UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC. Petitioner

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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 ANNEMARIE BOSWELL



I, Annemarie Boswell, declare as follows:

- 1. I have been employed by Bard Access Systems, a division of C.R. Bard ("Bard"), since June 1, 2004.
- 2. From 2004 to 2009, I worked for the port product team, and thereafter have worked with International Marketing.
- 3. From June 2004 to December 2005, I was a Marketing Associate of the implanted port product line wherein my duties and responsibilities included market research; downstream marketing including development of sales tools, training material, education program and marketing collaterals; and sales support.
- 4. From December 2005 to August 2006, I was the Associate Product Manager of the implanted port product line wherein my duties and responsibilities included product development, product management, and team management.
- 5. From August 2006 to September 2007, I was the Product Manager I of the implanted port product line wherein my duties and responsibilities included product development, product management, and team management.
- 6. From September 2007 to October 2009, I was the Product Manager II of the implanted port product line wherein my duties and responsibilities included product development, product management, strategy development, technology assessment, and team management.



- 7. From October 2009 to August 2014, I was the International Marketing Manager of the Bard Assess Systems Division wherein my duties and responsibilities included international marketing, strategic development of emerging markers, management of international markets, team management regarding new products, development and implementation of international sales and clinical training program, financial analysis and people management.
- 8. During August 2014, I was promoted to Associate Director of International Marketing.
- 9. I have been asked about the PowerPort* Guidelines for CT Technologists, February 2007 ("PowerPort") (attached to this Declaration as Attachment A, marked as Exhibit 1004).
- 10. I have reviewed the PowerPort document and understand that this document is being relied upon by Bard in an *Inter Partes* Review proceeding before the U.S. Patent and Trademark Office.
- 11. I am familiar with the standard procedures for preparing and distributing marketing materials relating to access ports from June 1, 2004 to present, including the PowerPort*- M.R.I.* Device disclosed in PowerPort.
- 12. The standard process for preparing and distributing marketing materials relating to access ports has been consistent since my employment at Bard. Once a brochure or other informational document is prepared, it must be reviewed and



- approved. Once a document is approved, the document is made publicly available through a distribution house.
- 13. Bard's standard practice relating to the marketing of access ports is to mark documents intended to be publicly distributed with a copyright date indicating the year they were first printed and publicly available.
- 14. Certain Bard documents relating to the marketing of access ports and intended to be publicly distributed are additionally marked with a revision date. It is Bard's standard practice to begin public distribution of such documents in the month indicated by the revision date.
- 15. Bard documents for the marketing of access ports intended to be publicly distributed have been freely distributed to individuals in the field associated with the technology, without restriction as to dissemination.

POWERPORT (Exhibit 1004)

- 16. My duties as Product Manager I and continuing as Product Manager II included responsibility for approval and dissemination of informational materials relating to PowerPort* implanted ports.
- 17. PowerPort is a printed document that provides guidelines for CT technologists in the use and maintenance of PowerPort* implanted ports.
- 18. PowerPort is marked with a copyright date of 2007. PowerPort is also marked with a revision date of February 2007: "Revised date: February 2007".



- 19. The PowerPort*- M.R.I.* Device depicted and described in PowerPort received Section 510(k) FDA clearance on January 25, 2007, Clearance Number K063377, permitting Bard to market the PowerPort*- M.R.I.* Device.
- 20. The trade name for the power injectable access port that received 510(k) FDA clearance in K063377 is the "PowerPort™ Implanted Polymeric Port."
- 21. In accordance with Bard's standard practice, PowerPort was released to the public in February 2007, *i.e.*, the document was freely distributed to those individuals in the field associated with the technology, without restriction as to dissemination.
- 22. I was involved with the distribution of PowerPort to the sales team in January 2007 when the PowerPort*- M.R.I.* Device was launched to the sales team. Launch packets for the PowerPort*- M.R.I.* Device were provided to the U.S. sales force which included marketing brochures, PowerPort, PowerPort Nursing Guides, PowerPort CT Guides, and Wall Charts.
- 23. Upon receipt of the launch packets the sales team had authority to freely distribute PowerPort to actual and potential customers without restriction as to dissemination, and it is my understanding that the sales team as of February 2007 freely distributed PowerPort to actual and potential customers without restriction as to dissemination.



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