(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 January 2014 (03.01.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/000105 A1

(51) International Patent Classification:
G01M 99/00 (2011.01) *A61F 2/24* (2006.01)

(21) International Application Number:
PCT/CA2013/050496

(22) International Filing Date:
25 June 2013 (25.06.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/664,107 25 June 2012 (25.06.2012) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

[Continued on next page]

(54) Title: HEART VALVE TESTING APPARATUS AND METHODS

(57) Abstract: Methods and apparatus for accelerated wear testing of prosthetic heart valves apply non-sinusoidal pressure waveforms. The waveforms may maintain a threshold reverse pressure for a desired duration while limiting a peak reverse pressure. Apparatus may include a fluid impeller such as a bellows or a piston driven by an actuator having a position controlled by a motion control system. The apparatus may include a pressure control system comprising one or more bypass channels and bypass valves controlling a resistance of the bypass channels to fluid flow. The bypass valves may be controlled in real time.

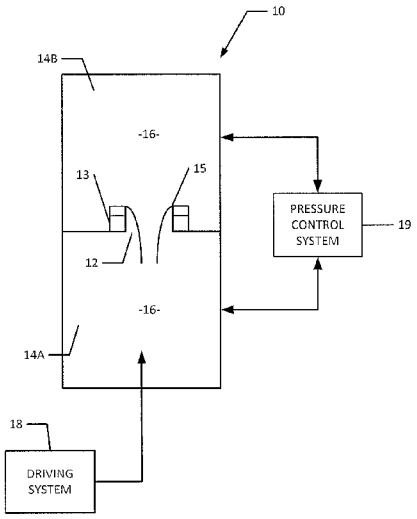

FIGURE 1

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

HEART VALVE TESTING APPARATUS AND METHODS

Technical Field

[0001] This application relates to apparatus and methods for testing replacement heart valves (e.g. prosthetic heart valves). Some embodiments perform accelerated wear testing.

Background

[0002] Prosthetic heart valves are normally tested for durability in accordance with the ISO5840 standard which calls for 200 million cycles of testing. In order to achieve these huge cycle numbers in a reasonable time the cycle rate may be set to 1200 cycles per minute or more. The standard requires that a certain proportion of each cycle (e.g. 5%) be at or above a certain reverse pressure.

[0003] It is difficult to perform accelerated tests that comply with the requirements of ISO 5840 and other standards because many common valves are made from animal tissue and are quite flexible. This fact combined with the high cycle rate and fluid dynamic effects can make it hard to test heart valves in a manner that complies with applicable standards.

[0004] Excess reverse pressure can cause heart valves to fail prematurely. Some valve testing apparatus causes pressure spikes or applies other excess pressures which can result in false testing failures.

[0005] There is a need for methods and apparatus for testing heart valves that are reliable and operate according to desired testing protocols. There is also a need for methods and apparatus capable of executing new testing protocols that may provide enhanced information about the long term reliability of heart valves being tested.

Summary

[0006] This invention has a number of aspects. One aspect provides apparatus for testing replacement heart valves that comprises a fluid impeller such as a bellows or piston that is reciprocated in a non-sinusoidal trajectory. Another aspect provides apparatus for testing replacement heart valves that comprises a bypass and a controllable bypass valve that is controlled to limit reverse pressures applied to a heart valve under test. Another aspect provides apparatus for testing replacement heart valves that includes a pressure control system comprising compliance devices

upstream and/or downstream of a heart valve under test. Another aspect provides methods for testing replacement heart valves.

[0007] An example aspect provides apparatus for testing replacement heart valves. The apparatus comprises a mounting structure for supporting a heart valve in a passage extending between first and second chambers and a driving system for driving the flow of fluid through a heart valve supported on the mounting structure. The driving system comprises an actuator and a controller connected to control the actuator to provide a desired non-sinusoidal motion to a fluid impeller.

[0008] In example embodiments the fluid impeller comprises a piston or a bellows. The actuator may comprise a linear or rotary actuator In some embodiments the actuator comprises a servo motor. Where the actuator comprises a rotary actuator the apparatus may comprise a rotary-to-linear motion converter driven by the rotary actuator and connected to drive the fluid impeller. The rotary-to-linear converter may, for example comprise a screwor a cam.

[0009] In some embodiments the driving system comprises a position sensor connected to monitor a position of the fluid impeller. The controller may comprise a position-feedback controller or a position and velocity feedback controller.

[0010] The controller may comprise one or more of the following features:

- a motion control system that is configurable to operate the actuator to provide a desired profile of position as a function of time.
- the controller is configured to provide control over one or more of: the amplitude of motions driven by the actuator; the frequency of the motions driven by the actuator; and the waveform of the wave input provided by motions driven by the actuator.
- the controller is configured to control the actuator to move the fluid impeller according a first profile having a first shape when the fluid impeller is moving in a direction such that the heart valve is closed and to move the fluid impeller according a second profile having a second shape different from the first shape when the fluid impeller is moving in a direction such that the heart valve is open.
- the controller is configured to execute an algorithm that uses feedback of pressure measured on one or both sides of the valve under test to provide proportional control of the drive wave shape to minimize pressures

experienced by the test valve during the full closed cycle while achieving a threshold reverse pressure for at least a specified portion of each cycle.

- the controller is configured to execute a learning algorithm that automatically tunes parameters that define the waveform with which the actuator is driven to achieve a desired pressure profile at the valve under test.
- the controller is configured to provide a plurality of operator selectable, preprogrammed wave forms.
- a user interface or API configured to permit a user to tailor the waveforms to achieve a desired wave shape, amplitude and/or frequency.

[0011] The inventive apparatus may comprise a pressure control system. The pressure control system may comprise a bypass providing a fluid connection between the first and second chambers and one or more bypass valves controllable to regulate a flow of fluid through the bypass. The one or more bypass valves may provide resistance to fluid flow that is set manually and/or a resistance of the one or more bypass valves to fluid flow may be automatically controlled.

