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 NOTICE

Petitioner hereby submits the attached exhibit 1039, a "Notice of Commission Final Determination of No Violation of Section 337; Termination of the Investigation" issued by the U.S. International Trade Commission in Investigation 337-TA-1110 (the "1110 Investigation"). In relevant part, Ex. 1039 indicates that the Commission determined 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. *Id.* at 2.

The Board authorized the instant filing by e-mail on December 5, 2019.

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

Respectfully submitted,

Date: December 6, 2019

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Attorneys for Petitioner JUBILANT DRAXIMAGE INC.

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, In the Matter of Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators, 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, Bracco Diagnostics Inc. v. Jubilant DraxImage Inc. |
| 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," Applied Radiation and Isotopes, 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," Engr. in Med. and Biology Soc. 26th Annual International Conference of the IEEE, 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) |

| EXHIBIT | DESCRIPTION |
|---------|---|
| 1029 | EN 62274:2005 – Medical Electrical Equipment – Safety of Radiotherapy Record and Verify Systems (December 28, 2005) |
| 1030 | The Chemical Rubber Co., Handbook of Radioactive Nuclides, Yen Wang ed., 1969 |
| 1031 | Complainant Bracco Diagnostics Inc.'s Responses to Respondent's Fourth Set of Interrogatories (No. 68), In the Matter of Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators, Inv. No. 337-TA-1110 (U.S.I.T.C.) |
| 1032 | Declaration of Carol Wadke |
| 1033 | deKemp, U.S. Patent Publication No. 2007/0213848 |
| 1034 | deKemp, U.S. Patent Publication No. 2007/0140958 |
| 1035 | Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond), In the Matter of Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators, Inv. No. 337-TA-1110 (U.S.I.T.C. Aug. 1, 2019) |
| 1036 | U.S. Patent No. 9,814,826 |
| 1037 | Exhibit 1002 from Dr. Murthy's Deposition in IPRs 2018-01448, - 01449, and -01450 (Bracco CardioGen-82® Infusion System User's Guide, Rev. 11 (July 3, 2007)) |
| 1038 | Petitioner's Demonstrative Exhibits |
| 1039 | Notice of Commission Final Determination of No Violation of Section 337; Termination of the Investigation, <i>In the Matter of</i> <i>Certain Strontium-Rubidium Radioisotope Infusion Systems, and</i> <i>Components Thereof Including Generators</i> , Inv. No. 337-TA-1110 (U.S.I.T.C. Dec. 2, 2019) |
| 2001 | U.S. Patent Application Publication No. 2011/0178359, filed December 28, 2007 |

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