IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	12/718,316	Confirmation No.	:	4620
First Applicant	:	Benjamin McCloskey	Art Unit	:	4125
Filed	:	5 March 2010	Examiner	:	Jahangir, Naeem M.
Title	:	Fatigue testing system for prosthetic devices			
Docket No.	:	P201384.US.02	Customer No.	:	20686

DECLARATION OF CRAIG WEINBERG, Ph.D. UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I, CRAIG WEINBERG, having a residence at 4132 Decatur Street, Denver, Colorado 80211 and being a U.S. citizen, hereby declare as follows:

1. I am a named inventor on the patent application captioned above and am an owner and president of the assignee of the application, Biomedical Device Consultants and Laboratories of Colorado, LLC. I have held this position for over 7 years.

2. I have a Ph.D. in Mechanical/Biomedical Engineering from the University of Colorado - Boulder (2003).

3. My primary expertise is with the cardiovascular system and my research experience is focused on statistically based experimental design and analysis, cardiovascular system experimental modeling, and control system algorithm development. My doctoral thesis was in the area of ultrasound imaging, experimental fluid dynamics and flow visualization. Additional research and development experience includes vascular implants (synthetic and biologic), endovascular implants, radio-frequency tissue treatments (tissue fusion, division, and coagulation), control system logic development, and management of acute and chronic preclinical animal studies.

4. I participated in the preparation of the subject patent application captioned above and have also reviewed the pending claims in this application and the references cited by the examiner in the Office action dated 3 January 2013.

5. The examiner cites the Vilendrer reference in the Office action as disclosing a similar system as the system of claim 25 of our application. I would note particularly that the Vilendrer system employs the use of two metal bellows on each end of the system to drive the

system. The use of metal bellows is something that we intentionally avoided in the design of the system of claim 25.

6. Metal bellows technology requires a substantially increasing force during compression, once beyond the initial, relatively small displacement, to increase the bellows compression. Therefore to achieve higher flow rates through larger displacements as required for testing some larger sized valved prosthetic devices (such as tested by the claimed invention) and to ensure full opening and closing performance of the test article, one must provide a larger electromagnetic driver(s) for a metal bellows that can generate the necessary higher forces during operation. Consequently, further challenges to the test equipment result from this factor such as increased heat generation from the driver, increased operating stresses on adjacent components, and increased physical size requirements for the driver and test system.

7. In addition, metal bellows possess their own spring constant and effective mass. During cyclic, oscillatory motion the bellows therefore responds as a standard mass-spring system with a respective vibrational natural frequency and subsequent harmonic response. This characteristic can impact the operation of the test system by producing undesirable excitation of the valved test prosthesis(es) under evaluation and/or impart artificial limitations in the system operating frequency.

8. By utilizing a flexible elastomeric rolling bellows diaphragm technology as provided in claim 25, higher system flow generated by large displacements can be achieved without any need for increased force requirements to the driver beyond the loading requirements of the valved test prosthesis(es) under evaluation. No incremental load considerations are necessary for the motion of the rolling bellows. Furthermore, a flexible rolling bellows diaphragm does not possess an effective spring constant; therefore, the rolling bellows does not respond as a mass-spring system nor possess its own natural frequency. These points combine to an added benefit of requiring a smaller electromagnetic driver(s), fewer system component stresses, and no operational or frequency restrictions stemming from the prior art metal bellows component.

9. The examiner secondarily identified the system in the Kruse et al. reference as using a diaphragm to drive a prosthetic test system.. The system described in the Kruse et al. is for evaluation and testing of heart valve frames (referred to in Kruse at al. as a “valve stent”) and describes a preferred embodiment that has limited to no system flow through the test article. Therefore, the Kruse et al. system does not require the large driver / diaphragm displacements since the opening and closing of the test article leaflets are not desired. The

diaphragm in the Kruse et al. system performs in a manner similar to a loudspeaker cone, with the diaphragm merely flexing inward and outward with respect to a fixed circumferential position. Such a diaphragm does not have a rolling interface along the diaphragm like a rolling bellows and would not be applicable to the system of claim 25 in which much larger displacements are achieved using the rolling bellows diaphragm. This allows the system of claim 25 to test larger valved prosthetic devices that require larger fluid volume flows.

10. Additionally, test requirements for valved endovascular prostheses, as outlined by the United States Food & Drug Administration (FDA) and all worldwide regulatory agencies, provide that the valved prosthesis(es) be loaded through 200,000,000 – 600,000,000 cycles. This extremely high cycle requirement prohibits the use of a standard piston with seal(s) as used in the Pickard reference (which is a real-time, not accelerated system) to provide a driving member, since seal technologies such as O-rings, cup seals, and others do not have an anticipated life-duration equivalent to one test run. Moreover, standard seal technologies function by interference between the seal and the piston cylinder. The amount of interference is a delicate balance of providing adequate pressure on the seal-cylinder interface to prohibit the leaking of working fluid while recognizing that the resulting pressure will create friction and require additional input force to overcome and increase the wear of the seals during operation. This friction can also generate heat in the test system and additional wear and stresses on the components and driver.

11. Since a rolling bellows diaphragm does not generate a fluid seal by an interference fit and contact between a piston and piston cylinder as with classic seals, the shortcomings of classic seals such as friction and inadequate life-span during a test run are overcome. Thus, the rolling bellows overcomes the problems of prior driver technologies used in these test systems requiring extremely high test cycles.

12. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that the making of willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardized the validity of the application or any patent issuing thereon.

Dated: 10 May 2013 By: ______________________

Craig Weinberg, Ph.D.