[0012] The apparatus may comprise one or more pressure sensors. The controller may be configured to monitor fluid pressure at the one or more pressure sensors and to control the one or more bypass valves and/or the motion of the fluid impeller based on the monitored fluid pressure.

[0013] In some embodiments the controller is configured to operate the driving system such that a reverse pressure on the heart valve rises to a target peak pressure somewhat in excess of a reverse threshold pressure more slowly than a sinusoidal waveform would and holds at a pressure exceeding the reverse threshold pressure for longer than a sinusoidal waveform having the same target peak pressure.

[0014] Another example aspect provides apparatus for testing replacement heart valves. The apparatus comprises a mounting structure for supporting a heart valve in a passage extending between first and second chambers and a driving system for driving the flow of fluid through a heart valve supported on the mounting structure. The driving system comprises an actuator operable to move the fluid impeller to, in a first period, cause a flow of fluid through a heart valve under test in a forward direction wherein the heart valve is open; and, in a second period cause a flow of fluid in a reverse direction that causes the heart valve to close and applies a reverse pressure to the heart valve. The apparatus comprises a pressure control system comprising a bypass extending between the first and second chambers, a bypass valve in the bypass,

the bypass valve controllable to alter a resistance of the bypass valve to fluid flow and a pressure sensor. A controller is configured to control the bypass valve in response to a pressure sensed by the pressure sensor to limit the reverse pressure applied to the heart valve in the second period.

[0015] Another example aspect provides a method for testing replacement heart valves. The method comprises controlling an actuator to, in a first period, cause a flow of fluid through a heart valve under test in a forward direction wherein the heart valve is open; and in a second period cause a flow of fluid in a reverse direction that causes the heart valve to close and applies a reverse pressure to the heart valve. In the second period, the actuator is controlled to apply a non-sinusoidal pressure waveform to the closed heart valve.

[0016] The method may comprise, during the second period, controlling a flow of fluid through a bypass channel so as to limit a reverse pressure on the heart valve. Controlling the flow of fluid through the bypass channel may be performed in real time in response to one or more pressure sensor readings.

[0017] Additional aspects of the invention and features of example embodiments are described below and/or illustrated in the accompanying drawings.

Brief Description of the Drawings

[0018] The accompanying drawings illustrate non-limiting example embodiments of the invention.

[0019] Figure 1 is a schematic illustration showing a heart valve testing apparatus according to an example embodiment of the invention.

[0020] Figure 2 shows some example waveforms.

[0021] Figure 3 shows valve testing apparatus according to another example embodiment.

Description

[0022] Throughout the following description specific details are set forth in order to provide a more thorough understanding to persons skilled in the art. However, well known elements may not have been shown or described in detail to avoid unnecessarily obscuring the disclosure. The following description of examples of the

technology is not intended to be exhaustive or to limit the system to the precise forms of any example embodiment. Accordingly, the description and drawings are to be regarded in an illustrative, rather than a restrictive, sense.

[0023] Figure 1 shows example apparatus **10** for testing the durability of heart valves. Apparatus **10** comprises a passage **12** extending between chambers **14A** and **14B**. A suitable mounting structure **13** is provided for supporting a heart valve **15** to be tested. Chambers **14A** and **14B** and passage **12** may contain a suitable fluid **16** such as a saline solution. Heart valve **15** may be tested by controlling the flow of fluid **16** in apparatus **10** such that, in a first phase, heart valve **15** opens to allow fluid **16** to flow through passage **12** in a forward direction and then, in a second phase heart valve **15** closes to block flow of fluid **16** though passage **12** in the reverse direction. In the second phase a reverse pressure is applied to heart valve **15**.

[0024] This disclosure describes a driving system **18** for driving the flow of fluid through heart valve **15** and also describes a pressure control system **19** for controlling reverse pressure on a heart valve **15**. A heart valve testing apparatus may comprise both systems **18** and **19** as described herein. However, a driving system **18** as described herein has application in heart valve testing apparatus which lacks a pressure control system **19** and a pressure control system **19** as described herein may be applied in heart valve testing apparatus that uses driving systems different from driving system **18**. The apparatus described herein advantageously includes both a driving system **18** and a pressure control system **19**. Pressure control system **19** may operate by actively controlling a bypass whereby fluid **16** can pass between chambers **14A** and **14B** bypassing valve **15** and/or actively controlling one or more compliance devices which can temporarily receive some fluid **16** and/ or actively controlling one or more valves which allow fluid **16** to flow out of chamber **14A** and/or **14B**.

[0025] Driving system **18** may be configured to cause especially the reverse pressure on heart valve **15** to vary with time in a manner that is non-sinusoidal. Driving system **18** may drive fluid **16** such that reverse pressure on heart valve **15** rises to a target peak pressure somewhat in excess of a reverse threshold pressure more slowly than a sinusoidal waveform would and holds at a pressure exceeding the reverse threshold pressure for longer than a sinusoidal waveform having the same target peak pressure. This is illustrated in Figure 2. It can be seen that pressure waveform **20** more slowly reaches a peak **21** and then stays at or above the reverse threshold pressure **22** for longer than a sinusoid **23**, while minimizing the peak pressure **24**. To achieve the same duration of pressure exceeding the reverse threshold pressure **22** as provided by

a waveform like waveform **20** with a sinusoidal pressure waveform would require a sinusoidal waveform **25** having a significantly higher peak pressure **26**. Ideally pressure waveform **20** rises to its peak reverse pressure more slowly than a sinusoid while allowing valve **15** to open more quickly than a sinusoidal flow of fluid **16** would provide.

