

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

AMERICAN REGENT, INC.,

Plaintiff,

v.

Civil Action No. _____

BPI LABS, LLC

Defendant.

PERMANENT INJUNCTIVE
AND DECLARATORY RELIEF
REQUESTED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. (“ARI” or “Plaintiff”), by its undersigned attorneys, for its Complaint against Defendant BPI Labs, LLC (“BPI”) 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 BPI’s submission to the United States Food and Drug Administration (“FDA”) of Abbreviated New Drug Application No. 220051 (“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 Product”) prior to the expiration of United States Patent No. 11,998,565 (“the ’565 patent”) and 12,150,957 (“the ’957 patent”) (collectively, the “Asserted Patents”).

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, BPI Labs is a corporation organized and existing under the laws of Florida, having a principal place of business at 12393 South Belcher Road, Suite 450, Largo, FL 33773.

JURISDICTION AND VENUE

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

5. This Court has personal jurisdiction over BPI at least because BPI has a place of business at 12393 Belcher Rd S., Largo, FL 33773.

6. This Court further has personal jurisdiction over BPI because it has purposefully availed itself of the rights and benefits of Florida law by engaging in systematic and continuous contact with the State of Florida. On information and belief, BPI regularly and continuously transacts business within Florida, including by making pharmaceutical products for sale in Florida and selling pharmaceutical products in Florida. On information and belief, BPI derives substantial revenue from the sale of those products in Florida and has availed itself of the privilege of conducting business within Florida.

7. This Court has personal jurisdiction over BPI because, on information and belief, BPI 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.

8. This Court has personal jurisdiction over BPI because, *inter alia*, BPI has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intend a future course of conduct that includes acts of patent infringement in Florida. These acts have led and will lead to foreseeable harm and injury to ARI in Florida. Further, on information and belief, following approval of the ANDA, BPI will make, use, import, sell, and/or offer for sale the ANDA Product in the United States, including in Florida, prior to the expiration of the Asserted Patents.

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

10. On information and belief, venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b) at least because BPI has a regular and established place of business in this Judicial District.

11. On information and belief, venue further is proper at least because BPI has committed and will commit further acts of infringement in Florida. In addition, BPI does business in Florida through a permanent and continuous presence in the State of Florida. Upon information and belief, if BPI succeeds in obtaining FDA approval of the ANDA, BPI will sell the ANDA Product in the State of Florida.

12. On information and belief, BPI 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 Product in Florida, and by the acts that it non-speculatively intends to take in Florida if the ANDA receives final FDA approval.

13. As set forth above, on information and belief, if the ANDA is approved, BPI intends to commit acts of patent infringement in Florida, including marketing, distributing, offering for sale, and/or selling the ANDA Product.

BACKGROUND

14. ARI holds New Drug Application (“NDA”) No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), which was originally approved by the FDA on April 30, 2019, which ARI manufactures and sells in this Judicial District and throughout the United States.

15. ARI’s Selenious Acid products or the use of ARI’s Selenious Acid products are covered by one or more claims of the Asserted Patents.

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

17. The ’565 patent has been listed in connection with ARI’s Selenious Acid products in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

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

19. 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 B.

20. The ’957 patent has been listed in connection with ARI’s Selenious Acid products in the Orange Book.

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

22. By letter dated April 23, 2025 (the “Notice Letter”), BPI notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, BPI 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 a generic version of ARI’s Selenious Acid product(s), prior to the expiration of the Asserted Patents.

23. On information and belief, as indicated in the Notice Letter, the ANDA Product is a generic version of ARI’s Selenious Acid product(s), as its reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts and will be indicated for use in the same or equivalent manner.

24. In the Notice Letter, BPI disclosed that the ANDA Product is a solution for intravenous administration, containing selenious acid (equivalent to 60 mcg/mL of selenium) as the active ingredient.

25. On information and belief, the ANDA Product contains the same or equivalent ingredients in the same or equivalent amounts as ARI’s Selenious Acid product(s).

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

COUNT I: INFRINGEMENT OF THE '565 PATENT

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

28. BPI’s submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the ’565 patent, constitutes direct and indirect infringement of the ’565 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

29. On information and belief, the ANDA Product, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by BPI or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '565 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with BPI's specific intent and encouragement, and will constitute conduct that BPI knows or should know will occur. On information and belief, BPI 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.

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

31. ARI will be irreparably harmed if BPI is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and are 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.

32. BPI has had knowledge of the '565 patent since at least the date BPI submitted the ANDA with a Paragraph IV Certification and were aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

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

COUNT II: INFRINGEMENT OF THE '957 PATENT

34. ARI realleges paragraphs 1–33 as if fully set forth herein.

35. BPI’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.

36. 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 BPI 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 BPI’s specific intent and encouragement, and will constitute conduct that BPI know or should know will occur.

On information and belief, BPI 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.

37. On information and belief, BPI'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, BPI's intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, BPI 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.

38. ARI will be irreparably harmed if BPI is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and a 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.

39. 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 BPI has infringed at least

one claim of the Asserted Patents through BPI'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 Product before the expiration of the Asserted Patents;

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

(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 Patents, 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 BPI, and its affiliates and subsidiaries, and each of their 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 Product, or any product that infringes the Asserted Patents, or inducing or contributing to the infringement of the Asserted Patents until after the expiration date of the Asserted Patents, 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 BPI, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Asserted Patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

- (f) Damages or other monetary relief to ARI if BPI engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Product prior to the expiration of the Asserted Patents, 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), Plaintiff hereby demands a trial by jury on all issues triable to a jury. Specifically, Plaintiff demands a jury trial in the event that there is a launch at risk and damages are in issue.

Dated: June 6, 2025.

BEDELL, DITTMAR, DeVAULT, PILLANS & COXE
Professional Association

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