UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ABBOTT LABORATORIES,
Petitioner

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IPR2025-00114
U.S. Patent No. 11,572,879

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DECLARATION OF PETER CROSBY UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

Page

EXHIBIT LIST 7
I. INTRODUCTION 10
II. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE 12
III. LEVEL OF ORDINARY SKILL IN THE ART 15
IV. RELEVANT LEGAL STANDARDS 16
V. OVERVIEW OF THE 879 PATENT 18
A. The 879 Patent's specification is generally directed to a catheter device. 19
B. The 879 Patent's specification describes that its rotor design was already disclosed in the prior art. 23
VI. BACKGROUND OF THE TECHNOLOGY ACCUSED OF INFRINGEMENT IN THE PARALLEL LITIGATION 25
A. Historical development of LVAD Devices. 25
1. Disadvantages of early-generation LVADs included mechanical bearings and increased risk of infection associated with their large size. 26
2. Third-generation LVADs aimed to eliminate mechanical bearings. 30
a. Two types of drives existed for third-generation devices. 32
b. Two types of bearings existed for third generation devices. 34
c. The smaller third-generation devices could be placed at the cardiac apex within the pericardial space. 36
VII. CLAIM CONSTRUCTION 40
A. Plain and Ordinary Meaning of Certain Claim Terms 40
1. "magneto coupling" (Claim 11) 41

a. The specification and prior art consistently distinguish magnetic coupling from other types of drive. 43

b. The Patent Owner conflates magnetic coupling with other types of drive. 51

2. "both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor" (Claim 11)..... 53

a. The specification and prior art consistently use this claim language to refer to a hydrodynamic bearing. 53

b. The Patent Owner renders this claim language meaningless. 58

VIII. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE 60

IX. THE PRINCIPAL PRIOR ART 61

A. Summary of Wampler-169 61

B. Summary of Bourque-2001 67

C. Summary of Akamatsu-1999 75

D. Summary of Schima 80

X. CLAIMS 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, AND 20 OF THE 879 PATENT ARE RENDERED OBVIOUS BY THE PRIOR ART 84

A. Ground 1: Wampler 169 Renders Obvious Claims 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20 of the 879 Patent 86

1. Claim 11 86

2. Claim 12 139

a. [12] The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components. 139

3. Claims 14-15 141

a. [14], [15] 141

4. Claim 16 145

a. [16] The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis. 145

5. Claim 18 148

a. [18] The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber. 148

6. Claim 19 151

a. [19] The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber, ... 151

7. Claims 1-2, 4-5, 7-8, 20 152

B. Ground 2: Bourque-2001 in view of Wampler-169 Renders Obvious Claims 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20 of the 879 Patent 155

1. Claim 11 155

2. Claim 12 206

a. [12] The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components. 206

3. Claims 14-15 208

a. [14], 15. 208

4. Claim 16 211

a. [16] The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis. 211

5. Claim 18 214

a. [18] The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber. 214

6. Claim 19 216
a. [19] The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber. 216
7. Claims 1-2, 4-5, 7-8, 20 217
8. Motivation to Combine Bourque-2001 with Wampler-169 219
C. Ground 3: Akamatsu 1999 Renders Obvious Claims 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20 of the 879 Patent 236
1. Claim 11 236
2. Claim 12 280
a. [12] The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components. 280
3. Claims 14-15 282
a. [14], [15]. 282
4. Claim 16 285
a. [16] The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis. 285
5. Claim 18 286
a. [18] The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber. 286
6. Claim 19 288
a. [19] The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber. 288
7. Claims 1-2, 4-5, 7-8, 20 289
D. Ground 4: Schima in view of Akamatsu-1999 Renders Obvious Claims 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20 of the 879 Patent 291

1. Claim 11 291
2. Claims 12 334
   a. [12] The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components. 334
3. Claims 14-15 336
   a. [14], [15] 336
4. Claim 16 340
   a. [16] The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis. 340
5. Claim 18 342
   a. [18] The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber. 342
6. Claim 19 344
   a. [19] The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber. 344
7. Claims 1-2, 4-5, 7-8, 20 346
8. Motivation to Combine Schima with Akamatsu-1999 348
   a. The Akamatsu-1999 configuration ("*inflow tube … insertable into a left ventricle*") 348
   b. The Akamatsu-1999 *external control unit* 355

XI. CONCLUSION 362

EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 11,572,879
1002	U.S. Patent No. 11,572,879 File History
1003	Declaration of Peter Crosby
1004	CV of Peter Crosby
1005	U.S. Pat. Pub. No. US 2003/0124007A1 to Heinrich Schima, et al., titled "*Rotary Pump Comprising a Hydraulically Mounted Motor*"
1006	Akamatsu et al., *Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump*, J Artif Organs 1999, Vol. 2, pp. 3-7
1007	Bourque et al., *HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor*, ASAIO Journal 2001
1008	U.S. Pat. Pub. No. US 2002/0102169A1 to Richard Wampler, et al., titled "*Sealless rotary blood pump*"
1009	Miracor's Supplemental Initial Response to Invalidity Contentions, dated September 20, 2024
1010	Frazier et al. *Total Heart Replacement with Dual Centrifugal Ventricual Assist Devices*, ASAIO Journal 2005
1011	Schob, *Centrifugal pump without bearings or seals*, World Pumps Vol. 2002, No. 430, pp. 34-37
1012	Rose et al., *Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term use of a left ventricular assist device for end-stage heart failure*, N Engl J Med. 2001 Nov 15, Vol. 345, No. 20, pp. 1435-43
1013	HeartMate® II LVAS: Patient Management Guidelines, December 14, 2006
1014	Schulman et al., *Comparisons of infection complications between continuous flow and pulsatile flow left ventricular assist devices,*

	The Journal of Thoracic and Cardiovascular Surgery 2007, Vol. 133, No. 3, pp. 841-842
1015	LaRose et al., *Heartware – A novel miniaturized passive maglev centrifugal VAD*, ASAIO Journal 2004 Mar, Vol. 50, No. 2, p. 137
1016	Qian et al., *Permanent magnetic-levitation of rotating impeller: a decisive breakthrough in the centrifugal pump*, Journal of Medical Engineering & Technology 2002 Jan/Feb, Vol. 26, No. 1, pp. 36-38
1017	Akamatsu et al., *Chronic Animal Experiment with Magnetically Suspended Centrifugal Pump*, Artificial Organs 1997, Vol. 21, No. 7, pp. 645-638
1018	U.S. Patent No. 6,050,975
1019	Exhibit 11 of Complaint, dated November 27, 2023
1020	Bottone et al., *Magnetos for automobilists, how made and how used*, Crosby Lockwood and Son, Ch. 1 (1907) (accessed at https://archive.org/details/ magnetosforauto00bottgoog/page /n6/mode/2up)
1021	"Ignition magneto," accessed via https://en.wikipedia.org/wiki/Ignition_magneto (last accessed October 28, 2024)
1022	Masuzawa et al. *Magnetically Suspended Centrifugal Blood Pump with an Axially Levitated Motor*, Artificial Organs 2003, Vol. 27, No. 7, pp. 631-638
1023	U.S. Patent No. 6,152,704
1024	U.S. Patent No. 6,589,030
1025	European Patent No. 0 834 326
1026	Miracor's Response to Exhibit D-1 (Bourque-2001) of Supplemental Invalidity Contentions
1027	U.S. Pat. No. 5,324,177
1028	Allaire, et al., *Prototype Continuous Flow Ventricular Assist Device*, J. Artificial Organs 1996, Vol. 20, No. 7, pp.582-690

1029	Kung and Hart, *Design Considerations for Bearingless Rotary Pumps*, J. Artificial Organs 1997, Vol. 21, No. 7, pp. 645-650
1030	Declaration of Sylvia Hall-Ellis

I, Peter Crosby, do hereby declare as follows:

I. INTRODUCTION

1. I am making this declaration at the request of Petitioner in the matter of the *Inter Partes* Review of U.S. Patent No. 11,572,879 ("the 879 Patent") to Mohl et al.

2. I am being compensated for my work in this matter at my standard hourly rate. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this proceeding. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

3. I have been asked to provide my opinions regarding whether the subject matter of claims 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20 ("the Challenged Claims") of the 879 Patent are anticipated or otherwise would have been obvious to a person having ordinary skill in the art ("POSITA") at the time of the alleged invention, in light of the prior art. It is my opinion that the Challenged Claims would have been obvious to a POSITA.

4. In the preparation of this declaration, I have studied:

a. the 879 Patent, Ex.1001.

b. the prosecution history of the 879 Patent ("879 File History"), Ex.1002.

c. U.S. Pat. Pub. No. US 2002/0102169A1 to Richard K. Wampler, titled "*Sealless Rotary Blood Pump*" ("Wampler-169"), Ex.1008.

d. Bourque et al., *HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor*, ASAIO Journal 2001 ("Bourque-2001"), Ex.1007.

e. Akamatsu et al., *Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump*, J. Artif. Organs (1999) 2:3-7 ("Akamatsu-1999"), Ex.1006.

f. U.S. Pat. Pub. No. US 2003/0124007A1 to Heinrich Schima, et al., titled "*Rotary Pump Comprising a Hydraulically Mounted Motor*" ("Schima"), Ex.1005.

g. The additional references I refer to below and/or identified in the exhibit list.

5. In forming the opinions expressed below, I have considered: the documents listed above; the relevant legal standards as explained to me, including the standards for anticipation and obviousness; and my own knowledge and experience based upon my work in the field of network communications and security as described below.

6. Unless otherwise noted, all **emphasis** in any quoted material has been added. Claim terms are *italicized*. Exhibit titles are underlined.

II. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE

7. My complete qualifications and professional experience are described in my *Curriculum Vitae*, a copy of which can be found in Ex.1004. The following is a brief summary of my relevant qualifications and professional experience.

8. I have over 45 years of experience in the medical device industry. I earned my Bachelor's degree in Electrical Engineering in 1974 and my Master's degree in Engineering Science in 1976, both from the University of Melbourne, Australia. My M.Eng.Sci. degree was in Biomedical Engineering, and I took courses and received training in advanced engineering, anatomy, and physiology as part of my M.Eng.Sci. work.

9. I am a named inventor of over 50 issued U.S. patents and public applications (and foreign equivalents). Most of my patents are in the general field of medical devices. Some of my patents are in the field of Left Ventricular Assist Devices (LVADs), the subject matter of the 879 Patent.

10. During my career I have worked as an engineer in research and development responsible for developing medical devices and have run the research and development function for several medical device companies. I spent

approximately 15 years in product research and development, including participation in design, engineering, manufacturing ramp-up, clinical trial design and execution, and regulatory submissions. Since then, I have spent most of my career in general management.

11. I have served as the Chief Executive Officer of six medical device companies in four countries, and as a member of the Board (including Chairman of the Board) of thirteen companies. In my career, I have brought over a dozen products from concept to market release, through research and development, manufacturing introduction, and clinical trials and regulatory approval in the United States as well as other markets worldwide, followed by development of a sales force and sales growth. I am keenly aware of the work and investment required to create a successful company in the medical device industry.

12. I have worked on the clinical trials and regulatory submissions for multiple products, starting in 1984 when I was the primary author of the Pre-Market Approval Application (PMAA) for Cochlear (a multi-channel implantable hearing prosthesis). I have developed clinical trial protocols, analyzed clinical data, and written or co-authored applications to the FDA for 510(k) clearance and Pre-Market Approval (PMA) in multiple fields.

13. I have worked in several clinical specialties, including cardiology and cardiac surgery, clinical pathology, medical software, otolaryngology, ophthalmology, intensive care, orthopedics, pain management, gastroenterology, medical imaging, and clinical education and training.

14. I have direct experience in the subject matter of the 879 Patent. From 2005, I worked for Ventracor, a company developing, manufacturing and marketing the VentrAssist Left Ventricular Assist Device (LVAD), and served as CEO from 2006 until 2009. The intellectual property assets of Ventracor were acquired by Thoratec in 2009, which was subsequently acquired by St. Jude Medical in 2015, which was subsequently acquired by Abbott in 2017. Those intellectual property assets are therefore now owned by the Petitioner. I have no financial interest in, and I do not receive a royalty or any other payment for any of those assets.

15. Earlier in my career, I was head of the Biomedical Engineering Department at a large metropolitan teaching hospital. Part of my responsibilities included support of all medical equipment in the hospital, including devices used in intensive care such as an Intra-Aortic Balloon Pump (IABP), part of the subject matter of the 879 Patent.

16. I currently work as a consultant, board member, and expert through my consulting business, Biomedical Business Resources, LLC. I am the Chairman of

the Board of two companies and a member of the Board of Directors of one other company.

III. LEVEL OF ORDINARY SKILL IN THE ART

17. I understand there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including (1) the levels of education and experience of persons working in the field at the time of the invention; (2) the sophistication of the technology; (3) the types of problems encountered in the field; and (4) the prior art solutions to those problems.

18. A Person of Ordinary Skill in The Art ("POSITA") as of the February 27, 2007 priority date of the 879 Patent would have: a) at least a bachelor's degree in engineering; b) knowledge and experience in the anatomy and physiology of the human circulatory system; and c) at least five years of experience in design and development of implantable medical devices.

19. For purposes of this Declaration, in general, and unless otherwise noted, my statements and opinions, such as those regarding my own experience and what a POSITA would have understood or known generally (and specifically related to the references I consulted herein), reflect the knowledge that existed in the relevant field as of the priority date of the 879 Patent.

IV. RELEVANT LEGAL STANDARDS

20. I am not an attorney. In preparing and expressing my opinions and considering the subject matter of the 879 Patent, I am relying on certain basic legal principles that counsel has explained to me.

21. I understand that prior art to the 879 Patent includes patents and printed publications in the relevant art that predate the priority date of the 879 Patent. For purposes of this Declaration, I am applying February 27, 2007, as the priority date of the 879 Patent, but I take no position on that issue.

22. I have been informed by counsel that a claimed invention is invalid if it is "anticipated" by the prior art. I understand that, for a patent claim to be "anticipated" by the prior art, each and every requirement of the claim must be found, expressly or inherently, in a single prior art reference as recited in the claim. I understand that claim limitations that are not expressly described in a prior art reference may still be there if they are "inherent" to the thing or process being described in the prior art.

23. I understand that if a reference incorporates other documents by reference, the incorporating reference and the incorporated reference(s) should be treated as a single prior art reference for purposes of analyzing anticipation.

24. I understand that it is acceptable to consider evidence other than the information in a particular prior art document to determine if a feature is necessarily present in or inherently described by that reference.

25. I have been informed by counsel that a claimed invention is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a POSITA. I have also been informed by counsel that the obviousness analysis considers factual inquiries, including the level of ordinary skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed subject matter.

26. I have been further informed by counsel that there are several recognized rationales for combining references or modifying a reference to show obviousness. These rationales include: (a) combining prior art elements according to known methods to yield predictable results; (b) simple substitution of one known element for another to obtain predictable results; (c) use of a known technique to improve a similar device (method, or product) in the same way; (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (e) choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (f) some teaching,

suggestion, or motivation in the prior art that would have led a POSITA to modify the prior art or to combine prior art teachings to arrive at the claimed invention.

V. OVERVIEW OF THE 879 PATENT

27. The 879 Patent states that it is a continuation of and claims priority to U.S. application Ser. No. 16/282,948, filed on Feb. 22, 2019 (now U.S. Pat. No. 11,123,540), which is a continuation of U.S. application Ser. No. 14/454,965, filed on Aug. 8, 2014 (now U.S. Pat. No. 10,251,984), which is a continuation of and claims priority to U.S. application Ser. No. 13/555,318, filed on Jul. 23, 2012 (now U.S. Pat. No. 8,801,590), which is a divisional of and claims priority to U.S. application Ser. No. 12/449,632, filed on Aug. 18, 2009 (now U.S. Pat. No. 8,255,050), which is the U.S. national phase of International Application PCT/IB2008/000421, filed on Feb. 27, 2008, which designated the U.S. and claims benefit of AT A 306/2007, filed Feb. 27, 2007. Ex.1001, 1:7-17.

28. I have been asked to assume that **February 27, 2007** is the effective filing date, but I take no position on that issue.

29. I have reviewed the file history of the 879 Patent, including that of the aforementioned U.S. and International Patents, to which the 879 Patent claims priority, and note that none of the activity there is pertinent to my analysis.

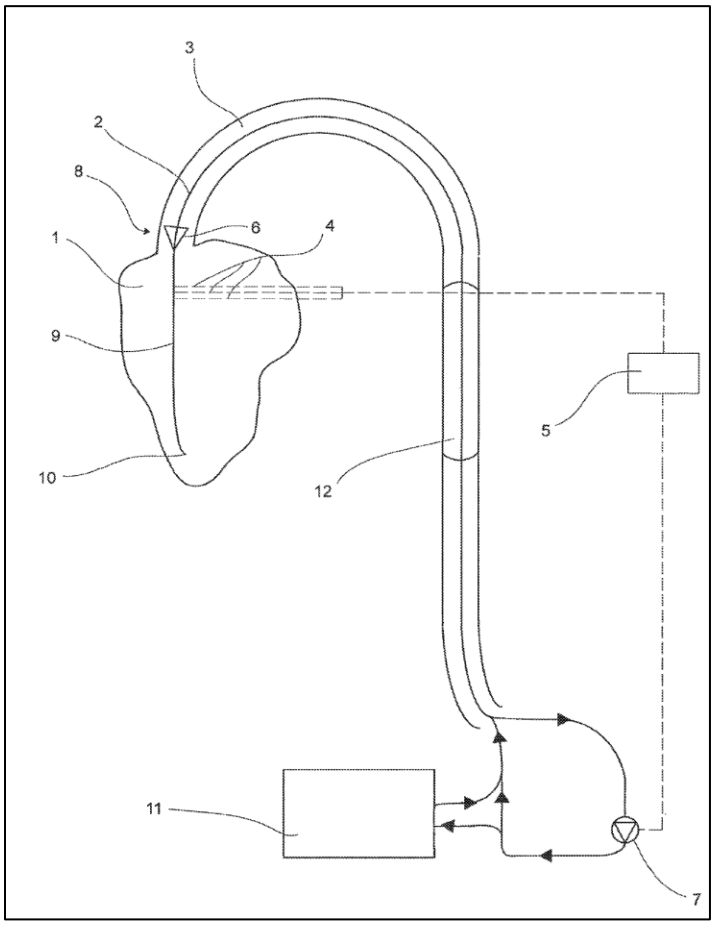
A. The 879 Patent's specification is generally directed to a catheter device.

30. The 879 Patent's specification is generally directed to a catheter device (and method of using the device) for assisting blood flow in the heart, which purports to improve upon conventional heart-lung machines that used external pumps to maintain a forced circulation of blood without entering the heart. Ex.1001, 1:32-40 (describing "the catheter according to the invention"); Ex.1001, 2:1-12, 2:19-22. The 879 Patent seeks to improve on a known device in which "fluid is removed from the blood vessels via an external pump and returned into blood vessels via a return catheter." Ex.1001, 1:62-2:1. The improvement is "that an external pump can be dispensed with and, at the same time, the desired pressure increase can be brought into effect systemically at particular locations." Ex.1001, 2:19-22.

31. According to the specification, the invention sought to improve the fluid flow provided by the pump in a way in which the mechanical stress on the blood is kept low, while circulation is ensured at desired locations. Ex.1001, 2:23-28. The 879 Patent purports to solve that problem with a pump "constructed as a rotary pump at the distal end of a catheter, in which the rotor lying distally on the outside is coupled via a magneto coupling with a drive wheel which is arranged

inside the catheter and is formed as a paddle wheel operated hydraulically or pneumatically." Ex.1001, 2:31-36.

32. Figure 1 of the 879 Patent shows the overall configuration and is reproduced below:



Ex.1001, Fig. 1.

33. As shown in Figure 1 of the 879 Patent, "heart ventricle catheter 2" is introduced to a "heart 1" for example "via the femoral artery and the aortic arch 3 into the heart chamber and carries a series of sensors 4 via which the volume can be

determined. The measurement signals are passed to a control arrangement 5." Ex.1001, 4:6-10. The heart ventricle catheter 2 is formed with "several lumina" which supply fluid to drive a rotor 6 "arranged at the distal end, which forms the pump to assist the blood circulation." Ex.1001, 4:10-16. A "fluid pump 7" is used as the driving medium for the rotor and is regulated "as a function of the control signals generated in the control arrangement 5." The catheter 2 has "at its distal end a tube 9 leading to the suction end 10." Ex.1001, 4:23-24.

34. The 879 Patent does not specify what the "driving fluid" is but a POSITA would understand it to refer to either a liquid or gas as the described paddle wheel "is operated hydraulically or pneumatically." Ex.1001, 2:35-36. A POSITA would understand that "pneumatic" drive would be limited to a small number of gases (e.g., helium) because of the risk of gas embolism in the case of rupture or breakage of any element of the system. A POSITA would also understand that "hydraulic" drive is limited to a small number of fluids, of which isotonic saline is typically the most appropriate. Blood cannot be used as a driving fluid because it would coagulate in the hydraulic reservoir.

35. Figure 2 depicts an embodiment of the catheter 2 described in the 879 Patent, and is reproduced below:

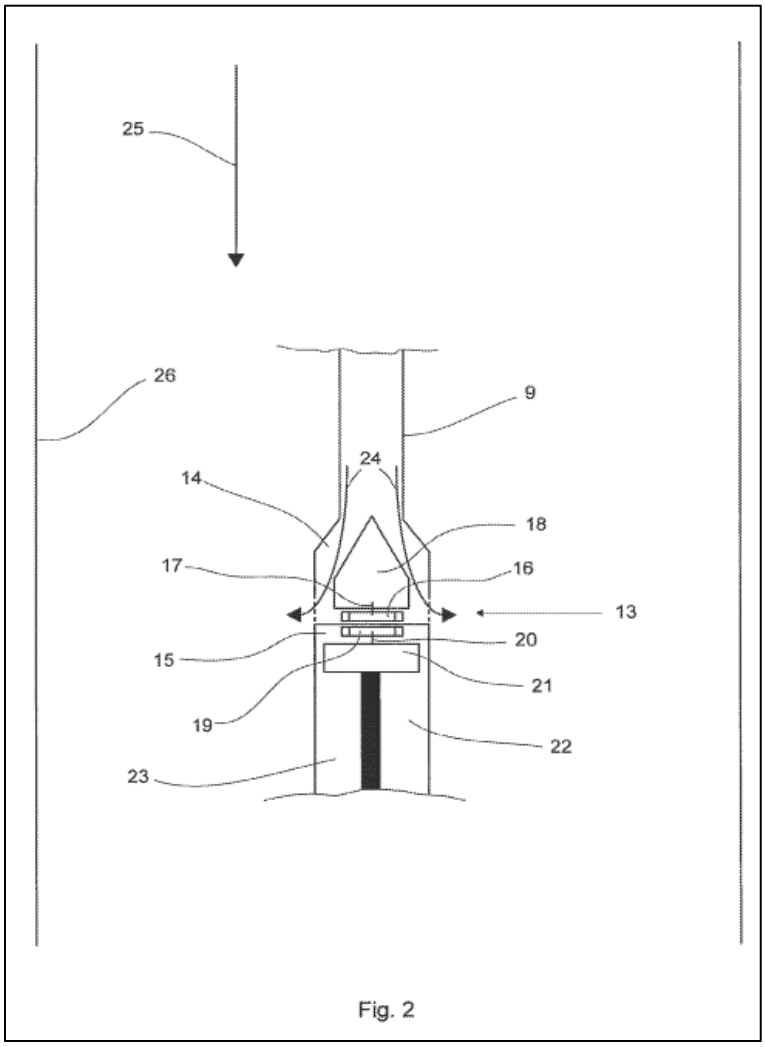


Fig. 2

Ex.1001, Fig. 2.

36. Figure 2 illustrates that the end side 13 of the catheter "has two pocketshaped chambers 14 and 15, in which bar magnets are respectively arranged." Ex.1001, 4:44-47. In the chamber 14, the "bar magnet 16" is connected at the "distal end outwards via a shaft 17 with a rotor 18." Ex.1001, 4:47-48. In chamber 15, "bar magnet 19" lies on the inside "connected via a shaft 20 with a drive wheel 21."

Ex.1001, 4:49-50. The drive wheel 21 is formed as a "paddle wheel 21" that is acted upon with fluid via lumen 22, which flows off again via lumen 23. Ex.1001, 4:50-53. Lumen 22 and lumen 23 of the catheter, each located in chamber 15, are completely sealed from chamber 14. Ex.1001, Fig. 2, 4:58-59. The rotation of the paddle wheel 21 is regulated by "corresponding control of the fluid pressure in the lumen 22 serving for the supply of fluid, in which the magnet 19, which is connected so as to be locked against relative rotation with the paddle wheel 21, is set into corresponding rotation." Ex.1001, 4:53-58. As a result of the rotation of magnet 19 in chamber 15, magnet 16 in chamber 14 is caused to rotate accordingly and "drives the rotor 18 via the shaft 17, whereby a flow is formed in the region of the tube 9." Ex.1001, 4:58-64.

B. The 879 Patent's specification describes that its rotor design was already disclosed in the prior art.

37. The 879 Patent's specification describes:

> The rotor itself can follow design principles such as described for example in WO 01/70300 A1. The rotary pump shown and described there for conveying blood and other highly sensitive fluids is formed as an external electromagnetically driven pump which is not directly suitable for incorporation into a catheter. The known design namely assumes that centrifugal flow components

> and flow components directed against a housing are present, in which the flow components directed against the housing serve primarily for the non-contact mounting and stabilizing of the rotor in the housing.

Ex.1001, 3:13-24. This statement—that "the known design" of the rotor "can follow design principles" from the prior art—supports my views outlined in the grounds below that there was nothing novel disclosed in the 879 Patent's specification about the design of the rotor.

38. As I explain below in connection with "Schima" (Ex.1005) which is a related publication to WO 01/70300 Al, I understand that in parallel litigation, the Patent Owner argues that WO 01/70300 Al would have enabled a POSITA to practice the full scope of the claimed invention without undue experimentation. Ex.1009, Miracor's Supp. Initial Response to Invalidity Contentions at 7 ("Defendants recite…that the specification does not enable a POSITA to practice the full scope of the claimed invention without undue experimentation. However, this cited excerpt refers to known design principles for a rotor as described in WO 01/70300 Al.") (internal quotation marks omitted). This statement in the specification and concession from Patent Owner confirms my opinion that the 879 Patent's specification does not disclose anything novel about rotor designs for

devices to assist the performance of a heart, because such designs were already disclosed, *e.g.*, by Schima.

39. Further, as discussed below, the use of magnetic components in a heart assist pump device to drive the flow of blood while reducing mechanical stress on such components was well-known in the art at the time of the purported invention.

VI. BACKGROUND OF THE TECHNOLOGY ACCUSED OF INFRINGEMENT IN THE PARALLEL LITIGATION

40. As I described above, the 879 Patent's specification is directed to a catheter device. In the parallel litigation, however, I understand that the Patent Owner has accused of infringement Abbott's HeartMate 3 LVAD, which is not a catheter device. Thus, I provide below a summary of the development of LVAD devices, such as the HeartMate 3 accused of infringement, and the types of bearings that can be used in an LVAD.

A. Historical development of LVAD Devices.

41. It was widely recognized prior to February 2007 that "[c]ongestive heart failure (CHF) [was] an important and increasing cause of cardiovascular disability and premature death in the United States." Ex. 1010 (Frazier 2005) at 224. For example, as of 2001, "[e]ach year in the United States, 400,000 people [were] diagnosed with congestive heart failure (CHF)." Ex. 1007 (Bourque-2001) at 401.

Driven by a growing need for heart failure treatment options to address these problems and the limited availability of donor heart transplants, researchers began designing and developing left ventricular assist devices (LVADs) in the 1990s, which assist in circulating blood from the left ventricle of a patient's heart to the aorta. Ex.1007 (Bourque-2001) at 401; Ex.1010 (Frazier 2005) at 224.

42. The terms Left Ventricular Assist System (LVAS) and Left Ventricular Assist Device (LVAD) are synonymous. An LVAS consists of several main elements: a) an inflow cannula (tube, or conduit) placed with its opening in the left ventricle of the heart; b) the pump itself; c) an outflow cannula from the pump to the circulatory system, typically to the aortic root; d) a system to provide power and control to the pump; and e) a power source (typically a body worn battery pack).

1. Disadvantages of early-generation LVADs included mechanical bearings and increased risk of infection associated with their large size.

43. First-generation LVADs were pulsatile devices, such as the HeartMate XVE, and while effective, "contain[ed] mechanical parts that wear, such as ball bearings, flexible diaphragms or sacs, and valves." Ex.1007 (Bourque-2001) at 401. Further, "[b]iological fluids like blood get destroyed in the bearing and tend to clot." Ex.1011 (Schob 2002) at 1.

44. A disadvantage of these first-generation devices is that because of their larger size they were "implanted into a preperitoneal pocket" in the patient:

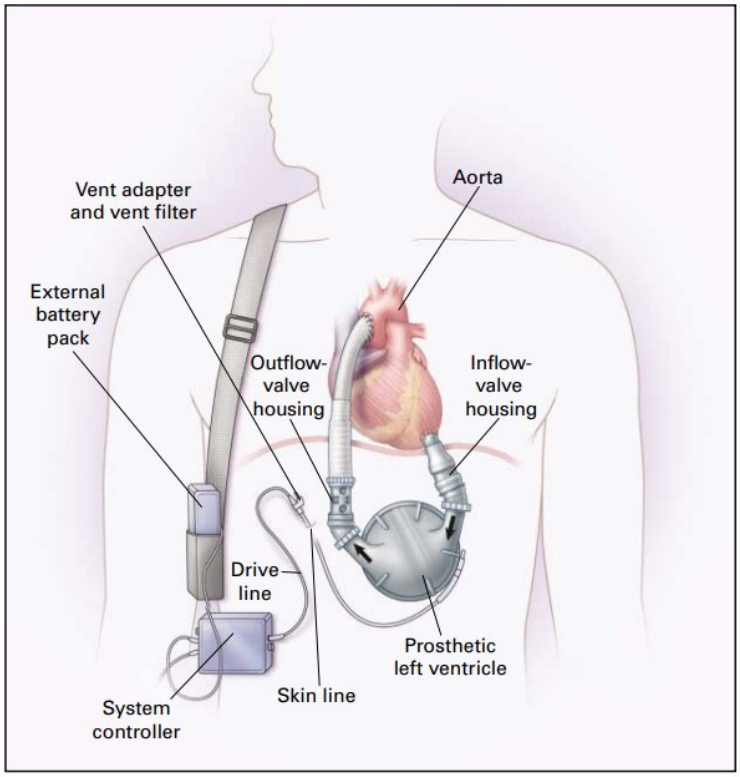


Figure 1. Components of the Left Ventricular Assist Device.
The inflow cannula is inserted into the apex of the left ventricle, and the outflow cannula is anastomosed to the ascending aorta. Blood returns from the lungs to the left side of the heart and exits through the left ventricular apex and across an inflow valve into the prosthetic pumping chamber. Blood is then actively pumped through an outflow valve into the ascending aorta. The pumping chamber is placed within the abdominal wall or peritoneal cavity. A percutaneous drive line carries the electrical cable and air vent to the battery packs (only the pack on the right side is shown) and electronic controls, which are worn on a shoulder holster and belt, respectively.

Ex.1012 (Rose 2001), Fig. 1, 1436.

45. The larger size of these devices required "surgical dissection" to place the device in a "pump pocket," which was associated with increased risk of infection. Ex.1014 (Schulman 2007) at 842. One clinical study reported that "[w]ithin three months after implantation, the probability of infection of the left ventricular assist

device was 28 percent" and that the infection of the pocket was the most commonly reported type of infection. Ex.1012, Table 5. The "morbidity and mortality associated with the…infection…were major factors in the two-year survival rate of only 23 percent." Ex.1012 at 1441. The "increased rates of adverse events" signaled a "need for further improvements in…the design of the device." Ex.1012 at 1442.

46. Recognizing these problems, by the early 2000s researchers in the industry "ha[d] focused their efforts on continuous flow-type pumps (*e.g.*, HeartMate II, Thoratec Corp.) for the second generation of LVADs to exploit inherently fewer mechanical parts and many additional benefits such as smaller size and lower cost." Ex.1007 (Bourque-2001) at 401. Unlike the first-generation pulsatile devices, the later generation devices were "continuous flow-type" pumps, which are rotating pumps (axial flow or centrifugal flow), and therefore their implementation needed to address the engineering problems created by the use of bearings and the supply of torque. Ex.1007 at 401. That is, the so-called "second-generation" pumps were rotating pumps with mechanical bearings (albeit, fewer mechanical bearings) that supported the rotating part of the pump. Ex.1007 at 401.

47. Like the first-generation devices, the second-generation devices (e.g., the HeartMate II) were also typically implanted into a preperitoneal pocket in the patient.

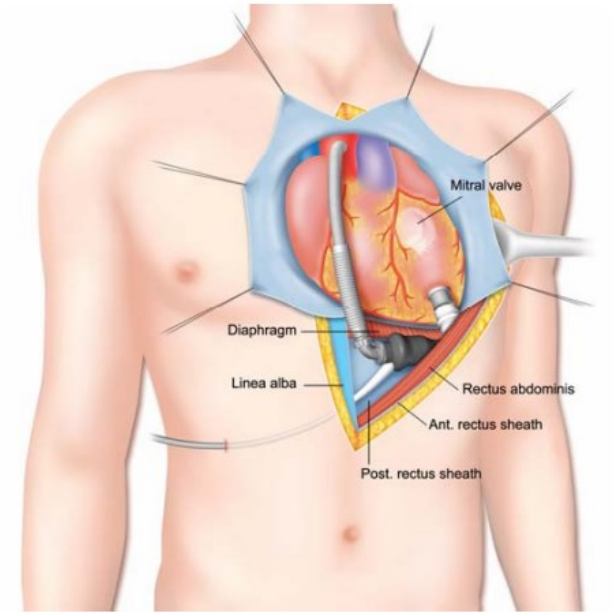


Figure 3: Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).

Ex.1013 (HeartMate® II LVAS: Patient Management Guidelines) at 25. For instance, "[a]s with preperitoneal placement of the HeartMate XVE device, preperitoneal placement of the HeartMate II requires the dissection of a pocket." Ex.1013 at 25.

48. Because the second-generation devices were "smaller" "and d[id] not require a great deal of surgical dissection," they had a "low[er] infection rate" compared to the earlier devices. Ex.1014 at 842. It was well understood that the "[d]ifferences in infection rates between [first-generation] pulsatile and [second-

generation] continuous flow LVADs [were] a reflection of differences in device design." Ex.1014 at 842.

49. Although better than the first-generation devices, the pump pocket dissection was still considered a disadvantage. For example, it was recognized that although "the pocket dissection is smaller with the HeartMate II [second-generation device],…potentially introducing less risk of infection" than the larger pockets required for the first-generation devices, the "preperitoneal pocket position" was still considered a "disadvantage[]" due to the "increased risk of infection" and "[p]otential for prolonged pocket drainage." Ex.1013 at 25-26.

2. Third-generation LVADs aimed to eliminate mechanical bearings.

50. The third-generation of LVADs sought "to feature the advantageous qualities of such second generation pumps" "such as smaller size" "while carrying expected device life one step further [by eliminating] mechanical bearings." Ex.1007 at 401.

51. Eliminating mechanical bearings was achieved by "magnetic levitation technology." The aim to eliminate mechanical bearings altogether in these so-called "third-generation pumps" began in the late 1990s and early 2000s. Ex.1007 at 401; Ex.1008 (Wampler-169), [0003]-[0005]. It was recognized that this could be

accomplished by the use of centrifugal pumps with "magnetic levitation technology." Ex.1007 at 401; Ex.1008, [0003]-[0005]; Ex.1006 at 3; Ex.1011 (Schob 2002) at 34. "Major problem[s]" existed with previous centrifugal pumps delivering sterile or delicate fluids (e.g., blood), such as "mechanical seal failures" and "failure of bearings, couplings and other associated items" that result in costly maintenance and shorten the operable lifespan of the pump. Ex.1011 at 1. It was widely recognized, however, that "[a]ll these problems [could] be addressed by magnetic levitation technology." Ex.1011 at 1. For example, the HeartMate III as described in Bourque-2001 features "a centrifugal pump with a magnetically levitated rotor" and "[t]he rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely." Ex.1007 at 401.

