent, entitled “Trace element compositions, methods of making and use,” which was duly and legally issued on June 4, 2024. A copy of the ’565 patent is attached as Exhibit 1.

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that the ’565 Patent was “duly and legally issued.” Cipla admits that ARI is listed as the assignee of the ’565 patent in the U.S. Patent and Trademark

assignment database. Cipla further admits that the title of the '565 patent is "Trace element compositions, methods of making and use" and that the face of the '565 patent indicates that it was issued on June 4, 2024. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in this paragraph and therefore denies them.

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

Cipla admits that the Orange Book associates the '565 patent with NDA No. 209379.

Cipla denies any remaining allegations in this paragraph.

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

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla lacks sufficient information or knowledge to admit or deny that the '565 Patent expires on July 1, 2041, and, therefore, denies the same. Cipla admits that the Orange Book lists the expiration date of the '565 patent as July 1, 2041. Cipla denies any remaining allegations in this paragraph.

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

Answer

Admitted.

29. In the Notice Letter, Cipla notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Cipla had submitted the ANDA to the FDA with a Paragraph IV Certification to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the '565 patent.

Answer

Admitted.

30. On information and belief, Cipla 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

Admitted.

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

Answer

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the allegations set forth in this paragraph.

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

Answer

Cipla admits that its ANDA describes a selenious acid product with two different dose strengths ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)) that list NDA No. 209379 as the reference listed drug. Cipla denies any remaining allegations in this paragraph.

33. In the Notice Letter, Cipla disclosed that the ANDA Products: are selenious acid injection USP, selenious acid, eq. 12 mcg selenium/2 mL (eq. 6 mcg selenium/mL) and eq. 600 mcg selenium/10 mL (eq. 60 mcg selenium/mL).

Answer

Cipla admits that its ANDA describes a selenious acid product with two different dose strengths ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) eq. 12 mcg

Selenium/2 mL (eq. 6 mcg Selenium/mL)) that list NDA No. 209379 as the reference listed drug.

Cipla denies any remaining allegations in this paragraph.

34. 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 Selenium/2 mL (eq. 6 mcg Selenium/mL)).

Answer

This paragraph contains legal conclusions to which no answer is required, including at least with respect to the term "same or equivalent." To the extent an answer is required, Cipla's ANDA Product is intended to be therapeutically equivalent to the product described in NDA No. 209379.

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

This paragraph contains legal conclusions to which no answer is required, including at least with respect to the term "same or equivalent." To the extent an answer is required, Cipla's ANDA Product is intended to be therapeutically equivalent to the product described in NDA No. 209379.

COUNT I: INFRINGEMENT OF THE '565 PATENT

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

Answer

In response to this paragraph, Cipla repeats and realleges its responses to the allegations of paragraphs 1-35 of the Complaint as if fully set forth herein.

37. Cipla'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 Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Cipla 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 Cipla's specific intent and encouragement, and will constitute conduct that Cipla knows or should know will occur. On information and belief, Cipla 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, Cipla'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, Cipla intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, know 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 noninfringing use.

Answer

Denied.

40. ARI will be irreparably harmed if Cipla 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. Cipla has had knowledge of the '565 patent since at least the date Cipla 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

Cipla admits that it was aware of the '565 patent as of at least the date Cipla submitted a Paragraph IV Certification to the FDA in connection with Cipla's ANDA. Cipla denies the remaining allegations of this paragraph.

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

Answer

Denied.

ARI'S PRAYER FOR RELIEF

The remainder of the Complaint is a prayer for relief and does not require a response. To the extent any response is required, Cipla denies that Plaintiff is entitled to any remedy or relief sought in paragraphs (a) through (h) of Plaintiff's Prayer for relief. All other allegations in the Complaint not specifically admitted or denied are hereby denied.