[0026] To achieve the desired pressure/fluid flow profiles, driving system **18** may comprise an actuator that is controlled to provide a desired non-sinusoidal motion to a piston, bellows, or the like. Figure 3 shows apparatus **30** according to an example embodiment wherein driving system **18** comprises a bellows **32** and an actuator **34** which applies a force to compress bellows **32**. Compression of bellows **32** causes fluid **16** to apply pressure to the valve **15** under test. On the reverse cycle actuator **34** pulls on bellows **32** which sucks fluid **16** through valve **15**. Valve **15** opens to allow the fluid **16** to pass, returning the device to the starting condition and ready for another compression. Bellows **32** may be made from any suitable material. In some embodiments, bellows **32** are made from Inconel.

[0027] In some embodiments actuator **34** comprises a servo motor, either linear or rotary. Where actuator **34** comprises a rotary motor then a suitable rotary to linear converter such as a ball screw, a cam or the like may be provided to drive motion of bellows **32**. Actuator **34** may comprise alternative structures, such as a voice-coil driver or the like. Actuator **34** is driven by a controller **35** that applies driving electrical signals to actuator **34**. The actuating electrical signals result in non-sinusoidal motion of bellows **32** (or of a piston or other alternative fluid-propelling structure).

[0028] In some embodiments driving system **18** comprises a position sensor connected to monitor a position of bellows **32** and controller **35** comprises a position-feedback controller or a position and velocity feedback controller. In some embodiments, controller **35** comprises a motor amplifier **37** configured to drive actuator **34** with non-sinusoidal signals.

[0029] Controller **35** may comprise a motion control system that is configurable to operate actuator **34** to provide a desired profile of position as a function of time which will result in the desired pressure profile acting on valve **15**. Controller **35** may provide control over one or more of the amplitude of motions of actuator **34** or an alternative wave input mechanism that bi-directionally drives fluid through the valve under test; the frequency of the driven motions of actuator **34**; and the shape

(waveform) of the wave input provided by motions of actuator **34**. In some embodiments the shape of the profile of the motion of actuator **34** is different when actuator **34** is moving in a direction such that the valve under test is closed than it is when actuator **34** is moving in a direction such that the valve under test is open.

[0030] In some embodiments controller **35** executes an algorithm that uses feedback of pressure measured on one or both sides of a valve under test to provide proportional control of the drive wave shape to minimize pressures experienced by the test valve during the full closed cycle of the durability test while achieving a necessary threshold reverse pressure for at least a specified portion of each cycle. In some embodiments, controller **35** executes a learning algorithm that automatically tunes parameters that define the waveform with which actuator **34** is driven to achieve a desired pressure profile at the valve under test.

[0031] In some embodiments controller **35** may provide operator selectable, preprogrammed wave forms. Controller **35** may provide a user interface or API such that the waveforms are capable of being tailored by the user to the wave shape, amplitude and/or frequency as desired for a particular test protocol.

[0032] The pressures on valve **15** resulting from the fluid motion driven by actuator **34** may also be affected by providing one or more compliance elements. In the illustrated embodiment an upstream compliance element **37A** and a downstream compliance element **37B** are shown. Each compliance element may comprise, for example, an accumulator such as an air or gas pocket, a viscoelastic element such as a coated sponge, an elastic wall of a chamber, a compressible balloon, or the like. Upstream compliance element **37A** may function to reduce transient pressure spikes which may have the effect of over-stressing valve **15**. Downstream compliance element **37B** accommodates the flow of fluid into and out of chamber **14B**. In some embodiments, downstream compliance element **37B** is omitted and chamber **14B** is be open to atmospheric pressure.

[0033] Compliance elements may optionally be adjustable to provide enhanced control over the pressure waveform applied to the valve under test. In some embodiments the compliance elements are controlled in real time in concert with the application of fluid motion by actuator **34.**

[0034] In Figure 3 the valve under test **15** is illustrated as being of a type comprising flexible leaflets **15A** that open to allow fluid flow in one direction and close to block

fluid flow in the reverse direction. This is not mandatory. Apparatus such as apparatus **30** may be applied for testing heart valves having any suitable constructions.

[0035] Apparatus **30** provides a variable bypass valve **40** which helps to regulate reverse pressure on valve **15**. Valve **40** may have a resistance that is set manually. In a preferred embodiment the resistance of valve **40** to the flow of fluid is automatically controlled. In the illustrated embodiment, one or more pressure sensors are provided to monitor fluid pressure and to control the opening of bypass valve **40** based on the monitored fluid pressure. In the illustrated embodiment, automatic pressure control system **19** comprises valve **40**, pressure sensors **42A** and **42B** at pressure measuring ports **43A** and **43B** and a valve controller **44** that adjusts the opening of valve **40** based at least in part on pressure signals from sensors **42A** and/or **42B**.

[0036] In some embodiments apparatus includes a plurality of test chambers that may be applied for simultaneously testing a corresponding plurality of heart valves. In such embodiments it is not mandatory that every test chamber has its own set of one or more pressure transducers. In some embodiments one or more pressure transducers can be selectively connected to measure pressures in different test chambers by way of appropriate manifolds and valves or the like. In such embodiments a controller may implement a process of connecting one or more pressure transducers to a test chamber, monitoring pressures over one or more cycles or portions thereof, adjusting parameters controlling operation of an actuator **34** and/or bypass valve **40**, and then switching the pressure transducer(s) to monitor pressures in another test chamber.

[0037] Where heart valve testing apparatus includes both a driving system **18** and a pressure control system **19** as described herein then the controllers for systems **18** and **19** may optionally be integrated. Both systems may use pressure signals from the same pressure transducer(s) for control purposes.

