UNITED STATES PATENT AND TRADEMARK OFFICE —————— BEFORE THE PATENT TRIAL AND APPEAL BOARD ——————

R.J. REYNOLDS VAPOR COMPANY Petitioner,

V.

FONTEM HOLDINGS 1 B.V. Patent Owner.

Case No. IPR2016-01268 Patent No. 8,365,742

DECLARATION OF RICHARD MEYST IN SUPPORT OF PATENT OWNER'S OPPOSITION TO PETITION FOR INTER PARTES REVIEW



- I, Richard Meyst, declare as follows:
- 1. I have been retained by Patent Owner Fontem Holdings 1 B.V. as an expert witness in the above-captioned proceeding. I am being compensated for the time I spend on this proceeding at a rate of \$425 per hour. My field of expertise in this matter is electromechanical and medical devices. This Declaration is based upon my knowledge, skill, experience, training, and education in my field of expertise, and upon information reviewed in connection with my retention as an expert witness in this matter.
- 2. I am currently the President and Chief Executive Officer of Fallbrook Engineering, Inc. I am an engineer and consultant in the field of electromechanical devices, including medical devices. A copy of my CV, which includes, among other things, my academic credentials and my employment history, is attached as Exhibit A.
- 3. I received an M.S. (1972) and B.S. (1971) in mechanical engineering from the University of Wisconsin, Madison. My undergraduate academic work focused on design, manufacturing methods, fluid mechanics, and heat transfer. My graduate academic focus was on computer-based automatic controls of systems and my Master's thesis was on the concept development, design, fabrication, and testing of a prototype bench-top implantable mechanical human heart.



Additionally, I have participated in industry seminars and training programs covering design of experiments, statistical analysis, biocompatibility testing, sterilization method selection and validation, design of plastic parts, design for manufacturability, package design and testing, cellular therapy, and many others.

- 4. As an engineer, designer, consultant, program manager and entrepreneur at Fallbrook Engineering, Inc., I have been involved in the advanced design and development of a wide range of medical technology products for the healthcare industry for more than 25 years. Prior to 1989 when I became a partner in Fallbrook Engineering, I held various engineering and management positions at healthcare, medical device, and consumer product companies, including USCI (a division of CR Bard, Inc.), Fenwal (a division of Baxter Travenol Laboratories), Oak Communication, Imed Corp., a division of Warner Lambert, and Diatek Corp.
- 5. During my 40+ year professional career, I have focused on electromechanical devices and related technologies requiring expertise in design, fluid mechanics, thermodynamics, heat transfer, electronic power sources, circuit design and fabrication, sensors, manufacturing technologies, and other areas of engineering design and manufacturing methods. Based on my experience, I have developed extensive knowledge in medical product design and development, product prototyping, design verification and validation, production startup, manufacturing engineering, risk analysis, and strategic planning. In addition to



doing engineering work, my responsibilities have included running a medical design and development consulting firm which includes assembling and managing technical teams to develop new medical, consumer, industrial, and professional products.

- 6. I have also been a Principal Investigator on several NIH SBIR grants from the National Heart, Lung, and Blood Institute developing a device for the improved collection of Umbilical Cord Blood Stem Cells. I have served on the Board of Directors for the Society of Plastics Engineers/Medical Plastics Division and am a long time member. I am a member of the American Association of Blood Banks, the Association for the Advancement of Medical Instrumentation, the San Diego Regulatory Affairs Network, the American Association for Clinical Chemistry, and the American Filtration & Separation Society.
- 7. I have also been a long-time member of the Medical Device Steering Committee of BIOCOM, the largest regional life science association in the world. I was recently a juror in the annual Medical Design Excellence Awards competition, the premier awards program for the medical technology community, as well as a judge in the San Diego CONNECT capital competition for startup companies. I am also an experienced inventor and innovator. My inventions have been awarded 16 U.S. Patents, and I have applications pending. I have been an invited speaker and have presented talks at numerous scientific and medical industry meetings. Exhibit



A includes a list of my patents, publications and presentations, and professional associations.

- 8. I have also served as an independent technical expert witness or consultant relating to numerous intellectual property and patent litigations, product failure analyses, analyses of the use and misuse of various medical devices, development contract disputes, and medical product liability matters. A list of my expert assignments within the past four years appears in Exhibit A.
- 9. I have reviewed the specification, claims, and file history of U.S. Patent No. 8,365,742 ("'742 Patent," Ex. 1001). I have also reviewed the Petition for Inter Partes Review filed by Petitioner R.J. Reynolds Vapor Company in this matter (Paper 2, "Petition") and related exhibits, including the declaration of Petitioner's expert, Dr. Robert Sturges. (Ex. 1015) I have also reviewed the Board's Decision to institute Inter Partes review. (Paper 10). I have also reviewed the Supplemental Declaration of Dr. Robert H. Sturges (Ex. 1020) and the transcript of the deposition of Dr. Robert H. Sturges taken on March 8, 2017. (Ex. 2016). I have also reviewed the additional exhibits that Petitioner R.J. Reynolds Vapor Company has filed after my Preliminary Declaration was filed, as well as other documents that I understand Patent Owner will be filing along with this Declaration. I have paid particular attention to the exhibits that are discussed in this Declaration. I understand Petitioner has argued claims 2 and 3 of the '742



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