UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NIPRO CORPORATION,
Petitioner,

v.

NXSTAGE MEDICAL, INC.,
Patent Owner.

Case IPR2016-00744
Patent No. 8,092,414

DECLARATION OF GARY HEATH IN SUPPORT OF NXSTAGE MEDICAL, INC.'S PATENT OWNER PRELIMINARY RESPONSE

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P.O. Box 1450
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I, Gary Heath, declare as follows:

I. INTRODUCTION

1. I understand that Petitioner NIPRO Corporation ("Nipro") has filed a petition seeking institution of *inter partes* review proceedings concerning various claims of U.S. Patent 8,092,414, which is owned by NxStage Medical, Inc. ("NxStage").

2. I have been retained as an independent expert witness on behalf of NxStage to opine on certain matters relevant to Nipro's petition. I understand that this Declaration is being submitted along with Patent Owner's Preliminary Response to Nipro's Petition. At this time, I opine only with respect to certain issues that are discussed in this declaration. By doing so, however, I do not necessarily agree with the other positions taken by Nipro that I do not address here. Indeed, should Nipro's petition be granted, I reserve the right to and anticipate that I will submit another declaration detailing my opinions concerning various additional issues raised in Nipro's petition.

II. RESOURCES CONSULTED

3. I have reviewed the '414 Patent, its file history, and Nipro's Petition for *Inter Partes* Review filed with the United States Patent and Trademark Office on March 11, 2016 (Paper No. 1). I have also reviewed the Declaration of Mr. Charles E. Clemens (Ex. 1002) and all references cited in this declaration.

III. BACKGROUND AND QUALIFICATIONS

4. I am an expert in the research, development, manufacturing, operations, management, and regulatory aspects of medical devices, and in particular with medical equipment, single use-sterile disposables and sterile injectable solutions. I have studied, taught, practiced, consulted, and researched in the foregoing fields for over 37 years. I am presently Co-Owner and Principal Engineer for Evergreen Research, Inc. ("ERI"). ERI

specializes in Contract R&D, Contract Manufacturing, and Contract RA/QA services for the Medical Device Industry

5. I received a Bachelor of Science in Mechanical Engineering Technology from the University of Southern Colorado/CSU Pueblo, in 1979, and a Masters in Business Administration from the University of Phoenix in 1984.

6. I have had extensive experience in the medical device industry and technical fields relevant to the asserted patents. I have been the Co-Owner and Principal Engineer for ERI since November 2009. Prior to that, I was the President and Founder of Gary Heath & Associates, a medical device consulting company, from August 2007 to October 2009. Prior to that, I was the Director, Vice President, President, and Chief Operating Officer of COBE/Gambro/Terumo BCT, Inc. I worked in these positions from 1988 to 2007. During that time, I was extensively involved in single use disposables and their associated instruments that were developed and produced within the company. As President and COO of Gambro BCT, I was responsible for the patent estate of the company and the patent counsel of the company reported to me. I was involved in numerous patent issues, during my tenure in Gambro BCT. Prior to that, I was the Senior Manufacturing and R&D Engineer, Engineering Manager and Manufacturing Manager for COBE Laboratories, Inc. from 1983 to 1988. During my time at COBE, I was the lead design engineer on a team that created unique designs in the dialysis and blood banking markets, enabling COBE to replace generic disposables, with patent protected proprietary products. I spent approximately 5 years during this period of time as the recognized materials expert for the company, in regard to the selection, processing, and commercialization of single use disposables plastic materials. Prior to that, I worked at various other medical device companies.

7. I have been granted a number of patents for my work in the dialysis and blood handling field. These patents include U.S. Patent No. 4,666,598 entitled "Apparatus for use with fluid flow transfer device," granted on May 19, 1987; U.S. Patent No. 4,770,787 entitled "Method of operating a fluid flow transfer device," granted on September 13, 1988; and U.S. Patent No. 4,798,090 entitled "Apparatus for use with fluid flow transfer device," granted on January 17, 1989. These patents are all cited references on the face of the '414 patent. *See* Ex. 1001.

8. I have been a Senior Member of the Society of Manufacturing Engineers since 1979. In addition, I have been a Senior Member of the Society of Plastics Engineers since 1983.

9. Further details regarding my education, experience, publications, and other qualifications to render an expert opinion in this matter are provided in my *Curriculum Vitae*. *See* Exhibit 2005.

IV. RETENTION AND COMPENSATION

10. I have been retained to offer an expert opinion as to the scope and meaning of the Challenged Claims of the '414 patent.

11. My work on this matter is being billed at a rate of $250 per hour, with reimbursement for actual expenses. My compensation is not contingent upon the outcome of this case.

V. LEVEL OF ORDINARY SKILL IN THE ART

12. I believe that a person of ordinary skill in the art would have had any one of the following: (i) a Bachelor degree in Mechanical Engineering, Biomedical Engineering, or a related field, and about 3 years of practical experience in the field of blood handling systems; or (ii) 7 years of practical experience in the field of blood handling systems. These

descriptions are approximate, and a higher level of education or skill might make up for less experience, and vice-versa.

VI. TECHNICAL BACKGROUND

13. Conventional bloodline drip chambers rely on an air/blood interface for pressure monitoring during dialysis. The revolutionary technology disclosed in the '414 patent allows for the elimination of the air/blood interface. More specifically, the technology disclosed in the '414 patent uses an "airless pressure chamber (called a 'pod') which contains a diaphragm" that is "not connected to the pressure port on the face of a dialysis machine, but is spaced therefrom." Ex. 1001 at 2:12-17. To allow for this remote placement, the pod chamber is integrally attached to the pressure tubing, creating an air-tight seal between the air in the pod chamber and the air in the tubing. The '414 patent also discloses the novel use of a diaphragm that is flexible and can take a first position to substantially maximize blood volume in the pod chamber, and a second position to substantially minimize but not eliminate the blood volume in the pod chamber. Specifically, and contrary to the conventional wisdom in the art at the time, the '414 patent discloses the use of a dome-shaped diaphragm, which has two stable positions at manufacture and during shipping, prior to actual pressure measurement. The initial position of the dome optimizes the amount of air in the monitoring side needed for either measuring positive or negative pressures.

14. The diaphragm shape and remotely positioned, airless pressure chamber of the '414 patent have a number of important clinical and economic advantages. Indeed, the patent notes that with the disclosed pod, (1) it is "unnecessary to set a liquid level as in many prior art chambers, and a blood-air interface can be completely avoided," (2) the chamber "may be significantly smaller than the drip chambers of the prior art, and thus may have a

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