Charles Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailer@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

Attorneys for Plaintiff
American Regent, Inc.

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett (*pro hac vice* to be filed)
Adam LaRock (*pro hac vice* to be filed)
Alex Alfano (*pro hac vice* to be filed)
Ryan Conkin (*pro hac vice* to be filed)
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

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

AMERICAN REGENT, INC., *Plaintiff*, v. CIPLA USA, INC. and CIPLA LIMITED, *Defendants.*	Civil Action No. 24-11112 (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT TO CIPLA

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for their Amended Complaint against Defendants Cipla USA, Inc. and Cipla Limited (collectively "Cipla" or "Defendants") alleges as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from 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. 12,150,957 ("the '957 patent" or the "Asserted Patent"). As discussed below, this case involves the same ANDA No. 218661 and thus is a related case to *American Regent, Inc. v. Cipla USA, Inc. et al..*, C.A. No. 24-7796 (D.N.J.) (the "Related Action").

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.

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.

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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).

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 Asserted Patent.

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.

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

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).

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.

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.

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.

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.

24. The use of ARI's Selenious Acid products are covered by one or more claims of the Asserted Patent.

25. ARI is the owner of the '957 patent, entitled "Trace element compositions, methods of making and use," which was duly and legally issued on November 26, 2024. A copy of the '957 patent is attached as Exhibit A.

26. The '957 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").

27. As indicated in the Orange Book, the expiration date for the '957 patent is July 1, 2041.

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

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 U.S. Patent No. 11,998,565 ("the '565 patent'), which is at issue in the Related Action.

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.

31. Since ARI received the Notice Letter and filed its complaint against Cipla in the Related Action, the ’957 patent has been listed in connection with ARI’s Selenious Acid products in the Orange Book.

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.

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). .

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)).

35. On information and belief, the ANDA Products will feature the same or equivalent chemical and therapeutic properties as ARI’s Selenious Acid products.

COUNT I: INFRINGEMENT OF THE ’957 PATENT

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

37. Cipla’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 ’957 patent, constitutes direct and indirect infringement of the ’957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

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 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 '957 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 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 '957 patent.

39. On information and belief, Cipla'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 '957 patent, either literally or under the doctrine of equivalents. On information and belief, Cipla intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Cipla knows that the ANDA Product is especially made or adapted for use in infringing the '957 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

40. ARI will be irreparably harmed if Cipla 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 '957 patent, or any later expiration of exclusivity for the '957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

41. Cipla has had knowledge of the '957 patent since at least October 11, 2024, when ARI emailed all defendants in the Related Action to inform them that the '957 patent would issue in due course.

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

PRAYER FOR RELIEF

WHEREFORE, ARI prays that this Court grant the following relief:

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Cipla has infringed at least one claim of the Asserted Patent through Cipla's submission of the ANDA with a Paragraph IV Certification to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States the ANDA Products before the expiration of the Asserted Patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Cipla's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the ANDA Products before the expiration of the Asserted Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the Asserted Patent;

(c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the ANDA, shall not be earlier than the latest expiration date of the Asserted Patent, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(d) The entry of a permanent and/or preliminary injunction enjoining Cipla, and its affiliates and subsidiaries, and each of its officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, and importing in or into the United States the ANDA Products, or any product that infringes the Asserted Patent, or inducing or contributing to the infringement of the Asserted Patent until after the expiration date of the Asserted Patent, including any extension and/or additional periods of exclusivity to which ARI is or becomes entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(e) The entry of a permanent and/or preliminary injunction enjoining Cipla, and its affiliates and subsidiaries, and each of its officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Asserted Patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to ARI if Cipla engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Products prior to the expiration of the Asserted Patent, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(g) A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding ARI its attorney's fees incurred in this action; and

(h) Such further relief as this Court deems proper and just.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), ARI hereby demands a trial by jury on all issues triable to a jury. Specifically, ARI demands a jury trial in the event that there is a launch at risk and damages are in issue.

Dated: December 13, 2024

By: /s/ *Charles Chevalier*

Charles Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailer@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett
Adam LaRock
Alex Alfano
Ryan Conkin
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

Attorneys for Plaintiff
American Regent, Inc.

23616976.3