

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATERS TECHNOLOGIES CORPORATION
Petitioner

v.

BIOMEDICAL DEVICE CONSULTANTS & LABORATORIES
Patent Owner

US Patent 9,186,224
Inter Partes Review No.: _____
IPR2018-00498

**DECLARATION BY KRISTEN BILLIAR, PH.D.
UNDER 37 CFR § 1.132**

WATERS TECHNOLOGIES CORPORATION

TABLE OF CONTENTS

| | | |
|------|---|----|
| I. | QUALIFICATIONS, EXPERIENCE AND PUBLICATIONS..... | 3 |
| II. | COMPENSATION | 6 |
| III. | LEGAL PRINCIPLES..... | 6 |
| IV. | MATERIALS CONSIDERED..... | 8 |
| V. | OPINIONS..... | 10 |
| A. | RELEVANT FIELD, TIME AND PERSON OF ORDINARY SKILL IN THE ART | 10 |
| B. | THE '224 PATENT AND THE FILE HISTORY | 12 |
| C. | CLAIM CONSTRUCTION | 15 |
| D. | CARDIOVASCULAR DEVICE DESIGN PRINCIPLES AND RELATED TESTING CONSIDERATIONS AT THE TIME OF THE INVENTION | 17 |
| E. | THE USE OF COMPLIANCE CHAMBERS IN ACCELERATED TEST SYSTEMS WAS NOT NEW | 18 |
| F. | GROUND 1A: CLAIMS 1-7 ARE OBVIOUS IN VIEW OF PICKARD AND WOODWARD..... | 19 |
| G. | GROUND 1B: CLAIMS 1-7 ARE RENDERED OBVIOUS BY PICKARD IN LIGHT WOODWARD AND ST. JUDE | 28 |
| H. | GROUND 2A: CLAIMS 1-4 ARE ANTICIPATED BY ST. JUDE | 31 |
| I. | GROUND 2B: CLAIMS 3-7 ARE RENDERED OBVIOUS BY ST. JUDE IN LIGHT OF PICKARD..... | 42 |
| J. | GROUND 2C: CLAIMS 6 AND 7 ARE OBVIOUS IN VIEW OF ST. JUDE AND IWASAKI..... | 49 |

I, Kristen Billiar, Ph.D., do hereby make the following declaration:

I. QUALIFICATIONS, EXPERIENCE AND PUBLICATIONS

1. I am currently the Department Head of the Biomedical Engineering Department and Professor in the Biomedical Engineering and Mechanical Engineering Departments at Worcester Polytechnic Institute. I submit this Declaration in support of Waters Technologies Corporation's Petition for a *Inter Partes* Review of U.S. Patent No. 9,186,224 (the '224 Patent). In particular, I submit this Declaration to provide relevant background information regarding the technology at issue in the '224 Patent, and to set forth my opinions about the validity of the claims of the '224 Patent from the perspective of a person of ordinary skill in the pertinent field.

2. The following is a brief summary of my background and qualifications. My background and qualifications are more fully set out in my curriculum vitae (CV), attached as Exhibit 1004.

3. I have at least 22 years' experience in the biomedical engineering and medical device fields. I am currently a professor and department head of the Biomedical Engineering Department, and an affiliated professor in the Department of Mechanical Engineering at Worcester Polytechnic Institute (WPI), where my

responsibilities include developing and teaching courses for both the Biomedical and Mechanical Engineering Departments. Additionally, I am an adjunct professor in the Department of Surgery at the University of Massachusetts Medical School, Worcester, MA.

4. Prior to my current position, I was a staff engineer at Organogenesis, Inc., from 1998 to 2002, where my responsibilities included designing and testing blood vessel substitutes and testing systems.

5. I obtained a Ph.D. in Bioengineering from the University of Pennsylvania in 1998, where my dissertation investigated the effects of glutaraldehyde treatment and mechanical fatigue on bioprosthetic aortic valves. I also obtained a Master of Science in Bioengineering from the University of Pennsylvania in 1992. Additionally, I obtained a Bachelor of Science in Mechanical Engineering from Cornell University in 1991.

6. I currently teach undergraduate and graduate courses concerning mathematical modeling of physiologic materials and mechanisms, including biomechanics, biofluids, and I also teach courses on medical device development, including biomedical engineering design. In addition, I oversee a laboratory at WPI that performs predominantly grant-funded research concerning tissue mechanics and mechanobiology. The laboratory includes graduate, Ph.D., and post-doctorate level researchers. Also, I supervise teams of undergraduate and

graduate students with research projects, including implantable medical prosthetic and medical device development and testing.

7. As shown in my CV, I have authored or coauthored over 70 publications, including publications concerning mechanical evaluation of implantable cardiovascular devices subjected to mechanical and material testing. I also serve as a peer reviewer for scholarly publications and journals, including the Cardiovascular Engineering and Technology journal and the Journal of Biomechanical Engineering for the American Society of Mechanical Engineers.

8. I was also elected as a Fellow of the American Society of Mechanical Engineers (ASME) in 2013, where I have served on the executive board of the bioengineering division for 5 years. Also, I was elected as a Fellow of the American Institute for Medical and Biological Engineering (AIMBE) in 2016. Further, I serve as chair of a review committee for grants in biomedical engineering for the American Heart Association.

9. I have received \$10.75 million worth of grant funding from various organizations, including the American Heart Association, National Institutes of Health, National Science Foundation, and Whitaker Foundation, for my investigations into technology at the forefront of the bioengineering field.

10. I am an inventor on eight patents in the bioengineering field.

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