PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS**	**Inv. No. 337-TA-1110**

COMMISSION OPINION

On August 1, 2019, the presiding Administrative Law Judge ("ALJ") in the above-identified investigation issued a final initial determination ("FID") finding no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"). 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 ultimate conclusion of no violation of section 337. Specifically, the Commission has determined to affirm the FID's conclusion with respect to the invalidity of the asserted claims and supplements the FID's findings on that issue. In addition, the Commission has 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 consistent with this opinion are affirmed.

I. BACKGROUND

A. Procedural Background

The Commission instituted this investigation on May 1, 2018, based on a complaint, as amended, filed by Bracco Diagnostics Inc. ("Bracco") of Monroe Township, New Jersey. *See* 83 *Fed. Reg.* 19112 (May 1, 2018). The complaint, as amended, alleges violations of 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 claims 1-3, 5, 9-14, 17-19, 26, and 28 of U.S. Patent No. 9,814,826 ("the '826 patent") (JX-1); claims 1-5, 8, 14, 24, and 27-30 of U.S. Patent No. 9,750,869 ("the '869 patent") (JX-2); and claims 1, 2, 8-13, 16, 17, 22, and 27 of U.S. Patent No. 9,750,870 ("the '870 patent") (JX-3) (collectively, "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, "Jubilant") as respondents in this investigation. *See id.* The Office of Unfair Import Investigations is also a party to this investigation. *See id.*

On August 8, 2018, the Commission partially terminated the investigation as to claims 10 and 26 of the '826 patent, claims 27 and 28 of the '869 patent, and claims 9 and 22 of the '870 patent based on the withdrawal of the allegations pertaining to those claims. *See* Order No. 15 (Aug. 8, 2019), *unreviewed*, Comm'n Notice (Sept. 6, 2019). On September 4, 2018, the ALJ partially terminated the investigation as to claim 13 of the '870 patent based on the withdrawal of the allegations pertaining to that claim. *See* Order No. 18 (Sept. 4, 2019), *unreviewed*, Comm'n Notice (Sept. 26, 2019).[1]

On February 8, 2019, the ALJ issued an ID (Order No. 27) granting Bracco's motion for summary determination that Jubilant's RUBY Rubidium Elution System Version 3.0 ("the Version 3 product") infringes the Asserted Patents. *See* Order No. 27 (Feb. 8, 2019), *unreviewed*, Comm'n Notice (Mar. 8, 2019). In addition, the ID grants Jubilant's motion for summary determination that Jubilant's RUBY Rubidium Elution System Version 3.1 ("the

[1] Hereinafter, "Asserted Claims" means claims 1-3, 5, 9, 11-14, 17-19, and 28 of the '826 patent, claims 1-5, 8, 14, 24, and 29-30 of the '869 patent, and claims 1, 2, 8, 10-12, 16, 17, and 27 of the '870 patent.

Version 3.1 product") and the RUBY Rubidium Elution System Version 4 ("the Version 4 product") do not directly infringe the Asserted Patents. *See id.* The ID (Order No. 27) declines to reach indirect infringement on summary determination. *See id.* at 20.

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. In addition, the FID also contains the ALJ's recommended determination ("RD"), recommending, should the Commission find a violation of section 337, that the Commission issue a limited exclusion order ("LEO") barring entry of articles that infringe the Asserted Claims. However, the RD recommends delaying the effective date of the LEO by 12 months to allow sufficient time for facilities with infringing systems to switch to other models. The RD does not recommend that the Commission issue a cease and desist order ("CDO") 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 recommended remedy.

On August 14, 2019, both Bracco and the Commission's Investigative Attorney ("IA") filed petitions for review of the FID.[2] Bracco petitioned for review of the FID's findings with

[2] *See* Complainant Bracco Diagnostics Inc.'s Petition for Review of Initial Determination (hereinafter, "Bracco's Pet."); Office of Unfair Import Investigations' Petition for Review of the Final Initial Determination (hereinafter, "IA's Pet.").

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 petitions.[3]

On September 30, 2019, the Commission issued a notice determining to review the FID in part. *See* 84 *Fed. Reg.* 53177 (Oct. 4, 2019). Specifically, the Commission determined to review the FID's findings with respect to invalidity and domestic industry.

B. The Asserted Patents

The Asserted Patents are related and share the same specification. The Asserted Patents issued between September 5 and November 14, 2017.[4] *See* FID at 4. The Asserted Patents, titled "Integrated Strontium-Rubidium Radioisotope Infusion Systems," relate to computer-assisted medical devices that generate and infuse radiopharmaceuticals (*e.g.*, rubidium-82 or Rb-82) into a patient. *See* JX-1, '826 patent at Abstract, 1:27-30. The infused dose of radiopharmaceutical is absorbed by the cells of a target organ of the patient and emits radiation, which is detected by positron emission tomography ("PET"), thereby generating an image of the organ. *See id.* at 1:35-42.