[0038] The operation of driving system **18** to control the inflow and outflow of fluid **16** passing through a valve under test and a bypass pathway facilitates control of the peak pressure exerted on the valve during the valve closure phase of operation. Achieving a desired threshold reverse pressure while controlling to reduce maximum pressures may reduce or eliminate false negative results over the course of a test.

[0039] Various options and alternative embodiments may be provided. Many prosthetic cardiovascular valves are configured within stents (essentially cylindrical wire structures). Apparatus as described herein may optionally be configured to allow

stent-mounted valves to be tested within tubular conduits for example. Chamber **14B** may optionally be configured as a removable cartridge to allow rapid mounting of valves within the apparatus. Apparatus as described herein is not limited to having a single actuator **34**. In alternative embodiments there are two or more actuators **34**. For example, actuators **34** may be provided to drive fluid motion on both upstream and downstream sides of a valve under test.

[0040] Apparatus as described herein may be applied, for example, to testing aortic or mitral prosthetic heart valves.

INTERPRETATION OF TERMS

[0041] Unless the context clearly requires otherwise, throughout the description and the claims:

- "comprise," "comprising," and the like are to be construed in an inclusive sense, as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to" .
- "connected," "coupled," or any variant thereof, means any connection or coupling, either direct or indirect, between two or more elements; the coupling or connection between the elements can be physical, logical, or a combination thereof.
- "herein," "above," "below," and words of similar import, when used to describe this specification shall refer to this specification as a whole and not to any particular portions of this specification.
- "or," in reference to a list of two or more items, covers all of the following interpretations of the word: any of the items in the list, all of the items in the list, and any combination of the items in the list.
- the singular forms “a”, “an” and “the” also include the meaning of any appropriate plural forms.

[0042] Words that indicate directions such as "vertical", "transverse", "horizontal", "upward", "downward", "forward", "backward", "inward", "outward", "vertical", "transverse", “left”, “right” , “front”, “back” , “top”, “bottom”, “below”, “above”, “under”, and the like, used in this description and any accompanying claims (where present) depend on the specific orientation of the apparatus described and illustrated. The subject matter described herein may assume various alternative orientations. Accordingly, these directional terms are not strictly defined and should not be interpreted narrowly.

[0043] Data processing aspects of various embodiments of the invention may be implemented using specifically designed hardware, configurable hardware, programmable data processors configured by the provision of software (which may optionally comprise 'firmware') capable of executing on the data processors, special purpose computers or data processors that are specifically programmed, configured, or constructed to perform one or more steps in a method as explained in detail herein and/or combinations of two or more of these. Examples of specifically designed hardware are: logic circuits, application-specific integrated circuits ("ASICs"), large scale integrated circuits ("LSIs"), very large scale integrated circuits ("VLSIs") and the like. Examples of configurable hardware are: one or more programmable logic devices such as programmable array logic ("PALs"), programmable logic arrays ("PLAs") and field programmable gate arrays ("FPGAs") . Examples of programmable data processors are: microprocessors, digital signal processors ("DSPs"), embedded processors, graphics processors, math co-processors, general purpose computers, server computers, cloud computers, mainframe computers, computer workstations, and the like. For example, one or more data processors in a control circuit for a device may implement methods as described herein by executing software instructions in a program memory accessible to the processors.

[0044] Processing may be centralized or distributed.

[0045] For example, while processes or blocks are presented in a given order, alternative examples may perform routines having steps, or employ systems having blocks, in a different order, and some processes or blocks may be deleted, moved, added, subdivided, combined, and/or modified to provide alternative or subcombinations. Each of these processes or blocks may be implemented in a variety of different ways. Also, while processes or blocks are at times shown as being performed in series, these processes or blocks may instead be performed in parallel, or may be performed at different times.

[0046] Aspects of the invention may also be provided in the form of a program product. The program product may comprise any non-transitory medium which carries a set of computer-readable instructions which, when executed by a data processor, cause the data processor to execute a method of the invention. Program products according to the invention may be in any of a wide variety of forms. The program product may comprise, for example, non-transitory media such as magnetic data storage media including floppy diskettes, hard disk drives, optical data storage media including CD ROMs, DVDs, electronic data storage media including ROMs, flash

RAM, EPROMs, hardwired or preprogrammed chips (e.g., EEPROM semiconductor chips), nanotechnology memory, or the like. The computer-readable signals on the program product may optionally be compressed or encrypted.

[0047] In some embodiments, the invention may be implemented in part in software. A processor executing the software may control apparatus to execute heart valve testing methods as described herein. For greater clarity, "software" includes any instructions executed on a processor, and may include (but is not limited to) firmware, resident software, microcode, and the like. Both processing hardware and software may be centralized or distributed (or a combination thereof), in whole or in part, as known to those skilled in the art. For example, software and other modules may be accessible via local memory, via a network, via a browser or other application in a distributed computing context, or via other means suitable for the purposes described above.

[0048] Where a component (e.g. software, processor, support assembly, valve device, circuit, etc.) is referred to above, unless otherwise indicated, reference to that component (including a reference to a "means") should be interpreted as including as equivalents of that component any component which performs the function of the described component (i.e., that is functionally equivalent), including components which are not structurally equivalent to the disclosed structure which performs the function in the illustrated exemplary embodiments of the invention.

[0049] Specific examples of systems, methods and apparatus have been described herein for purposes of illustration. These are only examples. The technology provided herein can be applied to systems other than the example systems described above. Many alterations, modifications, additions, omissions and permutations are possible within the practice of this invention. This invention includes variations on described embodiments that would be apparent to the skilled addressee, including variations obtained by: replacing features, elements and/or acts with equivalent features, elements and/or acts; mixing and matching of features, elements and/or acts from different embodiments; combining features, elements and/or acts from embodiments as described herein with features, elements and/or acts of other technology; and/or omitting combining features, elements and/or acts from described embodiments.

[0050] It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions, omissions and sub-combinations as may reasonably be inferred.

