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 DETERMINATION ON REMAND CONCERNING DECLASSIFICATION; REQUEST FOR WRITTEN SUBMISSIONS

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to solicit further briefing from the parties concerning the presiding Administrative Law Judge's ("ALJ") Order No. 31 and the Commission's Notice of May 6, 2019, affirming Order No. 31 with modification.

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. ("Complainant" or "Bracco") of Monroe Township, New Jersey. *See* 83 Fed. Reg. 19112-13 (May 1, 2018). The complaint, as amended, alleges violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), 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. *See id.* The notice of investigation names Jubilant DraxImage Inc. ("JDI") of Kirkland, Québec, Canada; Jubilant Pharma Limited of Singapore; and Jubilant Life Sciences of Noida, Uttar Pradesh, India

(collectively, "Respondents") as respondents in this investigation. *See id.* The Office of Unfair Import Investigations is also a party to this investigation. *See id.*

On October 29, 2018, Respondents filed a motion for summary determination that the RUBY Rubidium Elution System Version 3.1 and the RUBY Rubidium Elution System Version 4 do not infringe the asserted patents. Bracco did not accuse the Version 3.1 and Version 4 products in this investigation but Respondents sought an adjudication of non-infringement as to those products. On February 8, 2019, the ALJ in the above-identified investigation issued an initial determination ("ID") (Order No. 27) granting Respondents' SD Motion to the extent that the RUBY Rubidium Elution System Version 3.1 and the RUBY Rubidium Elution System Version 4 do not directly infringe the asserted patents. *See* Order No. 27 (Feb. 8, 2019), *unreviewed*, Comm'n Notice (Mar. 8, 2019). The ALJ declined to reach indirect infringement by those two products on summary determination. *Id.*

On November 14, 2018, the Commission Investigative Attorney ("IA") filed a motion to declassify portions of Respondents' motion for summary determination on the basis that they do not qualify as confidential business information ("CBI") under Commission Rule 201.6 (19 C.F.R. § 201.6). On November 26, 2018, Respondents filed a response in opposition to the IA's Motion to Declassify. On March 21, 2019, the ALJ issued an ID (Order No. 31) granting-in-part the IA's Motion to Declassify. The ALJ granted the IA's Motion to Declassify with respect to certain claim limitations relating to the Version 4 product and denied it with respect to certain claim limitations relating to the Version 3.1 product. *See* Order No. 31 at 3-5. On April 2, 2019, Respondents filed a petition for review of the ID (Order No. 31), and on April 9, 2019, the IA filed a response in opposition to Respondents' petition. On May 6, 2019, the Commission determined to affirm Order No. 31 with modification, consistent with the redactions and declassifications proposed by the IA in its response to Respondents' petition for review and in Exhibit 1 thereof (showing redactions in yellow and declassified material in red) (EDIS Doc. No. 672558). Furthermore, the Commission determined to stay its final declassification determination for 21 days to allow Respondents to seek judicial relief from and/or a judicial stay of the determination.

On May 22, 2019, JDI filed a complaint and a motion for a preliminary injunction with the United States District Court for the District of Columbia (Docket No. 1:19-1494-RDM), seeking to set aside the Commission's declassification determination and to enjoin the Commission from disclosing the declassified information in the underlying investigation. On July 10, 2019, the district court granted JDI's motion for a preliminary injunction. *Jubilant DraxImage Inc. v. USITC*, No. 1:19-1494-RDM, 2019 WL 3037536 (July 10, 2019). On July 17, 2019, the Commission filed a motion for a voluntary remand and for a stay pending resolution of the remand proceeding before the Commission. On July 25, 2019, the district court granted the Commission's motion for a voluntary remand. Order, *Jubilant DraxImage Inc. v. USITC*, No. 1:19-1494-RDM (July 25, 2019) (ECF No. 17). The court explained that "[o]n remand, the Court imposes no limitations as to scope, and the Commission's authority shall extend to the full extent permissible under applicable law or regulation." *See id.*

In connection with the present remand to the Commission, the parties are requested to brief their positions with reference to the applicable law and the evidentiary record regarding the questions provided below:

(1) Please identify any inconsistencies in the Commission's May 6, 2019 declassification determination, including but not limited to inconsistencies between the confidentiality designations for the red and yellow highlighted material as shown in the IA's response to Respondents' petition for review and in Exhibit 1 thereof (showing redactions in yellow and declassified material in red) (EDIS Doc. No. 672558). For each such inconsistency, please explain why it is an inconsistency and where in the record you identified that inconsistency to the ALJ and the Commission prior to May 6, 2019.

(2) Please provide factual support for the confidentiality of each item in Exhibit 1 to the IA's response to Respondents' petition for review (EDIS Doc. No. 672558) that you believe should be redacted as confidential under Commission Rule 201.6. In particular, please explain how: (a) the allegedly confidential information concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value; (b) the disclosure of the allegedly confidential information is likely to have the effect of impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions; and (c) the disclosure of the allegedly confidential information is likely to have the effect of causing substantial harm to the competitive position of a party.

(3) Please discuss all legal precedent (including but not limited to Commission authority and federal court authority) supporting or against the position that public patent disclosure (including claim language, language from the specification, and/or patent figures) may be protected as confidential under Commission rules or the rules of any other tribunal.

(4) Please discuss all legal precedent (including but not limited to Commission authority and federal court authority) supporting or against the position that ultimate legal conclusions of patent infringement or non-infringement (*e.g.*, a "yes" or "no" assertion whether an accused product practices each claim limitation) may be protected as confidential under Commission rules or the rules of any other tribunal.

(5) If you support a binary/non-binary distinction for determining whether patent claim language can be considered confidential as discussed in Order No. 31, please provide all legal precedent (including but not limited to Commission authority and federal court authority) supporting that distinction.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the questions identified in this notice. Written submissions must be filed no later than close of business on September 4, 2019. Reply submissions must be filed no later than the close of business on September 11, 2019. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1110") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel[1], solely for cybersecurity purposes. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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.

Lisa R. Barton
Secretary to the Commission

Issued: August 16, 2019

[1] All contract personnel will sign appropriate nondisclosure agreements.