

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. Bard, Inc.
Petitioner

v.

Medline Industries, Inc.
Patent Owner

Patent No. 9,745,088
Title: Catheter Tray, Packaging System, Instruction Insert, and Associated
Methods

DECLARATION OF RICHARD MEYST

1. I, Richard Meyst, declare as follows:

2. I have personal knowledge of the facts stated in this declaration, and could and would testify to these facts under oath if called upon to do so.

I. INTRODUCTION AND QUALIFICATIONS

3. I have been retained by counsel for Patent Owner Medline Industries, Inc. (“Medline”) as an expert witness in the analysis of U.S. Patent No. 9,745,088 (“the ’088 patent”).

4. I am being compensated for my time in this case at a rate of \$425 per hour (plus expenses) for my review of materials and preparation of this declaration. My compensation in this matter is not determined by or contingent on the outcome of this case.

5. I am willing to testify at the hearing set by the Board regarding the contents of this declaration if asked to do so.

6. I reserve the right to supplement my opinions, as well as the bases for my opinions, expressed herein in light of additional materials, including other evidence that may be provided to me after submission of this declaration.

7. My qualifications for forming the opinions set forth in this declaration are summarized here and explained in more detail in my *curriculum vitae*, which is attached as part of Exhibit A.

8. I have experience in the advanced design and development of a wide range of successful medical technology products for the health care industry over the last 40+ years. This includes extensive knowledge in product design and development, product prototyping, production startup, manufacturing engineering, risk analysis, strategic planning, grant preparation, and market research.

9. I have held various engineering, development, operations and management positions at CR Bard, Fenwal Division of Baxter, IMED, and other healthcare and consumer product companies. For the last 25+ years, I have been an owner of Fallbrook Engineering, a medical technology design and development firm. Since 2003, I have been the President and Chief Executive Officer.

10. My product experience includes product and packaging design and verification/validation including development of implantable vascular prostheses, DNA amplifiers, vital signs monitoring devices, IV drug infusion pumps and administration sets, medical lasers, surgical instruments, diagnostic and therapeutic catheters, microprocessor based diagnostic and therapeutic instruments, blood cell collection and processing, filtration devices for blood and intravenous solutions, as well as stem-cell harvesting and cell expansion systems.

11. I have been a Principal Investigator on multiple National Institute of Health Small Business Innovation Research grants from the National Heart, Lung and Blood Institute developing a device for the improved collection of umbilical

cord blood stem cells. I 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, and the American Filtration Society. I am also a member of the Medical Device Steering Committee of BIOCOM, an organization focused on medical devices and life sciences. I have been a juror in the UBM/Cannon Medical Design Excellence Awards competition.

12. I received my Bachelor's and Master's degrees in Mechanical Engineering from the University of Wisconsin, Madison. I have been awarded sixteen United States patents (two of which are for a medical device thermoform package), have multiple applications pending, and have been an invited speaker, presenting talks at numerous scientific and medical industry meetings.

II. PERSON HAVING ORDINARY SKILL IN THE ART ("POSITA")

13. In determining who would be a person of ordinary skill, I considered at least the following criteria: (a) the type of problems encountered in the art; (b) prior art solutions to those problems; (c) the rapidity with which innovations are made; (d) the sophistication of the technology; and (e) the education level of active workers in the field.

14. In my opinion, a person of ordinary skill in the art ("POSITA") would be a person with at least a Bachelor of Science degree in Engineering, plus a

minimum of 2 years of experience working in the field of designing catheters, catheter packaging or related medical packaging. In the alternative, the POSITA would have a bachelor's degree in an alternative field and about three years' experience working in the field of designing catheters, catheter packaging or related medical packaging. A POSITA would not need to be a health care practitioner that would perform catheterization procedures or use the claimed products (i.e., catheterization trays), but would have learned about the procedures from those skilled in catheterization procedures (e.g., a nurse).

III. LEGAL PRINCIPLES USED IN THE ANALYSIS

15. I am not a patent attorney, nor have I independently researched the law on patent validity. Attorneys for the Patent Owner explained certain legal principles to me that I have relied upon in forming my opinions set forth in this report.

A. Prior Art

16. I understand that the law provides categories of information that constitute prior art that may be used to anticipate or render obvious patent claims. To be prior art to a particular patent under the relevant law, a reference must have been made, known, used, published, or patented, or be the subject of a patent application by another, before the priority date of the patent. I also understand that the POSITA is presumed to have knowledge of the relevant prior art.

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