WHAT IS CLAIMED IS:

1. Apparatus for testing replacement heart valves, the apparatus comprising:

a mounting structure for supporting a heart valve in a passage extending between first and second chambers;

a driving system for driving the flow of fluid through a heart valve supported on the mounting structure, the driving system comprising an actuator and a controller connected to control the actuator to provide a desired non-sinusoidal motion to a fluid impeller.

2. Apparatus according to claim 1 wherein the fluid impeller comprises a piston.

3. Apparatus according to claim 1 wherein the fluid impeller comprises a bellows.

4. Apparatus according to claim 3 wherein the bellows are made from inconel.

5. Apparatus according to any one of claims 1 to 4 wherein the actuator comprises a servo motor.

6. Apparatus according to claim 5 wherein the actuator comprises a rotary motor.

7. Apparatus according to claim 6 wherein the actuator comprises a rotary-to-linear motion converter driven by the rotary motor and connected to drive the fluid impeller.

8. Apparatus according to claim 7 wherein the rotary-to-linear converter comprises a screw

9. Apparatus according to claim 7 wherein the rotary to linear converter comprises a cam.

10. Apparatus according to any one of claims 1 to 4 wherein the actuator comprises a voice coil.

11. Apparatus according to any one of claims 1 to 10 wherein the driving system comprises a position sensor connected to monitor a position of the fluid impeller

12. Apparatus according to claim 11 wherein the controller comprises a position-feedback controller.

13. Apparatus according to claim 11 wherein the controller comprises a position and velocity feedback controller.

14. Apparatus according to any one of claims 1 to 13 wherein the controller comprises a motion control system that is configurable to operate the actuator to provide a desired profile of position as a function of time.

15. Apparatus according to claim 14 wherein the controller is configured to provide control over one or more of: the amplitude of motions driven by the actuator; the frequency of the motions driven by the actuator; and the waveform of the wave input provided by motions driven by the actuator.

16. Apparatus according to claim 14 or 15 wherein the controller is configured to control the actuator to move the fluid impeller according a first profile having a first shape when the fluid impeller is moving in a direction such that the heart valve is closed and to move the fluid impeller according a second profile having a second shape different from the first shape when the fluid impeller is moving in a direction such that the heart valve is open.

17. Apparatus according to any one of claims 1 to 16 wherein the controller is configured to execute an algorithm that uses feedback of pressure measured on one or both sides of the valve under test to provide proportional control of the drive wave shape to minimize pressures experienced by the test valve during the full closed cycle while achieving a threshold reverse pressure for at least a specified portion of each cycle.

18. Apparatus according to any one of claims 1 to 17 wherein the controller is configured to execute a learning algorithm that automatically tunes parameters that define the waveform with which the actuator is driven to achieve a desired pressure profile at the valve under test.

19. Apparatus according to any one of claims 1 to 18 wherein the controller is configured to provide a plurality of operator selectable, preprogrammed wave forms.

20. Apparatus according to claim 19 wherein the controller comprises a user interface or API configured to permit a user to tailor the waveforms to achieve a desired wave shape, amplitude and/or frequency.

21. Apparatus according to claim 1 further comprising a pressure control system, the pressure control system comprising a bypass providing a fluid connection between the first and second chambers and one or more bypass valves controllable to regulate a flow of fluid through the bypass.

22. Apparatus according to claim 21 wherein the one or more bypass valves provide resistance to fluid flow that is set manually.

23. Apparatus according to claim 21 wherein a resistance of the one or more bypass valves to fluid flow is automatically controlled.

24. Apparatus according to claim 23 comprising one or more pressure sensors wherein the controller is configured to monitor fluid pressure and to control the opening of the one or more bypass valves based on the monitored fluid pressure.

25. Apparatus according to claim 21 wherein the pressure control system comprises an automatic pressure control system comprising a bypass valve, first and second pressure sensors and a valve controller configured to adjust the opening of the valve based at least in part on pressure signals from the first and second pressure sensors.

26. Apparatus according to any one of claims 21 to 25 wherein the pressure control system comprises one or more compliance devices which can temporarily receive some fluid.

27. Apparatus according to any one of claims 21 to 26 wherein the pressure control system comprises one or more controlled valves operable to allow fluid to flow out of the first chamber and/or the second chamber.

28. Apparatus according to any one of claims 1 to 20 further comprising a pressure control system, the pressure control system comprises one or more compliance devices which can temporarily receive some fluid.

29. Apparatus according to claim 28 wherein the compliance devices comprise an upstream compliance element upstream from the mounting structure.

30. Apparatus according to claim 29 wherein the upstream compliance element comprises an accumulator.

31. Apparatus according to claim 29 wherein the upstream compliance element comprises a viscoelastic element

32. Apparatus according to claim 29 wherein the upstream compliance element comprises an elastic wall of a chamber or a compressible balloon.

33. Apparatus according to claim 29 wherein one or more of the compliance devices is adjustable.

34. Apparatus according to claim 33 wherein the one or more of the compliance devices is controlled in real time.

35. Apparatus according to claim 1 wherein the controller is configured to operate the driving system such that a reverse pressure on the heart valve rises to a target peak pressure somewhat in excess of a reverse threshold pressure more slowly than a sinusoidal waveform would and holds at a pressure exceeding the reverse threshold pressure for longer than a sinusoidal waveform having the same target peak pressure.

36. Apparatus according to any one of claims 1 to 35 comprising a tubular conduit adapted for supporting a stent-mounted valve for testing.

37. Apparatus according to any one of claims 1 to 35 wherein the second chamber is configured as a removable cartridge.

38. Apparatus according to any one of claims 1 to 35 wherein the apparatus comprises first and second actuators, each controllable to drive fluid flow.