52. Smaller size was also achieved. For example, the HVAD, another third-generation type device, reported that its "small size" allowed for an "optimized fit" because "[t]he pump ha[d] a short integrated inflow cannula and an axial height less than one inch, thus, [t]he size of the device coupled with the perpendicular relationship of outflow to the inflow allow[ed] for intrapericardial pump placement and fast implantation." Ex.1015 (LaRose).

a. Two types of drives existed for third-generation devices.

53. The impeller (or rotor) of third-generation pumps could be driven in at least two different ways—by "magnetic coupling" or by "magnetic levitation" technology. Ex.1011 (Schob 2002) at 1. An "impeller" is a commonly used type of rotor that provides the pumping action when used in reference to a centrifugal pump, such as the "centrifugal pump" described for example in Bourque-2001. Ex.1007 at Abstract.

54. "In the magnetic coupling pump [a] rotating [magnetic] field is generated by rotating magnets" so that "torque is transmitted through the canning onto the rotor by means of [the] rotating magnetic field." Ex.1011 at 1. Said another way, an "impeller is fixed on one side of [a] rotor; on the other side…rotor magnets are mounted. Opposite these rotor magnets, a driving magnet is fastened to the motor axis. Thereafter, the motor drives the rotor via **magnetic coupling**." Ex.1016 (Qian) at 36. Figure 2 of "Akamatsu-1999" (Ex.1006) illustrates a schematic cross section of a centrifugal pump using magnetic coupling:

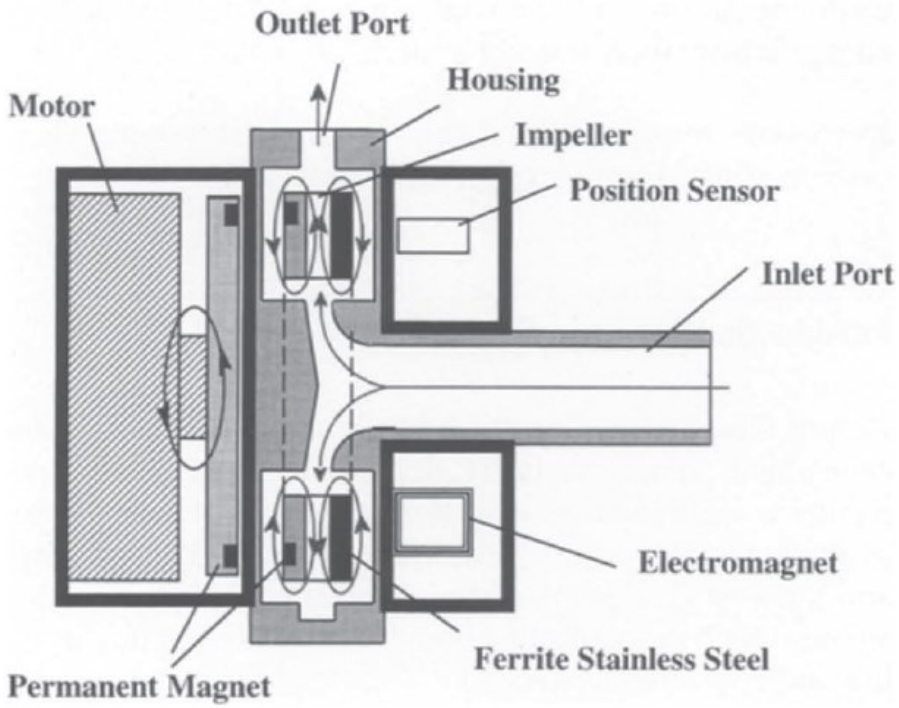


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2.

55. Put simply, "magnetic coupling" uses a motor to rotate a permanent magnet, which in turn rotates another permanent magnet on the impeller.

56. "Magnetic levitation" design, however, uses a stationary electric motor to produce a rotating magnetic field (as opposed to rotating a permanent magnetic to produce a rotating magnetic field). These designs use "a single motor/bearing unit that provides drive and magnetic bearing functions at one and the same time." Ex.1011 at 1-2; Ex.1011, Figure 1 ("Schematic showing the basic principles" of the

magnetic levitation design). Figure 4 of Bourque-2001 (Ex.1007) illustrates a schematic cross section of a centrifugal pump using magnetic levitation drive.

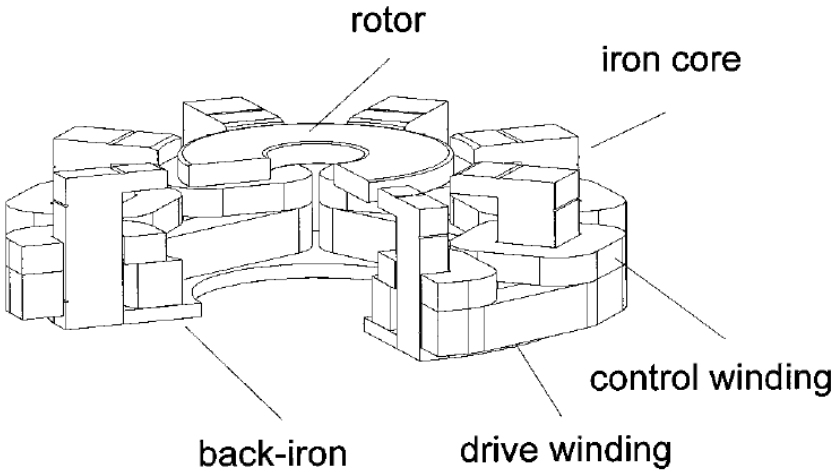


Figure 4. HeartMate III motor, drive, and levitation (control) in a single magnetic structure.

Ex.1007 at 402 (Fig. 4).

b. Two types of bearings existed for third generation devices.

57. To replace the mechanical bearings of past generation devices, third-generation LVADs devices generally used a hydrodynamic bearing or a magnetic bearing (or a hybrid of the two) to suspend the impeller.

58. Mechanical bearings rely on physical contact between components to stabilize a rotor in the housing during rotation.

59. A "hydrodynamic bearing" (also known as a fluid bearing), which was a well-known and commonly used term in the art when the 879 Patent was filed,

uses motion to create a pressure that forces a rotating component, such as a rotor, apart from a surface by a fluid flowing between the rotating component and the surface. Ex.1008 (Wampler-169), [0092]. The stationary surface (here, the pump housing) and rotating surface (here, the rotor) are separated by a thin film of fluid (here, blood) when the rotor is in rotation. The film pressure that separates the surfaces is created by the relative motion (rotation) of the surfaces as the lubricant is pulled into a converging geometry between the surfaces. As Qian describes it, there is a "'taking off' of the rotor [that] is generated by a hydraulic force (a reacting force of the flow), which acts on the impeller because the impeller propels the flow." Ex.1016 at 37, abstract ("the axial levitation is produced by hydraulic force").

60. Magnetic (or "electromagnetic") bearings, such as described in Bourque-2001 for the HeartMate III device (*supra* §IX.B), use electromagnets to levitate a rotor without physical contact:

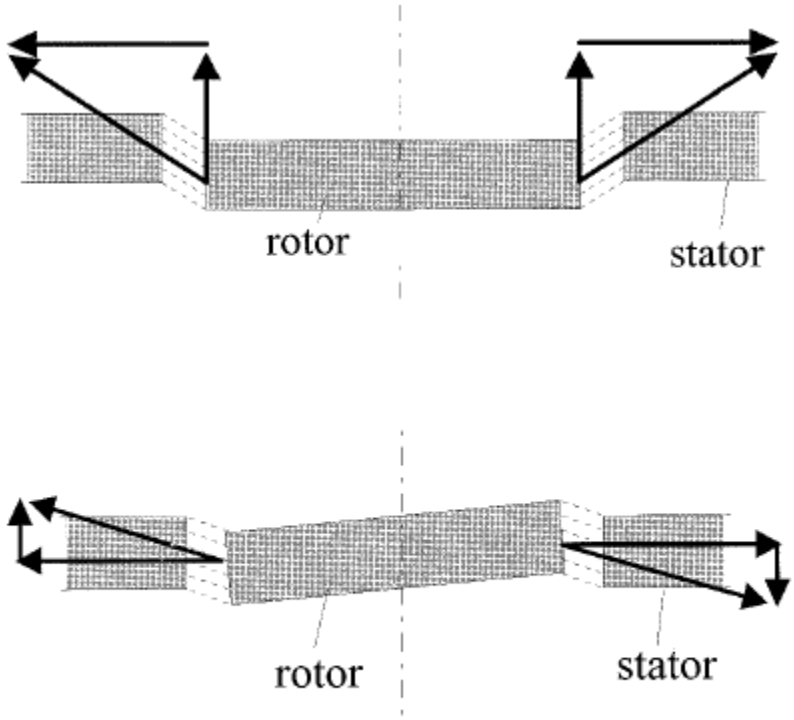


Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007 at 404 (Fig. 5); Ex.1016 (Qian) at 36 ("Some investigators have developed magnetic bearings with electromagnets [citing *Heartmate III: bearingless motor design for a maglev centrifugal LVAD*], achieving zero friction and no contact between rotor and stator. This results in no mechanical wear.").

c. The smaller third-generation devices could be placed at the cardiac apex within the pericardial space.

61. The smaller size of third-generation devices enabled these devices to be placed at the cardiac apex within the pericardial space instead of dissecting a

preperitoneal pocket, which was associated with infection in the earlier generation devices.

62. For example, Wampler-169 reported that "[g]ood anatomic compatibility is possible since the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm:":

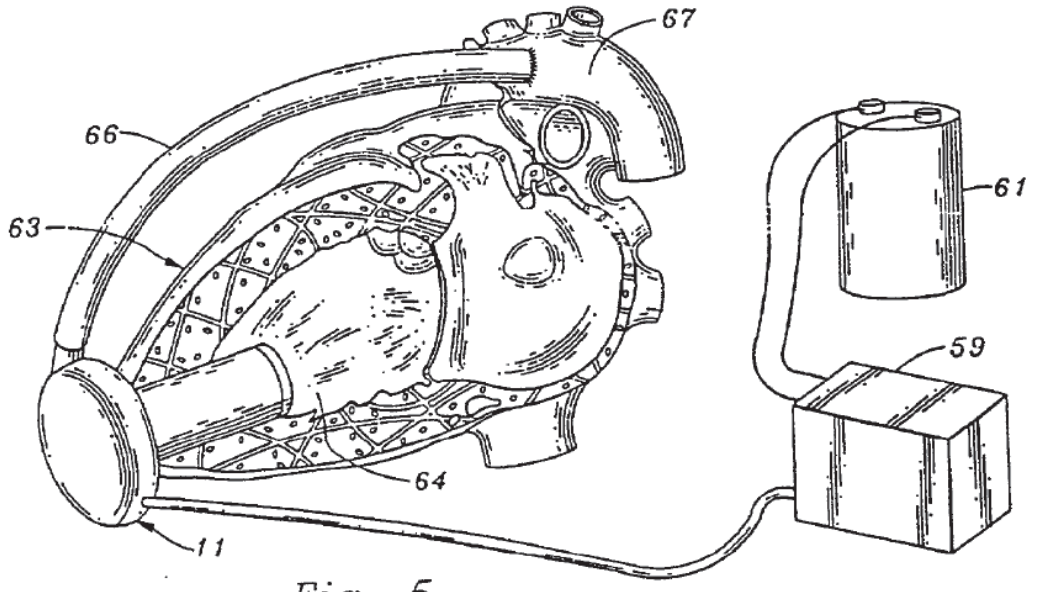


Fig. 5

Ex.1008, [0076], Fig. 5. When placed at the cardiac apex, an inlet tube and is placed into the apex of the left ventricle. Ex.1008, [0075]-[0076].

63. As another similar example, the HVAD reported that its "small size" allowed for an "optimized fit" because "[t]he pump ha[d] a short integrated inflow cannula and an axial height less than one inch," thus, "[t]he size of the device coupled with the perpendicular relationship of outflow to the inflow allow[ed] for

intrapericardial pump placement and fast implantation." Ex.1015 (LaRose). As yet another example, one of "[t]he advantages of the [Akamatsu-1999] rotary blood pump [is] its compactness" that allows it to be implanted in patients at the cardiac apex "even those of small body size." Ex.1006 at 3.

64. The Bourque-2001 HeartMate III was "implanted with routine surgical techniques via left ventricular apical cannulation and anastomosis to the descending aorta" of the test models and could be placed at the preperitoneal pocket as shown:

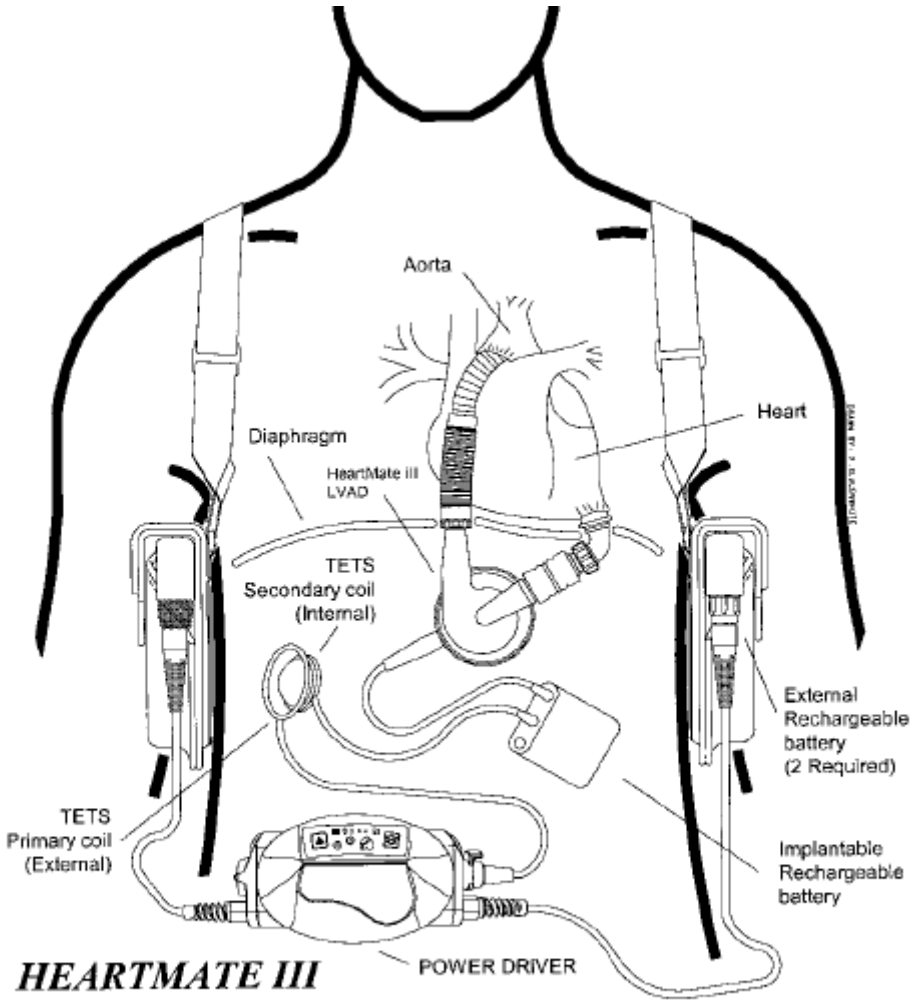


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3, 403. However, the Bourque-2001 HeartMate III was already planned for "enhancements [to] continue the progression of this LVAD's development as a compact" device, which would enable its placement at the cardiac apex as discussed below. Ex.1007, at 405.

65. As will be discussed further with respect to the Grounds below, the concept and design of the HeartMate III (now referred to as the "HeartMate 3") accused of infringement in the parallel litigation, and specifically, the use of magnetically driven rotors for use in LVAD heart pumps for the treatment of heart failure, was already well-known in the prior art. Section IX.B.

VII. CLAIM CONSTRUCTION

66. It is my understanding that to properly evaluate the 879 Patent, the terms of the claims must first be interpreted. It is my understanding that for the purposes of this *inter partes* review, the claims are to be construed under the so-called *Phillips* standard, under which claim terms are given their ordinary and customary meaning as would have been understood by a POSITA in light of the specification and prosecution history, unless the inventor has set forth a special meaning for a term. I have also been informed that claim terms only need to be construed to the extent necessary to resolve the unpatentability inquiry.

A. Plain and Ordinary Meaning of Certain Claim Terms

67. I have reviewed the Patent Owner's complaint served in the parallel litigation, and the Patent Owner's apparent construction of two claim terms significantly differs from those terms' plain and ordinary meanings. The challenged

claims, however, are unpatentable under any interpretation, thus, in my opinion, the claim terms need not be expressly construed.

1. "magneto coupling" (Claim 11)

68. In my opinion, a POSITA as of February 27, 2007, would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating permanent magnetic component to another rotating permanent magnetic component via a magnetic field." As I discussed above, "magneto coupling" drive differs from, for example, "magnetic levitation" drive.

69. As a preliminary matter, I note that a POSITA would understand that the term "magnet**o** coupling," when read in view of the 879 Patent's specification, refers to the concept of "magnet**ic** coupling" between two permanent magnets, as described in further detail in the prior art below. In my experience, the term "magnet**o** coupling" is not generally used in the field of rotary pump devices. A "magneto" is a traditional type of electrical generator that uses permanent magnets to produce pulses of electricity, and which was a well-known device in other fields of art as of February 2007.[11] For example, from my own experience, a magneto is a

[11] *See, e.g.*, Ex.1020, Bottone et al., *Magnetos for automobilists, how made and how used*, Crosby Lockwood and Son, Ch. 1 (1907) (accessed at https://archive.org/details/magnetosforauto00bottgoog/page/n6/mode/2up).

technology over 100 years old used in ignition systems, such as reciprocating aircraft engines to provide the high voltage to the spark plugs for ignition.[12] The 879 Patent's specification includes no discussion of a "magneto" device, nor is the "magneto coupling" recited in the claims directed to the functionality of a traditional "magneto." The specification refers instead to a "bar magnet" driven in rotation via a coupling with a rotating second "bar magnet," which corresponds to the type "magnet**ic** coupling" between permanent magnets in rotary pump systems that was known in the art. Ex.1001, 4:44-58.[13] Thus, for the purposes of my analysis, I interpret the plain and ordinary meaning of "magneto coupling," as used in the 879 Patent's specification to refer to the same concept as "magnetic coupling." The term does not refer to "electromagnetic coupling" which I interpret as a rotating magnetic

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[12] *See, e.g.*, Ex.1021, "Ignition magneto," accessed at https://en.wikipedia.org/wiki/Ignition_magneto (last accessed October 28, 2024).

[13] I note that the word "magneto" is also used in the specification in the context that the "lumina for the driving fluid" have "controllable closure members via which driving fluid can arrive in the balloon or out of the balloon into the respective lumina, in which preferably the closure members are formed as ***magneto valves***." Ex.1001, 3:36-43. As with the term "magneto coupling," the term "magneto valve" is also not generally used in the field of rotary pump devices. However, "magnet**ic** valves" were well known components in mechanical systems that use magnetism to move a plunger within the valve to regulate flow. Thus, this additional usage of "magneto" further supports my understanding that the specification refers to "magneto coupling" as the same concept as "magnetic coupling."

field produced by a stationary electromagnet coupled to one or more permanent magnets in the rotated device.

70. Accordingly, "magneto coupling" (i.e., magnet**ic** coupling) was a commonly used and understood term in the art as of the priority date of the 879 Patent, and it was understood to refer to exactly this type of non-contact transfer of energy used in a mechanical system to transfer torque from one rotating permanent magnet to another rotating permanent magnet via a magnetic field.

a. The specification and prior art consistently distinguish magnetic coupling from other types of drive.

71. As noted, my understanding is also consistent with the use of the term in the 879 Patent's specification. For example, the 879 Patent explicitly identifies "magneto coupling" as referring to a transfer of torque between two magnetic components—a "bar magnet 16" connected "at the distal end outwards via a shaft 17 with a rotor 18" and a "bar magnet 19 lying on the inside…connected via a shaft 20 with a drive wheel 21."[14] Ex.1001, 4:47-50. Specifically, the 879 Patent explains that "the rotor lying distally on the outside is coupled via a magneto coupling with a drive wheel." Ex.1001, 2:28-38. It is the *rotation* of the first magnetic component

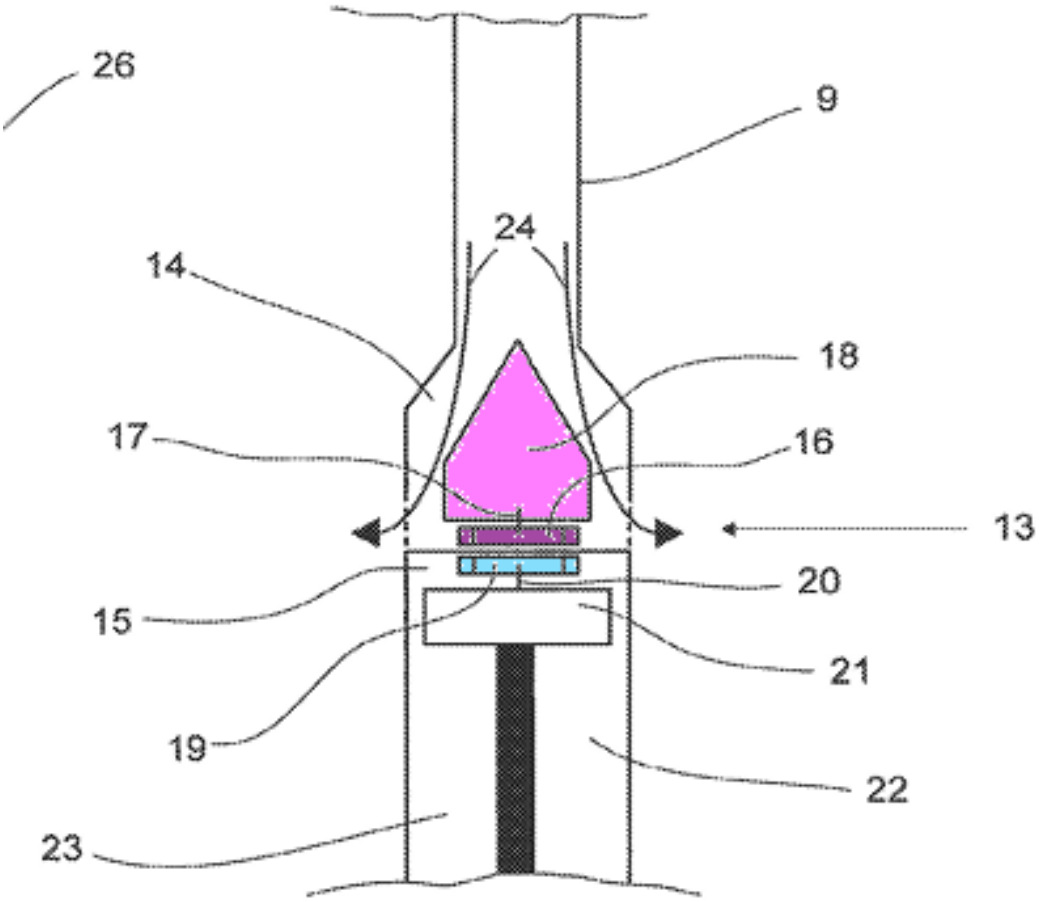
[14] I note that a "bar" magnet was a commonly used type of permanent magnet as of the February 2007 priority date.

(bar magnet 19) that causes the rotation of the rotor by the magneto coupling with the second magnetic component (bar magnet 16):

> The rotation of the paddle wheel 21 is regulated here accordingly by corresponding control of the fluid pressure in the lumen 22 serving for the supply of fluid, in which the [rotor] magnet 19, which is connected so as to be locked against relative rotation with the paddle wheel 21, is set into corresponding rotation.

Ex.1001, 4:53-58.

72. Figure 2 (annotated and enlarged for illustrative purposes) of the 879 Patent, shows the "bar magnet 19" (**light blue**), which when locked in relative rotation with the paddle wheel 21 via shaft 20, transfers torque to "bar magnet 16" (**purple**), which drives rotation of the "rotor 18" (**pink**):



Ex.1001, Fig. 2 (annotated).

73. This plain and ordinary meaning is also consistent with the use of the term in the art as of February 27, 2007. Further, the art distinguishes rotation by magneto coupling from, for example, rotation caused by an electromagnetic field induced by an electric current (e.g., drive by magnetic levitation).

74. For example, Schob 2002 (Ex.1011) describes and distinguishes "magnetic coupling" pumps from pumps that are driven by "magnetic levitation."

Schob 2002 states that "[i]n the magnetic coupling pump [a] rotating [magnetic] field is generated by rotating magnets" so that "torque is transmitted through the canning onto the rotor by means of [the] rotating magnetic field." Ex.1011 at 1. "Magnetic levitation" design, however, has a single motor/bearing unit that provides drive and magnetic bearing functions at one and the same time." Ex.1011 at 1-2.

75. Qian (Ex.1016) provides similar descriptions, stating that "magnetic coupling" refers to a "motor [that] drives the rotor via magnetic coupling" by "using only permanent magnets." Ex.1016 at 37. Qian further describes that "[t]he magnetic coupling transmits the rotating torque from the motor to the pump" where "driving magnets and…driven magnets attract each other" so "that the two magnet assemblages will stay concentric with each other." Ex.1016 at 37; *see also* Ex.1016 at abstract ("The impeller is fixed on one side of the rotor; on the other side the rotor magnets are mounted. Opposite these rotor magnets, a driving magnet is fastened to the motor axis. Thereafter, the motor drives the rotor via **magnetic coupling.**").

76. Qian also distinguishes magnetic coupling devices from devices like the Heartmate III, which use magnetic levitation for drive. Ex.1016 at 36 ("Some investigators have developed magnetic bearings with electromagnets [citing *Heartmate III: bearingless motor design for a maglev centrifugal LVAD*]….the authors have developed a levitated impeller pump using only permanent magnets.").

The fact that Qian distinguishes "magnetic coupling" using permanent magnets from the type of drive used by the Heartmate III, which uses magnetic levitation by a rotating electromagnetic field, supports my opinion that the plain and ordinary meaning of "magneto coupling" refers to a transfer of torque from one rotating permanent magnet to another rotating permanent magnet.

77. Similarly, Masuzawa (Ex.1022) describes that "a magnetic coupling mechanism to rotate [a] levitated rotor" includes "[a] motor with bearings…used to rotate permanent magnets that transfer torque to the rotor." Ex.1022 at 631. Further, Masuzawa distinguishes magnetic coupling (i.e., the mechanism used in the DuraHeart developed by Terumo) from the use of an electromagnet (i.e., the mechanism used in the HeartMate III developed by Thoratec):

> Magnetic suspension techniques have been used to eliminate the mechanical parts of centrifugal blood pumps (1–6). In particular, a group at Kyoto University introduced an axial-type magnetically suspended centrifugal pump as a ventricular assist device—the DuraHeart, currently developed by Terumo Corp.—and demonstrated survival of over 1 year in animal experiments. However, **that device uses a magnetic coupling mechanism** to rotate the levitated rotor. A motor with bearings, which limits the lifetime of the device, is used **to rotate permanent magnets that transfer torque to the rotor**. The HeartMate III developed by Thoratec Corp. uses a radially suspended self-bearing motor whose smaller diameter inner rotor helps to miniaturize the pump.

Ex.1022 at 631. The fact that Masuzawa describes magnetic coupling as a mechanism that uses rotating permanent magnets to transfer torque to the rotor, and the fact that Masuzawa distinguishes magnetic coupling from the magnetic levitation drive used in the HeartMate III device (which uses electromagnets) support my opinion on this term's plain and ordinary meaning.

78. Likewise, Aboul-Hosn (U.S. Patent No. 6,152,704; Ex.1023) similarly uses "magnetic coupling" to describe transmitting rotation from one rotating permanent magnet to another. For example, Aboul-Hosn discloses a blood pump where "[t]he pump snaps onto [a] turbine drive unit and a magnetic coupling between the pump and the drive unit is used to transmit the rotation of a turbine shaft to the pump impeller." Ex.1023 at abstract; *see also* Ex.1023 at 2:54-57 ("The disk-shaped member 34 and magnets 36 provide one half of the magnetic coupling for transmitting rotation from the turbine drive unit 12 to the blood pump 10.").

79. Further, Ozaki (U.S. Patent No. 6,589,030; Ex.1024) also uses "magnetic-coupling" to refer to a transfer from one rotating permanent magnet on a motor to another permanent magnet on a rotor:

> Motor unit 140 houses a motor 141 and a rotor 142. Rotor 142 has a surface facing pump unit 130 and having a permanent magnet 143 buried therein opposite to permanent magnet 132 of impeller 131 with a partition 104 posed therebetween. …

> [A] significant attractive force created by permanent magnets 132 and 143 configuring **magnetic-coupling**.

Ex.1024, 1:29-33, 1:60-61.

80. Yet another reference, Araki (European Patent No. 0 834 326 B1; Ex.1025), uses "magnetic-coupling" to refer to a transfer from one rotating permanent magnet on a motor to another permanent magnet on a rotor:

> FIG. 1 schematically shows a construction of the present invention. The casing 3 comprises an inlet 1 at its upper end and an outlet 2 at the bottom thereof. In a plurality of the vanes of the impeller, driven magnets 15 in the magnet casing 14 at the lower portion is **magnetically coupled** with the driving magnet 16 located out of the casing 3. **Driving magnet 16 is rotated by a motor placed out of the pump. As a result, the impeller containing the driven magnet 15 is rotated** so as to supply energy to the blood.

Ex.1025 at [0039].

81. The fact the 879 Patent's specification and these prior art references—Schob 2002, Qian, Masuzawa, Aboul-Hosn, Ozaki, and Araki—all consistently use "magnetic coupling" to refer to a transfer of torque from one rotating permanent magnet to another rotating permanent magnet via a magnetic field supports my opinion as to the plain and ordinary meaning of *magneto coupling*.

82. In addition to the prior art, the 879 Patent itself refers to an international patent application (WO 01/70300 A1, later filed at the USPTO as U.S. Pat. App. No.

10/239,602 and published as U.S. Pat. Pub. No. 2003/0124007A1 to Schima et al. ("Schima," Ex.1005)) which describes a rotor that may either be driven by "a rotating magnetic field" created by a "stator" having "coils," or alternatively, "the drive can also be an electric motor 26 which drives a rotating disk 24 with magnets 10 by means of a shaft 25" (i.e., magnetic coupling). Ex.1005, [0012], [0013]. Schima discloses that the latter embodiment using magnetic coupling "has the advantage that no electrical energy is used to journal the rotor." Ex.1005, [0013].

83. As discussed above, the 879 Patent discloses only this latter method of driving rotation of the rotor, and in fact, the specification explicitly states that an "external electromagnetically driven pump," i.e., drive by magnetic levitation, "is not directly suitable" for the described invention. Ex.1001, 3:13-33 ("The rotor itself can follow design principles such as described for example in WO 01/70300 A1. The rotary pump shown and described there for conveying blood and other highly sensitive fluids is formed as an external electromagnetically driven pump which is **not directly suitable** for incorporation into a catheter."). Thus, the 879 Patent's specification is consistent with Schima in addition to the prior art references described above in that they all consistently distinguish between drive using magnetic coupling and drive using magnetic levitation technology.

b. The Patent Owner conflates magnetic coupling with other types of drive.

84. Patent Owner wrongly conflates magnetic coupling with other types of drive, such as drive by magnetic levitation. I have reviewed the Patent Owner's complaint served in the parallel litigation, and I understand that the Patent Owner accuses the HeartMate 3 Left Ventricular Assist System (LVAS) of infringing Claims 11-12, 14, 16 and 18-19 of the 879 Patent. In doing so, I understand that the Patent Owner's apparent construction of "magneto coupling" is not limited to the term's plain and ordinary meaning (a transfer of torque from one rotating permanent magnet to another rotating permanent magnet), but broadly includes a transfer of torque from one **stationary** magnetic component (i.e., a stator) to another rotating magnetic component using an **electro**magnetic field (i.e., drive by magnetic levitation). Ex.1019, Exhibit 11 of Complaint, 10 (identifying "Motor, Stator, and/or MagLev Flow Technology" as "configured to orient the magnetically driven rotor in its housing via the magneto coupling between the second magnetic device and the first magnetic device" for a similar limitation). That is, Patent Owner interprets "magnetic coupling" to include the application of torque to a rotor generated by an electric motor via an electromagnetic field (i.e., magnetic levitation technology).

85. I disagree with the Patent Owner's broad construction of this term. Both the patent specification and the extrinsic evidence are consistent with my understanding of "magneto coupling" to refer to the narrower definition of a transfer of torque from one rotating permanent magnet to another rotating permanent magnet.

86. To the extent the Patent Owner argues that a "magneto coupling" exists between a stationary magnetic component, such as a motor stator, and a rotating permanent magnet because the stationary magnetic component generates a rotating magnetic field, I disagree. That definition does not comport with the plain and ordinary meaning of "magneto coupling" in view of the 879 Patent specification and the extrinsic evidence, as discussed above.

87. In any event, even if "magneto coupling" is broadly interpreted under the Patent Owner's understanding, my narrower understanding of the plain and ordinary meaning term to refer to "a transfer of torque from one rotating magnetic component to another rotating magnetic component via a magnetic field" would be also included in such a broad interpretation.

2. "both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor" (Claim 11)

88. The plain and ordinary meaning of this claim limitation is that it means a "hydrodynamic bearing." In my opinion, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls **by the blood** in response to rotation of the magnetically driven rotor" to mean that the "in response to rotation of the magnetically driven rotor," "the blood" ***causes*** the "magnetically driven rotor and the first magnetic device" to "remain spaced apart from the one or more walls." A POSITA would therefore understand this limitation to refer to, for example, the "blood" being used as a hydrodynamic bearing to assist in suspending the magnetically driven rotor such that it "remains spaced apart" from the surrounding rotor housing while the magnetically driven rotor is in rotation.

a. The specification and prior art consistently use this claim language to refer to a hydrodynamic bearing.

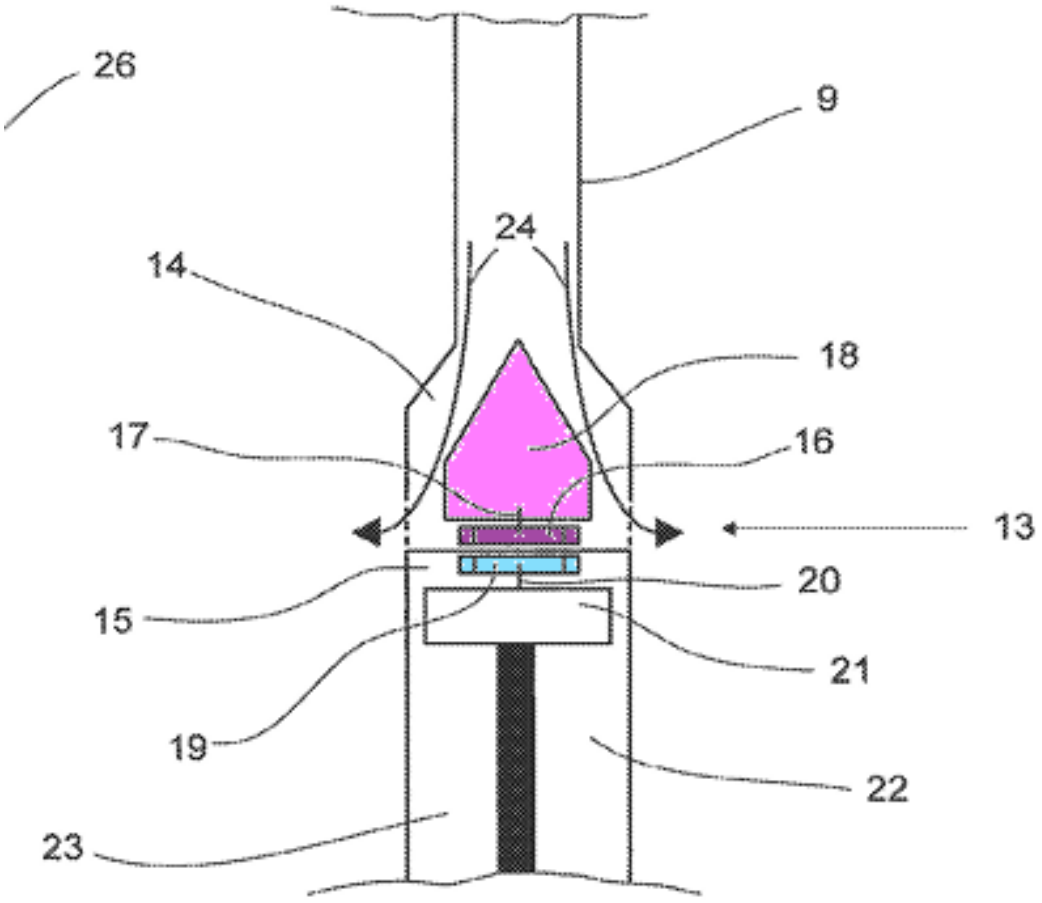
89. As described above, LVADs use three types of bearings—mechanical, hydrodynamic, or magnetic, either alone or in combination. Mechanical bearings rely on physical contact between components to stabilize a rotor in the housing during rotation. Magnetic bearings, such as described in Bourque-2001 for the

HeartMate III device (see Section IX.B), use electromagnets to levitate and stabilize a rotor without physical contact.