AFFIRMATIVE DEFENSES

Cipla reserves all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure and any other defense at law or at equity that may now exist or in the future be available based on discovery and further factual investigation in this case, whether or not expressly stated herein. Without prejudice to the denials set forth in its Answer and without any admissions as to the burden of proof, burden of persuasion, or the truth of any allegations not expressly admitted in Plaintiff's Complaint, Cipla states the following defenses:

FIRST AFFIRMATIVE DEFENSE

The allegations set forth in Plaintiff's Complaint fail to state a claim for which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of the '565 patent are invalid and/or unenforceable for failure to satisfy or comply with the requirements of Title 35 of the United States Code, including, without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120, non-statutory (obviousness-type) double patenting, the defenses recognized in 34 U.S.C. § 282(b) and/or any other judicially created bases for invalidity.

THIRD AFFIRMATIVE DEFENSE

Cipla has not infringed, is not infringing, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '565 patent. Cipla has not contributed to, is not contributing to, and will not contribute to any infringement of any valid and enforceable claim of the '565 patent. Cipla has not induced, is not inducing, and will not induce infringement of any valid and enforceable claim of the '565 patent.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to injunctive relief because any injury to Plaintiff is not immediate or irreparable, because any such injunction would be against the public interest, and because Plaintiff has an adequate remedy at law.

FIFTH AFFIRMATIVE DEFENSE

Cipla has not intentionally, willfully, or deliberately infringed any valid claim of the '565 patent.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's case is not exceptional under 35 U.S.C. § 285.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's infringement claims against Cipla regarding the Patents-in-Suit are barred and the '565 patent is unenforceable against Cipla under the equitable doctrines of laches, waiver, estoppel, and/or acquiescence.

RESERVATION OF ADDITIONAL DEFENSES

The Cipla Parties hereby reserve the right to assert additional defenses and/or counterclaims if such defenses or counterclaims are discovered during the course of this litigation.

COUNTERCLAIMS

Without admitting any of the allegations in the Complaint, other than those allegations expressly admitted in the Answer, *supra*, and without prejudice to Cipla's right to plead additional counterclaims as the facts of the matter warrant, the Defendants/Plaintiffs-In-Counterclaim, Cipla Limited ("Cipla") and Cipla USA, Inc. ("Cipla USA") (collectively "Cipla" or "Counterclaim-Plaintiffs"), for its Counterclaims against Plaintiff American Regent, Inc. ("ARI" or "Counterclaim-Defendant"), hereby allege as follows:

THE PARTIES

1. Counterclaim-Plaintiff Cipla Limited is a corporation organized and existing under the laws of India, having its corporate office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

2. Counterclaim-Plaintiff Cipla USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059. Cipla USA is an indirect subsidiary of Cipla Limited.

3. On information and belief, Counterclaim-Defendant American Regent, Inc. (“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, Shirely, New York 11967.

JURISDICTION AND VENUE

4. These counterclaims arise 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 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

5. Personal jurisdiction over the Plaintiff/Counterclaim-Defendant exists because the Plaintiff/Counterclaim-Defendant has submitted to the personal jurisdiction of the Court.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

The Patents-in-Suit

7. On July 16, 2024, Plaintiff/Counterclaim-Defendant filed a Complaint alleging, *inter alia*, infringement of United States Patent No. 11,998,565 (the “’565 patent”).

8. Prior to the filing of this action, upon information and belief, Plaintiffs/Counterclaim-Defendants listed and caused to be listed the ’565 patent in the publication of the Federal Food and Drug Administration (“FDA”) entitled “Approved Drug Products for Therapeutic Equivalents Evaluations” (commonly known as the “Orange Book”) for NDA No. 209379.

9. The ’565 patent is entitled, “Trace element compositions, methods of making and

use,” and indicates on the face of that patent that it issued on June 4, 2024.

10. Upon information and belief, Plaintiff/Counterclaim-Defendant is listed as the owner by assignment of the ’565 patent in the U.S. Patent and Trademark assignment database.

Cipla’s Notice Letter and ARI’s Suit

11. Cipla has filed with the FDA an Abbreviated New Drug Application (“ANDA”) bearing No. 218661, seeking to obtain approval to engage in the commercial manufacture, use, sale, or importation of a proposed generic trace element nutrition product containing selenious acid in three dosage strengths: ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)) (“Cipla’s ANDA Product”).