39. Apparatus according to claim 38 wherein the first actuator is upstream from the mounting structure and the second actuator is downstream from the mounting structure.

40. A method for testing replacement heart valves, the method comprising:

controlling an actuator to, in a first period, cause a flow of fluid through a heart valve under test in a forward direction wherein the heart valve is open; and

in a second period cause a flow of fluid in a reverse direction that causes the heart valve to close and applies a reverse pressure to the heart valve;

wherein, in the second period, the actuator is controlled to apply a non-sinusoidal pressure waveform to the closed heart valve.

41. A method according to claim 40 comprising, during the second period, controlling a flow of fluid through a bypass channel so as to limit a reverse pressure on the heart valve.

42. A method according to claim 40 wherein controlling the flow of fluid through the bypass channel is performed in real time in response to one or more pressure sensor readings.

43. A method according to any one of claims 40 to 42 wherein controlling the actuator comprises closed loop control over motion of the actuator, the closed loop control causing the actuator to move according to a predetermined profile of position as a function of time.

44. Apparatus for testing replacement heart valves, the apparatus comprising:

a mounting structure for supporting a heart valve in a passage extending between first and second chambers;

a driving system for driving the flow of fluid through a heart valve supported on the mounting structure, the driving system comprising an actuator operable to move the fluid impeller to, in a first period, cause a flow of fluid through a heart valve under test in a forward direction wherein the heart valve is open; and, in a second period cause a flow of fluid in a reverse direction that causes the heart valve to close and applies a reverse pressure to the heart valve;

a pressure control system comprising a bypass extending between the first and second chambers, a bypass valve in the bypass, the bypass valve controllable to alter a resistance of the bypass valve to fluid flow and a pressure sensor; and

a controller configured to control the bypass valve in response to a pressure sensed by the pressure sensor to limit the reverse pressure applied to the heart valve in the second period.

45. Apparatus comprising any new and useful feature, combination of features or sub-combination of features as described herein.

46. Methods comprising any new and useful act, step, combination of acts and/or steps or subcombination of acts and/or steps as described herein.

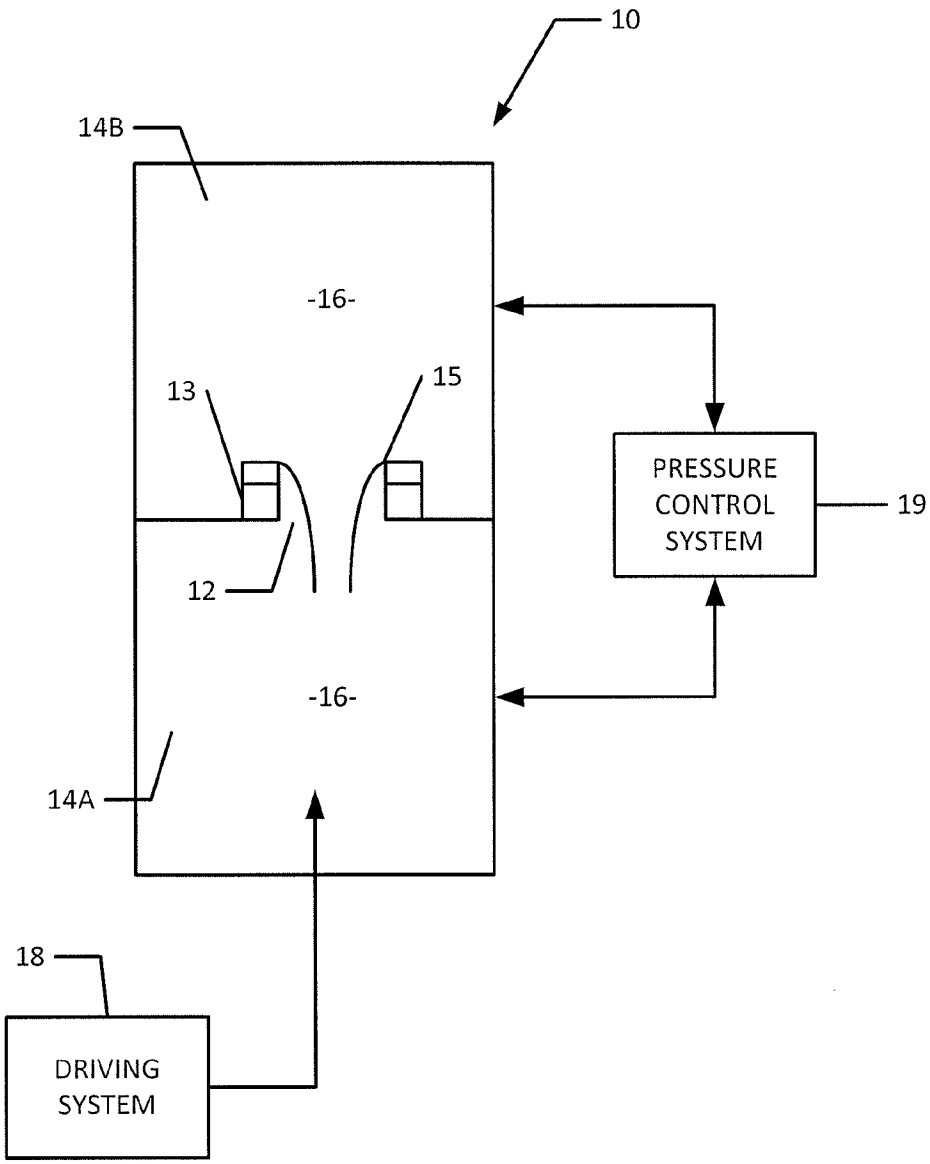
10
14B
-16-
13
15
PRESSURE
CONTROL
SYSTEM
19
12
-16-
14A
18
DRIVING
SYSTEM