90. A "hydrodynamic bearing" (also known as a fluid bearing), which was a well-known and commonly used term in the art when the 879 Patent was filed, uses motion to create a pressure that forces a rotating component, such as a rotor, apart from a surface by a fluid flowing between the rotating component and the surface. *See, e.g.*, Ex.1008, [0092]. The history of hydrodynamic bearings dates to the 19th century. As Qian describes it, there is a "'taking off' of the rotor [that] is generated by a hydraulic force (a reacting force of the flow), which acts on the impeller because the impeller propels the flow." Ex.1016 at 37, abstract ("the axial levitation is produced by hydraulic force"). The stationary surface (here, the walls of the pump housing) and rotating surface (here, the rotor) are separated by a thin film of fluid (here, blood) when the rotor is in rotation. The film pressure that separates the surfaces is created by the relative motion (rotation) of the surfaces as the lubricant is pulled into a converging geometry between the surfaces.

91. While Claim 11 does not recite the use of a "hydrodynamic bearing," that meaning is the only logical interpretation of the limitation as recited in Claim 11 when read in light of the 879 Patent's specification. This limitation recites that "both the magnetically driven rotor and the first magnetic device remain spaced apart

from the one or more walls **by the blood** in response to rotation of the magnetically driven rotor…" For example, Figure 2 (annotated and enlarged) of the 879 Patent shows that the "bar magnet 19" (**light blue**) is spaced apart from the "bar magnet 16" (**purple**) and the "rotor 18" (**pink**) is spaced apart from the walls of the tube 9 while the blood is flowing as indicated by arrows 24:



Ex.1001, Fig. 2 (annotated). In order for the "magneto coupling" to orient the "magnetically driven rotor" to remain "spaced apart from the one or more walls **by**

the blood" as recited in Claim 11, and without the recitation of a magnetic bearing or other non-contact bearing, the limitation must refer to the pressure created between the rotor and the housing "***by the blood***" to cause suspension of the magnetically driven rotor in the surrounding rotor housing such that it is not in contact with the housing. By definition, that suspension is a hydrodynamic bearing.

92. This hydrodynamic suspension of the rotor is disclosed in the Schima application, which the 879 Patent incorporates by reference. Ex.1001, 3:13-14 ("The rotor itself can follow design principles such as described for example in WO 01/70300 A1."). For example, Schima discloses "a rotor 1 that is formed of two superposed conical sleeves 31 and 32 that are connected together by centrifugal vanes or flow surfaces 33. Rotor openings 18 and the outer vanes 4 serve to produce the flow component 5 against the upper part 15 of the housing as well as against the conical middle part 16 of the lower housing part 19. **In this manner the rotor is hydrodynamically stabilized in the housing**." Ex.1005, [0019]. Claim 1 of the Schima application recites "a rotor journaled hydraulically and if necessary magnetically in a housing," which includes "flow components (5) directed against the housing serving mainly for contact-free journaling and stabilizing of the rotor in the housing." Ex.1005, Claim 1. This understanding from the 879 Patent's claims and specification is consistent with the use of the term "hydrodynamic bearing" in

the art as of February 27, 2007. In addition to Qian described above, Wampler-169 similarly describes that, "hydrodynamic bearings can be located on the surface of [an] impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. Specifically, Wampler-169 discloses that the "hydrodynamic bearings" can be "formed by a raised pad **spaced from a contact surface by the blood gap**. Although at rest there may be contact between the impeller and the casing, **once rotation begins** each hydrodynamic bearing is structured so that during relative movement between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap **which forces the raised pad and the contact surface apart**." Ex.1008, [0092].

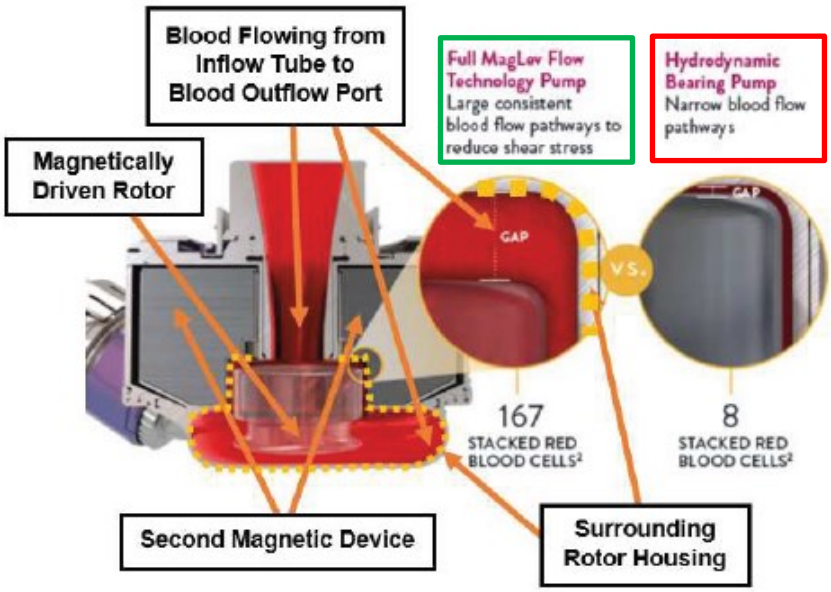
93. I note that while the 879 Patent does not disclose the use of "pads" as discussed for example in Wampler-169, the "outer vanes 4" on the rotor described in Schima (incorporated by reference into the 879 Patent) serve the same purpose: "to produce the flow component 5 against the upper part 15 of the housing" such that "the rotor is hydrodynamically stabilized in the housing." Ex.1005, [0019].

94. Thus, Schima discloses the rotor (which is incorporated by reference in the 879 Patent specification) is suspended hydrodynamically, and if necessary, magnetically. Because Claim 11 of the 879 Patent recites only that the magneto

coupling orients the magnetically driven rotor" to "remain spaced apart from the one or more walls by the blood" and not, for example, "by the blood and **by a magnetic bearing**," a POSITA would understand the limitation to mean that the "blood" causes the separation.

b. The Patent Owner renders this claim language meaningless.

95. I have reviewed the Patent Owner's complaint served in the parallel litigation, and I understand that the Patent Owner accuses the HeartMate 3 Left Ventricular Assist System (LVAS) of infringing Claims 11-12, 14, 16 and 18-19 of the 879 Patent. I understand that in doing so, the Patent Owner's apparent construction of this claim term is not limited to the term's plain and ordinary meaning (i.e., hydrodynamic bearing) but broadly includes that it may be met *exclusively* by magnetic suspension. However, the Patent Owner's apparent construction of this claim limitation reads out or renders the phrase "by the blood " meaningless, which I understand is improper. For example, the Patent Owner alleges that this limitation is infringed merely if the device acts upon blood flowing. Patent Owner's interpretation appears to capture rotor suspension using a magnetic bearing ("MagLev Flow Technology"; **green**) instead of a hydrodynamic bearing (**red**), as shown in PO's complaint distinguishing the two bearing types:



See, e.g., Ex.1019, 11 (for a similar limitation).

96. Ignoring this claim language, the Patent Owner asserts that the HeartMate 3 device meets this limitation even though the accused device obviates the need for a hydrodynamic bearing. *See e.g.*, Ex.1019, Exhibit 11 of Complaint, 12 (comparing benefit of "Full MagLev Flow Technology Pump" "vs." "**Hydrodynamic Bearing** Pump"). The magnetically driven rotor of the accused device is not spaced apart from the one or more walls *by the blood*, and is instead supported only by magnetic levitation.

97. I disagree with the Patent Owner's broad construction of this term that includes magnetic suspension of the magnetically driven rotor (i.e., a magnetic bearing). As I discuss above, a POSITA would understand the plain and ordinary

meaning of the limitation to require that the "blood" causes the magnetically driven rotor to remain spaced apart from the one or more walls.

98. In any event, even if the "by the blood…" limitation is broadly interpreted under the Patent Owner's understanding (that the limitation is met by a magnetic bearing), my interpretation of the plain and ordinary meaning of this limitation would nonetheless be included in such a broad interpretation. Said another way, this term should mean a "hydrodynamic bearing." Or if Patent Owner's apparent construction is correct, then the term should include either a "hydrodynamic bearing" or a "magnetic bearing."

VIII. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE

99. A POSITA would find the challenged claims unpatentable under any interpretation consistent with their plain and ordinary meaning. The following discussion in this Declaration provides a detailed analysis of how the asserted prior art teaches each limitation of the Challenged Claims.

100. As part of my analysis, I have considered, and discuss in detail, the scope and content of the prior art and any differences between the alleged invention and the prior art.

101. It is my opinion that the alleged invention recited in the Challenged Claims would have been obvious in view of the teachings of the asserted prior art and the knowledge of a POSITA.

IX. THE PRINCIPAL PRIOR ART

A. Summary of Wampler-169

102. U.S. Pat. Pub. No. US 2002/0102169A1 to Richard K. Wampler, titled "Sealless Rotary Blood Pump" (Ex.1008, "Wampler-169") was published August 1, 2002 and issued February 10, 2004 as U.S. Pat. 6,688,861. I understand that Wampler-169 is therefore prior art to the 879 Patent at least under 35 U.S.C. § 102(b).

103. Wampler-169 seeks to address the problems faced by patients with "left ventricular heart failure" who "could benefit from cardiac transplantation," but are unable to receive a donor. Wampler-169 states that "if a left ventricular assist device ("LVAD") were available for chronic use, many of these patients could be returned to prolonged and productive lives." Ex.1008, [0003]. Wampler-169 explains that "[p]rior art LVADs…provide a cyclic or pulsating delivery of blood to emulate the natural pulsatile blood through the heart." Ex.1008, [0004]. However, these cyclic delivery systems presented "anatomic and engineering problems" due to their physically large size and complexity, making implantation difficult and expensive.

Ex.1008, [0004]. Further, while rotary pumps, as opposed to cyclic pumps, "provide substantially continuous liquid flow," "the prior art has not developed a durable rotary blood pump, owing to unique problems with the rotary pump's driveshaft seal," which have a "short life" and "contribute to a premature failure of the pump." Ex.1008, [0005].

104. Accordingly, Wampler-169 discloses "a small centrifugal pump" that "fit[s] well between the apex of the heart and the adjacent diaphragm." Ex.1008, [0065], [0076]. This "implantable rotary sealless blood pump" that "advantageously" uses "magnets…in the pump drive system" such that "[t]orque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing," which eliminates the need for a driveshaft seal and thereby allows for a mechanically frictionless system. Ex.1008, [0006], [0018].

105. Figure 5 of Wampler-169 illustrates the positioning of the rotary sealless blood pump having an "inlet tube 13" (see Fig. 13) that serves as the "inflow cannula" implanted within the left ventricle of a heart:

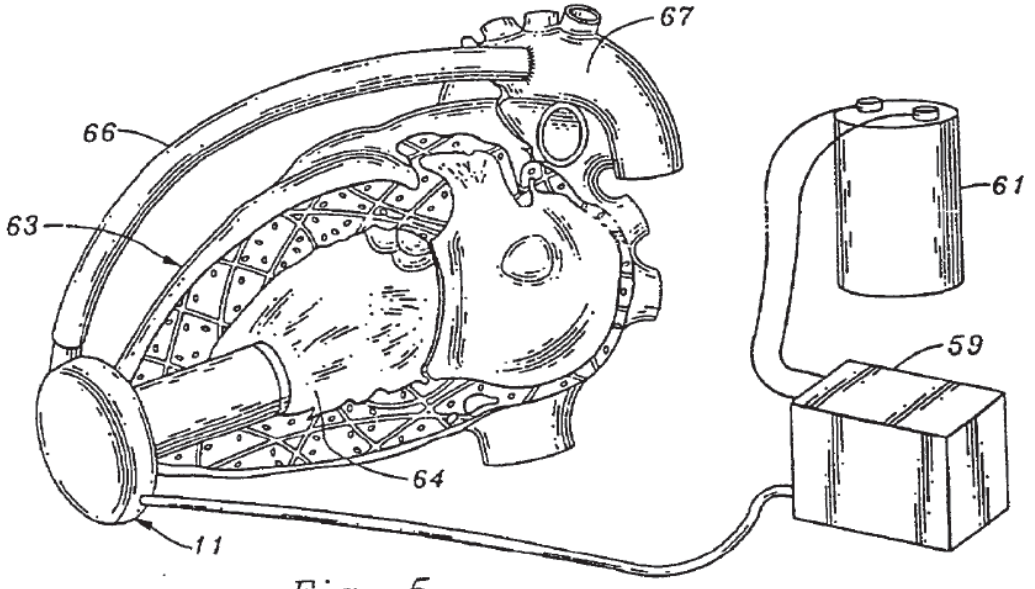
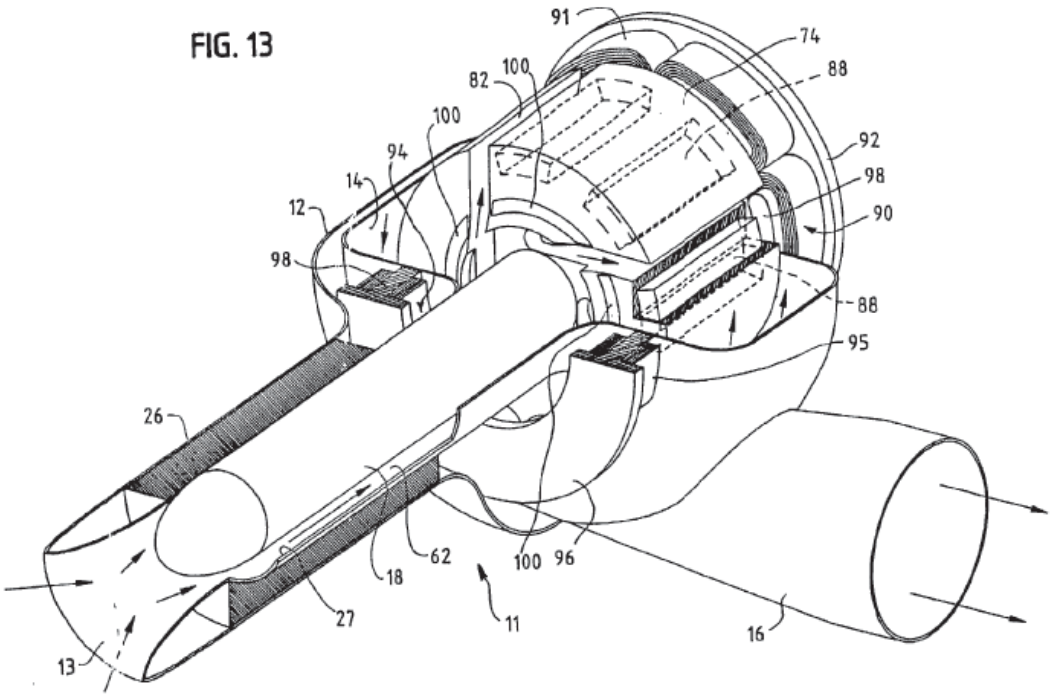


Fig. 5

Ex.1008, Fig. 5, [0050].

106. In embodiments described with respect to FIGs. 11-16, the "blood pump 11' shown therein is similar in many respects to blood pump 11 illustrated in FIGs. 1-8, and includes housing 12, having an elongated inlet tube 13, and a scroll-shaped impeller casing or volute 14. A discharge tube 16 extends through the housing to communicate with the interior periphery of casing 14." Ex.1008, [0080]. "Pump rotor 17 is located within the housing 12, within casing 14, and includes an elongated right-circular cylindrical support shaft or spindle 18, attached to impeller 74." Ex.1008, [0081]. Figure 13 of Wampler-169 illustrates a perspective, partially broken for clarity view of the pump 11 having the impeller 74:



Ex.1008, Fig. 13.

107. Wampler-169 teaches that the rotor 17 is driven via an "electromagnetic field." Ex.1008, [0072]. In the embodiment described with respect to FIGs. 1-8, "a brushless rotor motor 53 includes arcuate magnetic segments 54, imbedded within the upper face portion 36 of blade sectors 49" of the impeller 19. Ex.1008, [0070]. The "segments 54 have alternating orientations in their polarities, and are directed toward an adjacent motor stator 56," which includes "windings 57 and a circular pole piece or back iron 58, mounted on the outer surface of impeller casing 14." Ex.1008, [0070]. "The windings 57 are energized by the electrical output of controller 59 to produce an electromagnetic field. This field is concentrated by pole

piece 58, and is effective to drive magnets 54 and the rotor 17, in rotary fashion." Ex.1008, [0072]. Wampler-169 discloses that the "[m]otor 53, with windings 57 and pole piece 58, together with magnets 54, function not only to transmit torque but also provide a restoring radial magnetic force that acts as a radial bearing." Ex.1008, [0073].

108. Wampler-169 describes the resulting blood flow path, where "[r]otation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62." Ex.1008, [0074]. Finally, "[d]ischarge tube 16 allows the blood to be expelled from the casing an [sic] into the user's cardiovascular system. Ex.1008, [0074].

109. In the embodiment described with respect to FIGs. 11-16, the mechanism by which the electromagnetic field drives the magnetic pieces 88 to thereby rotate the rotor 17 is the same, except that the motor consists of a "first motor stator 90, comprising conductive coils or motor windings 91…located at the rear of the impeller 74," and a "second motor stator 94, comprising windings 95, is positioned on the forward side of the impeller 74." Ex.1008, [0083]-[0084].

110. In this embodiment, Wampler-169 discloses that "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device."

Ex.1008, [0089]. "Depending upon the location of the hydrodynamic bearings, they can aid in axial support, radial support or both axial and radial support." Ex.1008, [0093]. "The hydrodynamic bearings are formed by a raised pad spaced from a contact surface by the blood gap. Although at rest there may be contact between the impeller and the casing, once rotation begins each hydrodynamic bearing is structured so that during relative movement between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap which forces the raised pad and the contact surface apart." Ex.1008, [0092].

111. Wampler-169 also discloses percutaneous wires that connect the pump to a "controller" that may be "worn externally by the user." Ex.1008, [0070]. "Controller 59 may include circuitry as simple as a variable voltage or current control, manually adjusted or programmed to determine the running rate of pump" or "may also have interactive and automatic capabilities." Ex.1008, [0071]. The controller may be interconnected to sensors to "tailor operation of the pump to the user's physical activity and condition." Ex.1008, [0070], [0071].

B. Summary of Bourque-2001

112. Bourque et al., *HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor* (Ex.1007, "Bourque-2001") was published in the American Society for Artificial Internal Organs (ASAIO) Journal in 2001.

113. I understand that a prior art reference is proven to be a "printed publication" upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.

114. Bourque-2001 would have been disseminated or otherwise made available to the extent that a POSITA, exercising reasonable diligence, could have located it as of the time of its publication in ASAIO Journal in 2001. Ex.1030 (Hall-Ellis Dec.) at ¶¶45-52. In addition, Bourque-2001 was cited in at least 29 other publications prior to the February 27, 2007 priority date of the 879 Patent.[15] I understand that Bourque-2001 is therefore a printed publication prior art to the 879 Patent at least under 35 U.S.C. § 102(b).

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[15] *See* Google Scholar search results for articles citing Bourque-2001 prior to 2007 (accessed via https://scholar.google.com/scholar?hl=en&as_sdt=5%2C33&sciodt=0%2C33&cites=9100739476171713774&scipsc=&as_ylo=&as_yhi=2006) (last accessed Nov. 3, 2024).

115. The "HeartMate III" device described in Bourque-2001 appears to be designed in a very similar manner as the HM3 device accused of infringement in the parallel litigation. *See e.g.*, Ex.1019, Exhibit 11 of Complaint.

116. Bourque-2001 describes the design and testing of a "long-term, compact left ventricular assist device (LVAD)," known as the HeartMate III. Ex.1007 at 401. Bourque-2001 describes that at the time of the publication, "[e]ach year in the United States, 400,000 people are diagnosed with congestive heart failure (CHF), some of whom are eligible for heart transplant (1% or so), but many of whom are not." Ex.1007 at 401. Accordingly, "[t]he advent of the left ventricular-assist device (LVAD) has provided significant benefit to certain CHF patients since becoming clinically available. These devices seek to ameliorate increases in mortality due to the divergence of the increasing population of those awaiting cardiac transplant and the somewhat dwindling availability of organs." Ex.1007 at 401.

117. Bourque-2001 states the LVADs that were clinically available at the time were positive-displacement-type pumps that "contain[ed] mechanical parts that wear, such as ball bearings, flexible diaphragms or sacs, and valves." Ex.1007 at 401. The "second generation of LVADs" (*e.g.*, HeartMate II) were "continuous flow-type pumps," which exploit inherently fewer mechanical parts and additional

benefits such as a smaller size and lower cost. Ex.1007 at 401. Accordingly, HeartMate III as described in Bourque-2001 intended to feature these qualities while also eliminating the problems of all mechanical bearings.

118. Instead, the HeartMate III features "a centrifugal pump with a magnetically levitated rotor" and "[t]he rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely." Ex.1007 at 401. The HeartMate III described in Bourque-2001 was designed "to achieve a design point of 7 L/min against 135 mm Hg at high hydrodynamic efficiency (30%) and to be capable of up to 10 L/min under such a load." Ex. 1007 at 401.

119. The HeartMate III in its implanted configuration is illustrated in Figure 3 of Bourque-2001:

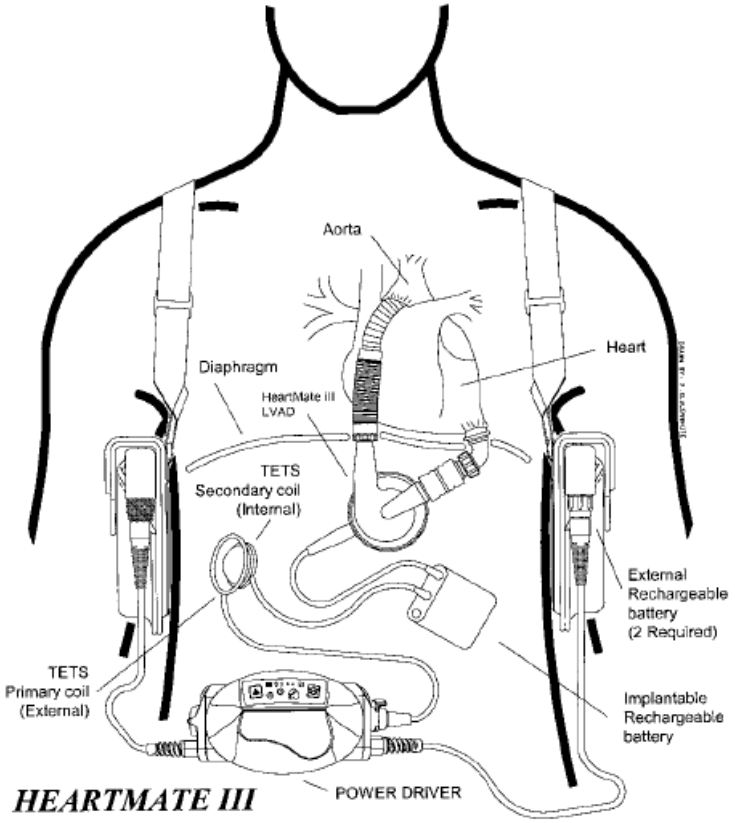


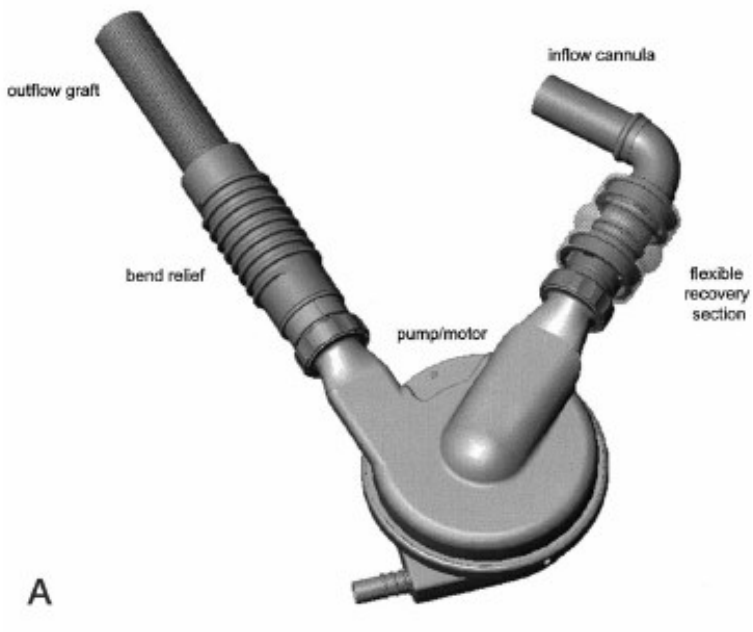
Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3.

120. The HeartMate III pump described in Bourque-2001 includes an "upper housing that includes the inflow and outflow channels and the upper half of the volute; a lower housing that includes the lower half of the volute and a cavity for the rotor, in which the motor is enclosed; a rotor that includes an impeller and passively magnetic elements;" "an inflow subassembly that includes a left ventricular (LV) cannula"; an "outflow subassembly"; "an electronic cable to be exteriorized percutaneously"; and additional subcomponents and hardware. Ex.1007 at 401.

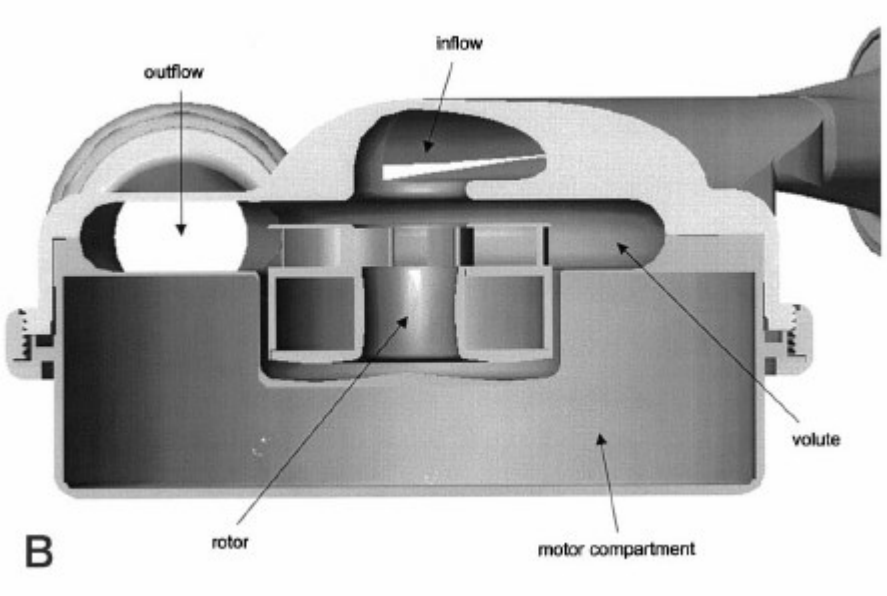
121. In this explanation, Bourque-2001 describes the "impeller" as being part of the "rotor." A POSITA would understand that the impeller is the part in contact with the blood that provides the pumping action, and the impeller is enclosed within the rotor. The rotor also includes passively magnetic elements. Ex.1007 at 401. The rotor is a single integral part which includes the impeller. The rotor described in Bourque-2001 appears to be designed in the same manner as the rotor of the HM3 device accused of infringement in the parallel litigation. *See e.g.*, Ex.1019, Complaint, Ex. 11.

122. Figure 1A of Bourque-2001 illustrates an overall view of the HeartMate III pump:



Ex.1007, Fig. 1A.

123. Figure 1B of Bourque-2001 illustrates a cross-sectional view of the HeartMate III pump:

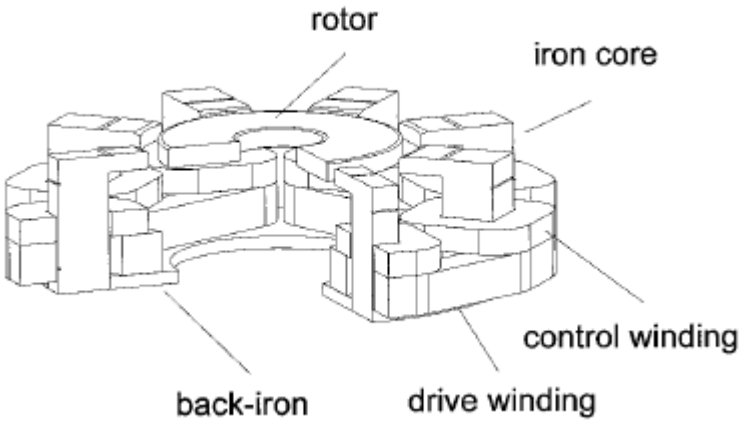


Ex.1007, Fig. 1B.

124. "The flow path is of circular cross-section through the inflow and outflow sections." Ex.1007 at 402. Blood enters the impeller through an opening in the "shroud (i.e., the cover across the top of the blades on the rotor)," and "exits the backswept blades of the impeller into a volute of uniformly increasing width." Ex.1007 at 402. Backflow clearances above and below the rotor allow space for the magnetic levitation of the rotor while balancing "reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402. These backflow clearances were also "constrained by the stiffness of the magnetic suspension

(passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position" and "permit up to 7× gravitational loads in any direction without contact between the rotor and housing." Ex.1007 at 402.

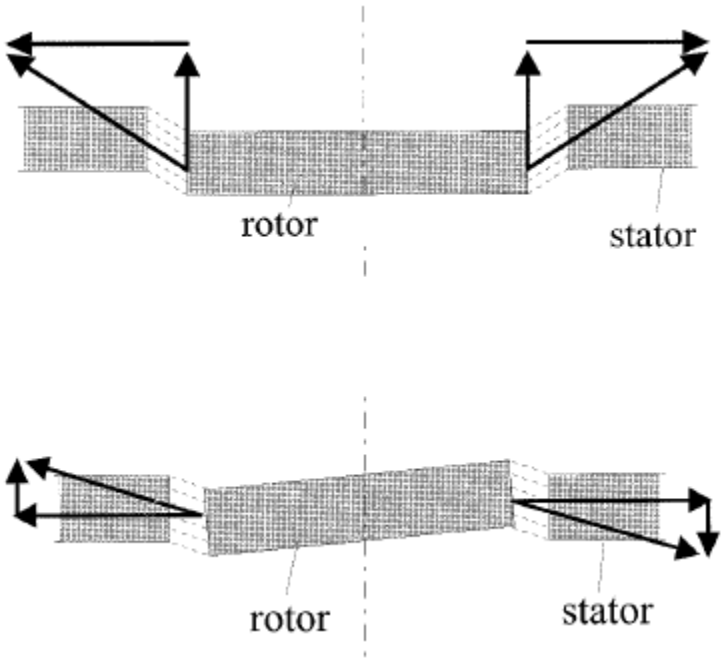
125. Figure 4 of Bourque-2001 illustrates the HeartMate III motor which includes "drive and levitation (control) in a single magnetic structure":



Ex.1007, Fig. 4.

126. Bourque-2001 discloses that "[t]he rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom…and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 402-403.

127. Figure 5 illustrates the passive magnetic levitation of the rotor which causes both a restoration force under axial-translational (above) and transverse-rotational (below) degrees of freedom:



Ex.1007 at 404, Fig. 5.

128. The "stators" illustrated in Figure 5 are stationary parts of the system that create a magnetic field when a current is applied to the windings around the cores (refer to Ex.1007, Fig. 4) causing the rotation of the rotor. Bourque-2001 discloses that "[t]he very simple main flow path is a consequence of the motor's "J" core configuration (i.e., the stator laminations are J shaped), which places an imaginary plane near the mid-height of the pump, below which are confined the

motor and levitation elements, and above which the hydrodynamic elements are permitted free reign"). Ex.1007 at 404.

129. For the testing of the HeartMate III device described in Bourque-2001, "[t]he electronics for power and control of the LVAD and for data acquisition resided on a shelf." Ex.1007 at 403. In addition, the *in vivo* testing described in Bourque-2001 was performed on bovines. However, "the only difference between the pump used for *in vivo* studies and the eventual human configuration is the presence of the elbow in the inflow segment, included to accommodate the bovine anatomy and presently regarded as unnecessary in humans." Ex.1007 at 405.

C. Summary of Akamatsu-1999

130. The scientific journal by Nojiri, C., Maekawa, J., Kido, T., Mori, T., Asada, T., Suzuki, M., & Akatsu, T., Kijima, T., Horiuchi, K., Sugiyama, T., Sugiura, N., Ozaki, T., and Akamatsu, T., titled *Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump*, Japanese Society for Artificial Internal Organs, 2:3-7 (1999) is referred to herein as "Akamatsu-1999" (Ex.1006).[16] I understand that a prior art reference is

[16] Although the first-author of Ex.1006 is Nojiri, numerous other articles discussing the development of this same Terumo device list Akamatsu as the first author. For ease of reference, they are referred to collectively as Akamatsu references.

proven to be a "printed publication" upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.

131. Akamatsu-1999 would have been disseminated or otherwise made available to the extent that a POSITA, exercising reasonable diligence, could have located it as of the time of its publication in the Japanese Society for Artificial Internal Organs Journal in 1999. Ex.1030 (Hall-Ellis Dec.) at ¶¶53-60. In addition, Akamatsu-1999 was cited in at least 5 other publications prior to the February 27, 2007 priority date of the 879 Patent.[17] I understand that Akamatsu-1999 is therefore prior art to the 879 Patent at least under 35 U.S.C. § 102(b).

132. Akamatsu-1999 describes that as of the publication date, "[r]otary blood pumps, such as the axial flow pump and the centrifugal pump, are being developed worldwide as implantable ventricular assist systems (VAS). The advantages of the rotary blood pump are its compactness, simplicity, and low cost."

[17] *See* Google Scholar search results for articles citing Akamatsu-1999 prior to 2007 (accessed via https://scholar.google.com/scholar?hl=en&as_sdt=5%2C33&sciodt=0%2C33&cites=4553201015857277871&scipsc=&as_ylo=&as_yhi=2006) (last accessed Nov. 3, 2024).

Ex.1006 at 3. Akamatsu-1999 accordingly describes the design and development of "an implantable left ventricular assist system (T-ILVAS) featuring a centrifugal blood pump, with a magnetically suspended impeller (MSCP)." Ex.1006 at Abstract. "Because the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material wear, it is expected to be one of the most durable blood pumps." Ex.1006 at 3.

133. The design of the Akamatsu-1999 centrifugal pump was "composed of four parts: a magnetic bearing, an impeller, a housing, and a DC brushless motor." Ex.1006 at 4. Figure 2 of Akamatsu-1999 illustrates a schematic cross section of the centrifugal pump:

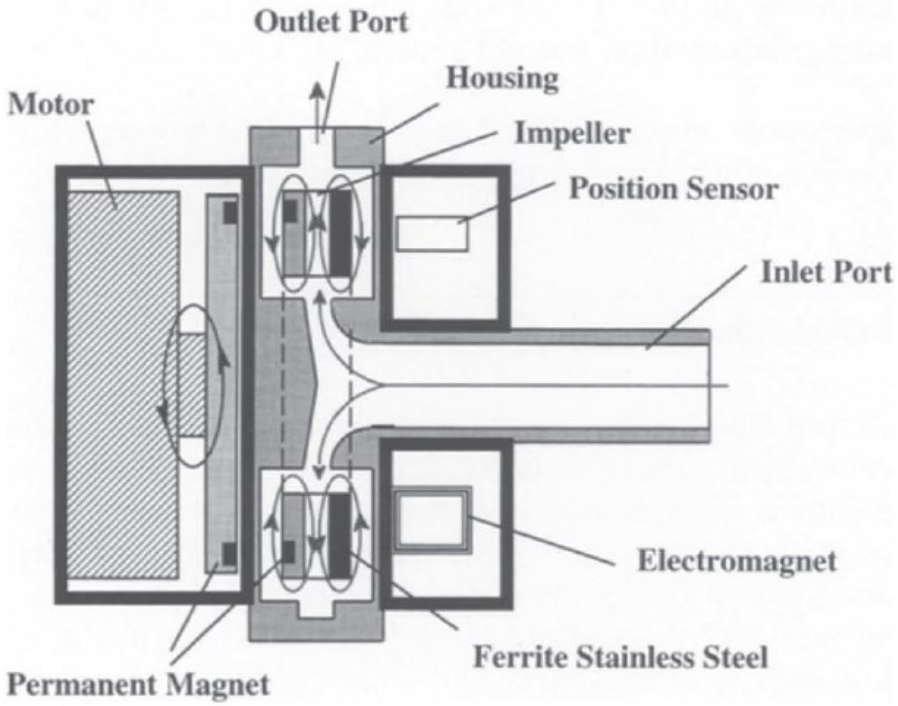


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2.

