IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Inventors:	Benjamin McCloskey *et al.*	Confirmation No:	3190
Serial No.:	14/523,104	Group Art Unit:	2855
Filed:	24 October 2014	Examiner:	Philip L. Cotey
Title:	FATIGUE TESTING SYSTEM FOR PROSTHETIC DEVICES	Docket No.:	P201384.US.05

AMENDMENT B AND RESPONSE TO OFFICE ACTION

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Office Action dated 20 March 2015, please amend the above-identified application as follows:

Claim Amendments begin on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

CLAIM AMENDMENTS

The following listing of claims replaces all prior versions and listings of claims in this application. Additional terms are presented in underline text and deleted terms are indicated in ~~strikethrough~~ text or are enclosed in [[double brackets]].

1. (Currently Amended) A method for operating an accelerated cyclic test system for evaluating a valved prosthetic device comprising

driving a test system fluid cyclically above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the test system;

storing a volume of test system fluid in an excess volume area during a system driving stroke that opens the valved prosthetic device; and

releasing the stored volume of test system fluid during a return stroke that closes the valved prosthetic device.

2. (Original) The method of claim 1, wherein the excess volume area enlarges in response to a pressure on the test system fluid during the driving stroke and decreases during the return stroke.

3. (Previously Presented) The method of claim 2, wherein the excess volume area provides a spring force counter to and in response to the pressure on the test system fluid.

4. (Original) The method of claim 3 further comprising altering a spring factor of the spring force provided by the excess volume area through selection of a material forming at least a portion of a boundary of the excess volume area.

5. (Original) The method of claim 4, wherein the material is an elastomeric material that expands and contracts in response to the pressure on the test system.

6. (Previously Presented) The method of claim 1, further comprising compressing a volume of a compressible gas with the volume of test system fluid to provide a spring force counter to and in response to a pressure on the test system fluid when the volume of test system fluid is stored in the excess volume area.

7. (Original) The method of claim 6 further comprising altering a spring factor of the spring force provided by the excess volume area by adjusting the volume of the compressible gas.

8. (Withdrawn) A device for accelerated cyclic testing of a valved prosthetic device comprising

a pressurizable test chamber for containing test system fluid and further comprising

a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with a pressure source;

a fluid return chamber positioned on a second side of the valved prosthetic device;

a fluid return conduit both structurally and fluidily connecting the fluid distribution chamber to the fluid return chamber; and

an excess volume area in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.

9. (Withdrawn) The device in claim 8 further comprising

a drive motor; and

a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on the test system fluid in the test chamber.

10. (Withdrawn) The device of claim 8, wherein the excess volume area enlarges in response to compression of the test system fluid and decreases during depressurization of the test system fluid.

11. (Withdrawn) The device of claim 8 further comprising an elastomeric material that forms at least a portion of a boundary of the excess volume area and that expands and contracts in response to changes in pressure on the test system fluid within the test chamber.

12. (Withdrawn) The device of claim 8, wherein the excess volume area further contains a volume of a compressible gas that is compressed by the volume of the test system fluid to provide a spring force when the volume of the test system fluid is stored in the excess volume area.

13. (Withdrawn) The device of claim 8, wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.

14. (Withdrawn) The device of claim 13 further comprising an elastomeric membrane separating at least a portion of the compliance chamber from fluid in the fluid return chamber.

15. (Withdrawn) The device of claim 13 further comprising a porous material at least partially filling the compliance chamber.

16. (Withdrawn) The device of claim 13, wherein the compliance chamber provides a volume for holding a gas or elastomeric material that compresses under a pressure placed upon the test system fluid in the test chamber and allows the test system fluid in the test chamber to occupy a portion of the volume in the compliance chamber.

17. (Withdrawn) The device of claim 8, wherein

the test chamber defines a first port on a first side of the valved prosthetic device and a second port on a second side of the valved prosthetic device; and

the first port and the second port are configured to receive one or more sensor devices.

18. (Withdrawn) The device of claim 9, wherein the drive motor is configured to operate cyclically, acyclically, or a combination of both, to provide cyclic and acyclic fluid pressures within the test chamber.

19. (Withdrawn) The device of claim 9, wherein the drive motor comprises a linear motor.

20. (Withdrawn) The device of claim 9, wherein the fluid displacement member further comprises a flexible rolling bellows connected to a shaft of the drive motor.

REMARKS

This Response is considered fully responsive to the Office Action mailed 20 March 2015. Claims 1-20 are pending in the application. Claims 8-20 are withdrawn. Claims 1-7 stand rejected. In this Response, claim 1 is amended. Reexamination and reconsideration are requested.

Interview Summary

Applicant thanks the Examiner and Supervisory Examiner Lisa Caputo for their time on 7 May 2015 and participation in a telephone interview with the undersigned and Craig Weinberg, Ph.D., one of the inventors.

Dr. Weinberg discussed the differences between the invention claimed in claims 1-77 and the prior art references of record, namely, Pickard and Lundell et al. Dr. Weinberg noted that Pickard discloses a "real-time" test system (e.g., operating at physiologic rates on the order of 72 beats per minute, or 1.2 Hz) for hydrodynamic performance testing of heart valves to characterize and define their anticipated fluid mechanical performance post implantation Dr. Weinberg noted that Pickard's disclosure is thus not an accelerated durability testing system (e.g., operating at rates ≥ 3.5 Hz or 200 beats/cycles per minute) like the presently claimed invention and trying to cycle the Pickard system faster would frustrate the purpose of the test it is trying to perform (i.e., characterizing valve performance in a simulated circulatory system under which the valve is to be used) while not being able to perform the accelerated durability wear testing of the claimed invention. Dr. Weinberg also discussed the different purpose of system compliance between the claimed durability test system and the hydrodynamic performance system of Pickard. Dr. Weinberg noted that in the Pickard system, compliance is used to shape the systemic pressure waveform and modify the systemic pressures to mimic the response of the circulatory system distensiblity (e.g., arterial vascular compliance) and create a physiological relevant environment to characterize the prosthetic heart valve performance. In contrast, Dr. Weinberg noted the purpose of the excess volume area as claimed in the method of independent claim 1 is to prevent or minimize the kinetic energy of fluid flow generated by the system driver from translating into high static fluid pressure in the test system during the accelerated frequency testing.

The Examiner expressed concern that the term "accelerated" in the preamble of claim 1 was insufficient to differentiate the types of test systems disclosed in the cited prior art from the test system in which the claimed method operates. While Applicant disagreed with this analysis, the Applicant and Examiner discussed possible amendments to provide the clarity

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