UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC. Petitioner

v.

INNOVATIVE MEDICAL DEVICES, LLC, MEDICAL COMPONENTS, INC.

Patent Owners

Case IPR ______ U.S. Patent No. 8,257,325 Issue Date: September 4, 2012

Title: VENOUS ACCESS PORT WITH MOLDED AND/OR RADIOPAQUE INDICIA

DECLARATION OF STEVEN J. TALLARIDA



I, Steven J. Tallarida, declare as follows:

Introduction

- 1. I have been retained on behalf of C.R. Bard, Inc. ("Petitioner") in this case as an expert in the relevant art.
- 2. I have been asked to provide my opinions concerning U.S. Patent No. 8,257,325 ("the '325 patent")(Exhibit 1001), as well as the materials I have reviewed that are related to the subject matter of the '325 patent.
- 3. I have also been asked to provide my opinions concerning the state of the relevant art in the field of access ports prior to around June 20, 2007 (which is also referred to herein as "the relevant time frame" or "time of the invention"), and the level and knowledge of one of ordinary skill in the art in the field of designing implantable access ports during the relevant time frame.
- 4. My opinions and views set forth in this declaration are based on my education, training, and experience in the field of designing access ports, as well as the materials I reviewed and referenced in this declaration.

Documents Reviewed

- 5. I have reviewed U.S. Patent No. 8,257,325 (Exhibit 1001).
- 6. I have also reviewed the following documents: (1) PORTS Bard Access Systems, 2003 ("PORTS") (Exhibit 1002); (2) U.S. Patent No. 7,785,302 ("Powers")(Exhibit 1003); (3) PowerPort Guidelines for CT Technologists, February



2007 ("PowerPort")(Exhibit 1004); (4) FR 1,509,165 and its English translation ("Meyer")(respectively Exhibits 1005 and 1006); (5) U.S. Patent No. 6,826,257 ("Sayre")(Exhibit 1007); (6) U.S. Provisional Application No. 60/658,518 filed on March 4, 2005 (Exhibit 1016); and (7) Hickman® Subcutaneous Ports & Hickman® / Broviac® Catheters, 1992 ("Hickman")(Exhibit 1017).

- 7. I have additionally reviewed the Affidavit of Christopher Butler (Exhibit 1008), the Declaration of Annemarie Boswell (Exhibit 1018) and the Declaration of David Blaber (Exhibit 1019).
- 8. I have reviewed the dictionary definitions referenced herein. Exhibits 1010-1015.
 - 9. I have also reviewed the other documents referenced in this declaration.

Qualifications

- 10. In 1985, I earned a Bachelor of Science from American University.
- 11. After graduating American University, I worked for STDMED, a privately held medical device company.
- 12. I have been President of President of Primo Medical Group, formerly known as STDMED, for 25 years.
 - 13. I hold many U.S patents, several are in vascular access.
- 14. Primo Medical Group / STDMED has designed and built access ports for implantation into a patient since 1991.



- 15. Primo Medical Group / STDMED has designed and built access ports for many medical device companies, including C.R. Bard, Boston Scientific, Allergan and Angiodynamics.
- 16. In 1991, Primo Medical Group / STDMED began producing ports of the type known as "Hickman ports", including its version known as Titanium Implanted Port (Exhibit 1002, p. 10 and 16).
- 17. Primo Medical Group / STDMED has also produced, beginning in February 2010, the identification triangle disclosed in PowerPort (Exhibit 1004), which is formed of titanium having voids (cutouts) "C" and "T" in the titanium.

A Person Of Ordinary Skill In The Relevant Art In The Relevant Time Frame

18. I have been informed that "a person of ordinary skill in the relevant art" is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (1) type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology; and (5) educational level of active workers in the field. In a given case, every factor may not be present, and one or more factors may predominate. In many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.



- 19. With respect to the '325 patent, the relevant art is the field of designing, using, and building implantable access ports.
- 20. I have been informed that the "time of the invention" with respect to the '325 patent would be the earliest effective filing date to which the '325 patent is entitled. I have been further informed that based upon the information available on the cover page of the '325 patent, the earliest effective filing date to which the '325 patent might be entitled is the date Provisional Application No. 12/143,377 (cited on the cover page) was filed with the U.S. Patent and Trademark Office, *i.e.*, June 20, 2007.
- 21. A person of ordinary skill in the relevant art would have been aware of the structures of venous access port assemblies, including those access ports comprising a housing with a base, a reservoir, a discharge port extending from the reservoir and a septum. A person of ordinary skill in the relevant art would also have been aware of power injectable access ports and would have known that power injectable access ports could be used with CT scanning processes, where it is desirable to power inject contrast media at a higher pressure and using a greater flow rate than can be handled by conventional access ports.
- 22. A person of ordinary skill in the relevant art at the time of the invention would also have known of the desirability to be able to identify an access port as power injectable using X-rays subsequent to subcutaneous implantation of the port,



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