12. Pursuant to 21 U.S.C. § 355(j)(2)(A)(iv), Cipla’s ANDA No. 218661 contains a “Paragraph IV” certification stating that the ’565 patent is invalid or will not be infringed by the manufacture, use, sale, offer to sell, or importation into the United States of the proposed drug product which is the subject of Cipla’s ANDA No. 218661.

13. Pursuant to the applicable statutes, rules, and regulations, Cipla notified Plaintiff/Counterclaim-Defendant that it had submitted to the FDA ANDA No. 218661 for Cipla’s ANDA Product by letter dated June 10, 2024 (“Cipla’s Notice Letter”).

14. Plaintiff/Counterclaim-Defendant filed their Complaint against Cipla alleging infringement of the ’565 patent on July 16, 2024.

15. By virtue of Plaintiff/Counterclaim-Defendant having listed the ’565 patent in the Orange Book, by virtue of Cipla’s submission of a “Paragraph IV” certification regarding these patents and providing Plaintiff/Counterclaim-Defendant with notice and the basis for such certification, and by virtue of the Complaint filed herein, an actual case and controversy exists between Cipla and Plaintiff/Counterclaim-Defendant as to the infringement and validity of the

'565 patent.

16. Cipla does not infringe any valid and enforceable claim of the '565 patent, either directly or indirectly.

17. An actual and justiciable controversy exists between Plaintiff/Counterclaim-Defendant and Cipla relating to, *inter alia*, the '565 patent.

COUNT I

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

18. Cipla repeats and realleges each of the foregoing paragraphs of the counterclaim as if fully set forth herein.

19. There is an actual, substantial, and continuing justiciable case or controversy between the Cipla Parties and ARI regarding the invalidity of the '565 patent.

20. The '565 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, 120, non-statutory (obviousness-type) double patenting, the defenses recognized in 34 U.S.C. § 282(b) and/or any other judicially created bases for invalidity.

21. The '565 patent is invalid at least for the reasons set forth in Cipla's Notice Letter.

22. Cipla is entitled to a declaratory judgment that the claims of the '565 patent are invalid.

COUNT II

(Declaratory Judgment of Non-Infringement – U.S. Patent No. 11,998,565)

23. Cipla repeats and realleges each of the foregoing paragraphs of the counterclaim as if fully set forth herein.

24. There is an actual, substantial, and continuing justiciable case or controversy between the Cipla Parties and ARI regarding the non-infringement of the '565 patent.

25. Cipla's manufacture, use, offer for sale, sale, and/or importation into the United States of Cipla's ANDA Product upon FDA approval to do so pursuant to ANDA No. 218661 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '565 patent, either literally or under the doctrine of equivalents.

26. Cipla does not and has not committed any acts in violation of 35 U.S.C. § 271.

27. Cipla is entitled to a declaratory judgment that its manufacture, use, offer for sale, sale, and/or importation into the United States of Cipla's ANDA Product pursuant to ANDA No. 218661 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '565 Patent, either literally or under the doctrine of equivalents.

PRAAYER FOR RELIEF

WHEREFORE, Cipla respectfully requests that the Court enter judgment for Cipla, and against Plaintiff/Counterclaim-Defendant, and decree as follows:

A. That the Complaint be dismissed with prejudice and that each and every prayer for relief contained therein be denied;

B. Declaring that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Cipla's ANDA No. 218661 has not infringed, does not infringe, would not infringe, would not contributorily infringe and would not induce the infringement of any valid and enforceable claim of the '565 patent, either literally or under the doctrine of equivalents;

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

D. That this case is exceptional and awarding Cipla reasonable attorneys' fees, costs, and expenses in this action, pursuant to 35 U.S.C. § 285 and/or other applicable laws;

- E. That Cipla be awarded their fees, costs, and expenses in this action;
- F. That the effective date of any FDA approval of Cipla's ANDA Product shall not be stayed thirty months from the date of the Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii); and
- G. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Respectfully submitted,

Dated: August 26, 2024

By: /s/ Rebekah Conroy
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 26, 2024, a copy of the foregoing document was filed electronically using the Court's CM/ECF system. Notice of this filing will be sent by operation of the CM/ECF system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail.

By: /s/ Rebekah Conroy
Rebekah Conroy

*Counsel for Defendants
Cipla Limited and Cipla USA, Inc.*