

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JUBILANT DRAXIMAGE INC.,
Petitioner,

v.

BRACCO DIAGNOSTICS INC.,
Patent Owner.

Case IPR2018-01449
Patent 9,299,467

**PETITIONER'S SUBMISSION OF
ITC COMMISSION OPINION**

Petitioner hereby submits the attached exhibit 1040, a public version of the Commission Opinion issued by the U.S. International Trade Commission in Investigation 337-TA-1110 (the “1110 Investigation”), which provides the Commission’s reasoning supporting its determination to affirm with modification and to supplement the prior Final Initial Determination’s findings with respect to the invalidity of the patent claims asserted in the 1110 Investigation. Ex. 1039.

The Commission Opinion addresses several issues that are relevant to the present *inter partes* review, including:

- At pp. 24-26, the Commission considered teachings of the Klein reference against claim elements that require a computer not to allow a patient infusion when a strontium breakthrough test result is greater than or equal to an allowed limit, holding that Klein teaches or discloses such subject matter; and
- At pp. 18, 20-21, and 25-26, the Commission evaluated and rejected testimony from Bracco’s expert, Dr. Norbert Pelc, on several issues.

The Board authorized the instant filing by email on December 5, 2019. Patent Owner does not oppose filing of this exhibit.

A supplemental exhibit list is provided in the attached Appendix A.

Respectfully submitted,

Date: December 12, 2019

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APPENDIX A: EXHIBIT LIST

EXHIBIT	DESCRIPTION
1001	U.S. Patent No. 9,299,467
1002	Complaint, <i>Bracco Diagnostics Inc. v. Jubilant DraxImage Inc.</i> , Case No. 3-18-cv-04422 (D.N.J.)
1003	Complaint, <i>In the Matter of Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators</i> , Inv. No. 337-TA 3303 (U.S. I.T.C.)
1004	Order Granting Joint Motion to Stay Pending Resolution of ITC Proceedings (D.I. 9) Case No. 3-18-cv-04422 (D.N.J.)
1005	Waiver of Service, <i>Bracco Diagnostics Inc. v. Jubilant DraxImage Inc.</i>
1006	Prosecution History, U.S. application s.n. 12/137,356
1007	Prosecution History, U.S. application s.n. 12/137,377
1008	Prosecution History, U.S. application s.n. 12/137,363
1009	Prosecution History, U.S. application s.n. 12/137,364
1010	Prosecution History, U.S. application s.n. 12/808,467
1011	Prosecution History, U.S. application s.n. 14/455,623
1012	Alvarez-Diez, "Manufacture of strontium-82/rubidium-82 generators and quality control of rubidium-82 chloride for myocardial perfusion imaging in patients using positron emission tomography," <i>Applied Radiation and Isotopes</i> , v. 50, pp. 1015-23 (1999)
1013	Klein et al, "Precision Control of Eluted Activity from a Sr/Rb Generator for Cardiac Positron Emission Technology," <i>Engr. in Med. and Biology Soc. 26th Annual International Conference of the IEEE</i> , vol. 1, pp. 1393-1396 (2004)

EXHIBIT	DESCRIPTION
1014	Ran Klein, "Precise 82Rb Infusion System for Cardiac Perfusion Measurement Using 3D Positron Emission Tomography," Ottawa-Carleton Institute for Electrical and Computer Engineering (Feb. 2005)
1015	Declaration of Robert T. Stone, Ph.D.
1016	Curriculum Vitae of Robert T. Stone, Ph.D.
1017	Declaration of Ventakesh Murthy, M.D.
1018	Barker, et al., U.S. Patent 4,585,009, granted April 29, 1986
1019	U.S. Pharmacopeia 23 National Formulary 18 (1995)
1020	Declaration of Andy Adler, Ph.D. with Attachments A-C
1021	Bracco CardioGen-82® Infusion System User's Guide, Rev. 07 (July 20, 2004)
1022	Tate, et al., U.S. Patent Publication No. 2008/0177126, filed October 31, 2007 and published July 24, 2008
1023	ISO 13485:2003 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes (July 2003)
1024	21 CFR Part 820.1 (2005)
1025	Chatal, et al., "Story of rubidium-82 and advantages for myocardial perfusion PET Imaging," Frontiers in Medicine, v. 2, art. 65, pp. 1-7 (Sept. 11, 2015)
1026	Bracco CardioGen-82® Rubidium Rb 82 Generator, Rev. 43-8200 (May 2000)
1027	10 CFR Part 20 (10 CFR 20.1001-2)
1028	10 CFR Part 20 (10 CFR 20.1003)

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