134. Akamatsu-1999 discloses that the "impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets. The electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4. During the testing described in the study, "the inflow conduit was inserted into the left ventricle through a cuff sutured to the left ventricular apex." Ex.1006 at 4.

135. Akamatsu-1999 discloses that during the described testing, "[t]he pump was operated at a fixed rotational speed." Ex.1006 at 4, 5; *see also* Ex.1006 at 7 ("The implantable controller has different driving modes, including a fixed rotational speed mode, a fixed motor current mode, a controlled motor current mode, and a pulsatile mode."). In addition, "[a]ortic pressure and pump flow rate were continuously measured throughout the experiments." Ex.1006 at 4, 5.

136. Figure 1 of Akamatsu-1999 illustrates the T-ILVAS in its implanted configuration in the ventricle of the heart:

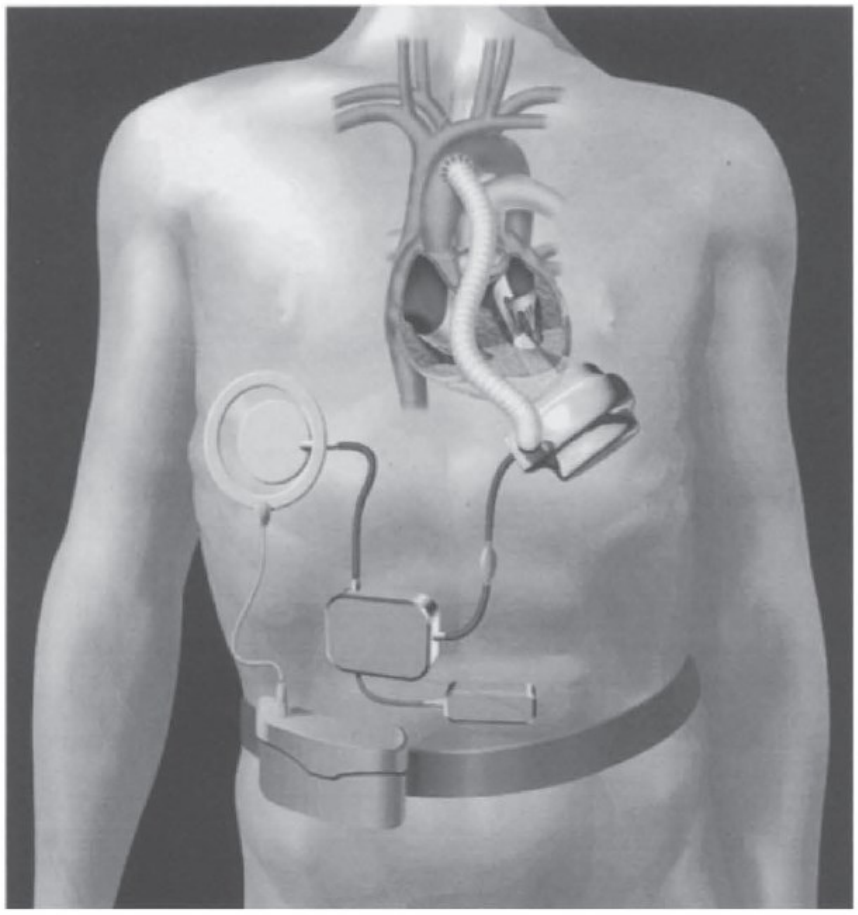


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, at Fig. 1

D. Summary of Schima

137. U.S. Pat. Pub. No. US 2003/0124007A1 to Heinrich Schima, et al., titled "Rotary Pump Comprising a Hydraulically Mounted Motor" (Ex.1005, "Schima") was published July 3, 2003. I understand that Schima is therefore prior art to the 879 Patent at least under 35 U.S.C. § 102(b). Schima claims priority to international PCT No. PCT/AT01/00086 (WIPO No. WO 01/70300 A1), originally

filed in Austria in German language. The 879 Patent specification references that same Schima priority WIPO application stating that "[t]he rotor itself can follow design principles such as described for example in WO 01/70300 A1."

138. I note that the German language application (WO 01/70300 A1) was included in the Information Disclosure Statement to the USPTO and is therefore listed on the face of the 879 Patent as a foreign reference cited. However, based on my review of the 879 Patent prosecution history, and the prosecution histories of related patents in the same family, the English language version of Schima that I discuss herein was never disclosed by the applicant to the USPTO, nor was it used as the basis of any rejection of the patent application leading to the 879 Patent during prosecution.

139. Schima seeks to address problems with existing heart assist pumps at the time. Indeed, existing "conventional axle-type pumps" used at the time had an "axle…mounted in a standard seal, for example in a needle bearing in the pump chamber, so as to produce regions of high shear, friction and also often of low flow velocity near the axle." Ex.1005, [0003]. However, because of the seal required for those pumps, "low-flow and dead-water areas" could create deposits, which is "referred to as thrombosis- or clot-forming." Ex.1005, [0002].

140. According to Schima, "solutions have been suggested to provide pumps without axles or mechanical bearings." Ex.1005, [0004]. Schima describes a number of existing heart assist pump devices that were in development at the time. *See* Ex.1005, [0004], [0005], [0006], [0007], [0008]. However, Schima states that each of those existing solutions had drawbacks, including with respect to complexity, cost, and effectiveness. Ex.1005, [0004], [0005], [0006], [0007], [0008].

141. Therefore, Schima sought to overcome those disadvantages by its disclosure of a rotary pump for moving blood and other shear-sensitive liquids, that has a rotor 1 that is "journaled hydraulically and, if necessary, magnetically in a housing" such that it may rotate "contact-free" from the housing." Ex.1005, [0001], [0010], Abstract, Claim 1.

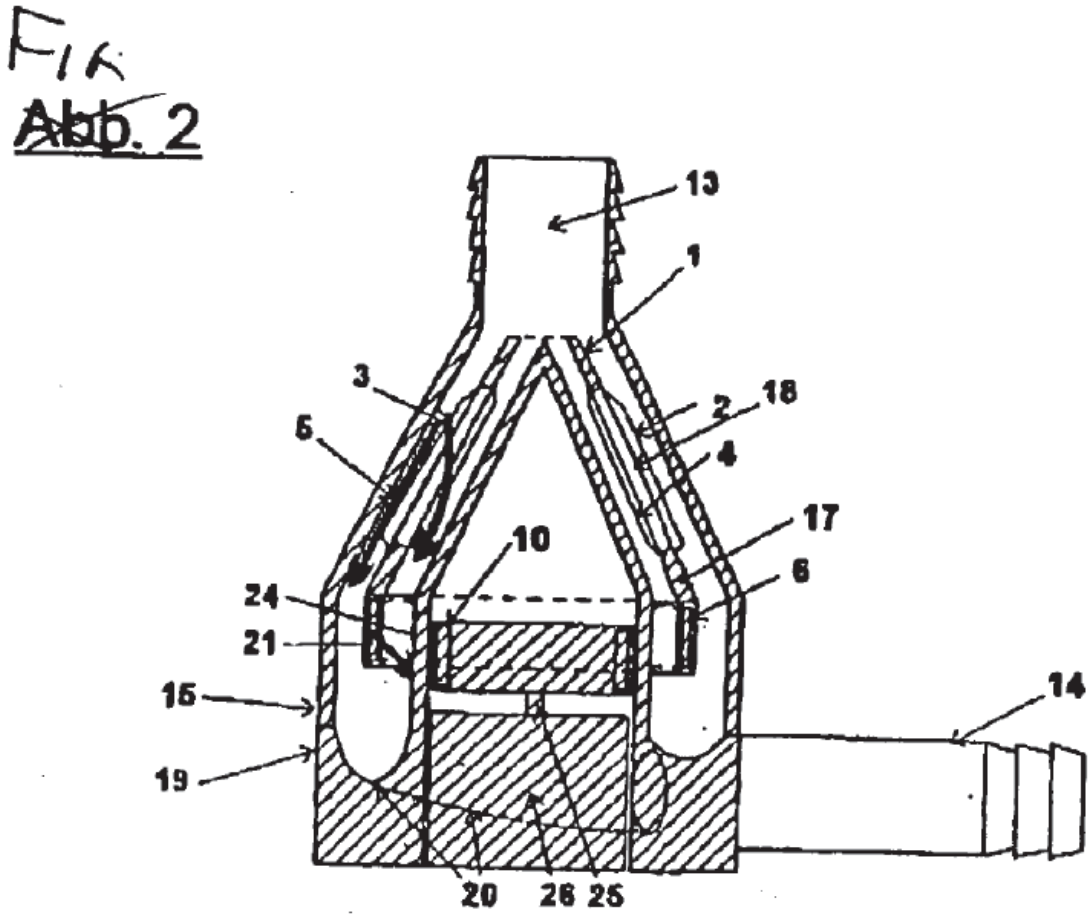
142. The "rotor 1" of the pump described in Schima "has as flow surfaces 2 and 4 vanes that produce centrifugal flow components 3 and flow components 5 directed against the housing." Ex.1005, [0012]. "This hollow conical rotor 1 rotates in a pump housing 30 comprised of a housing lower part 19 with a conical middle part 16 and a hollow conical upper part 15, centering of the hollow conical rotor in the middle part 16 of the housing lower part 19 being effected by the flow components 5 directed against the housing, this flow being preferably axially against the conical upper surface of the middle part 16." Ex.1005, [0012]. In addition, the

centering can "be wholly or additionally effected by flow components (5) directed against the housing or centrifugally (3) against the hollow conical upper part 15." Ex.1005, [0012].

143. "The rotor 1 has at an inlet 13 an inlet opening 36 that distributes the incoming liquid to both sides of the rotor and against the point of the cone-shaped middle part 16." Ex.1005, [0012]. "A spiral-shaped outlet passage 20 in the lower housing part 19 leads to an outlet 14" of the pump. Ex.1005, [0012].

144. In order to drive rotation, "[t]he rotor holds rotor magnets 6 that preferably transfer rotation energy and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. In an embodiment of the rotor 1, that "drive" can be "an electric motor 26 which drives a rotating disk 24 with magnets 10 by means of a shaft 25. This embodiment has the advantage that no electrical energy is used to journal the rotor and as a result the axial offset of the disk 24 ensures an axial component for the magnetic force 21." Ex.1005, [0013].

145. Figure 2 of Schima illustrates a cross-sectional view of the embodiments of the pump described above having the rotor 1 driven by the "rotor magnets 6" transferring of rotation energy from the "magnets 10" within the "rotating disk 24" driven by the "electric motor 26" via the "magnetic force 21":



Ex.1005, Fig. 2.

X. CLAIMS 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, AND 20 OF THE 879 PATENT ARE RENDERED OBVIOUS BY THE PRIOR ART

146. As an initial matter, I will summarize the grounds of my analysis. Because there are two potential interpretations for each of two different claim terms—the "magneto coupling" term and the "by the blood" term—there are four permutations of the potential claim interpretations. The claims are rendered obvious under all four permutations:

i. **Ground 1:** Wampler-169 alone applies the Patent Owner's apparent broad interpretation of "magneto coupling" and my narrower interpretation of the "by the blood …" term.

ii. **Ground 2:** Bourque-2001 in view of Wampler-169 applies the Patent Owner's apparent broad interpretation of "magneto coupling" and the Patent Owner's apparent broad interpretation of the "by the blood…" term.

iii. **Ground 3:** Akamatsu-1999 alone applies my narrower interpretation of "magneto coupling" and the Patent Owner's apparent broad interpretation of the "by the blood …" term.

iv. **Ground 4:** Schima in view of Akamatsu-1999 applies my narrower interpretation of "magneto coupling" and my narrower interpretation of the "by the blood…" term.

147. The table below also summarizes how the grounds correspond with the possible claim interpretation:

Summary of four permutations of claim interpretations:		"magneto coupling"	
		Plain and ordinary meaning (i.e., rotating permanent magnets)	PO's apparent construction (includes drive by magnetic levitation)
"by the blood"	Plain and ordinary meaning (i.e., hydrodynamic bearing)	**Schima in view of Akamatsu-1999**	**Wampler-169**
	PO's apparent construction (includes magnetic bearing)	**Akamatsu-1999**	**Bourque-2001 alone or in view of Wampler-169**

148. The table above is not meant to be limiting. For example, Wampler-169 is listed for the hydrodynamic bearing permutation, but it also discloses the use of

magnetic bearings; Schima is listed for the drive by magneto coupling limitation but it also discloses use of drive by magnetic levitation; and other grounds also render obvious the alternative interpretations. Further, should any of the terms be interpreted broadly according to Patent Owner's interpretations, my narrower interpretations would in any event be included within those broader interpretations.

A. Ground 1: Wampler 169 Renders Obvious Claims 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20 of the 879 Patent

1. Claim 11

i. [11PRE] A system for assisting blood circulation of a heart, the system comprising:

149. To the extent that the preamble is a limitation, Wampler-169 discloses "*a system for assisting blood circulation of a* ***heart***."

150. For example, Wampler-169 seeks to address the problems faced by patients with "left ventricular heart failure" who "could benefit from cardiac transplantation," but are unable to receive a donor. Wampler-169 states that "if a left ventricular assist device ("LVAD") were available for chronic use, many of these patients could be returned to prolonged and productive lives." Ex.1008, [0003]. Therefore, Wampler-169 discloses a "left ventricular assist device ('LVAD')" which uses an "improved rotary blood pump" that uses "passive, magnetic radial bearings to maintain an impeller and its support shaft for rotation about an axis." Ex.1008,

[0007]. Further, Wampler-169 discloses that the "invention relates to the field of blood pumps" and in particular, "pertains to continuous flow pumps of rotary design, suitable for permanent implantation in humans for use as chronic ventricular assist devices." Ex.1008, [0002].

151. Accordingly, Wampler-169 discloses "*a system for assisting blood circulation of a* ***heart***."

ii. [11A] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle

152. Wampler-169 discloses "*a* ***heart assist pump device*** *deliverable to the heart and comprising: an* ***inflow tube*** *defining a blood inflow path along an* ***inflow axis*** *and being insertable into* ***a left ventricle****"*

153. The 879 Patent does not define the term "a heart assist pump device deliverable to the heart." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that assumes "a heart assist pump device" being "deliverable to the heart" includes inserting an inflow tube of the heart assist pump device into a left ventricle of a patient's heart. *See, e.g.*, Ex.1019, at 3-4 (Complaint, Ex. 11). For the purposes of my analysis, I adopt that construction of "a heart assist pump device deliverable to the heart."

154. Accordingly, Wampler-169 discloses the "anatomical placement of the pump 11," in the "human heart 63," which "includes a left ventricle 64 and an aorta." Wampler-169, [0075]. Further, the pump 11 includes an "inlet tube 13" that "serves as the inflow cannula and is placed into the apex of the left ventricle 64."[18] Ex.1008, [0075]; *see also* Ex.1008, Abstract ("An implantable rotary sealless blood pump is provided. The pump includes a housing having ***an inlet tube*** on one end and an impeller casing on the other end."), [0050] ("Turning now to FIGs. 1-8 of the drawings, a sealless rotary blood pump 11 includes a housing 12, having an ***elongated inlet tube 13*** and an impeller casing or volute 14."), [0080] ("Referring to FIGS. 11, 11*a*, 12, 13 and 14, the blood pump 11' shown therein is similar in many respects to blood pump 11 illustrated in FIGS. 1-8, and includes housing 12 having an elongated inlet tube 13 and a scroll-shaped impeller casing or volute 14.").

155. Thus, Wampler-169 discloses ***a heart assist pump device*** (e.g., "blood pump 11," Ex.1008, [0080]) deliverable to the ***heart*** (e.g., "inlet tube [13] ... is placed into the apex of the left ventricle 64" of "human heart 63," Ex.1008, [0075])

[18] I note that paragraph [0075] of Wampler 169 denotes the "inlet tube" with the reference number 16. However, the "inlet tube" is denoted elsewhere in the reference with the number 13, while the "discharge tube" is denoted with the number 16. Therefore, I understand the reference to "inlet tube 16" in paragraph [0075] to be a drafting error, and will refer to the inlet tube as "inlet tube 13."

that comprises ***an inflow tube*** (e.g., "inlet tube 13," Ex.1008, [0075]) defining a blood inflow path (e.g., "serves as the inflow cannula," Ex.1008, [0080]) and being insertable (e.g., "implantable," Ex.1008, Abstract) into **a left ventricle** (e.g., "inlet tube [13] ... is placed into the apex of the left ventricle 64," Ex.1008, [0075]).

156. Figure 5 (annotated) of Wampler-169 illustrates a representation of a human heart 63, showing the inlet tube 13 (**green**) of the pump 11 (**blue**) inserted ("implant[ed]") within the left ventricle 64 (**red**) of the heart:

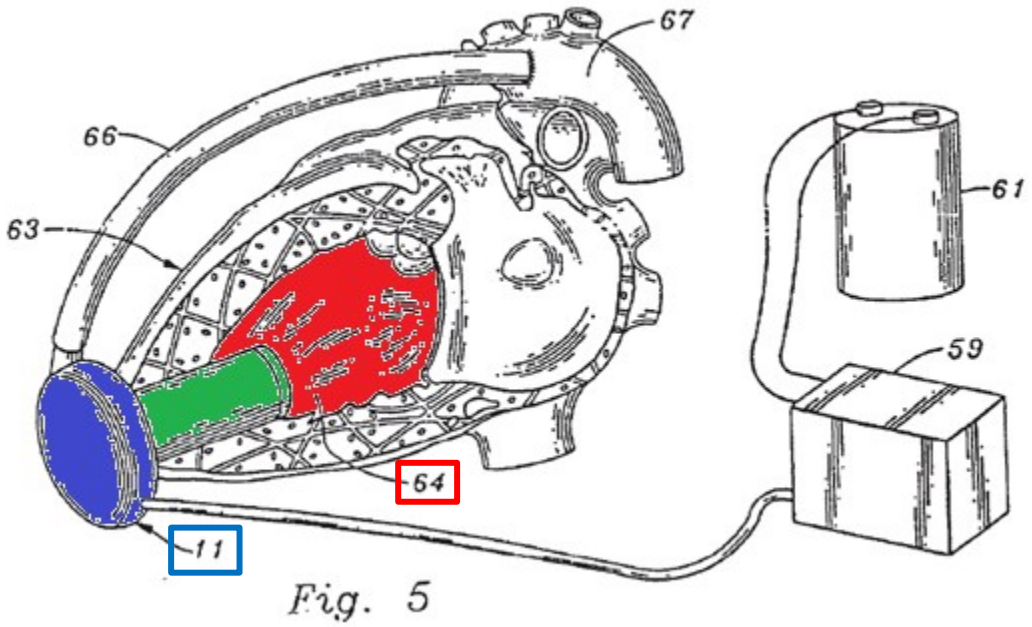


Fig. 5

Ex.1008, Fig. 5 (annotated).

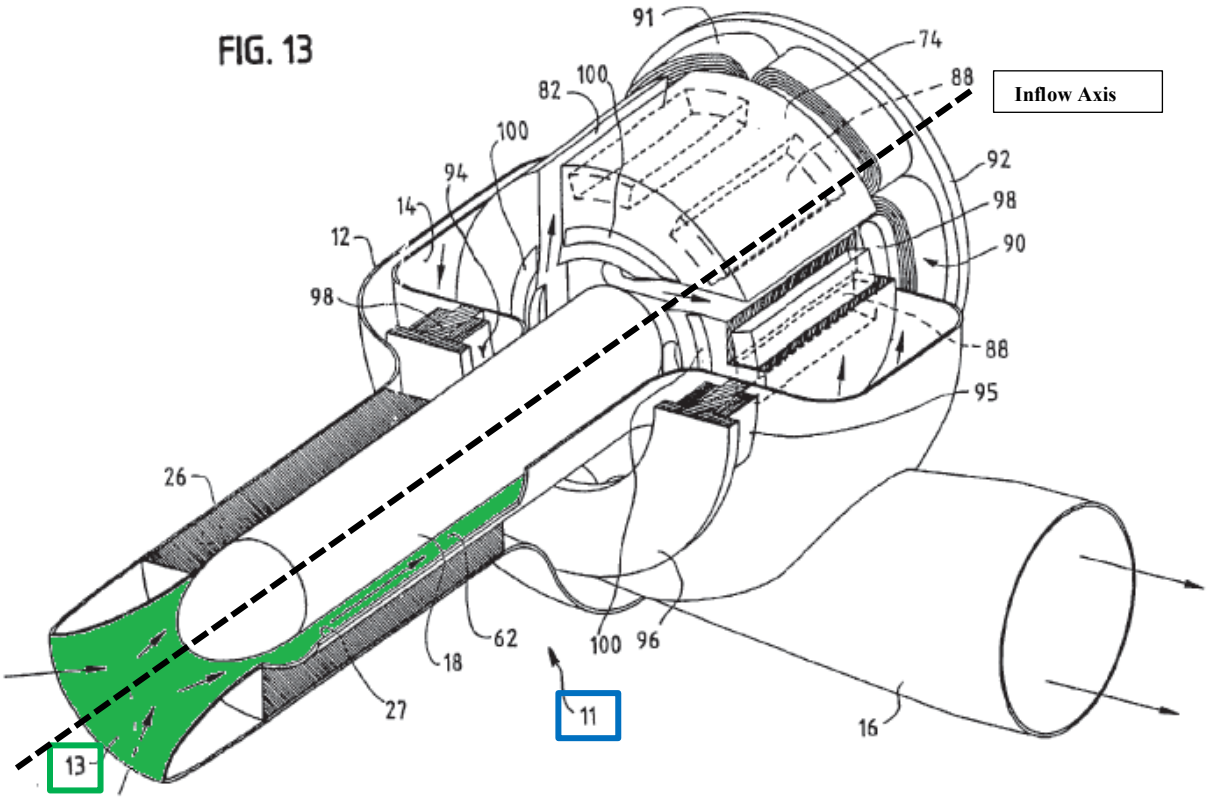
157. Wampler-169 further discloses that "[o]wing to the ***axial inflow*** and radial outflow of the pump, a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076]. Wampler-169

discloses that "[r]otor 17 is mounted for rotation about an ***longitudinal axis*** which extends both through shaft 18 and impeller 74." Ex.1008, [0081], [0051]; *see also* Ex.1008, [0013] ("Radial magnetic bearings of passive design, maintain the support shaft and the impeller about a ***rotational axis***."), [0052] ("The pump 11 of the present invention includes a forward magnetic bearing 21 and a rearward magnetic bearing 22 to levitate rotor 17 and maintain it in proper radial alignment with respect to its ***longitudinal axis***."). Wampler-169 further discloses the flow path of blood through the pump as follows:[19] "Rotation of the rotor 17, including shaft 18 and impeller 19, causes **blood to flow through inlet tube 13 in the direction of arrows 62**. The blood continues its path from the upper edge of passage 51 to the interior of casing 14. Discharge tube 16 allows the blood to be expelled from the casing an [sic] into the user's cardiovascular system." Ex.1008, [0074], *see also* Abstract ("A rotor is mounted for rotation within the housing…").

[19] Note, while this flow path is described with respect to the embodiment of the pump 11 described with respect to FIGs. 1-8, Wampler 169 states that the "blood pump 11'" shown in FIGs. 11, 11*a*, 12, 13, and 14 "is similar in many respects to blood pump 11 illustrated in FIGS. 1-8," including with respect to the flow path of blood. Ex.1008, [0080]; *see also* Ex.1008, [0103] ("Various elements from the FIGS. 1-8 embodiment can be used in the FIGS. 11-20 embodiments.").

158. Indeed, the pump described in Wampler-169 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, an inflow tube defining a blood inflow path along an inflow axis is a characteristic feature of a centrifugal pump.

159. Thus, Wampler discloses the ***inflow tube*** (e.g., "inlet tube 13," Ex.1008, [0075]) defining a blood inflow path (e.g., "serves as the inflow cannula," Ex.1008, [0080]) along an ***inflow axis*** (e.g., "axial inflow" along "longitudinal axis," Ex.1008, [0076], [0081]). Figure 13 (annotated) of Wampler-169 illustrates a fragmentary, cross-sectional view of an embodiment of pump 11 (**blue**), which includes an inlet tube 13 (**green**) defining a blood inflow path, shown by arrows 62, along the "longitudinal" or "rotational" axis of the inlet tube:



Ex.1008, Fig. 13 (annotated); *see also* Fig. 1, 2, 4, 5.

160. Accordingly, Wampler-169 discloses "***a heart assist pump device*** ("blood pump 11'") *deliverable to the* ***heart*** *and comprising: an* ***inflow tube*** ("inlet tube 13") *defining a blood inflow path* ("serves as the inflow cannula") *along an* ***inflow axis*** ("longitudinal axis") *and being insertable* ("implantable") *into* ***a left ventricle*** ("placed into the apex of the left ventricle 64").

iii. [11B] one or more walls at least partially defining a chamber to receive blood from the inflow tube

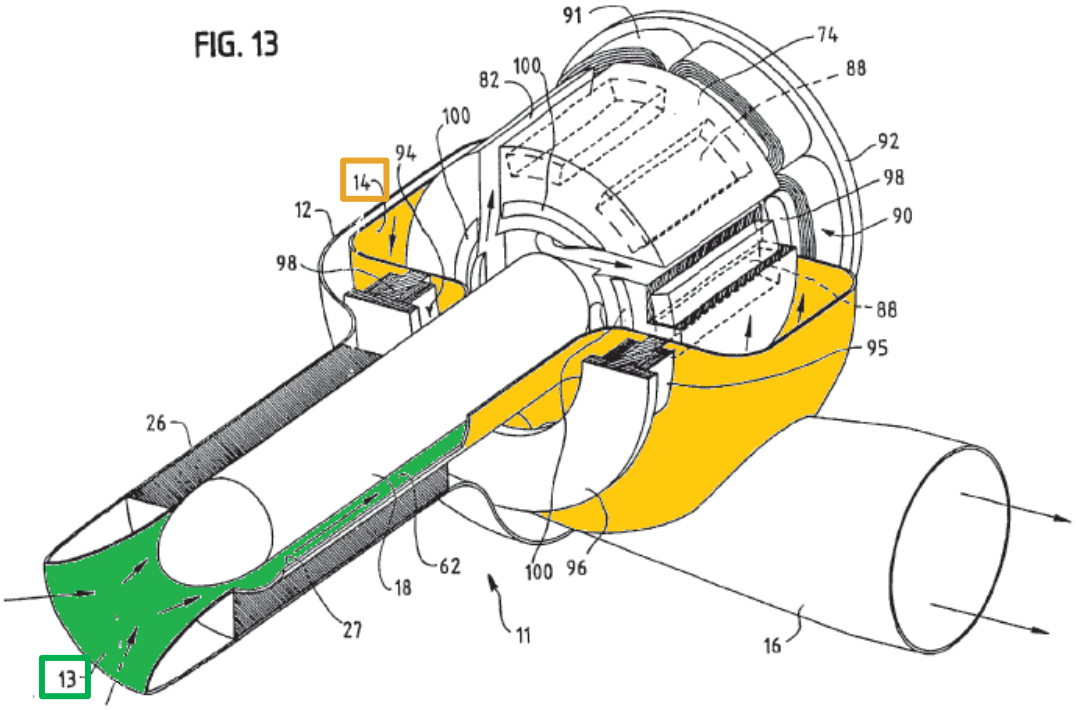
161. Wampler-169 discloses "***one or more walls*** *at least partially defining* ***a chamber*** *to receive blood from the* ***inflow tube***"

162. For example, Wampler-169 discloses that the "rotary blood pump includes a housing and a pump rotor," where the housing "includes an elongated inlet tube surrounding the shaft, and ***a scroll-shaped casing***, or volute, with a discharge outlet, ***enclosing the impeller***." Ex.1008, [0012]; *see also* [0081] ("Pump rotor 17 is located within housing 12, ***within casing 14***, and includes an elongated, right-circular cylindrical support shaft or spindle 18, attached to impeller 74"), [0050], [0070] ("windings 57" and "back iron 58" are "mounted on ***the outer surface of impeller casing 14***"), [0018] ("A ring of back iron is fixed to the casing to aid in completing a flux return path for the permanent magnets …"), [0060] ("For example, an annular thrust bearing surface could be provided on the ***inner wall of casing 14***…"). As will be discussed will be respect to element [11C], the impeller 74 of the rotor enclosed within casing 14 is a **magnetically driven rotor**. *See infra* Section X.A.1.iv.

163. Wampler-169 further discloses the flow path of blood through the pump as follows:[20] "Rotation of the rotor 17, including shaft 18 and impeller 19, causes ***blood to flow through inlet tube 13*** in the direction of arrows 62. The blood continues its path from the upper edge of passage 51 to the ***interior of casing 14***. Discharge tube 16 allows the blood to be expelled from the casing an [sic] into the user's cardiovascular system." Ex.1008, [0074], *see also* Abstract ("A rotor is mounted for rotation within the housing…").

164. Thus, the "interior of casing 14" that "enclose[s] the impeller" is a **chamber** at least partially defined by **one or more walls** (e.g., "interior," "inner wall," "outer surface," Ex.1008, [0074], [0070], [0060]) to receive blood from the **inflow tube** (e.g., "blood to flow through inlet tube 13 … to the interior of casing 14," Ex.1008, [0074]). For example, Figure 13 (annotated) of Wampler-169 illustrates the "interior" and "outer surface" at least partially defining the casing 14 (**orange**) to receive blood from the inlet tube (**green**), as shown by arrows 62:

[20] Note, while this flow path is described with respect to the embodiment of the pump 11 described with respect to FIGs. 1-8, Wampler 169 states that the "blood pump 11'" shown in FIGs. 11, 11*a*, 12, 13, and 14 "is similar in many respects to blood pump 11 illustrated in FIGS. 1-8," including with respect to the flow path of blood. Ex.1008, [0080]; *see also* Ex.1008, [0103] ("Various elements from the FIGS. 1-8 embodiment can be used in the FIGS. 11-20 embodiments.").



Ex.1008, Fig. 13 (annotated).

165. Accordingly, Wampler-169 discloses "*one or more walls* ("interior" and "outer surface") *at least partially defining a chamber* ("casing 14") *to receive blood from the inflow tube* ("inlet tube 13")."

iv. [11C] a magnetically driven rotor axially aligned with the inflow axis

166. Wampler-169 discloses "*a magnetically driven rotor axially aligned with the* ***inflow axis***."

167. The pump 11 described in Wampler-169 includes a "**magnetically driven rotor**" that is axially aligned with the inflow axis of the pump. Wampler-169

describes that the pump 11 includes "a pump rotor 17" within "housing 12" that includes "an elongated, right-circular cylindrical support shaft or spindle 18, attached to impeller 74." Ex.1008 at [0081]; *see also* Ex.1008, [0051]. The "[r]otor 17 is mounted for rotation about a[] **longitudinal axis** which extends both through shaft 18 and impeller 74." Ex.1008, [0051].

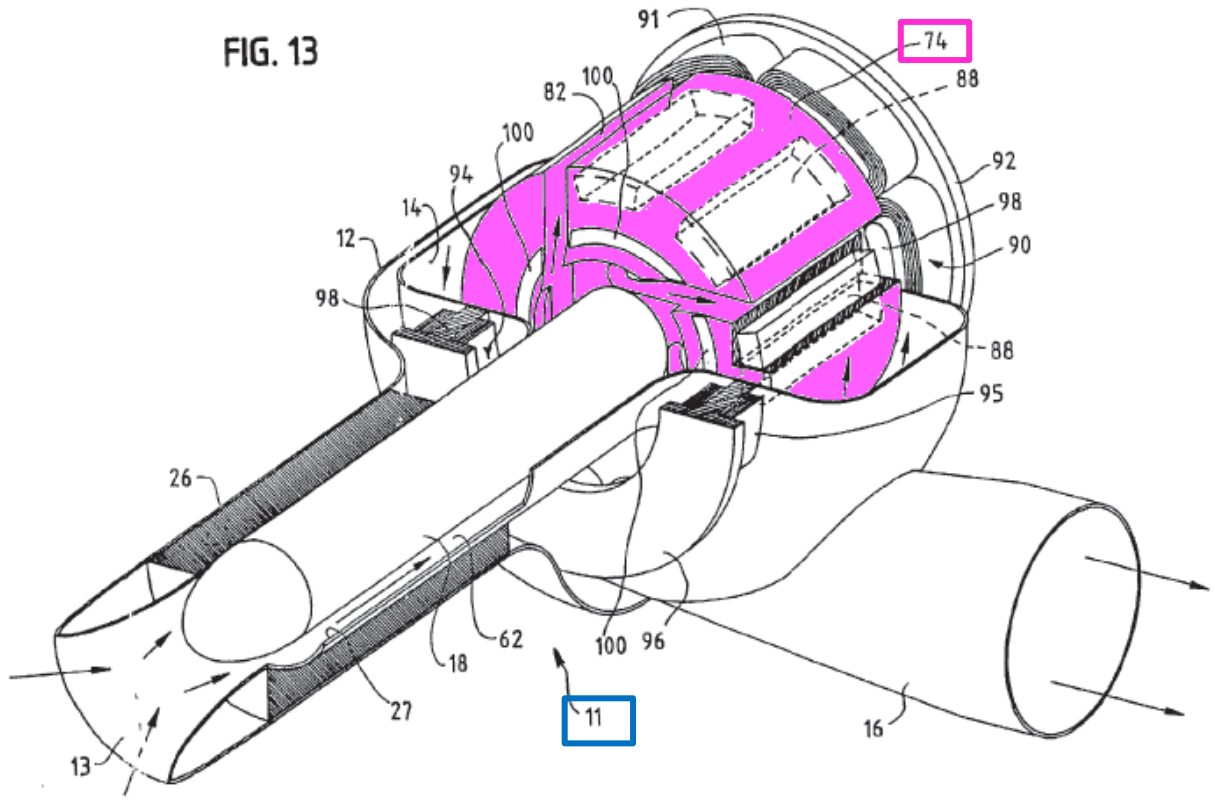
168. An impeller is a commonly used type of rotor used in a centrifugal pump, such as the "centrifugal pump" described in Wampler-169. Ex.1008, [0012] ("A centrifugal pump impeller is attached to an impeller support shaft, or spindle, to form the pump rotor."); *see also* Ex.1008, [0051] ("It should be noted that the preferred embodiment disclosed herein includes an impeller and a casing of centrifugal design."), [0065] ("It is generally preferable in a large centrifugal pump, to have a substantial number of thin, sharp impeller blades with relatively large voids or passages, between the blades, for the passage of low viscosity liquid."). I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that maps the impeller portion of the "rotor" of the "HeartMate 3" to the "magnetically driven rotor" element recited in Claim 1, which is similar to Claim 11. Ex.1019, at 5-6 (Complaint, Ex. 11). For the purposes of my analysis, I map the limitation of a "magnetically driven rotor" to the "impeller 74" of the embodiment of the rotor 17 described in Figure 11 of Wampler-169 in the same way.

169. Thus, based on the disclosures above, the "impeller 74" of the rotor 17 of pump 11 described in Wampler-169 is a "**rotor**."

170. Wampler-169 further discloses that the "impeller 74" of the rotor 17 is "**magnetically driven**" as recited in claim 11. For example, Wampler-169 discloses that the "thick impeller blades are also used advantageously to house magnets used in the pump drive system. Torque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing." Ex.1008, [0018]; *see also* Ex.1008, [0019] ("In certain embodiments of the invention, the motor includes a plurality of permanent magnets carried by the impeller and a motor stator including an electrically conductive coil located with the housing.").