FIGURE 1

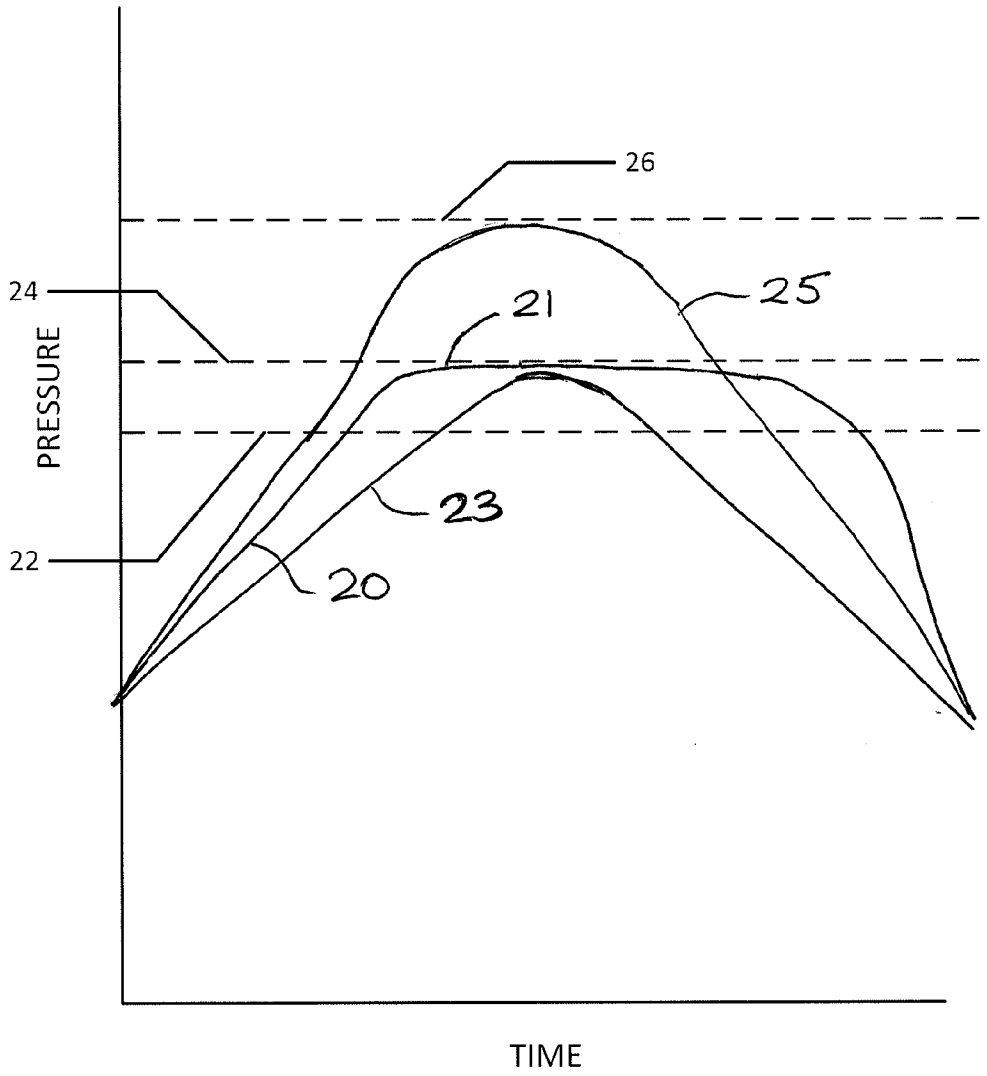

FIGURE 2

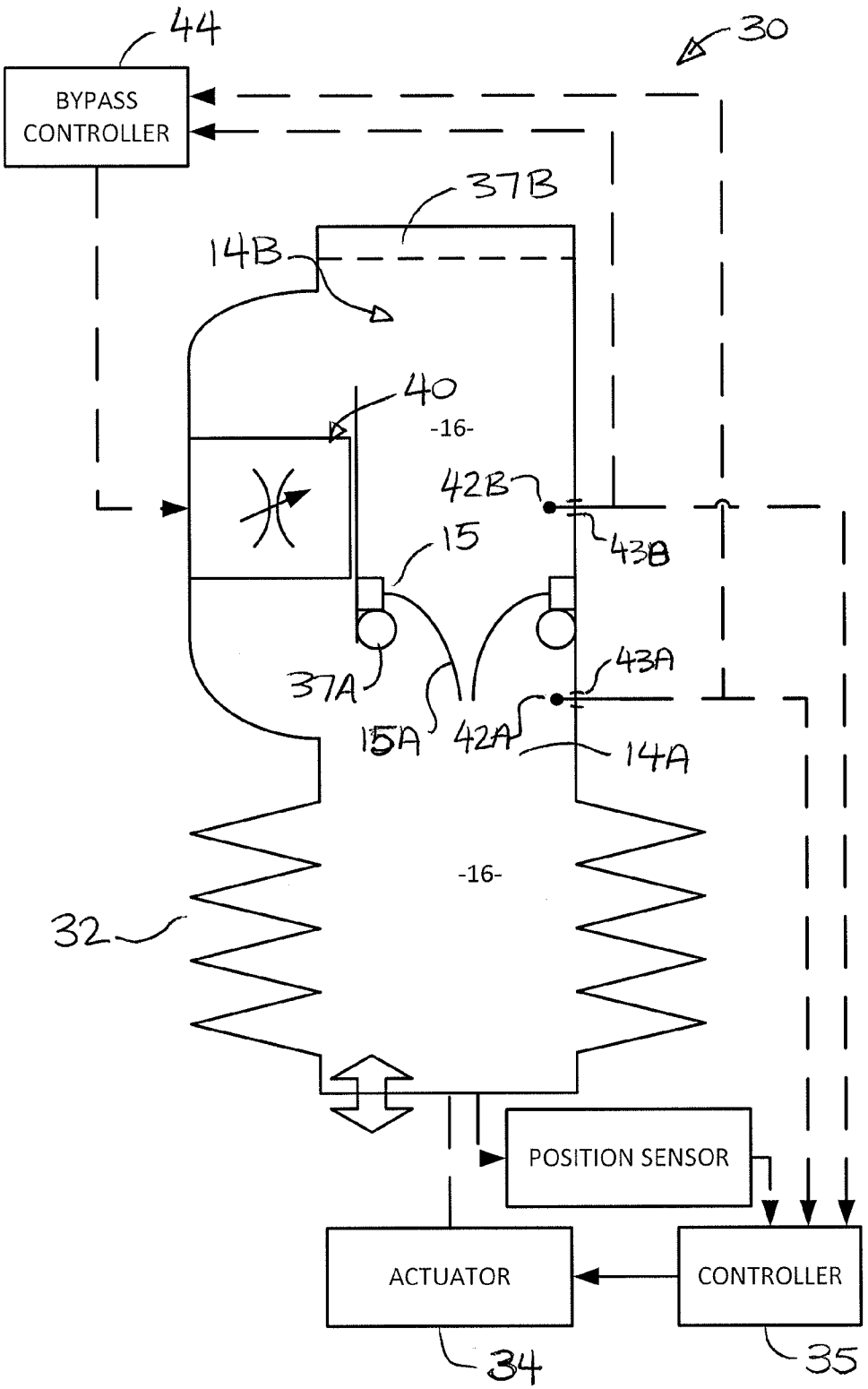
44
30
BYPASS CONTROLLER
37B
14B
40
-16-
42B
43B
15
37A
43A
15A
42A
14A
-16-
32
POSITION SENSOR
ACTUATOR
CONTROLLER
34
35