For example, the common specification explains that:

> [C]ircuit **300** includes: an eluant reservoir **15**, for example, a bag, bottle or other container, containing saline as the eluant, . . . ; a syringe pump **33**, for pumping the eluant from reservoir **15**, and a pressure syringe **34** (or other device or sensor), for monitoring pumping pressure; a filter **37**, which may also serve as a bubble trap,

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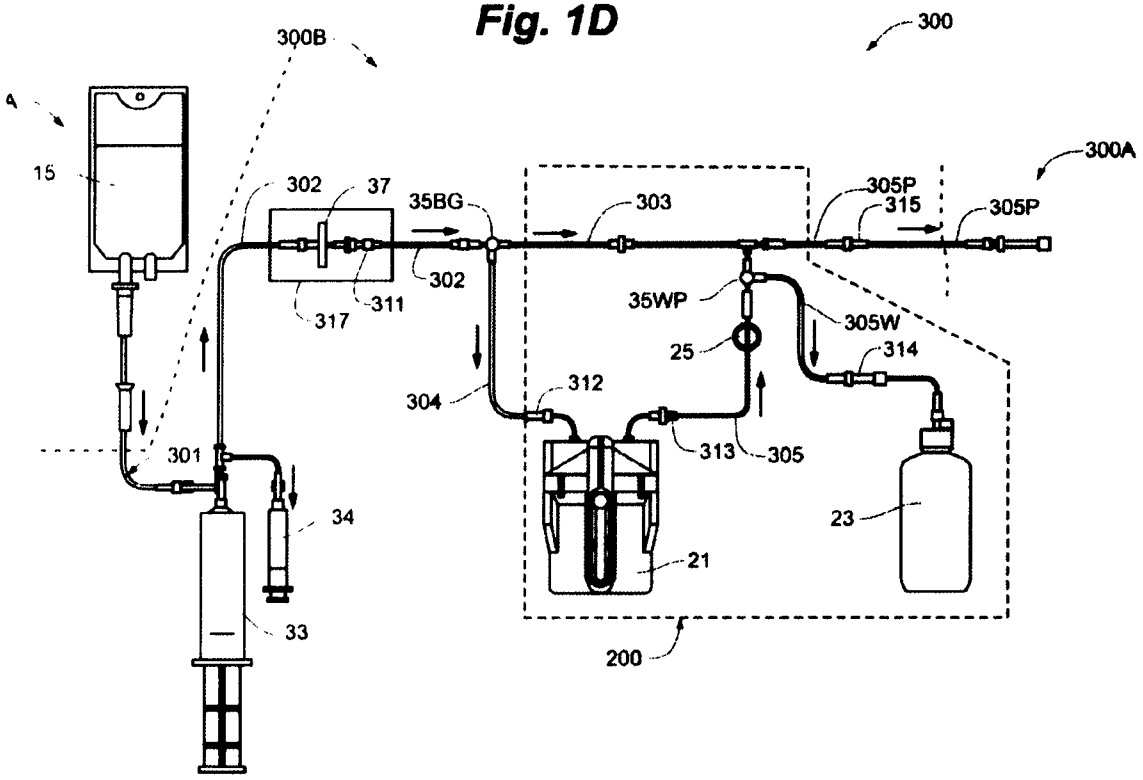
[3] *See* Complainant Bracco Diagnostics Inc.'s Response to Office of Unfair Import Investigations' Petition for Review of Initial Determination (hereinafter, "Bracco's Resp."); Respondents' Response to Complainant's Petition for Review (hereinafter, "Jubilant's Resp."); Office of Unfair Import Investigations' Response to Complainant's Petition for Review of the Final Initial Determination (hereinafter, "IA's Resp.").

[4] On their face, the earliest priority date of the Asserted Patents appears to be June 11, 2008. However, the parties agree that the relevant priority date for all three patents is June 11, 2009. Jubilant argued for a later priority date in the context of an invalidity (anticipation) challenge but the FID rejected that challenge and determined that the priority date of the Asserted Patents was indeed June 11, 2009. *See* FID at 122-25. Jubilant did not petition for review of the finding.

> for the pumped eluant; a radioisotope generator **21**, through which the filtered eluant is pumped to create a radioactive eluate, for example an eluate carrying Rubidium-82 that is generated by the decay of Strontium-82, via elution, within a column of generator **21**; and an activity detector **25**, for measuring the activity of the eluate discharged from generator **21**, in order to provide feedback for directing the flow of the eluate, via a divergence valve **35WP**, either to a waste bottle **23** or through a patient line **305p**, for example, to inject a dose of the radiopharmaceutical eluate into a patient."

See id. at 5:3-20, Figure 1D (reproduced below).[5]

Fig. 1D



The specification also states that "circuit **300** [can be] expanded to include elements for an automated collection of eluate samples for activity measurements, via the on board dose calibrator." *See id.* at 8:13-16. The specification explains that "a sample collection reservoir

[5] As noted in the FID, "[a]s the generator ages, strontium starts to detach from the column and contaminate the eluate, posing a risk to patient health" (known as "strontium breakthrough"). To prevent any patient exposure from strontium breakthrough, operators must perform frequent quality-control checks on the generator. *See* FID at 7.

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