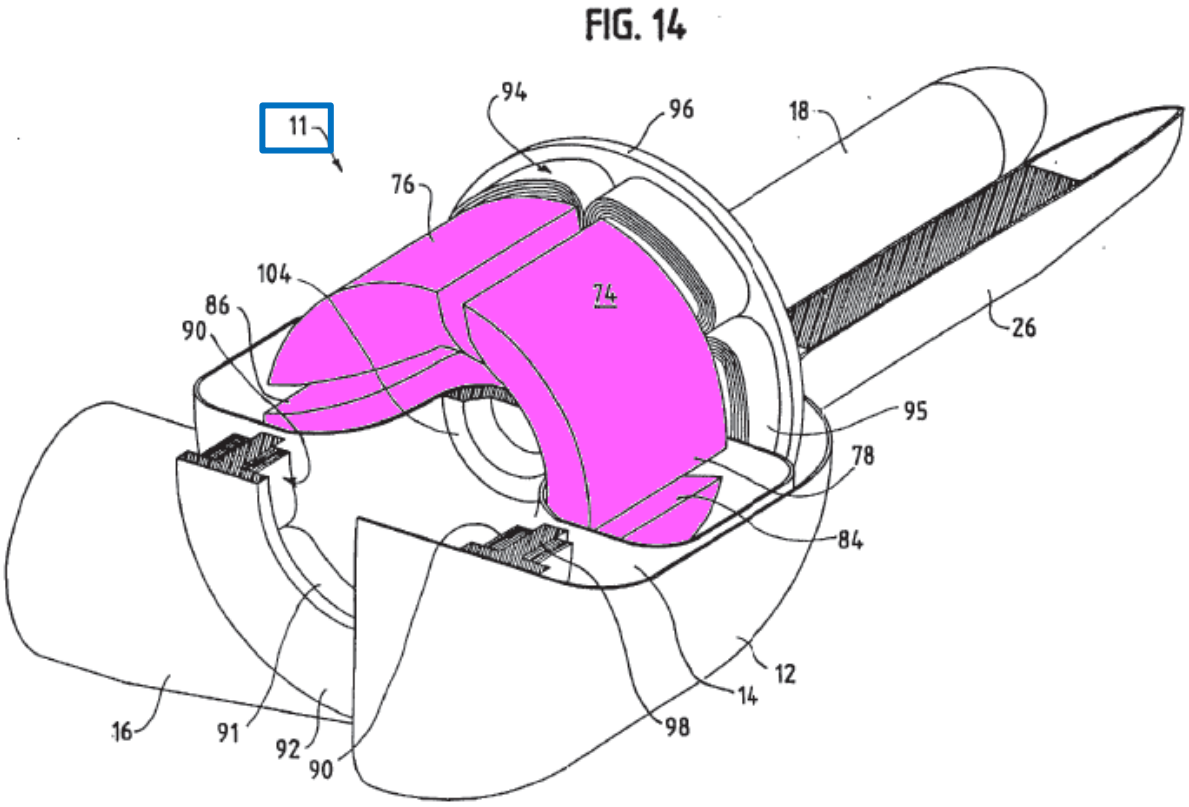
171. Thus, the impeller 19 of the rotor 17 described in Wampler-169 is a **magnetically driven rotor** because it is a rotor driven by the force generated by the electromagnetic field created between the "permanent magnetic segments imbedded within each impeller blade sector" and the "circular electromagnetic stator" of the motor. *See infra* Elements [11F] and [11J]; Ex.1008, [0070], [0072], [0080], [0083]-[0085]. Figure 13 (annotated) of Wampler-169 illustrates a perspective view of an

embodiment of pump 11 (**blue**), which includes "impeller 74" (**pink**) of the rotor 17:



Ex.1008, Fig. 13 (annotated); *see also* Fig. 1, 2, 3, 4.

172. As another example, Figure 14 (annotated) shows a rear perspective view of the same embodiment of pump 11 (**blue**), which includes "impeller 74" (**pink**) of the rotor 17:

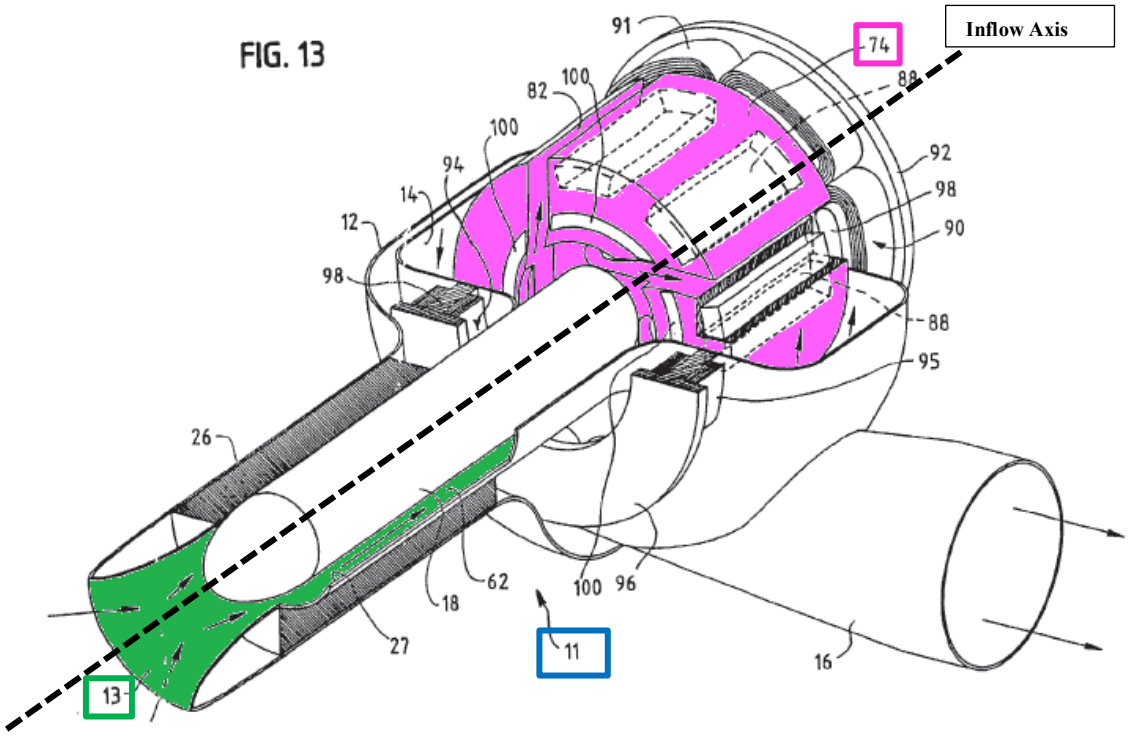


Ex.1008, Fig. 14 (annotated), *see also* Fig. 6, 7, 8,

173. Wampler-169 further discloses that "*the **magnetically driven rotor** is axially aligned with the **inflow axis***."

174. For components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis") in space. The pump 11 described in Wampler-169 has an "inflow axis" (e.g., "longitudinal axis," Ex.1008, [0051]) that is configured in axial alignment with the **inflow tube** (e.g., "inlet tube 13" which "serves as the inflow cannula," Ex.1008, [0075], [0080]) so as to provide the flow of blood to the **magnetically driven rotor**

(e.g., "impeller 74" of the rotor 17, Ex.1008, [0081]). For example, Figure 13 (annotated) of Wampler-169 illustrates the alignment of the impeller 74 (**pink**) of the rotor 17 and the inlet tube 13 (**green**) of pump 11 (**blue**) along a "longitudinal axis" (*inflow axis*) and the flow path of blood from the left ventricle the heart (indicated by black arrows entering the inlet tube):



Ex.1008, Fig. 13 (annotated).

175. Wampler-169 discloses that "[o]wing to the ***axial inflow*** and radial outflow of the pump, a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076]. Indeed, the pump described in Wampler-169 is a *centrifugal* pump, and by design, fluid enters a

centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, a magnetically drive rotor axially aligned with the inflow axis by which blood flood flows from the inflow tube is a characteristic feature of a centrifugal pump.

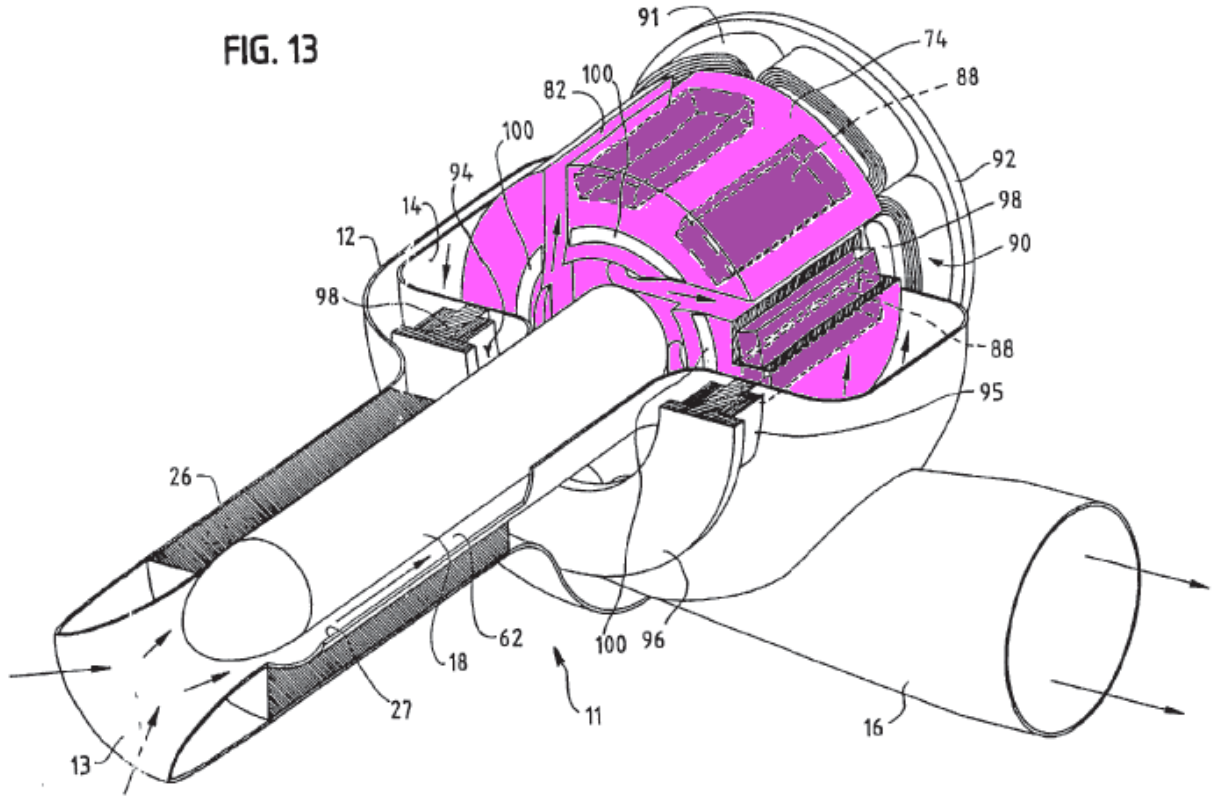
176. Accordingly, Wampler-169 discloses that "*a **magnetically driven rotor*** ("impeller 74") *is axially aligned with the **inflow axis*** ("longitudinal axis")."

v. [11D] and [the magnetically driven rotor] being rigidly coupled and axially adjacent to a first magnetic device that is axially aligned with the inflow axis

177. Wampler-169 discloses the **magnetically driven rotor** "*being rigidly coupled and axially adjacent to a **first magnetic device** that is axially aligned with the **inflow axis***."

178. Wampler-169 discloses that a "benefit of the thick impeller is the ability to utilize magnetic pieces 88 that are inserted in a manner enabling the stators to be on opposite sides of the impeller." Ex.1008, [0080]. I note that, while the configurations of the "motor stators" vary between the described embodiments, the "magnetic pieces 88" described with respect to the embodiment shown in Figures 11-14 are used in the same way as the "magnetic segments 54" described with respect to Figures 1-8. For example, Wampler-169 discloses that "a brushless rotor

motor 53 includes arcuate magnetic segments 54 imbedded within the upper face portion of blade sectors 49" of the impeller 19 of the rotor 17. Ex.1008, [0070], [0064] ("[T]he impeller includes a plurality of large blade sectors 49."). As discussed with respect to element [11C], the "impeller 74" of the rotor 17 is a **magnetically driven rotor**. *See supra* Section X.A.1.iv. The "magnetic pieces 88" are a **first magnetic device** which is *rigidly coupled* to the **magnetically driven rotor** because they are "imbedded" in the blade sectors 49 of the impeller 74 as shown:



Ex.1008, Fig. 13.

179. As will be discussed with respect to elements [11F], "segments 54 have alternating orientations in their polarities, and are directed toward an adjacent motor stator 56," which includes "windings 57" that are "energized by the electrical output of controller 59 to produce an electromagnetic field." Ex.1008, [0070], [0072]; *see infra* Section X.A.1.vii. "This field is concentrated by pole pieces 58, and is effective to drive magnets 54 and the rotor 17, in a rotary fashion." Ex.1008, [0072]; *see also* Ex.1008, [0073] ("Motor 53, with windings 57 and pole piece 58, together with magnets 54, function not only to transmit torque but also provide a restoring radial magnetic force that acts as a radial bearing.").

180. In the embodiment described with respect to Figures 11-14, a "dual stator design" is used wherein a "first motor stator 90" having "conductive coils or motor windings 91, is located at the rear of impeller 74" and a "second motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74." Ex.1008, [0084]. Wampler-169 states that the "dual stator design is adapted to provide system redundancy for a fail safe mode, since each stator can be made to operate independently of the other in the case of emergency." Ex.1008, [0088].

181. Thus, for the purposes of my analysis, I understand the interaction between the "magnetic segments 54" / "magnetic pieces 88" and the "motor stator

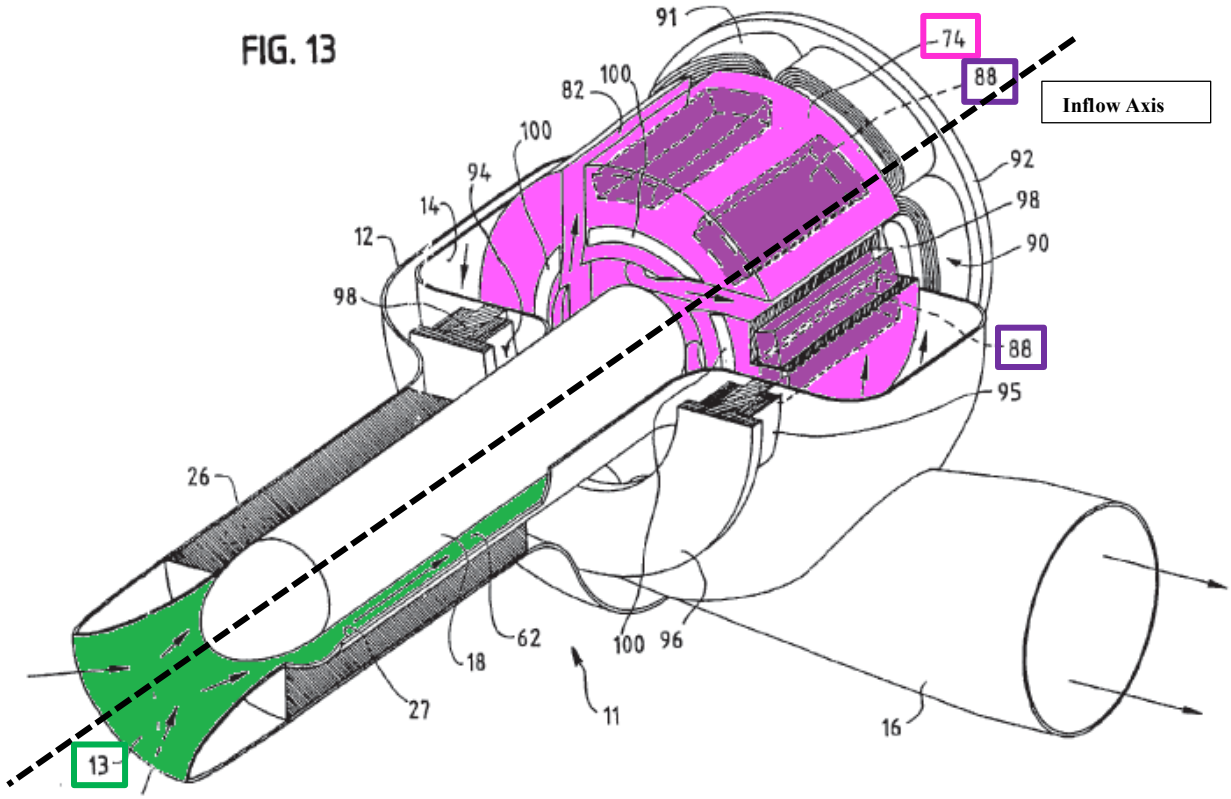
56" / "motor stators 90 and 94" to drive rotation of the impeller 74, is the same between the two embodiments. *See infra* element Section X.A.1.vii.

182. Wampler-169 further discloses that "[r]otor 17 is mounted for rotation about a[] **longitudinal axis** which extends both through shaft 18 and impeller 74." Ex.1008, [0081]; *see also* Ex.1008, [0013] ("Radial magnetic bearings of passive design, maintain the support shaft and the impeller about **a rotational axis**."), [0052] ("The pump 11 of the present invention includes a forward magnetic bearing 21 and a rearward magnetic bearing 22 to levitate rotor 17 and maintain it in proper radial alignment with respect to its **longitudinal axis**."). Further, the described pump implements an "axial inflow and radial outflow," so that "a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076].

183. As discussed for element [11C], for components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis") in space. The pump 11 described in Wampler-169 thus has an **inflow axis** (e.g., "longitudinal axis") that is configured in axial alignment with the **inflow tube** (e.g., "inlet tube 13" which "serves as the inflow cannula," Ex.1008, [0075], [0080]) so as to provide the flow of blood to the **magnetically driven rotor** (e.g., "impeller 74" of the rotor 17, Ex.1008, [0081]) that is *rigidly*

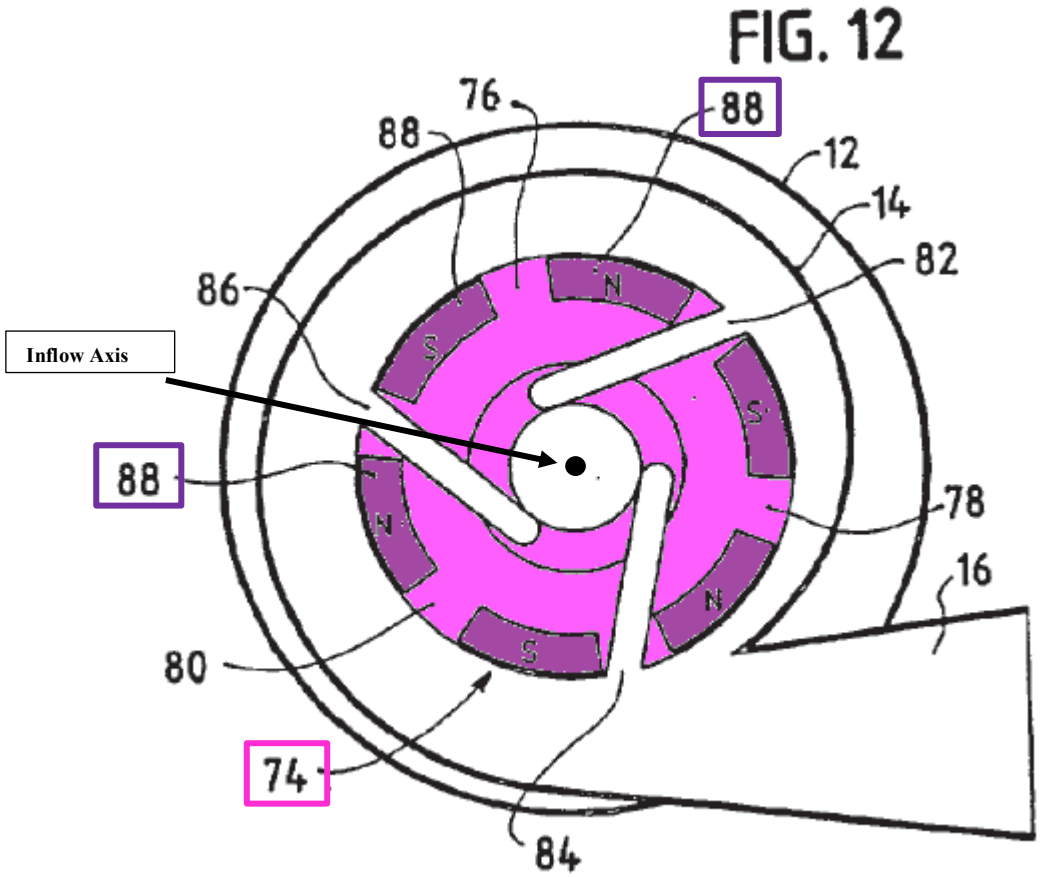
coupled and axially adjacent to the **first magnetic device** (e.g., "imbedded" "magnetic pieces 88," Ex.1008, [0070]).

184. Figure 13 of Wampler-169 thus depicts a perspective view of the impeller 74 (**pink**) being *rigidly coupled* to the magnetic pieces 88 (**purple**), and both components being *axially adjacent* and *axially aligned* along the longitudinal (or "rotational") axis (**black**) of the inlet tube 13 (**green**) on which the inflow path of blood from the left ventricle the heart is indicated by arrows 62:



Ex.1008, Fig. 13 (annotated), *see also* Figs. 1, 2, 3, 5.

185. Figure 12 (annotated) of Wampler-169 illustrates a cross-sectional end view of the impeller 74 (**pink**) having the embedded magnetic pieces 88 (**purple**) where the impeller 74 and magnetic pieces 88 are *axially adjacent* and *axially aligned* along the longitudinal axis (**black**):



Ex.1008, Fig. 12 (annotated); *see also* Figs. 6, 13, 14, 16.

186. Accordingly, Wampler-169 discloses the **magnetically driven rotor** ("impeller 74") "*being rigidly coupled and axially adjacent to a* ***first magnetic***

device ("magnetic pieces 88") *that is axially aligned with the* ***inflow axis*** ("longitudinal axis")."

vi. [11E] the magnetically driven rotor and first magnetic device being rotatable about an axis of rotation aligned with the inflow axis to drive the blood flowing from the inflow tube

187. Wampler-169 discloses "*the* ***magnetically driven rotor*** *and* ***first magnetic device*** *being rotatable about an axis of rotation aligned with the* ***inflow axis*** *to drive the blood flowing from the* ***inflow tube*****.**"

188. As discussed with respect to element [11C], the impeller 74 of the rotor 17 is a **magnetically driven rotor**. *See supra* Section X.A.1.iv. And as discussed with respect to element [11D], "magnetic pieces 88" are a **first magnetic device** "inserted" within the blades of the impeller 74 of the rotor 17 such that they are *rigidly coupled*. Ex.1008, [0070], [0064], [0080]; *supra* Section X.A.1.v.

189. Wampler-169 further discloses that "[r]otor 17 is **mounted for rotation** about a **longitudinal axis which extends both through shaft 18 and impeller 74**." Ex.1008, [0081], [0051]; *see also* Ex.1008, [0013] ("Radial magnetic bearings of passive design, maintain the support shaft and the impeller about a rotational axis."), [0052] ("The pump 11 of the present invention includes a forward magnetic bearing 21 and a rearward magnetic bearing 22 to levitate rotor 17 and

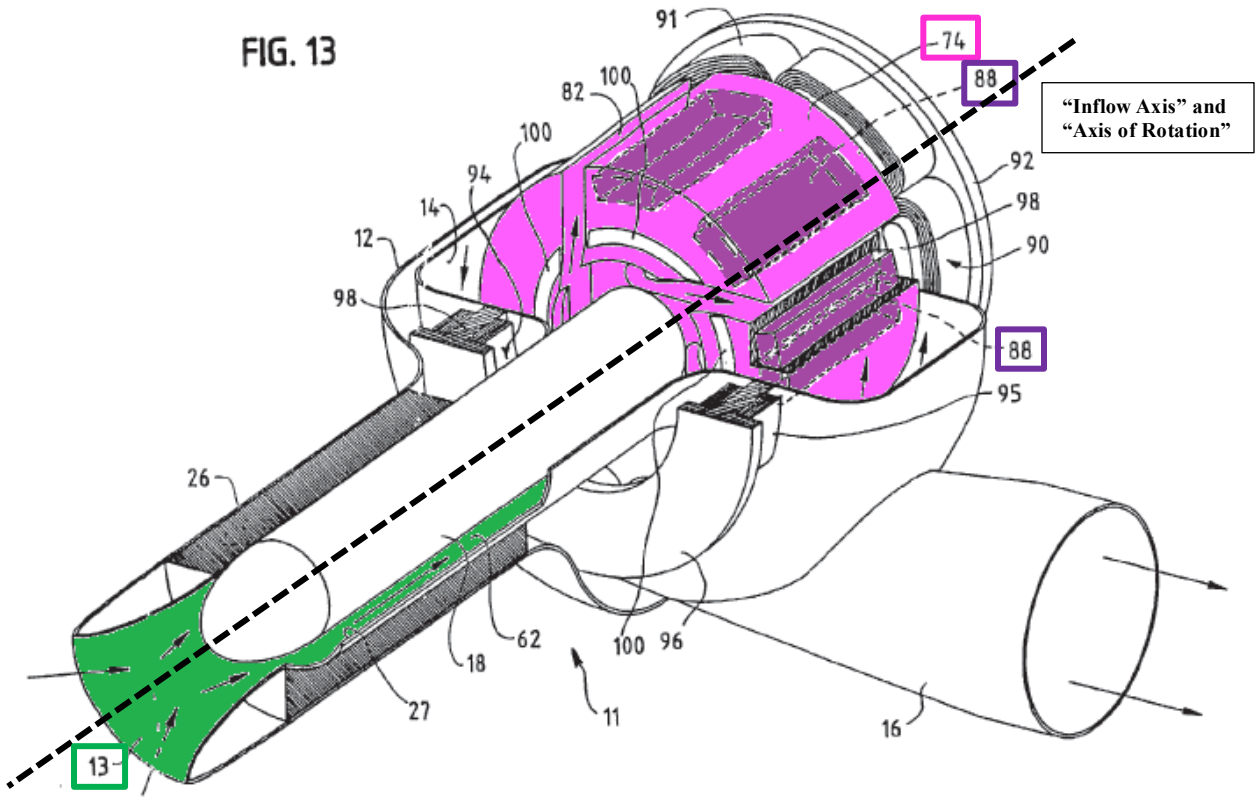
maintain it in proper radial alignment with respect to its longitudinal axis."). Further, the described pump implements an "axial inflow and radial outflow," so that "a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076].

190. As discussed with respect to element [11B], Wampler-169 further discloses the flow path of blood through the pump as follows: "Rotation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62. The blood continues its path from the upper edge of passage 51 to the interior of casing 14. Discharge tube 16 allows the blood to be expelled from the casing an [sic] into the user's cardiovascular system." Ex.1008, [0074], *see also* Abstract ("A rotor is mounted for rotation within the housing…").

191. Thus, the **magnetically driven rotor** (e.g., "impeller 74" of the rotor 17, Ex.1008 at [0081]) and the **first magnetic device** (e.g., "magnetic pieces 88," Ex.1008, [0070]) is rotatable about an **axis of rotation aligned with the inflow axis** (e.g., "mounted for rotation about a longitudinal axis" Ex.1008, [0081]) to drive the blood flowing from the **inflow tube** (e.g., "blood to flow through inlet tube 13 in the direction of arrows 62" is "expelled from the casing," Ex.1008, [0074]).

192. Figure 13 (annotated) Wampler-169 illustrates a cross-sectional view of pump 11, which includes "impeller 74" (**pink**) and its imbedded "magnetic pieces

88" (**purple**) rotatable about the "longitudinal axis" (**black**) to drive the blood flowing (arrows 62) from the inlet tube 13 (**green**):



Ex.1008, Fig. 13 (annotated), *see also* Figs. 1, 2, 3, 5.

193. Accordingly, Wampler-169 discloses "*the* ***magnetically driven rotor*** ("impeller 74") *and* ***first magnetic device*** ("magnetic pieces 88") *being rotatable about an axis of rotation aligned with the* ***inflow axis*** ("longitudinal axis") *to drive the blood flowing from the* ***inflow tube*** ("inlet tube 13")."

vii. [11F] a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis

194. Wampler-169 discloses "*a magnetic drive system comprising a second magnetic device axially aligned with the* ***inflow axis*****.**

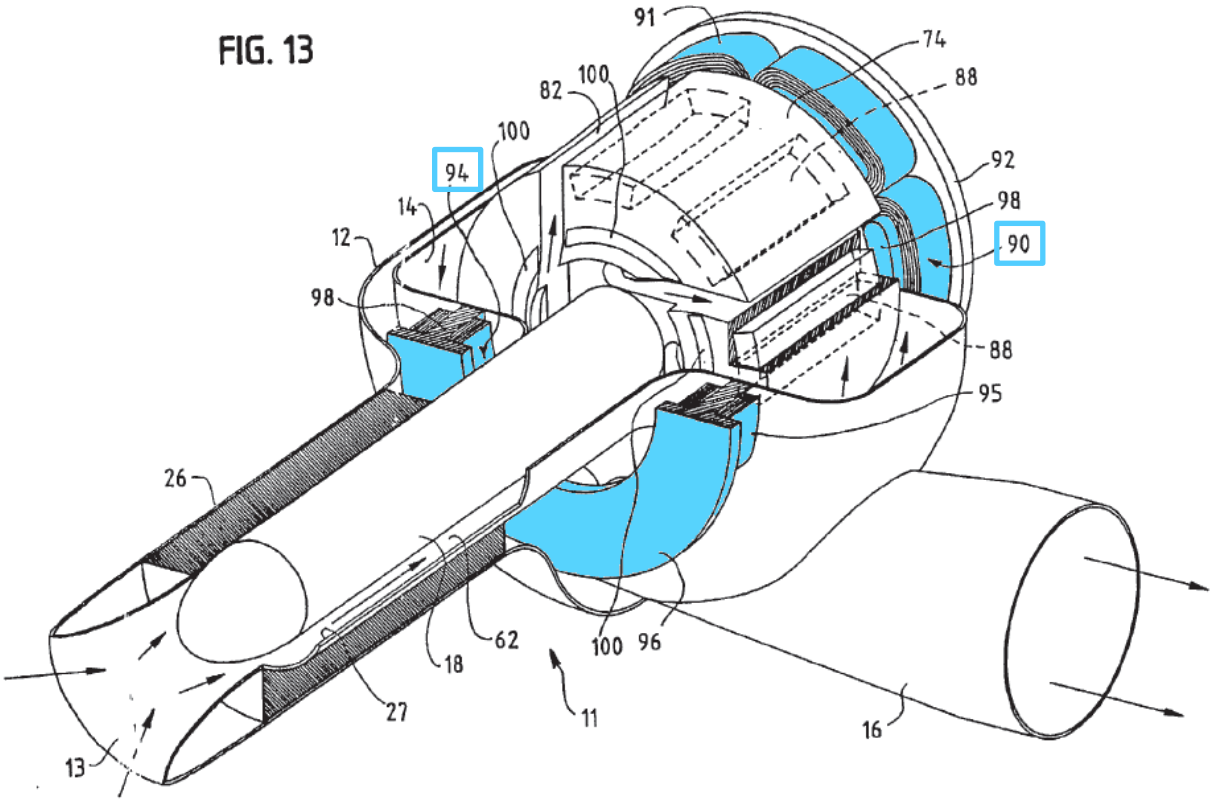
195. As discussed above, I understand that the interaction between the "magnetic segments 54" / "magnetic pieces 88" and the "motor stator 56" / "motor stators 90 and 94" to drive rotation of the impeller 74, is the same between the two embodiments. For example, Wampler-169 discloses that "segments 54 have alternating orientations in their polarities, and are directed toward an adjacent motor stator 56." Ex.1008, [0070]. The "motor stator 56" includes "windings 57 and a circular pole piece or back iron 58, mounted on the outer surface of impeller casing 14." Ex.1008, [0070].

196. In addition, with respect to the embodiment described with respect to Figures 11-14, "a first motor stator 90, comprising conductive coils or motor windings 91, is located at the rear of impeller 74" and "a ring of back iron 92 is located behind windings 91." Ex.1008, [0083]. "A second motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74" and "windings 95 are fixed to casing 14 and a ring of back iron 96 is positioned forward of windings 95." Ex.1008, [0084]. Wampler-169 discloses that the "motor stators 90

and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets 98. Back iron 92 and back iron 96 serve to complete a magnetic circuit." Ex.1008, [0085].

197. The "motor stators 90 and 94" described in Wampler-169 are a **magnetic drive system comprising a second magnetic device** as recited in Claim 11. Wampler-169 discloses that "[t]orque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing" ("*magnetic drive system*"). Ex.1008, [0018].

198. Figure 13 (annotated) of Wampler-169 is a perspective view of the pump 11 showing the elements of the pump motor, including "motor stators 90 and 94" (**light blue**), which each include subcomponents (for example, "motor windings 91," "back iron 92," "windings 95," "back iron 96," and "teeth 95"):



Ex.1008, Fig. 13 (annotated); *see also* Figs. 7, 8*a*, 8*b*, 13*a*, 13*b*, 14.

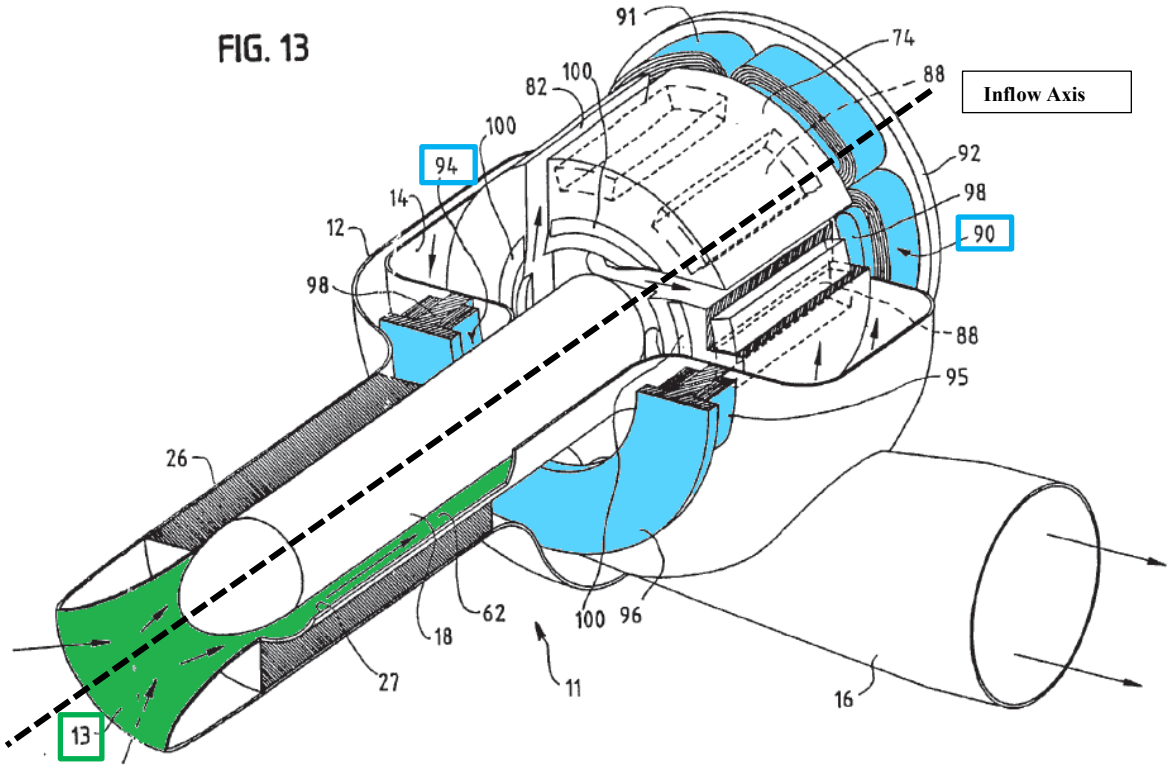
199. As discussed above with respect to element [11C], for components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis" of rotation) in space. *Supra* Section X.A.1.iv. The **heart assist pump device** (*e.g.*, "blood pump 11," [0080]) described in Wampler-169 has an **inflow tube** (*e.g.*, the "inlet tube 13," Ex.1008, [0080]) that "serves as the inflow cannula" through which blood flows to the **magnetically driven rotor** (*e.g.*, "impeller 74" of the rotor, Ex.1008, [0081]), which is driven by the electromagnetic interaction between the **first magnetic device** (*e.g.*, the

"magnetic pieces 88" embedded in the impeller 74, Ex.1008, [0070]) and the **second magnetic device** (*e.g.*, the "motor stators 90 and 94," Ex.1008, [0083]-[0084], Fig. 13).