FIGURE 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2013/050496

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***G01M 99/00*** (2011.01) , ***A61F 2/24*** (2006.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: G01M 99/00, A61F 2/24
US Cl. : 73/37, 73/168, 128/ 897, 435/293, 607/33, 623/2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
None

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
EPOQUE (X-Full and Internal (EPODOC)) Canadian Patent Database Internet Search Engines
IEEE Online Database ESPACENET
key words used: replacement, prosthetic, prosthesis, artificial, heart, mitral, aortic, valve, test+, sinusoid+, flow+, forward, reverse, backward, counter, liquid, fluid, pressure, chamber, volume, mount+, attach+, position, sensor, detect+, impeller, actuator, piston, bellows, coil, cam, rotary, pump, screw, waveform, profile, motion, cycle, control+, bypass, compliance, compliant, flexible, elast+, visco+, wall, cartridge, insert, holder, tuning and tunable

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US20110132073A1 McCLOSKEY ET AL. (09 June 2011) (09-06-2011) (see paragraphs [0003], [0006] to [0010], [0024], [0026], [0031], [0035], [0046], [0051], [0060] and [0066] to [0069] along with figs. 1, 3, 6 and 7)	1 to 5, 17, 28, to 30, 32, 40, 43, 45 and 46 10, 26, 37, 38, 39
X Y	"Testing method for artificial heart valves - bulk qualities" (2010) Medical University Berlin 2 pgs. in total http://www.charite.de/biofluidmechanik/en/research/fields_1.html (see entire document - 2 pgs. in total))	1 to 9, 11 to 25, 27, 35, 40 to 46 10, 26 (with US20110132073A1), 37, 38, 39
Y	US5176153 EBERHARDT (05 January 1993) (05-01-1993)	10, 38, 39

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 October 2013 (16-10-2013)	31 October 2013 (31-10-2013)
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Daniel Weslake (819) 997-2999

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US5899937 GOLDSTEIN ET AL. (04 May 1999) (04-05-1999) (see col. 1, lines 43 to 49 and col. 10, lines 25 to 47, along with fig. 3)	36
Y	US4682491 PICKARD (28 July 1987) (28-07-1987) (see col. 2, lines 49 to 68, col. 3, line 58 to col. 4, line 24, col.8, line 67 to col. 9, line 25 and col. 9, line 46 to col. 11, line 16, along with figs. 3 and 4)	37
A	US7326564B2 LUNDELL ET AL. (05 February 2008) (05-02-2008) (see col.1, line 62 to col. 2, line 15, col. 2, line 57 to col 3, line 4 and col. 9, line 58 to col. 10, line 61, along with figs. 10 and 11)	1, 21 to 25 and 44
A	US6062075 RITZ ET AL. (16 May 2000) (16-05-2000) (see col. 4, line 36 to 50, along with figs. 1 to 3)	1, 40 and 44

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2013/050496

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US2011132073A1	09 June 2011 (09-06-2011)	CA2754257A1	10 September 2010 (10-09-2010)
		EP2404153A2	11 January 2012 (11-01-2012)
		US2010225478A1	09 September 2010 (09-09-2010)
		WO2010102185A2	10 September 2010 (10-09-2010)
		WO2010102185A3	13 January 2011 (13-01-2011)
US5176153A	05 January 1993 (05-01-1993)	None	
US5899937A	04 May 1999 (04-05-1999)	None	
US4682491A	28 July 1987 (28-07-1987)	None	
US7326564B2	05 February 2008 (05-02-2008)	BR0207264A	01 March 2005 (01-03-2005)
		CA2438336A1	29 August 2002 (29-08-2002)
		EP1385454A2	04 February 2004 (04-02-2004)
		JP2005501574A	20 January 2005 (20-01-2005)
		US2002116054A1	22 August 2002 (22-08-2002)
		WO02065952A2	29 August 2002 (29-08-2002)
		WO02065952A3	20 November 2003 (20-11-2003)
US6062075A	16 May 2000 (16-05-2000)	None	