

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN STRONTIUM-RUBIDIUM
RADIOISOTOPE INFUSION SYSTEMS,
AND COMPONENTS THEREOF
INCLUDING GENERATORS**

Investigation No. 337-TA-1110

**NOTICE OF COMMISSION FINAL DETERMINATION OF NO VIOLATION
OF SECTION 337; TERMINATION OF THE INVESTIGATION**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to affirm with modification a final initial determination (“FID”) of the presiding administrative law judge (“ALJ”) finding no violation of section 337 of the Tariff Act of 1930, as amended. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 1, 2018, based on a complaint, as amended, filed by Bracco Diagnostics Inc. of Monroe Township, New Jersey (“Bracco”). *See* 83 FR 19112 (May 1, 2018). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337) (“section 337”), based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain strontium-rubidium radioisotope infusion systems, and components thereof including generators, by reason of infringement of U.S. Patent Nos. 9,814,826; 9,750,869; and 9,750,870 (collectively, “the asserted patents”). *See id.* The notice of investigation names Jubilant DraxImage Inc. of Kirkland, Québec, Canada; Jubilant Pharma Limited of Singapore; and Jubilant Life Sciences of Noida, Uttar Pradesh, India (collectively, “Respondents” or “Jubilant”) as respondents in this

investigation. *See id.* The Office of Unfair Import Investigations is also a party to this investigation. *See id.*

On February 8, 2019, the ALJ issued an initial determination (“ID”) (Order No. 27) finding by summary determination that Jubilant’s RUBY Rubidium Elution System Version 3.0 directly infringes the asserted patents. *See* Order No. 27 (Feb. 8, 2019), *unreviewed*, Comm’n Notice (Mar. 8, 2019). In addition, the ID determines that Jubilant’s RUBY Rubidium Elution System Version 3.1 and the RUBY Rubidium Elution System Version 4 do not directly infringe the asserted patents. *See id.* The ID (Order No. 27) declines to reach indirect infringement on summary determination. *See id.*

The ALJ conducted an evidentiary hearing on February 11-12 and 15-17, 2019, and on August 1, 2019, issued the FID finding no violation of section 337. Specifically, the FID finds that the domestic industry requirement is satisfied and that all the asserted claims are infringed but invalid as obvious over the prior art. The FID also contains the ALJ’s Recommended Determination (“RD”) recommending, should the Commission find a section 337 violation, that the Commission issue a limited exclusion order (“LEO”) barring entry of articles that infringe the asserted claims. The RD does not recommend that the Commission issue a cease and desist order or impose a bond during the period of Presidential review. Furthermore, as directed by the Commission, the RD provides findings with respect to the public interest and recommends a determination that the public interest factors do not preclude entry of the proposed LEO.

On August 14, 2019, both Bracco and the Commission’s Investigative Attorney (“IA”) filed petitions for review of the FID. Bracco petitioned for review of the FID’s findings with respect to invalidity, while the IA petitioned for review of the FID’s findings with respect to domestic industry. On August 22, 2019, the parties filed responses to the respective petitions.

On September 30, 2019, the Commission determined to review the FID in part with respect to invalidity and domestic industry. *See* 84 FR 53177 (Oct. 4, 2019). The Commission determined not to review the remainder of the FID. *See id.*

Having considered the FID, the parties’ petitions, responses thereto, and the record in this investigation, the Commission has determined to affirm with modification the FID’s findings and conclusion of no violation of section 337. Specifically, as explained in the Commission Opinion issued concurrently herewith, the Commission has determined to affirm with modification and to supplement the FID’s findings with respect to the invalidity of the asserted patent claims. The Commission has further determined to affirm in part and vacate in part the FID’s findings with respect to the domestic industry requirement. All findings in the FID that are not inconsistent with the Commission’s final determination are affirmed. The investigation is terminated except with respect to the declassification proceeding presently before the Commission.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', enclosed within a large, loopy circular flourish.

Lisa R. Barton
Secretary to the Commission

Issued: December 2, 2019