200. Each of the impeller 74, the embedded magnetic pieces 88, and motor stators 90 and 94 described in Wampler-169 are axially aligned with the **inflow axis** (e.g., "Rotor 17 is mounted for rotation about a[] **longitudinal axis** which extends both through shaft 18 and impeller 74," Ex.1008, [0081]). *See also* Ex.1008, [0013] ("Radial magnetic bearings of passive design, maintain the support shaft and the impeller about a rotational axis."), [0052] ("The pump 11 of the present invention includes a forward magnetic bearing 21 and a rearward magnetic bearing 22 to levitate rotor 17 and maintain it in proper radial alignment with respect to its longitudinal axis."). Further, the described pump implements an "**axial inflow** and radial outflow," so that "a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076].

201. Indeed, the pump 11 described in Wampler-169 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, an axially aligned inflow tube is a characteristic feature of a centrifugal pump.

202. For example, Figure 13 (annotated) illustrates the alignment of the "motor stators 90 and 94" (**light blue**) and the inlet tube 13 (**green**) of the pump 11 along the inflow axis (**black**):



Ex.1008, Fig. 13 (annotated); *see also* Figs. 3, 4, 7, 8*a*, 8*b*, 14.

203. Accordingly, Wampler-169 discloses "***a magnetic drive system comprising a second magnetic device*** ("motor stators 90 and 94") *axially aligned with the* ***inflow axis*** ("longitudinal axis").

viii. [11G] and [the second magnetic device is] spaced apart from the magnetically driven rotor such that a wall of the one or more walls defining the chamber is positioned between the magnetically driven rotor and the second magnetic device

204. Wampler-169 discloses that the ***second magnetic device*** is "*spaced apart from the* ***magnetically driven rotor*** *such that* ***a wall*** *of the* ***one or more walls*** *defining* ***the chamber*** *is positioned between the* ***magnetically driven rotor*** *and the* ***second magnetic device***."

205. As discussed with respect to element [11B], Wampler-169 discloses that the "rotary blood pump includes a housing and a pump rotor," where the housing "includes an elongated inlet tube surrounding the shaft, and a scroll-shaped casing, or volute, with a discharge outlet, enclosing the impeller." Ex.1008, [0012]; *see also* [0081] ("Pump rotor 17 is located within housing 12, ***within casing 14***, and includes an elongated, right-circular cylindrical support shaft or spindle 18, attached to impeller 74."), [0050].

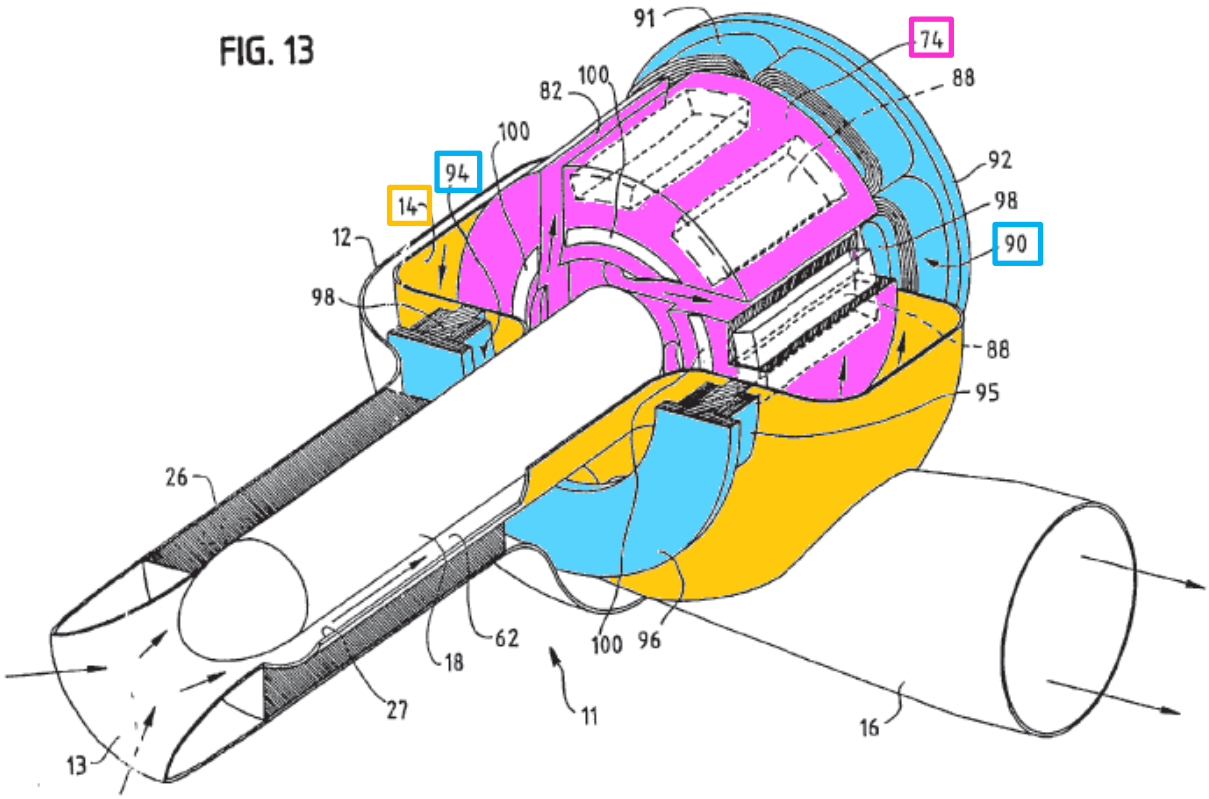
206. Wampler-169 further discloses that "the first motor stator 90 and back iron 92 are fixed between housing 12 and casing 14." Ex.1008, [0083]. The "second motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74," and the "windings 95 are fixed to casing 14 and a ring of back iron 96

is positioned forward of windings 95." Ex.1008, [0084]. In addition, "it can be seen that the motor stators 90 and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets 98." Ex.1008, [0085]; *see also* Ex.1008, [0070] ("windings 57" and "back iron 58" are "***mounted on the outer surface of impeller casing 14***"), [0018] ("A ring of back iron is fixed to the casing to aid in completing a flux return path for the permanent magnets …").

207. Indeed, the pump 11 described in Wampler-169 is a "sealless rotary blood pump." Ex.1008, [0050]. Wampler-169 describes problems in the art at the time with the short life of driveshaft seals in prior art LVADs, contributing to premature failure of the pump and the possibility of causing embolisms. Ex.1008, [0005]. The pump 11 of Wampler-169 "eliminat[es] the necessity for a driveshaft seal" by the use of the magnetic elements of the electric motor, such that torque is transferred to the drive the pump without contact between components. Ex.1008, [0005], [0018], [0019], [0070], [0072], [0073], 0074].

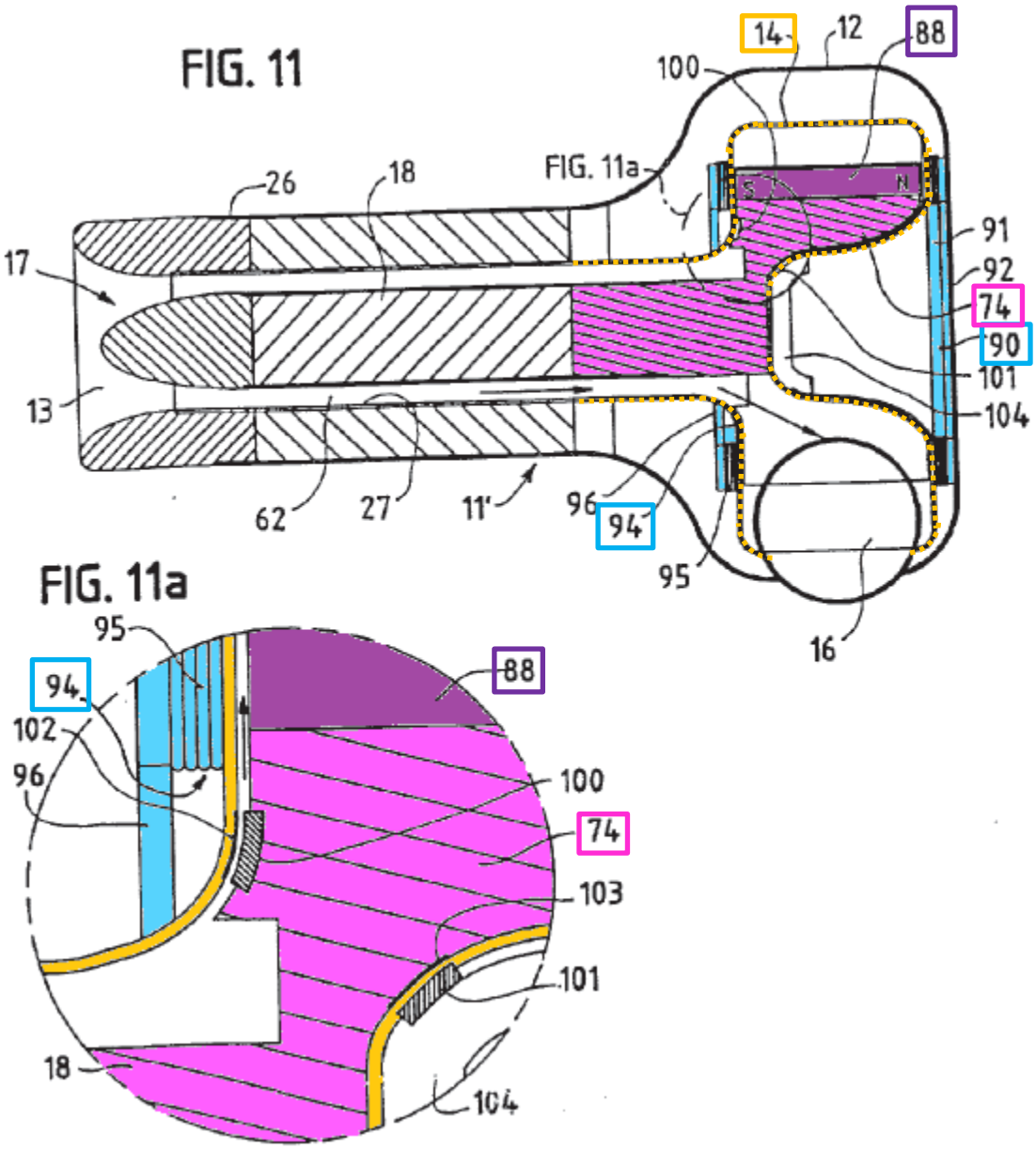
208. Thus, **a wall** (e.g., "outer surface") of the **one or more walls** ("interior" and "outer surface") defining **the chamber** ("casing 14") is positioned between the **second magnetic device** ("motor stators 90 and 94") and the **magnetically driven rotor** ("impeller 74").

209. Figure 13 (annotated) of Wampler-169 illustrates a cross-sectional view of the "motor stators 90 and 94" (**light blue**) being spaced apart from the "impeller 74" (**pink**) such that an "outer surface" of the casing 14 (**orange**) is positioned between the "impeller 74" and the "motor stators 90 and 94":



Ex.1008, Fig. 13 (annotated).

210. Figures 11 and 11*a* (annotated) of Wampler-169 are a cross-sectional side view of the pump 11 that illustrates the "magnetic pieces 88" (**purple**) of the impeller (**pink**) being spaced apart from the "motor stators 90 and 94" (**light blue**) by the "outer surface" of the casing 14 (**orange**):



Ex.1008, Figs. 11 and 11*a* (annotated).

211. Accordingly, Wampler-169 discloses that the ***second magnetic device*** ("motor stators 90 and 94") is "*spaced apart from the* ***magnetically driven rotor*** ("impeller 74") *such that* ***a wall*** ("outer surface") *of the* ***one or more walls*** ("interior"

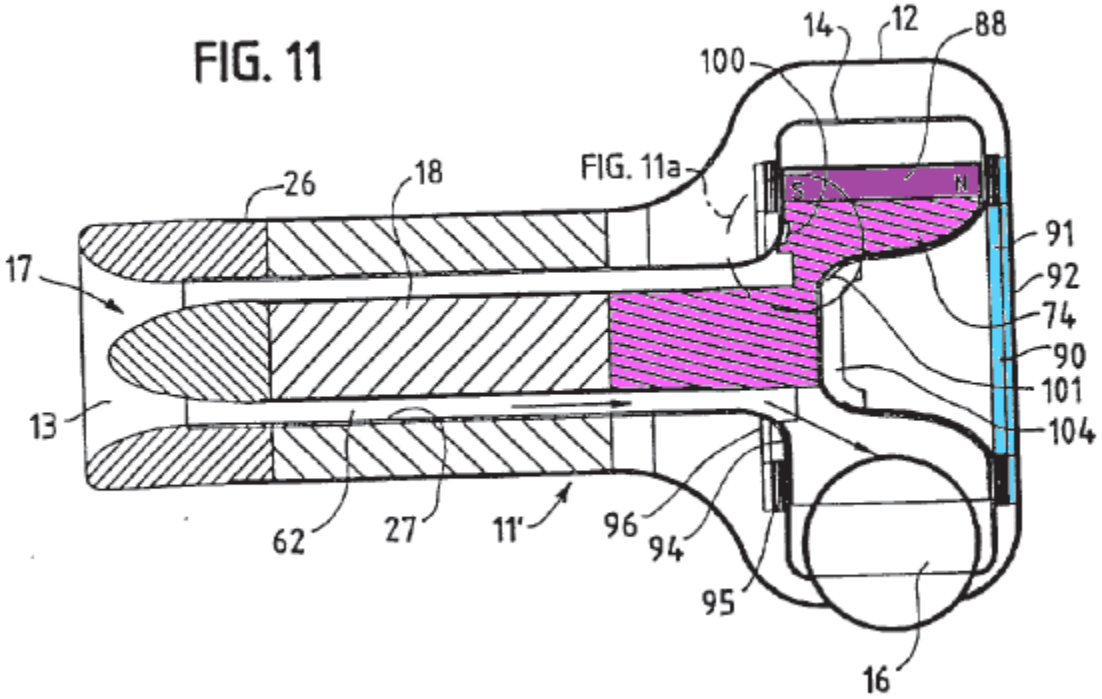
and "outer surface") *defining the* ***chamber*** ("casing 14") *is positioned between the* ***magnetically driven rotor*** *and the* ***second magnetic device***."

ix. [11H] the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor so as to magnetically drive rotation of the magnetically driven rotor relative to the one or more walls via a magneto coupling with the first magnetic device,

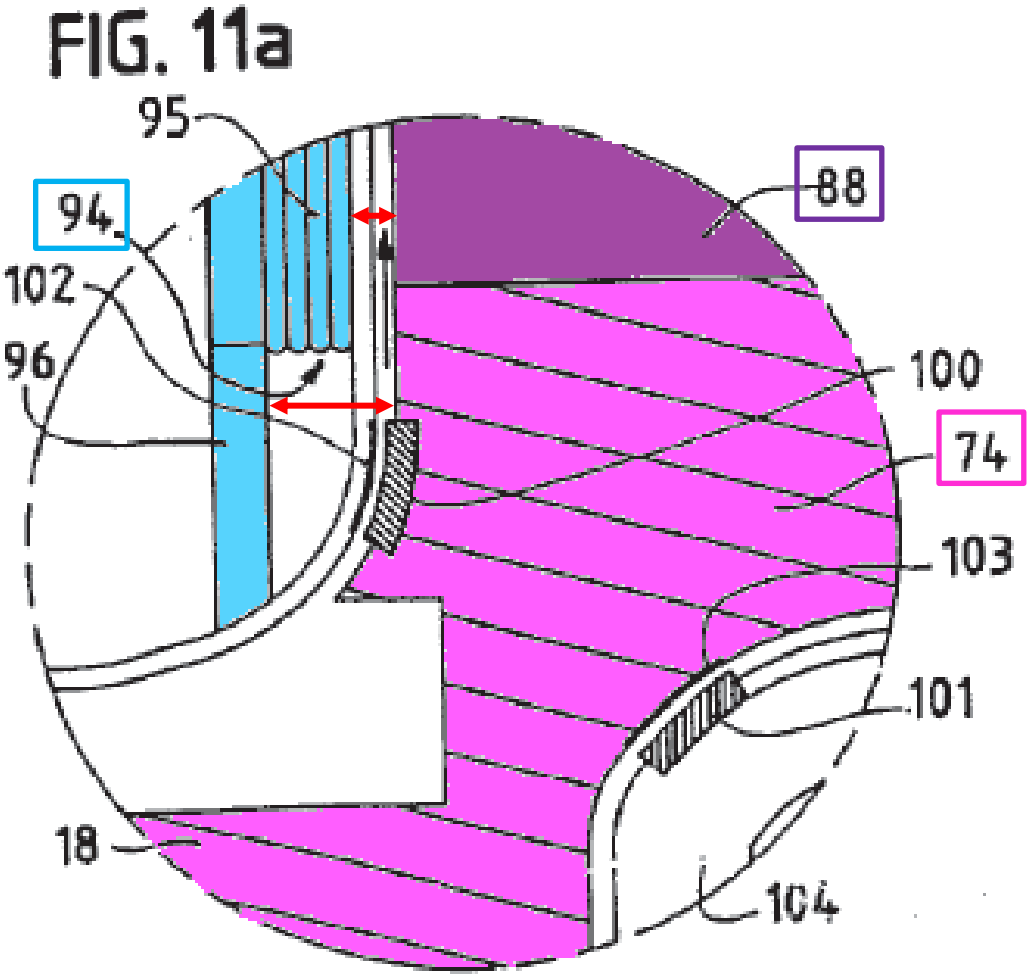
212. Wampler-169 discloses "*the* ***second magnetic device*** *positioned axially closer to the* ***first magnetic device*** *than to the* ***magnetically driven rotor*** *so as to magnetically drive rotation of the* ***magnetically driven rotor*** *relative to the* ***one or more walls*** *via a magneto coupling with the* ***first magnetic device***."

213. For the **second magnetic device** to be "axially closer" to the **first magnetic device** than the **magnetically drive rotor** as recited in Claim 11, each of the components are configured such that they are colinear, or in the same line (or "axis") in space, and the **second magnetic device** is closer to the **first magnetic device** along that axis than it is to the **magnetically driven rotor**. Wampler-169 thus discloses "it can be seen that the motor stators 90 and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets [88]." Ex. 1008, [0085]. As shown in Figure 11 of Wampler-169, the **second magnetic device** (e.g., "motor stator[] 90") is positioned *axially closer* to

the **first magnetic device** (e.g., "magnetic pieces 88") than to the **magnetically driven rotor** ("impeller 74").



214. Further, Figure 11*a* of Wampler-169 illustrates that the motor stator 94 (**light blue**), which includes the "windings 95," are *positioned axially closer to* the "magnetic pieces 88" (**purple**) than the "back iron 96" of the motor stator 94 is to the "impeller 74" (**pink**), as shown by the lengths of the **red** arrows:



Ex.1008, Figs 11-11*a*; *see also* Figs. 7, 8*a*, 8*b*.

215. Indeed, the "windings" of the "motor stators 90 and 94" must be positioned directly "adjacent" and therefore *axially closer* to the magnetic pieces 88 for the "produce[d] an electromagnetic field" to be "effective to drive magnets 88" and thereby drive rotation of the impeller 74. Ex.1008, [0072], [0085]. To the extent that there is some portion of the impeller 74 that is adjacent the "windings" of motors

stators 90 and 94, Figures 11 and 11a show the vast majority of the impeller 74 is spaced significantly farther apart from the stators than the magnetic pieces 88 are positioned from the stators.

216. In any event, it would have been obvious to position the "motor stators 90 and 94" "axially closer" to the "magnetic pieces 88" than to the "impeller 74." A POSITA would have been motivated to do because the "motor stators" act upon the "magnetic pieces"—positioning those elements closer to each other would facilitate that action. Indeed, as discussed below, it is the "magnetic interaction" ("*magneto coupling*") between the permanent magnetic segments [88] and the circular electromagnetic stator [90 and 94] that drives rotation of the impeller. Ex.1008, [0072], [0018]. Thus, it would have been obvious to a POSITA to position the **second magnetic device** (e.g., "circular electromagnetic stator[s] [90 and 94]") *axially closer* to the **first magnetic device** (e.g., "magnetic pieces 88"), than to the **magnetically driven rotor** (e.g., in order for the electromagnetic field produced by the stators to effectively generate the torque to drive the impeller via the "magnetic interaction" with the magnetic pieces 88.

217. Further, as discussed in Section VII.A.1, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating magnetic component to another

rotating magnetic component via a magnetic field." *See supra* Section VII.A.1. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in parallel litigation) of "magneto coupling" to also include not only a transfer of torque from one rotating magnetic component to another rotating magnetic component, but also to include "a transfer of torque from one *stationary* magnetic component (i.e., a stator) to another rotating magnetic component using an *electro*magnetic field," is correct. *See, e.g.*, Ex.1019.

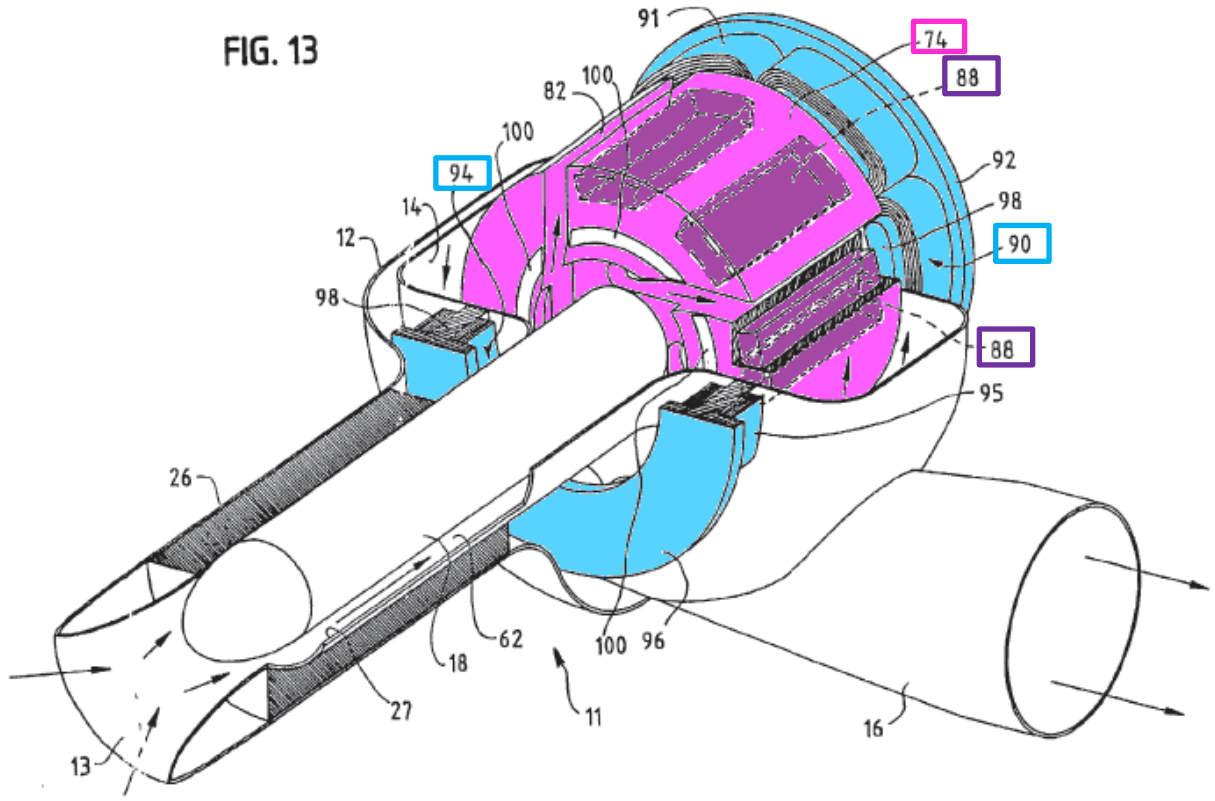
218. Accordingly, based on the Patent Owner's understanding of the term, Wampler-169 describes a magneto coupling between the **second magnetic device** (e.g., the "motor stators 90 and 94" of the motor 53, Ex.1008, [0085]) and the **first magnetic device** (e.g., the "magnetic pieces 88" of the impeller, Ex.1008, [0080]). For example, Wampler-169 discloses that "the motor stators 90 and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets 98." Ex.1008, [0085].

219. The interaction between the motor stator is described with respect to the embodiment of Figures 1-8; the "windings 57" of the motor stator 56 "are energized by the electrical output of controller 59 to produce an electromagnetic field. ***This field is concentrated by pole piece 58, and is effective to drive magnets***

54 and the rotor 17, in a rotary fashion." Ex.1008, [0072]; *see also* Ex.1008, [0018] ("Torque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing."), [0085]. The interaction between the "motor stators 90 and 94" and the "magnetic pieces 88" described with respect the embodiment of Figures 11-14 creates the same "torque drive" that is "imparted to the impeller."

220. Further, Wampler-169 describes the "[r]otation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62." Ex.1008, [0074]. Thus, the **second magnetic device** (*e.g.*, "motor stators 90 and 94," Ex.1008, [0085]) is positioned to drive rotation of the **magnetically driven rotor** (e.g., "impeller 74" of the rotor, Ex.1008, [0081]), via the magneto coupling with the **first magnetic device** (e.g., the "magnetic pieces 88" of the impeller, Ex.1008, [0080]).

221. Figure 13 (annotated) of Wampler-169 illustrates a perspective view of the pump 11 having the "motor stators 90 and 94" (**light blue**) to drive the rotation of the "impeller 74" (**pink**) by the magneto coupling with the imbedded "magnetic pieces 88" (**purple**):



Ex.1008, Fig. 3; *see also* Figs. 4, 7, 8*a*, 8*b*.

222. Finally, Wampler-169 further discloses that "[a]lthough at rest there may be contact between the impeller and the casing, once rotation begins each hydrodynamic bearing is structured so that ***during relative movement*** between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap which forces the raised pad and the contact surface apart." Ex.1008, [0092]; *see also* Ex.1008, [0074] ("Rotation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62.").

223. Thus, Wampler discloses the rotation of the **magnetically driven rotor** ("impeller 74") relative to and within the **one or more walls** ("interior" of "casing 14").

224. Accordingly, Wampler-169 discloses or at least renders obvious "*the **second magnetic device** positioned axially closer to the **first magnetic device*** ("magnetic pieces 88") *than to the **magnetically driven rotor*** ("impeller 74") *so as to magnetically drive rotation of the **magnetically driven rotor*** ("impeller 74") *relative to the **one or more walls*** ("interior" of "casing 14") *via a magneto coupling with the **first magnetic device*** ("magnetic pieces 88")."

x. [11I] and a blood outflow port positioned such that the blood driven by the magnetically driven rotor exits the chamber in a direction substantially perpendicular to the inflow axis

225. Wampler-169 discloses that a "***blood outflow port*** *positioned such that the blood driven by the **magnetically driven rotor** exits the **chamber** in a direction substantially perpendicular to the **inflow axis**.*"

226. Wampler-169 discloses that pump 11 includes a "discharge tube 16" which "extends through the housing to communicate with the interior periphery of casing 14." Ex.1008, [0080]; *see also* Ex.1008, [0050]. The discharge tube 16 "has a tangential orientation with respect to a radius of the casing, for effectively

channeling the blood output from the pump." Ex.1008, [0080]; *see also* Ex.1008, [0074] ("Rotation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62. The blood continues its path from the upper edge of passage 51 to the interior of casing 14***. Discharge tube 16 allows the blood to be expelled from the casing an into the user's cardiovascular system***.").

227. Wampler-169 further discloses that "[o]wing to the ***axial inflow*** and radial outflow of the pump, a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076]. Wampler-169 discloses that "[r]otor 17 is mounted for rotation about an ***longitudinal axis*** which extends both through shaft 18 and impeller 74." Ex.1008, [0081], [0051]; *see also* Ex.1008, [0013] ("Radial magnetic bearings of passive design, maintain the support shaft and the impeller about a ***rotational axis***."), [0052] ("The pump 11 of the present invention includes a forward magnetic bearing 21 and a rearward magnetic bearing 22 to levitate rotor 17 and maintain it in proper radial alignment with respect to its ***longitudinal axis***.").

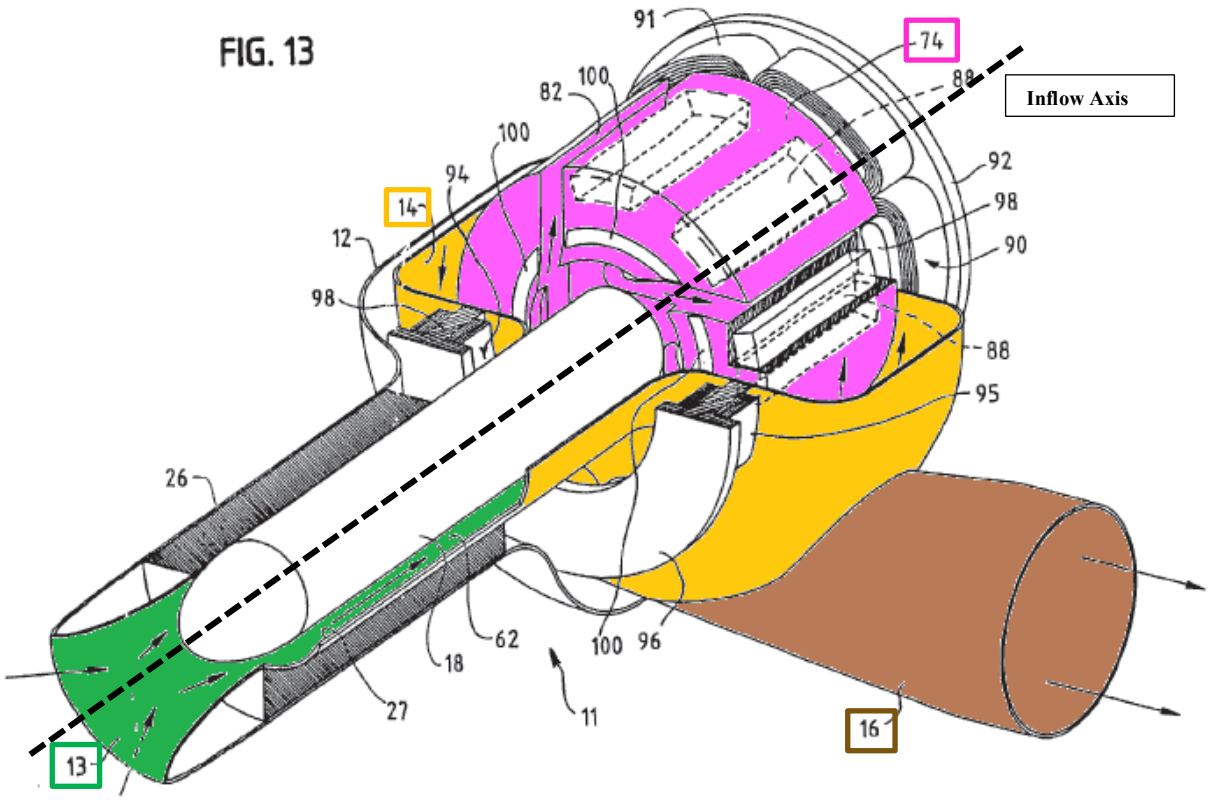
228. Because the "discharge tube 16" has a "tangential orientation with respect to a radius of the casing," which "encloses the impeller" that is axially aligned with the "longitudinal axis" (see element [11C]), blood driven by the

"impeller 74" exits the "casing 14" through the "discharge tube 16" in a direction substantially perpendicular to the "axial inflow" of blood through the inlet tube 13 the "longitudinal axis." Ex.1008, [0074], [0080], [0076], [0081]; *see supra* Section X.A.1.iv.

229. Thus, the **blood outflow port** (e.g., "discharge tube 16") is positioned such that the blood driven by the **magnetically driven rotor** (e.g., the "impeller 74" of the rotor) exits the **chamber** (e.g., "casing 14") in a direction substantially perpendicular to the **inflow axis** (e.g., "axial inflow" along "longitudinal axis"). I note that in parallel litigation, the Patent Owner has asserted the blood outflow port of the "HeartMate 3" is positioned such that blood driven by the accused magnetically driven rotor exits the chamber in the same way as described above in Wampler-169. *See e.g.*, Ex.1019, at 8-9 (Complaint, Ex. 11). For the purposes of my analysis, I also map the limitation that the **blood outflow port** (e.g., "discharge tube 16") is positioned such that blood driven by the **magnetically driven rotor** (e.g., the "impeller 74") exits the **chamber** ("casing 14") in a direction substantially perpendicular to the inflow axis in the same way.

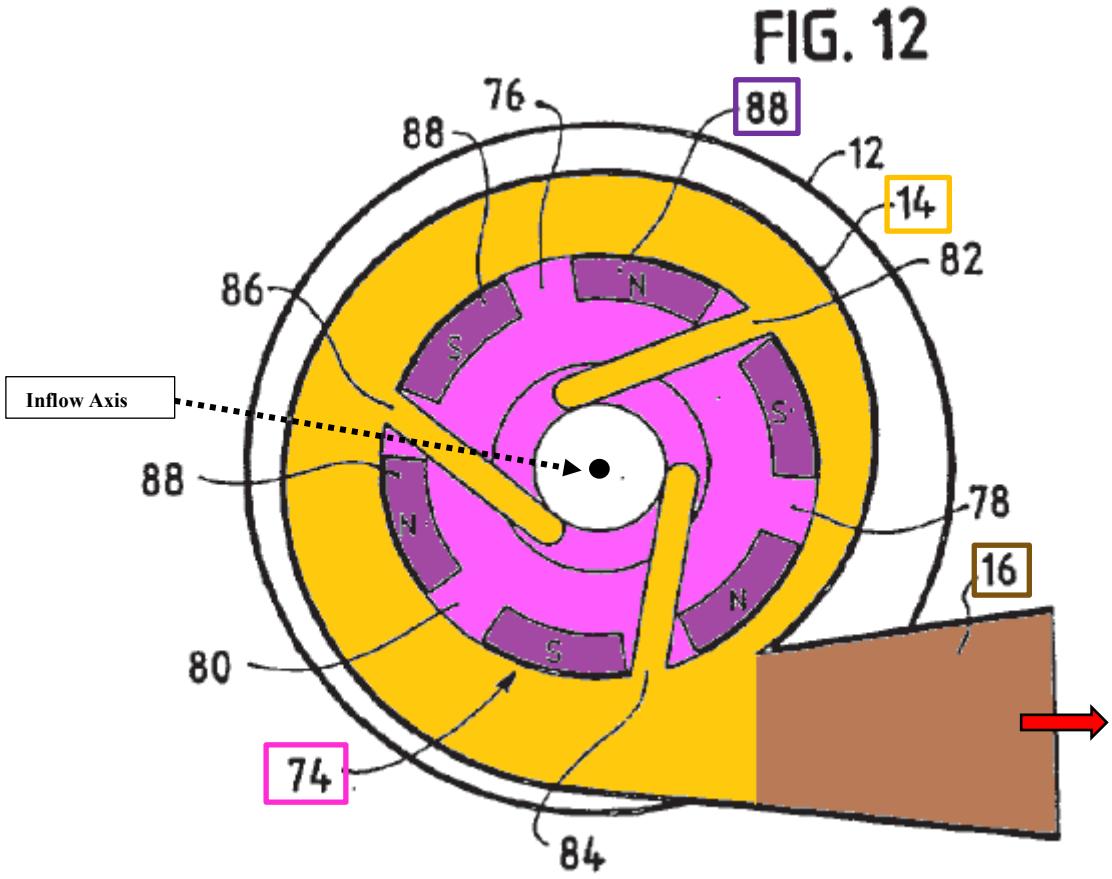
230. Figure 13 (annotated) illustrates a cross-sectional view of the pump 11 where the discharge tube 16 (**brown**) is positioned such that blood driven (black arrows) by the impeller 74 of the rotor (**pink**) exits the casing 14 (**orange**) in a

direction substantially perpendicular from the inflow (or "longitudinal") axis (**black**):



Ex.1008, Fig. 13 (annotated).

231. Similarly, Figure 12 (annotated) shows a top view of the pump 11 further illustrating that the discharge tube 16 (**brown**) is radially adjacent to the impeller 74 of the rotor (**pink**) having magnetic pieces 88 (**purple**) such that blood driven (**red** arrow) by the impeller exits the casing 14 (**orange**) in a direction substantially perpendicular from the inlet tube and the inflow (or "longitudinal") axis (**black**):



Ex.1008, Fig. 6 (annotated).

232. Accordingly, Wampler-169 discloses that a "***blood outflow port*** ("discharge tube 16") *positioned such that the blood driven by the* ***magnetically driven rotor*** ("impeller 74") *exits the* ***chamber*** ("casing 14") *in a direction substantially perpendicular to the* ***inflow axis*** ("axial inflow" along "longitudinal axis")."

xi. [11J] wherein the magneto coupling orients the magnetically driven rotor so that both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor,

233. Wampler-169 discloses that "*the magneto coupling orients the **magnetically driven rotor** so that both the **magnetically driven rotor** and the **first magnetic device** remain spaced apart from the **one or more walls** by the blood in response to rotation of the **magnetically driven rotor**.*"

234. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls **by the blood** in response to rotation of the magnetically driven rotor" to mean that "in response to rotation of the magnetically driven rotor" refers to a hydrodynamic bearing such that "the blood" ***causes*** the "magnetically driven rotor and the first magnetic device" to "remain spaced apart from the one or more walls." *See* Section VII.A.2. For the purposes of my analysis in this Ground, I assume that my narrower interpretation of the plain and ordinary meaning of this phrase is correct. *See* Ex.1019. However, whether this limitation is interpreted broadly (to include *exclusively* magnetic suspension) or narrowly (to require the blood flowing

to cause suspension of the rotor), my narrower interpretation would in any event be included within the broader interpretation.

235. Accordingly, as discussed with respect to element [11H], Wampler-169 discloses a magneto coupling between the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) and the **first magnetic device** (e.g., the "magnetic pieces 88" imbedded in the impeller 74, Ex.1008, [0080]) to drive rotation of the **magnetically driven rotor** (e.g., "impeller 74"). *See element* [11H].

236. In addition, Wampler-169 discloses that in the embodiments described with respect to Figures 11-14, "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Referring to FIGS. 11 and 11*a* in particular, hydrodynamic bearings in the form of raised pads 100, 101 and contact surfaces 102 and 103 are illustrated." Ex.1008, [0089]. Note that these embodiments do not include the mechanical "thrust bearings" included in the embodiments, described with respect to Figures 1-8.

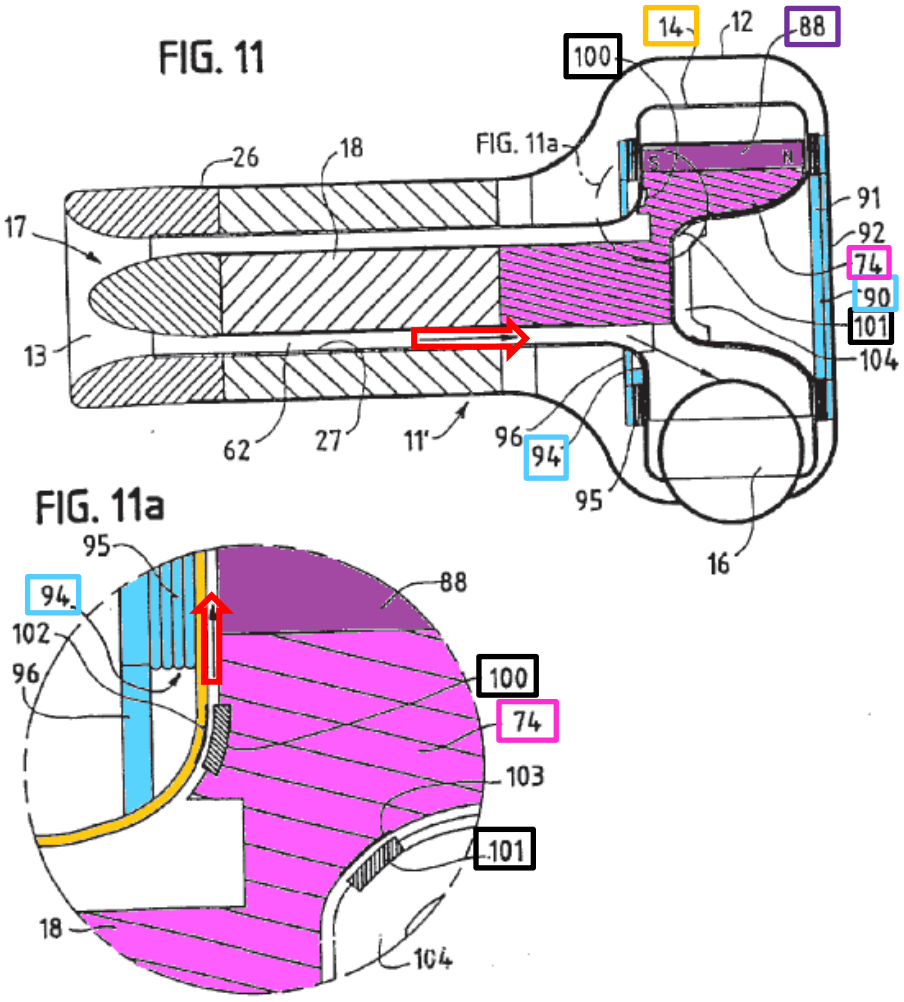
237. "The raised pads are carried by either the impeller or the casing, or an attachment to the casing. In the FIGS. 11 and 11 *a* embodiment, the raised pads 100 are carried by the impeller and the raised pads 101 are carried by a cup-shaped member 104 that is fastened to the casing." Ex.1008, [0091]. Such "hydrodynamic

bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Depending upon the location of the hydrodynamic bearings, they can aid in axial support, radial support or both axial and radial support." Ex.1008, [0093].

238. In the embodiment described with respect to Figures 11-14, Wampler-169 teaches that "[t]he hydrodynamic bearings are formed by a raised pad ***spaced from a contact surface by the blood gap***. Although at rest there may be contact between the impeller and the casing, ***once rotation begins*** each hydrodynamic bearing is structured so that during relative movement between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap ***which forces the raised pad and the contact surface apart***." Ex.1008, [0092].

239. Figures 11 and 11*a* (annotated) of Wampler-169 are a cross-sectional side view of the pump 11 that illustrates the hydrodynamic bearings formed by raised pads 100 and 101 (**black**), which serve to increase pressure within the bearing gap such that, once rotation of the impeller 74 (**pink**) begins by the magneto coupling between "magnetic pieces 88" (**purple**) of the impeller and the "motor stators 90

and 94" (**light blue**), the blood (**red** arrow) forces the impeller 74 and the "interior" of the casing 14 (**orange**) apart:



Ex.1008, Figs. 11 and 11*a* (annotated).

240. Thus, the "magneto coupling" between the "magnetic pieces 88" of the impeller 74 and the "motor stators 90 and 94" drives rotation of the impeller 74 and in response to that rotation, the hydrodynamic bearing "forces the raised pad and the

contact surface apart," such that the impeller 74 remains entirely spaced apart from the "interior" (Ex.1008, [0074]) of "casing 14" by the blood in response to rotation of the impeller 74.

241. Accordingly, Wampler-169 discloses that "*the magneto coupling orients the **magnetically driven rotor*** ("impeller 74") *so that both the **magnetically driven rotor** and the **first magnetic device*** ("magnetic pieces 88") *remain spaced apart from the **one or more walls*** ("interior" of "casing 14") *by the blood in response to rotation of the **magnetically driven rotor***."

xii. [11K] an external control unit configured to control operation of the second magnetic device based on a fixed value to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device,

242. Wampler-169 discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a fixed value to thereby magnetically drive the rotation of the **magnetically driven rotor** via the magneto coupling with the **first magnetic device***."

243. With respect to the embodiments described in Figures 1-8, Wampler-169 discloses the "windings 57" of the motor stator 56 "are energized by the electrical output of controller 59 to produce an electromagnetic field. This field is

concentrated by pole piece 58, and is effective to drive magnets 54 and the rotor 17, in a rotary fashion. The back EMF resulting from the magnets 54 passing by the windings is detected by the controller. The controller uses this back EMF voltage to continue generation of the electromagnetic field in synchronism with further rotation of the rotor." Ex.1008, [0072]. The "motor stators 90 and 94" described with respect to the embodiments of Figures 11-14 would be energized by the controller 59 to produce an electromagnetic field in the same way. Ex.1008, [0085]. Wampler-169 states that the difference in the "dual stator design" is that this design would provide additional "radial restoring force" and "system redundancy." Ex.1008, [0087]-[0088].

244. According to the disclosure, "it is contemplated that controller 59 and power supply 61 may be worn externally by the user …" Ex.1008, [0070]. The "controller 59" described in Wampler-169 may "include circuitry as simple as a variable voltage or current control, manually adjusted or programmed to determine the running rate of pump." Ex.1008, [0072]. However, the controller 59 may also "have interactive and automatic capabilities," for example by being "interconnected to sensors on various organs of the user…" Ex.1008, [0072].

245. In addition, Wampler-169 discloses that the "control unit allows the speed and drive cycle of the motor either ***to be programmed*** or interactively

determined by the user's physical activity or condition." Wampler-169, [0018], [0071] ("Controller 59 may include circuitry as simple as a variable voltage or current control, manually adjusted or programmed to determine the running rate of pump. However, controller 59 may also have interactive and automatic capabilities. For example, controller 59 may be interconnected to sensors on various organs of the user, automatically and instantaneously to tailor operation of the pump to the user's physical activity and condition.").

246. The "controller 59" described in Wampler-169 is an **external control unit** as recited in Claim 11 which regulates operation of the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) based on a fixed value (e.g., "allows the speed to be programmed," Ex.1008, [0018]) to thereby magnetically drive the rotation of the **magnetically driven rotor** (e.g., "impeller 74" of the rotor, Ex.1008, [0081]) via the magneto coupling with the **first magnetic device** (e.g., the "magnetic pieces 88" imbedded in the impeller, Ex.1008, [0080]).

247. Figure 5 (annotated) illustrates the connection of the controller 59 (**lime green**) to the pump 11 (**blue**):

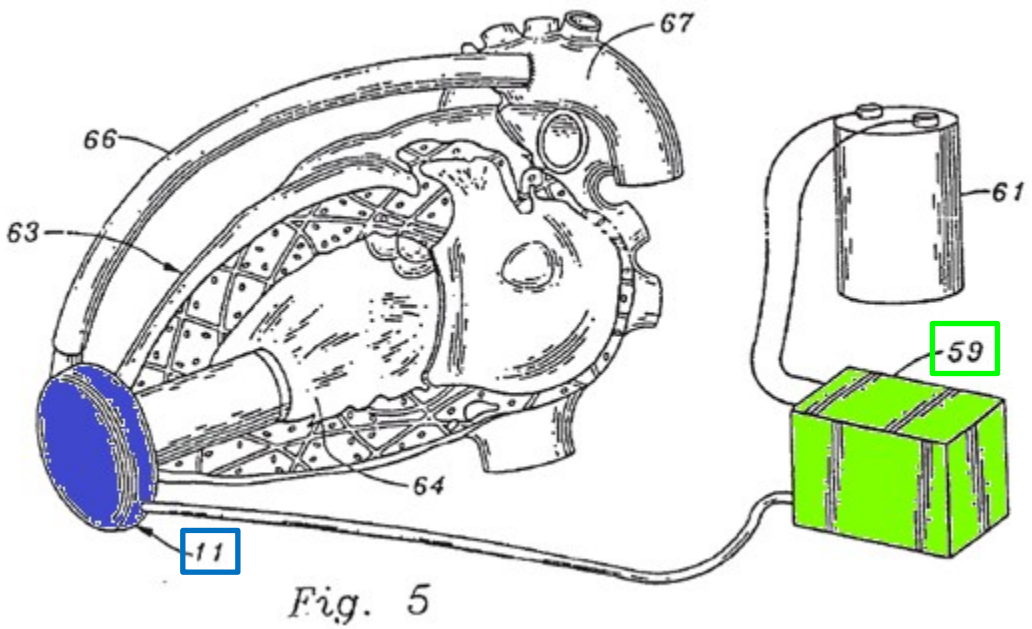


Fig. 5

Ex.1008, Fig. 5 (annotated).

248. Accordingly, Wampler-169 discloses "*an* ***external control unit*** ("controller 59") *configured to control operation of the* ***second magnetic device*** ("motor stators 90 and 94") *based on a fixed value to thereby magnetically drive the rotation of the* ***magnetically driven rotor*** ("impeller 74") *via the magneto coupling with the* ***first magnetic device*** ("magnetic pieces 88")."

2. Claim 12

a. [12] The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components.

249. Wampler-169 discloses claim 12. I have already explained how Wampler-169 discloses each and every element of claim 11. I incorporate that discussion into my analysis for claim 12.

250. Wampler-169 discloses that "*the **magnetically driven rotor** includes a guide surface to produce centrifugal flow components"* As discussed with respect to element [11H], Wampler-169 discloses that the **magnetically driven rotor** (e.g., "impeller 74") is rotated via a magneto coupling between the "magnetic pieces 88" imbedded in the impeller 74. *See supra* Section X.A.1.ix.

251. Wampler-169 further discloses that the "impeller 74" of the rotor 17 is a "centrifugal pump impeller" that "includes a plurality of large blade sectors 49." Ex.1008, [0012], [0064]. "When blood flows axially into the leading edges of impeller blades it tends to be damaged by the mechanical action and turbulence associated with the impeller blades. Thus, one of the design considerations of the present invention is to reduce such hemolysis, by minimizing the number of impeller blades and leading edges." Ex.1008, [0064]. Further, "[b]y increasing the thickness of the blade sectors and narrowing the blood passageway, the ratio between the area

of working surface of the blades and the volume of the passageway is increased." Ex.1008, [0068].

252. Each of the blade sectors 49 of the impeller 74 is a "guide surface," which serves to direct the flow of blood within the centrifugal pump to the outflow subassembly. For example, Wampler-169 discloses that [r]otation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62. The blood continues its path from the upper edge of passage 51 to the interior of casing 14. Discharge tube 16 allows the blood to be expelled from the casing an [sic] into the user's cardiovascular system." Ex.1008, [0074].

253. Indeed, the pump 11 described in Wampler-169 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, the production of centrifugal flow components by the components of the impeller are a characteristic feature of a centrifugal pump.

254. Accordingly, Wampler-169 discloses that "*the* ***magnetically driven rotor*** ("impeller 74") *includes a guide surface* ("blade sectors") *to produce centrifugal flow components* ("arrows 62")."

3. Claims 14-15

a. [14], [15]

255. Wampler-169 discloses claims 14-15. I have already explained how Wampler-169 discloses each and every element of claim 11. I incorporate that discussion into my analysis for claim 14.

256. Wampler-169 discloses that "*the **one or more walls** and the **magnetically driven rotor** define a gap separating the **magnetically driven rotor** from the **one or more walls**, the gap configured to be occupied by the blood when the **second magnetic device** drives the rotation of the **magnetically driven rotor**.*" Wampler-169 further discloses that "*wherein the gap surrounds the **magnetically driven rotor**.*"

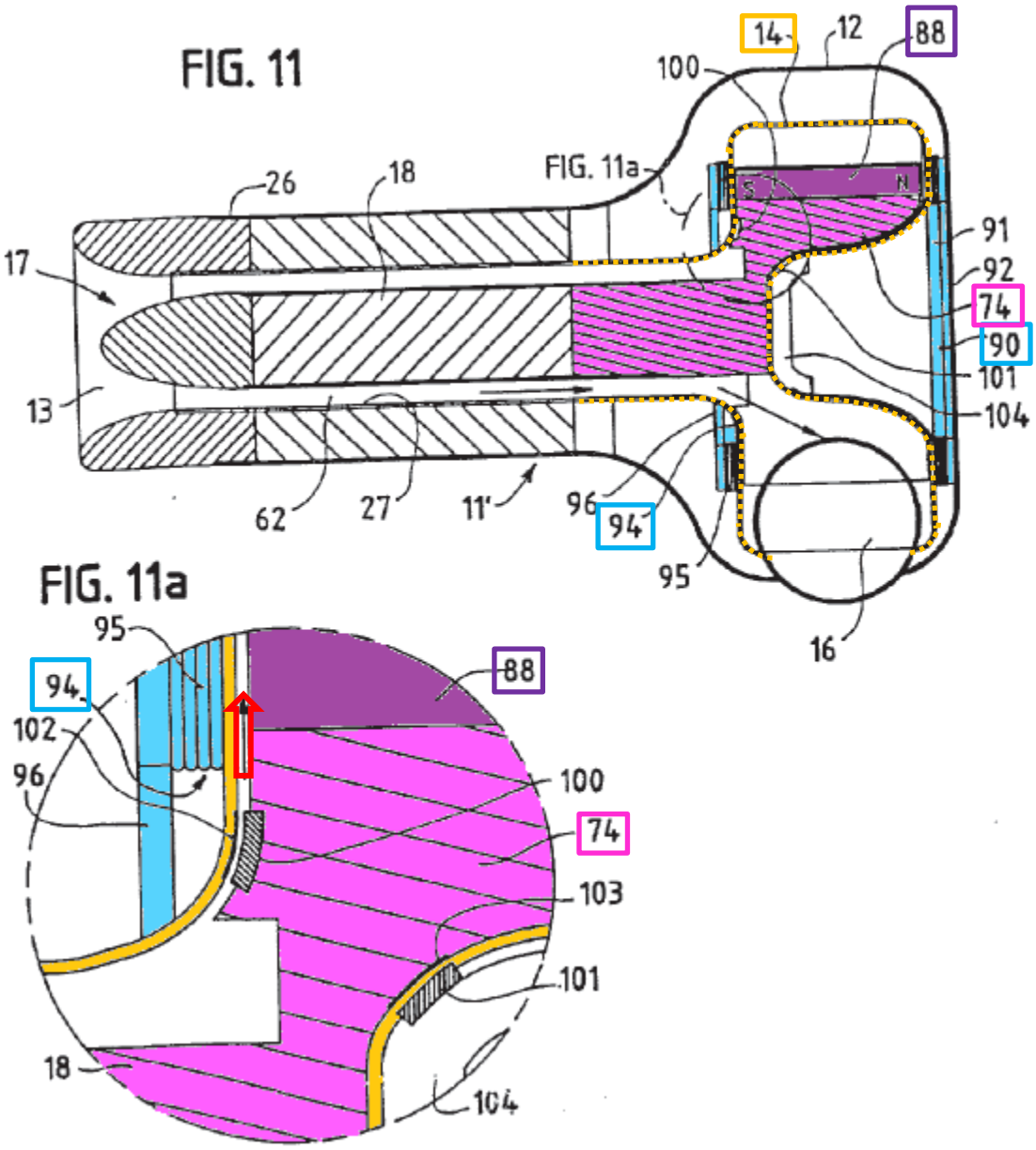
257. As discussed with respect to element [11H], Wampler-169 discloses a magneto coupling between the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) and the **first magnetic device** (e.g., the "magnetic pieces 88" imbedded in the impeller 74, Ex.1008, [0080]) to drive rotation of the **magnetically driven rotor** (e.g., "impeller 74"). *See element* [11H]. In addition, as discussed with respect to element [11J], Wampler discloses that the magneto coupling orients the **magnetically driven rotor** (e.g., "impeller 74") to be spaced apart from the **one or more walls** (e.g., "interior" of "casing 14," Ex.1008, [0080], [0081]) by the blood

in response to the rotation of the **magnetically driven rotor**. *See supra* element [11J].

258. Wampler-169 further discloses that in the embodiments described with respect to Figures 11-14, "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Referring to FIGS. 11 and 11*a* in particular, hydrodynamic bearings in the form of raised pads 100, 101 and contact surfaces 102 and 103 are illustrated." Ex.1008, [0089]. Note that these embodiments do not include the mechanical "thrust bearings" included in the embodiments, described with respect to Figures 1-8.

259. "The raised pads are carried by either the impeller or the casing, or an attachment to the casing. In the FIGS. 11 and 11 *a* embodiment, the raised pads 100 are carried by the impeller and the raised pads 101 are carried by a cup-shaped member 104 that is fastened to the casing." Ex.1008, [0091]. Such "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Depending upon the location of the hydrodynamic bearings, they can aid in axial support, radial support or both axial and radial support." Ex.1008, [0093].

260. In the embodiment described with respect to Figures 11-14, Wampler-169 teaches that "[t]he hydrodynamic bearings are formed by a raised pad ***spaced from a contact surface by the blood gap***. Although at rest there may be contact between the impeller and the casing, ***once rotation begins*** each hydrodynamic bearing is structured so that during relative movement between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap ***which forces the raised pad and the contact surface apart***." Ex.1008, [0092]. Figures 11 and 11*a* illustrate the "interior of the **casing"** and the **impeller** defining the "blood gap" (**red** arrow):



Ex.1008, Figs. 11-11*a*;

261. Thus, Wampler discloses that the **one or more walls** (e.g., "interior" of "casing 14," Ex.1008, [0080], [0081]) and the **magnetically driven rotor** (e.g., "impeller 74," [0081]) define a gap ("e.g., blood gap," Ex.1008, [0092]) configured

to be occupied by the blood when the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) drives rotation of the **magnetically driven rotor** via the magneto coupling. *See supra* element [11J].

262. Accordingly, Wampler-169 discloses that "***one or more walls*** ("interior" of "casing 14") *and the* ***magnetically driven rotor*** ("impeller 74") *define a gap* ("blood gap") *separating the* ***magnetically driven rotor*** *from the one or more walls, the gap configured to be occupied by the blood when the* ***second magnetic device*** ("motor stators 90 and 94") *drives the rotation of the* ***magnetically driven rotor***." Wampler-169 further discloses that "*wherein the gap surrounds the* ***magnetically driven rotor***."

4. Claim 16

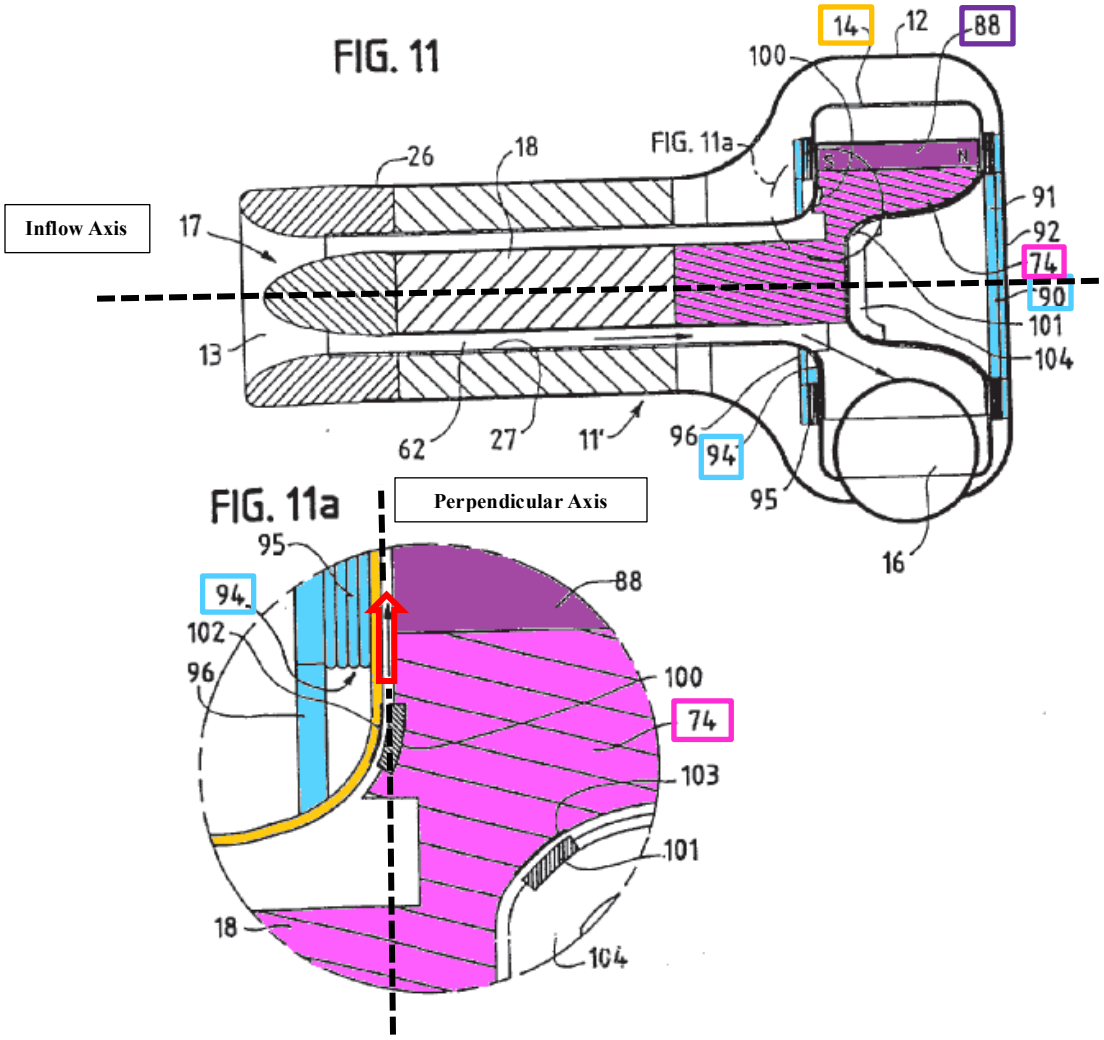
a. [16] The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis.

263. Wampler-169 discloses claim 16. I have already explained how Wampler-169 discloses each and every element of claims 11 and 14. I incorporate that discussion into my analysis for claim 16.

264. Wampler-169 discloses that "*at least part of the gap extends along a first axis substantially perpendicular to the* ***inflow axis***."

265. As discussed with respect to claim [14], Wampler-169 discloses that the **one or more walls** (e.g., "interior" of "casing 14," Ex.1008, [0080], [0081]) and the **magnetically driven rotor** (e.g., "impeller 74," [0081]) define a gap ("e.g., blood gap," Ex.1008, [0092]) configured to be occupied by the blood when the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) drives rotation of the **magnetically driven rotor** via the magneto coupling. In addition, as discussed with respect to element [11A], Wampler-169 discloses the ***inflow tube*** (e.g., "inlet tube 13," Ex.1008, [0075]) defining a blood inflow path (e.g., "serves as the inflow cannula," Ex.1008, [0080]) along an ***inflow axis*** (e.g., "axial inflow" along "longitudinal axis," Ex.1008, [0076], [0081]).

266. Figures 11 and 11*a* (annotated) of Wampler-169 illustrates that at least part of the "blood gap" (**red** arrow), defined when the "motor stators 90 and 94" (**light blue**) drive the rotation of the impeller 74 (**pink**) via the magneto coupling, extends along a first axis (**black** in Figure 11*a*) substantially perpendicular to the "axial inflow" along the "longitudinal axis" (**black** in Figure 11) of the pump:



Ex.1008, Figs. 11 and 11*a* (annotated).

267. Accordingly, Wampler-169 discloses that "*at least part of the gap extends along a first axis substantially perpendicular to the* ***inflow axis***."

5. Claim 18

a. [18] The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.

268. Wampler-169 discloses claim 18. I have already explained how Wampler-169 discloses each and every element of claim 11. I incorporate that discussion into my analysis for claim 18.

269. Wampler-169 discloses that "*the **chamber** is a first chamber within which the **magnetically driven rotor** is positioned, and the **magnetic drive system** is positioned within a second chamber sealed from the first chamber.*"

270. As discussed with respect to element [11B], the "interior of casing 14" that "enclose[s] the impeller" is a **chamber** at least partially defined by **one or more walls** (e.g., "interior," "inner wall," "outer surface," Ex.1008, [0074], [0070], [0060]) to receive blood from the **inflow tube** (e.g., "blood to flow through inlet tube 13 … to the interior of casing 14," Ex.1008, [0074]). *See supra* element [11B]. Thus, the "interior of casing 14" is a **first chamber** within which the **magnetically driven rotor** is positioned ("enclos[es] the impeller," Ex.1008, [0012]).

271. Wampler-169 further discloses that "the first motor stator 90 and back iron 92 are fixed between housing 12 and casing 14." Ex.1008, [0083]. The "second

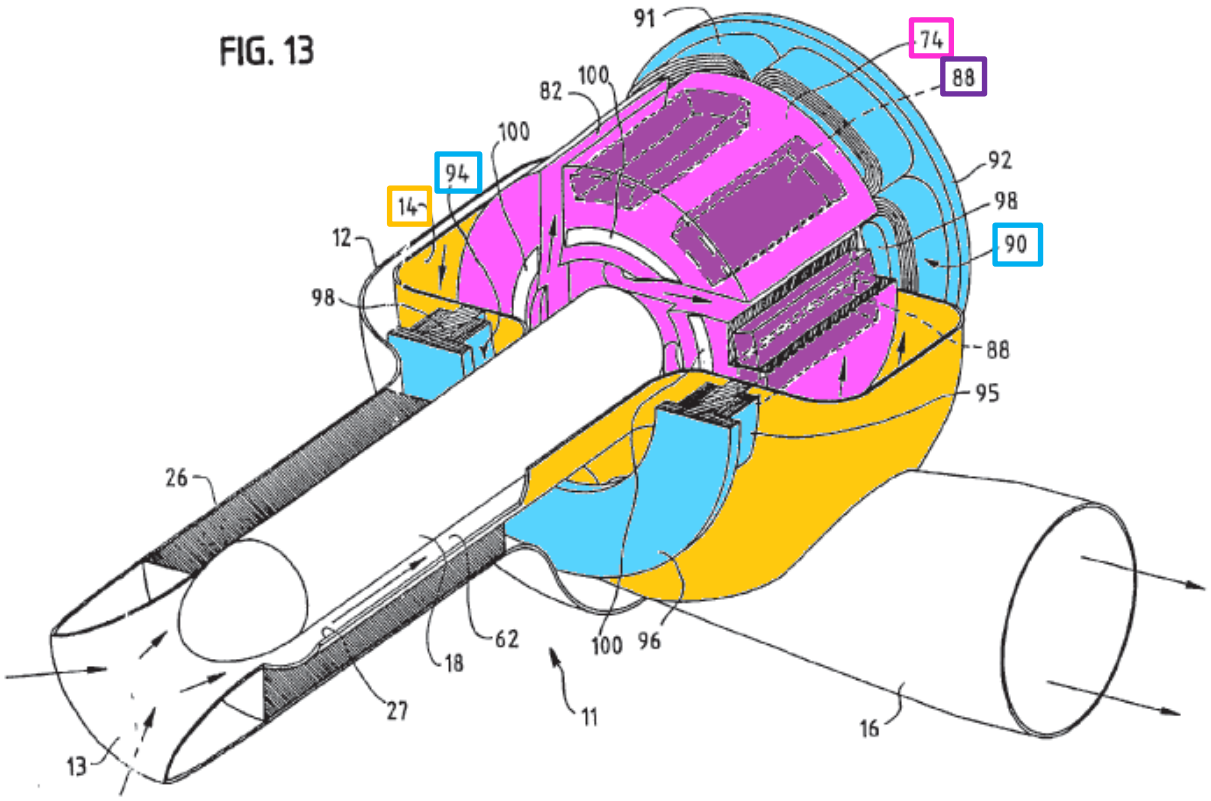
motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74," and the "windings 95 are fixed to casing 14 and a ring of back iron 96 is positioned forward of windings 95." Ex.1008, [0084]. In addition, "it can be seen that the motor stators 90 and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets 98." Ex.1008, [0085]; *see also* Ex.1008, [0070] ("windings 57" and "back iron 58" are "mounted on the outer surface of impeller casing 14"), [0018] ("A ring of back iron is fixed to the casing to aid in completing a flux return path for the permanent magnets …").

272. Indeed, the pump 11 described in Wampler-169 is a "sealless rotary blood pump." Ex.1008, [0050]. Wampler-169 describes problems in the art at the time with the short life of driveshaft seals in prior art LVADs, contributing to premature failure of the pump and the possibility of causing embolisms. Ex.1008, [0005]. The pump 11 of Wampler-169 "eliminat[es] the necessity for a driveshaft seal" by the use of the magnetic elements of the electric motor, such that torque is transferred to the drive the pump without contact between components. Ex.1008, [0005], [0018], [0019], [0070], [0072], [0073], 0074].

273. Thus, the **magnetic drive system** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) is positioned within a second chamber (e.g., "between housing 12

and casing 14," Ex.1008, [0083]) and sealed from the **first chamber** (e.g., "interior of casing 14" that "enclos[es] the impeller," Ex.1008, [0074], [0012]).

274. Figure 13 (annotated) of Wampler-169 illustrates a cross-sectional view of the "motor stators 90 and 94" (**light blue**) positioned "between housing 12 and casing 14" (**orange**) sealed from the "interior" of "casing 14" which "enclose[s] the impeller 74" (**pink**) and "magnetic pieces 88" (**purple**):



Ex.1008, Fig. 13 (annotated).

275. Accordingly, Wampler-169 discloses that "*the **chamber*** ("interior" of "casing 14") *is a first chamber within which the **magnetically driven rotor***

("impeller 74") *is positioned, and the* ***magnetic drive system*** ("motor stators 90 and 94") *is positioned within a second chamber* ("between housing 12 and casing 14") *sealed from the first chamber.*"

6. Claim 19

a. [19] The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber,

276. Wampler-169 discloses claim 19. I have already explained how Wampler-169 discloses each and every element of claims 11 and 18. I incorporate that discussion into my analysis for claim 19.

277. Wampler discloses that "*the wall of the* ***one or more walls*** *separates the first chamber from the second chamber*."

278. As discussed with respect to element [11B] and claim [18], the "interior of casing 14" that "enclose[s] the impeller" is a **chamber** at least partially defined by **one or more walls** (e.g., "interior," "inner wall," "outer surface," Ex.1008, [0074], [0070], [0060]).

279. In addition, Wampler-169 further discloses that "the first motor stator 90 and back iron 92 are fixed between housing 12 and casing 14." Ex.1008, [0083]. The "second motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74," and the "windings 95 are fixed to casing 14 and a ring of back

iron 96 is positioned forward of windings 95." Ex.1008, [0084]. In addition, "it can be seen that the motor stators 90 and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets 98." Ex.1008, [0085]; *see also* Ex.1008, [0070] ("windings 57" and "back iron 58" are "mounted on the outer surface of impeller casing 14"), [0018] ("A ring of back iron is fixed to the casing to aid in completing a flux return path for the permanent magnets …").

280. Thus, because the **magnetic drive system** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) is "mounted on the outer surface of impeller casing 14," while the "interior of the casing 14" "encloses the impeller," the "outer surface" is a wall of the **one or more walls** separating the first chamber (e.g., "interior of casing 14," Ex.1008, [0074]) from the second chamber (e.g., "between housing 12 and casing 14," Ex.1008, [0083]).

281. Accordingly, Wampler-169 discloses that "*the wall* ("outer surface") *of the one or more walls separates the first chamber* ("interior of casing 14") *from the second chamber* ("between housing 12 and casing 14")."

7. Claims 1-2, 4-5, 7-8, 20

282. In my opinion, claim 1 and dependent claims 2, 4-5, 7-8, and 20 recite elements that are identical or substantially analogous to independent claim 11 and dependent claims 12, 14, 16, 18-19, and are therefore rendered obvious for the same

reasons. For instance, the "surrounding rotor housing" of claim 1 is essentially the same as the "one or more walls at least partially defining a chamber" of claim 11. Similarly, the "inflow tube," "magnetically driven rotor," and "first magnetic device" are all axially aligned with the "inflow axis" of claim 11 in essentially the same way that they are all aligned with the "central axis" of claim 1. The below chart maps the limitations of these claims to their analogous claim limitations that I've analyzed above. *Supra* Section X.A.

Claims 1-2, 4-5, 7-8, 20	**Analogous Claim Limitations**	**Analogous Sections of Ground 1**
[1PRE]	[11PRE]	§X.A.1.i
[1A]	[11A]	§ X.A.1.ii
[1B]	[11C]	§ X.A.5
[1C]	[11B], [11E]	§ X.A.1.iii; § X.A.1.vi
[1D]	[11D]	§ X.A.1.v
[1E]	[11F]	§ X.A.1.vii
[1F]	[11H]	§ X.A.1.ix
[1G]	[11G], [14]	§ X.A.1.viii; § X.A.3
[1H]	[11I]	§ X.A.1.x
[1I]	[11J]	§ X.A.1.xi

[1J]	[11K]	§ X.A.1.xii
[2]	[12]	§ X.A.2
[4]	[18], [19]	§ X.A.1.iii; §X.A.5-9
[5]	[14], [18]	§ X.A.7.i; §X.A.3; §X.A.5
[7]	[18]	§ X.A.5
[8]	[19]	§ X.A.6
[20]	[11k]	§ X.A.1.xii

i. Claim 4

283. Wampler-169 discloses each and every element of claim [4] for the same reasons discussed in [11B] and Claims [18] and [19]. *See supra* [11B], [18]-[19]. In addition, Wampler-169 further discloses "*a sealing wall positioned between the **second magnetic device*** (e.g., "motor stators 90 and 94") *and the **magnetically driven rotor*** (e.g., "impeller 74") so that "a thin-walled non-magnetic jacket be placed over these portions, to prevent contact between the magnets and the blood." Ex.1008, [0057]. In my opinion, a POSITA would have been motivated to do so because "[s]uch contact, if it were allowed, would likely cause an undesirable chemical reaction, to the determinant of the blood." Ex.1008, [0057]; [0070]. *Supra* [11B] (analyzing "outer surface of impeller casing 14"); Ex.1008, [0070]).

ii. Claim 20

284. Wampler-169 discloses each and every element of claim [20] for the same reasons discussed in [11K] and Claims [18] and [19]. *See* [11K], [18]-[19], above. In addition, Wampler-169 further discloses the **external control unit** ("controller") can be "manually adjusted or programmed to determine the running rate of pump…[and] may be interconnected to sensors on various organs…[to] automatically…tailor operation of the pump to the user's physical activity and condition" ("*based on a defined cardiac output*"). Ex.1008, [0071]; *see also* [0018] ("The control unit allows the speed…to be…determined by the user's physical activity").

B. Ground 2: Bourque-2001 in view of Wampler-169 Renders Obvious Claims 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20 of the 879 Patent

1. Claim 11

i. [11PRE] A system for assisting blood circulation of a heart, the system comprising:

285. To the extent that the preamble is a limitation, Bourque-2001 discloses "*a system for assisting blood circulation of a* ***heart***."

286. For example, Bourque-2001 discloses the design and testing of a "long-term, compact left ventricular assist device (LVAD) ['*for assisting the blood circulation of a heart*']," known as the HeartMate III. Ex.1007 at 401, 405 ("reliable

device to treat CHF"). Bourque-2001 discloses that LVADs, like the HeartMate III and its predecessors (e.g., HeartMate II), have "provided significant benefit to certain [congestive heart failure] patients" by "seek[ing] to ameliorate increases in mortality due to the divergence of the increasing population of those awaiting cardiac transplant and the somewhat dwindling availability of organs." Ex.1007 at 401. Bourque-2001 further describes that the HeartMate III is a "continuous flow-type pump," which serves to assist the pumping of blood from the left ventricle to the aorta of a heart. The HeartMate III was designed "to achieve a design point of 7 L/min against 135 mm Hg at high hydrodynamic efficiency (30%) and to be capable of up to 10 L/min under such a load." Ex.1007 at 401. The HeartMate III LVAD (**blue**) in its implanted configuration in the heart (**red**) of a body is illustrated in Figure 3, annotated:

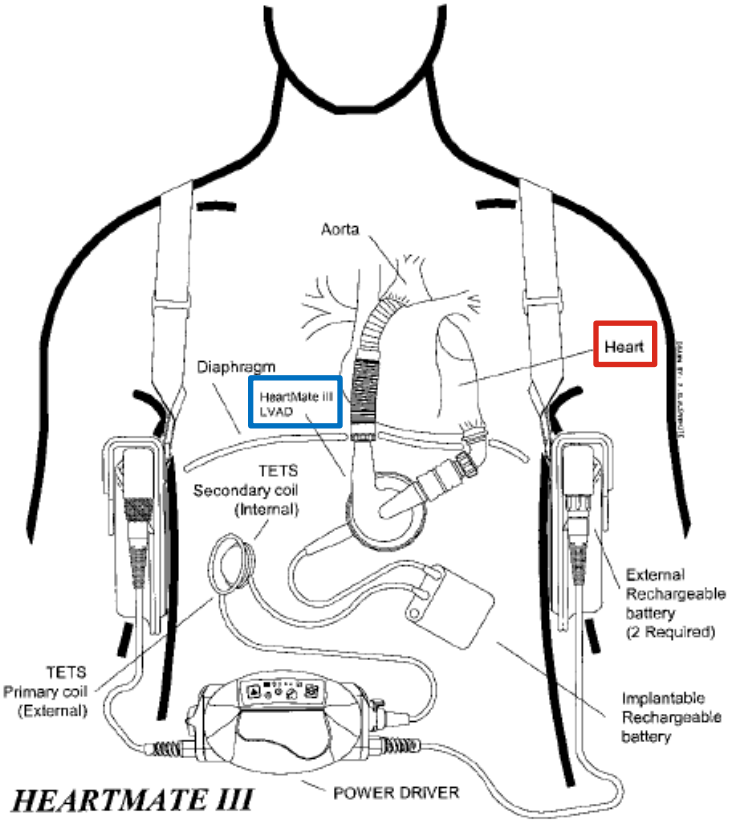


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3 (annotated).

287. Accordingly, Bourque-2001 discloses "*a system for assisting blood circulation of a* ***heart*** ("reliable device to treat CHF")*."*

288. Further, I have reviewed the Patent Owner's initial response to Abbott's invalidity contentions served in the parallel litigation, and I understand that the PO concedes that Bourque-2001 discloses this element. I have been informed that the rules required the PO to admit or deny whether an element was present in the prior art. Miracor admitted that Bourque-2001 discloses this limitation. *See* Ex.1026, at

pp. D-1 31 (Miracor Responsive Chart for U.S. Patent No. 11,572,879 over Bourque-2001).

ii. [11A] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle

289. Bourque-2001 discloses "***a heart assist pump device*** *deliverable to the* ***heart*** *and comprising:* ***an inflow tube*** *defining a blood inflow path along an* ***inflow axis*** *and being insertable into* ***a left ventricle***."

290. The 879 Patent does not define the term "a heart assist pump device deliverable to the heart." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that assumes "a heart assist pump device" being "deliverable to the heart" includes inserting an inflow tube of the heart assist pump device into a left ventricle of a patient's heart. *See, e.g.*, Ex.1019, at 3-4 (Complaint, Ex. 11). For the purposes of my analysis, I adopt that construction of "a heart assist pump device deliverable to the heart."

291. Accordingly, the HeartMate III "left ventricular assist device (LVAD)" described in Bourque-2001 is "***a heart assist pump device***" that is deliverable to the heart. Ex.1007, at 401. Bourque-2001 discloses that "[t]he advent of the left ventricular assist device (LVAD) has provided significant benefit to certain

[congestive heart failure] patients since becoming clinically available. Ex.1007, at 401.

292. The HeartMate III includes an ***inflow tube*** (e.g., "an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007 at 401) *defining a blood inflow path … and being insertable into a left ventricle* (e.g., "[i]s implanted with routine surgical techniques via left ventricular apical cannulation," Ex.1007 at 401, 403, Fig. 4.) A "cannula" in this context is a tube that is inserted in the left ventricle for the inflow of blood to the pump. The HeartMate III LVAD (**blue**), including the inflow subassembly (**green**), in its implanted configuration in the left ventricle of a heart (**red**) is illustrated in Figure 3, annotated:

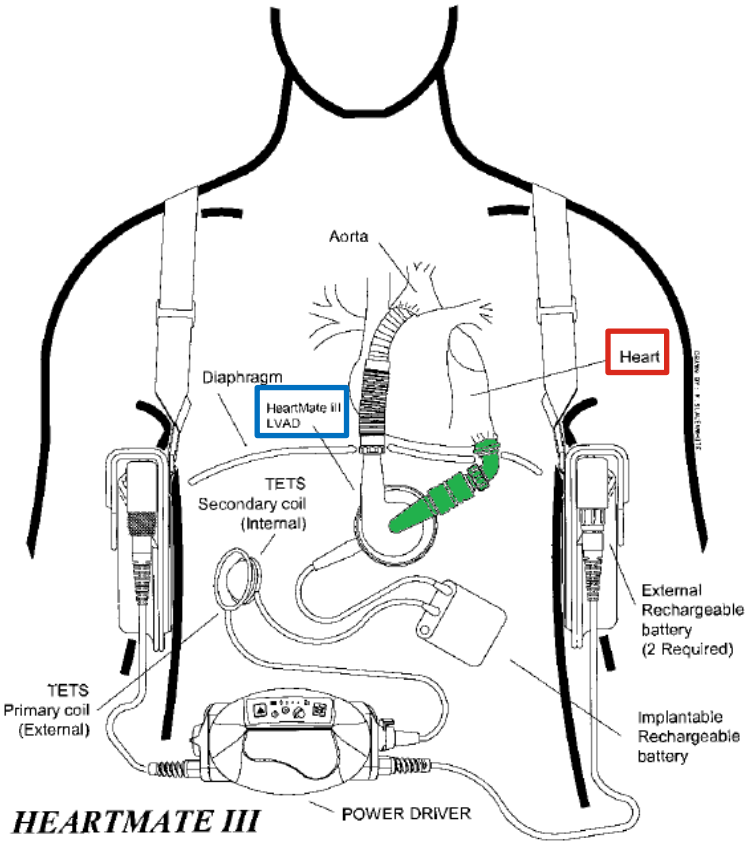
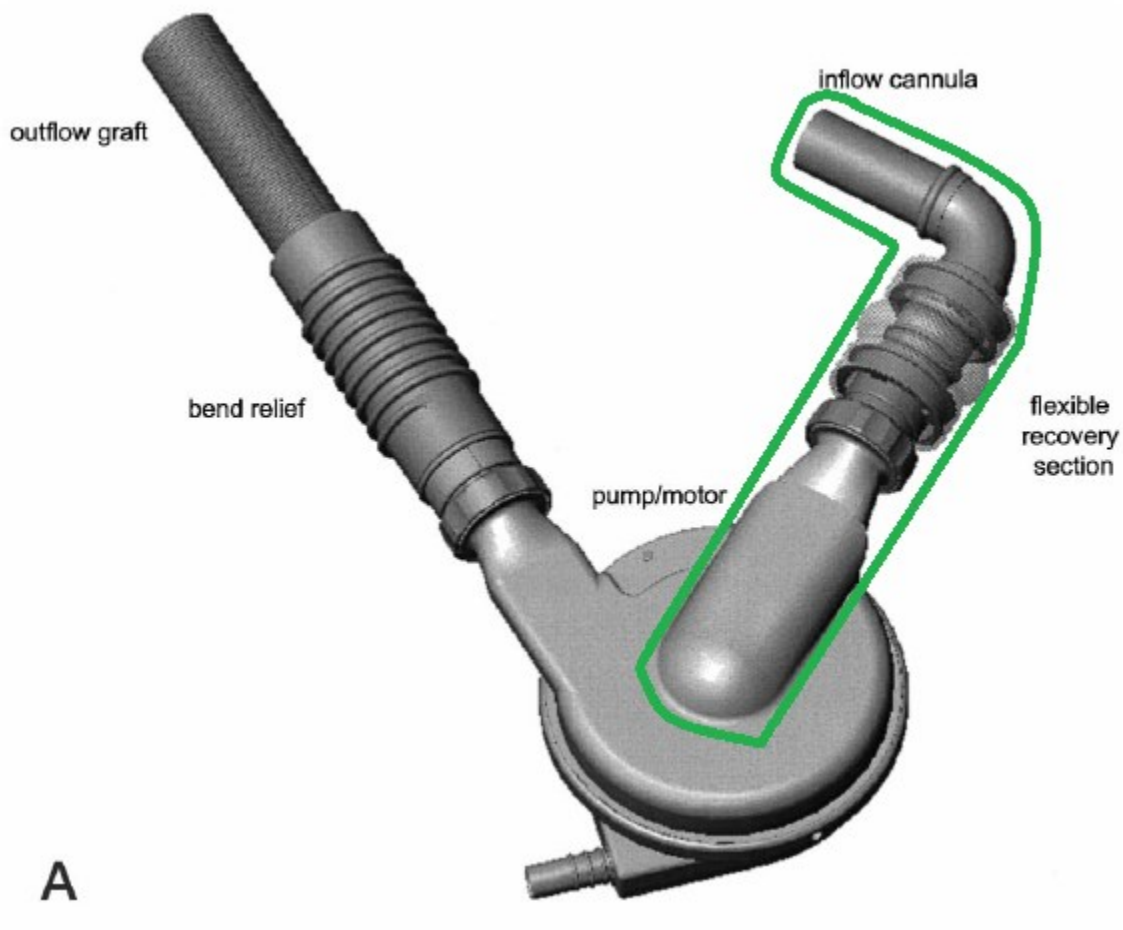


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3 (annotated).

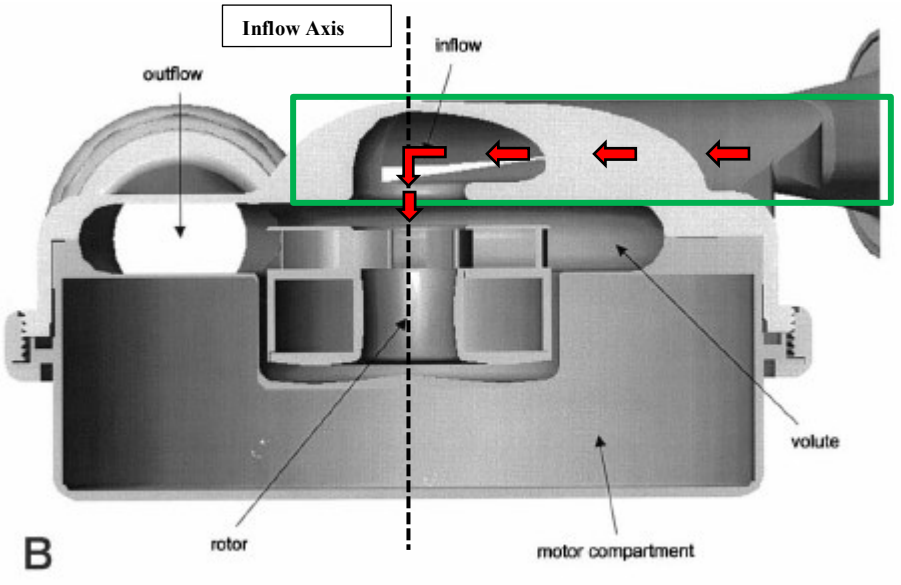
293. Figure 1A of Bourque-2001 illustrates an overall view of the HeartMate III pump, which includes the LV cannula of the inflow tube (cannula) (**green**) that defines a blood inflow path and is insertable into a ventricle of the heart(annotated):



Ex.1007, Fig. 1A.

294. In addition, the **inflow tube** (e.g., "an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007 at 401) of the HeartMate III pump described in Bourque-2001 has an inflow axis so as to provide the flow of blood to the ***magnetically driven rotor*** ("impeller" of the rotor, Ex.1007 at 401) (discussed below for element [11D]). For example, Figure 1B (annotated) illustrates the LV cannula of the inflow subassembly (**green**) of the HeartMate III defining a blood

inflow path along an inflow axis (**black**) and the flow path of blood from the left ventricle of the heart (**red** arrows):



Ex.1007 at Fig. 1B (annotated).

295. While the inflow subassembly of the HeartMate III includes an "elbow" through which blood flows from the LV cannula to the impeller, the portion of the inflow subassembly where blood flows into the pump chamber is along the "inflow axis" of the pump, as illustrated by the red arrows in Figure 1B above.

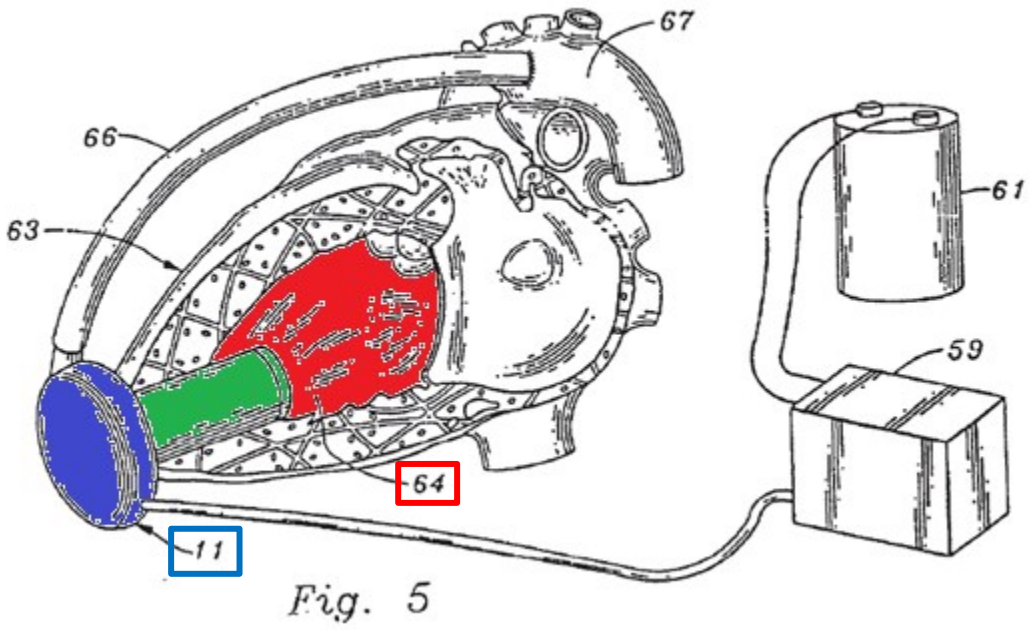
296. Indeed, the HeartMate III pump described in Bourque-2001 is a **centrifugal** pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference.

Said another way, an inflow tube defining a blood inflow path along an inflow axis is a characteristic feature of a centrifugal pump.

297. Accordingly, Bourque-2001 discloses "***a heart assist pump device*** ("HeartMate III LVAD") *deliverable to the* ***heart*** *and comprising:* ***an inflow tube*** *defining a blood inflow path* ("an inflow subassembly that includes a left ventricular (LV) cannula") *along an* ***inflow axis*** *and being insertable into* ***a left ventricle*** ("left ventricular apical cannulation")."

298. To the extent that Bourque-2001 does not expressly disclose the "*inflow tube defining a blood inflow path along an inflow axis*," it would have been obvious to a POSITA as of February 27, 2007 to modify the inflow subassembly of the HeartMate III described in Bourque-2001 in view of Wampler-169 to align the LV cannula along the "inflow axis" for numerous reasons as discussed below in Section X.B.8. Wampler-169 appreciated that "[t]he centrifugal design of the pump allows a considerable amount of flexibility during implantation." Ex.1008, [0076]. "Owing to the axial inflow and radial outflow of the pump," which is a characteristic feature of centrifugal pumps including the Bourque 2001 device, Wampler-169 explains that "a 90 degree redirection of the blood is effected **without the necessity of a flow-restrictive elbow fitting**." Ex.1008, [0076]. With this design, "[g]ood anatomic compatibility is possible since the pump casing is compact and disc-shaped, fitting

well between the apex of the heart and the adjacent diaphragm." Ex.1008, [0076]. Consequently, "[t]he inlet tube 16 serves as the inflow cannula and is placed into the apex of the left ventricle 64," thereby eliminating the need for any elbow or additional inflow assembly, as shown below. Figure 5 (annotated) of Wampler-169 illustrates a representation of a human heart 63, showing the inlet tube 13 (**green**) of the pump 11 (**blue**) implanted within the left ventricle 64 (**red**) of the heart:



Ex.1008, Fig. 5 (annotated).

299. In the combination of Bourque-2001 with the *inflow tube defining a blood inflow path along an inflow axis* technique of Wampler-169 (hereinafter Bourque/Wampler), the *inflow tube* aligned with *inflow axis* would have been implemented at the same location as the Bourque-2001 inflow tube so that

"[t]he inlet tube…serves as the inflow cannula and is placed into the apex of the left ventricle" as taught by Wampler-169. Ex.1008, [0076]. A POSITA would have had a reasonable expectation that the Bourque/Wampler combination would be successful because an author of Bourque-2001 taught that this specific modification was "not complex" and was "well-known in the art." Ex.1018 at 6:62-7:5. Victor L. Poirier is one of the engineers of Bourque-2001 HeartMate III device, co-author of Bourque-2001 reference, and also the inventor of U.S. Patent No. 6,050,975 (Ex.1018), assigned to Thoratec. The 975 Patent describes that its centrifugal pump (e.g., Bourque-2001 HeartMate III) can be modified to use this inflow cannula from the axial flow blood pump:

> [P]ump 400 may be modified to incorporate… inflow cannula apical tube 45…The modifications required are not complex and are well-known in the art.

Ex.1018 at 6:62-7:5. Because the 975 patent teaches that modifying the Bourque-2001 with "an inflow cannula apical tube 45" is "not complex," a POSITA would have had a reasonable expectation that the Bourque/Wampler combination would be successful.

300. Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious "***a heart assist pump device*** ("HeartMate III LVAD") *deliverable to the* ***heart*** *and comprising:* ***an inflow tube*** ("an inflow subassembly

that includes a left ventricular (LV) cannula," Ex.1007; "inlet tube [13] serves as the inflow cannula," Ex.1008) *defining a blood inflow path along an* ***inflow axis*** *and being insertable into* ***a left ventricle*** ("left ventricular apical cannulation")."

iii. [11B] one or more walls at least partially defining a chamber to receive blood from the inflow tube,

301. Bourque-2001 discloses "*one or more walls at least partially defining a* ***chamber*** *to receive blood from the* ***inflow tube****.*"

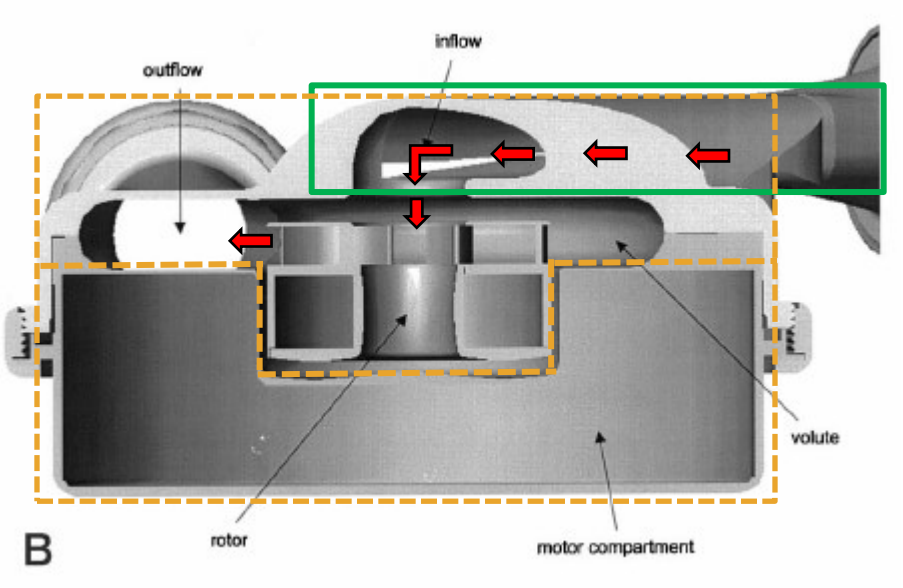
302. For example, Bourque-2001 discloses that the "HeartMate III pump (Figures 1 and 2) comprises an upper housing that includes the inflow and outflow channels and the upper half of the volute" and "a lower housing that includes the lower half of the volute and a cavity for the rotor, in which the motor is enclosed." Ex.1007 at 401. The HeartMate III pump further includes a "screw ring to clamp together the upper and lower housings." Ex.1007 at 401. Thus, the "upper housing" that includes "the upper half of the volute" and "a lower housing that includes the lower half of the volute and a cavity for the rotor" comprise "**one or more walls** at least partially defining a ***chamber***." Ex.1007 at 401.

303. Bourque-2001 further discloses the flow path of blood through the inflow section, and thereby to the impeller of the rotor of the HeartMate III. "An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits

fluid leaving the inflow conduit to enter the impeller," which is enclosed in the "housing." Ex.1007 at 401-402; *see also* Ex.1007 at 403 ("The pump was prescribed to run at 3,500 rpm perioperatively," i.e., 3,500 revolutions per minute).

304. Thus, the "upper housing" that includes "the upper half of the volute" and "a lower housing that includes the lower half of the volute and a cavity for the rotor" comprise "**one or more walls** at least partially defining a **chamber**" (Ex.1007 at 401) to receive blood from the **inflow tube** (e.g., "fluid leaving the inflow conduit … enter[s] the impeller," which is enclosed in the "housing," Ex.1007, 402).

305. Figure 1B (annotated) illustrates the "upper housing and lower housing" forming the "volute" and rotor "cavity" (**orange**) of the HeartMate III to receive blood (**red** arrows) from the inflow subassembly (**green**):



Ex.1007, Fig. 1B.

306. Accordingly, Bourque-2001 discloses that "***one or more walls*** ("upper housing" and "lower housing") *at least partially defining a* ***chamber*** ("volute" and "cavity") *to receive blood from the* ***inflow tube*** ("an inflow subassembly that includes a left ventricular (LV) cannula")."

iv. [11C] a magnetically driven rotor axially aligned with the inflow axis

307. Bourque-2001 discloses "*a* ***magnetically driven rotor*** *axially aligned with the* ***inflow axis***."

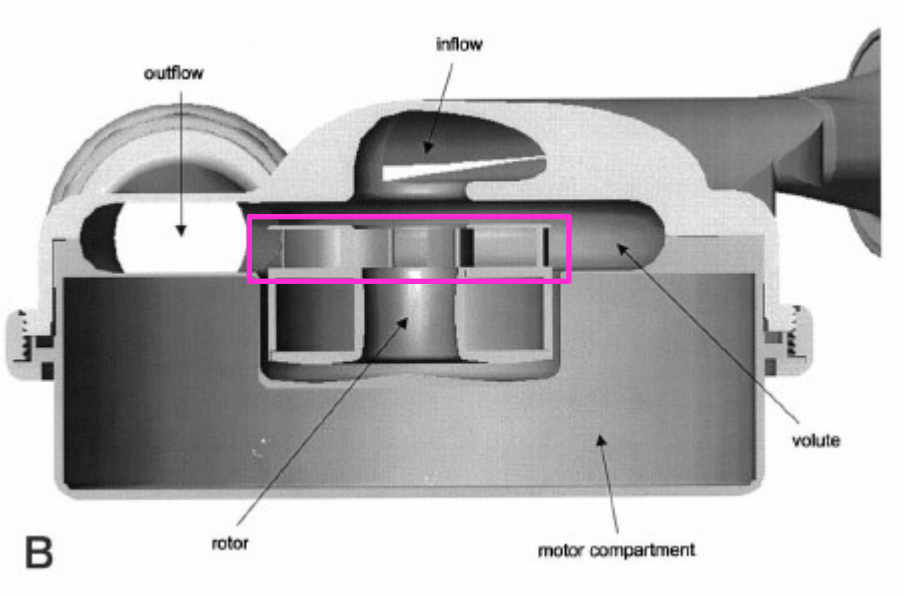
308. The HeartMate III pump includes "a rotor that includes an impeller and passively magnetic elements," which is a "***magnetically driven rotor.***" Ex.1007 at 401.

309. An "impeller" is a commonly used type of rotor that provides the pumping action when used in reference to a centrifugal pump, such as the "centrifugal pump" described in Bourque-2001. Ex.1007 at Abstract ("A long-term compact left ventricular assist device (LVAD), the HeartMate III, has been designed and fabricated, featuring **a centrifugal pump with a magnetically levitated rotor**."). I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that maps the impeller portion of the "rotor" of the

"HeartMate 3" to the "magnetically driven rotor" element recited in Claim 11. Ex.1019, at 5 (Complaint, Ex. 11 for the same limitation of claim 1). For the purposes of my analysis, I map the limitation of a "magnetically driven rotor" to the "impeller" portion of the rotor described in Bourque-2001 in the same way.

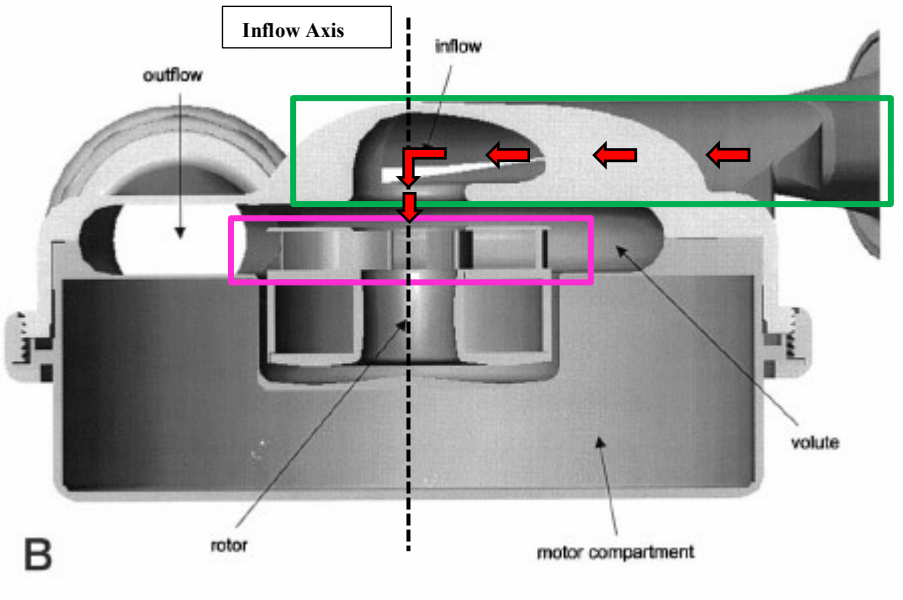
310. The "impeller" of the rotor described in Bourque-2001 is a ***magnetically driven rotor*** because it is a rotor driven by the force generated by the magnetic field created between the "passively magnetic elements" and the "actively controlled" magnetic elements of the motor. *See infra* Sections X.A.1.v and X.B.1.viii; Ex.1007 at 402; Ex.1007 at 402-403 ("HeartMate III motor includes drive and levitation in a single magnetic structure as shown in Figure 4. The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom and actively magnetically levitated in the remaining degrees of freedom."); *see also* Ex.1007 at 401 ("[T]he pump has no mechanical bearings. The rotor is magnetically suspended, eliminating contact between the moving parts and consequently extending wear life indefinitely.").

311. Figure 1B of Bourque-2001 illustrates a cross-sectional view of the positioning of the impeller of the rotor (**pink**) in the lower housing of the HeartMate III pump:



Ex.1007, Fig. 1B.

312. In addition, for components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis") in space. The HeartMate III pump described in Bourque-2001 has an ***inflow tube*** (e.g., "an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007 at 401) that provides the flow of blood to the ***magnetically driven rotor*** ("impeller" of the rotor, Ex.1007 at 401) such that each is "axially aligned" along an "inflow axis." For example, Figure 1B (annotated) illustrates the alignment of the impeller of the rotor (**pink**) and the LV cannula of the inflow subassembly (**green**) of the HeartMate III along the inflow axis (**black**) and the flow path of blood from the left ventricle of the heart (**red** arrows):



Ex.1007 at Fig. 1B (annotated).

313. While the inflow subassembly of the HeartMate III includes an "elbow" through which blood flows from the LV cannula to the impeller, the portion of the inflow subassembly where blood flows into the pump chamber is axially aligned along the "**inflow axis**" with the impeller of the pump, as illustrated by the red arrows in Figure 1B above.

314. Indeed, the HeartMate III pump described in Bourque-2001 is a **centrifugal** pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, an inflow tube axially aligned with an impeller along an "inflow axis" is a characteristic feature of a centrifugal pump.

315. Accordingly, Bourque-2001 discloses "*a **magnetically driven rotor*** ("impeller") *axially aligned with the **inflow axis***."

316. To the extent that Bourque-2001 does not expressly disclose the "impeller" "*axially aligned with the…inflow axis*," it would have been obvious to a POSITA as of February 27, 2007 to modify the inflow subassembly of the HeartMate III described in Bourque-2001 in view of Wampler-169 to axially align the LV cannula with the impeller of the rotor for the same reasons discussed for element [11A], and for numerous reasons as discussed below in Section X.B.8. *See supra* [11A].

317. Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious "*a **magnetically driven rotor*** ("impeller") *axially aligned with the **inflow axis***."

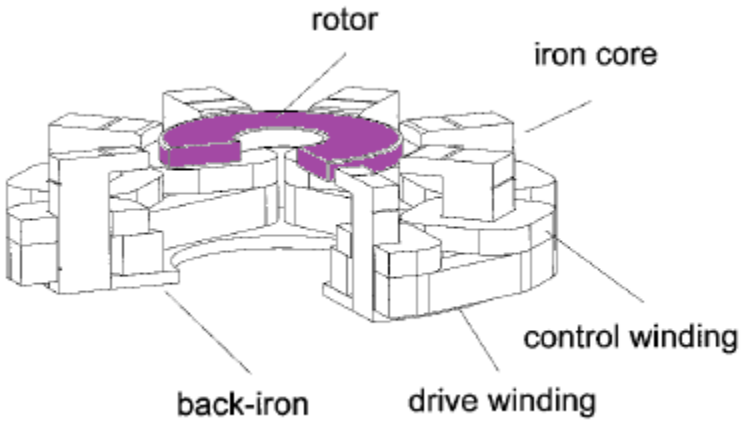
v. [11D] and [the magnetically driven rotor] being rigidly coupled and axially adjacent to a first magnetic device that is axially aligned with the inflow axis,

318. Bourque-2001 discloses the **magnetically driven rotor** "*being rigidly coupled and axially adjacent to a **first magnetic device** that is axially aligned with the **inflow axis***."

319. Bourque-2001 discloses that the "rotor includes an impeller and passively magnetic elements." Ex.1007 at 401. As discussed with respect to element [11C], the "impeller" of the rotor is a ***magnetically driven rotor***. *See supra* Section X.B.1.iv. The "passively magnetic elements" of the rotor are *a* ***first magnetic device***.

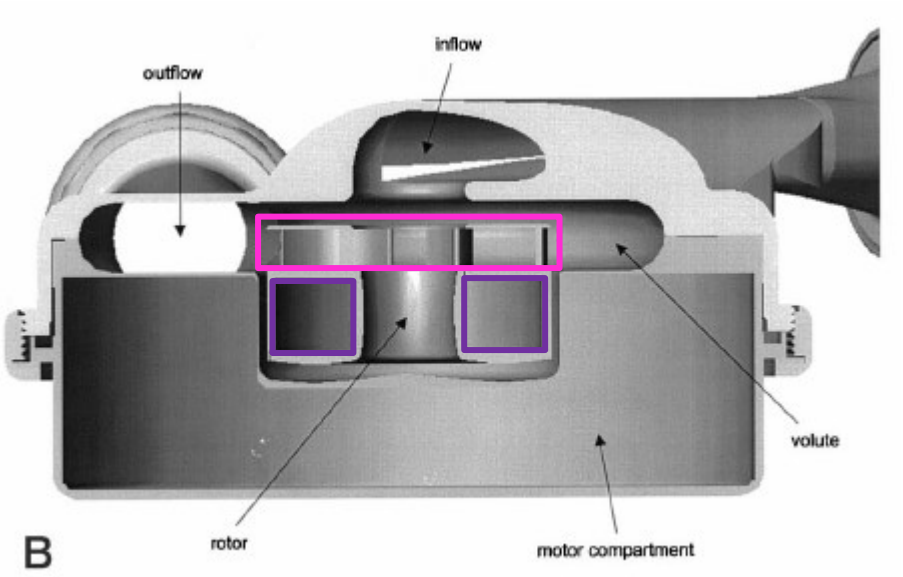
320. As will be discussed with respect to elements [11G], [11H], and [11I], the rotation of the passively magnetic elements of the rotor causes rotation of the impeller of the rotor, resulting in the flow path of blood through the inflow section, to the impeller of the rotor, and finally "exit[ing] the backswept blades of the impeller into a volute…and directing toward the outflow of the HeartMate III. Ex.1007 at 402; *infra* Sections X.B.1.viii, X.B.1.ix, X.B.1.x. A POSITA would understand the "impeller" and the "passively magnetic elements" to be "rigidly coupled" to one another such that they are locked in relative rotation so that the magnetic force applied to passively magnetic elements of the rotor may effect rotation of the impeller.

321. Figure 4 of Bourque-2001 depicts the passively magnetic element of the rotor (**purple**) of the HeartMate III:



Ex.1007, Fig. 4 (annotated).

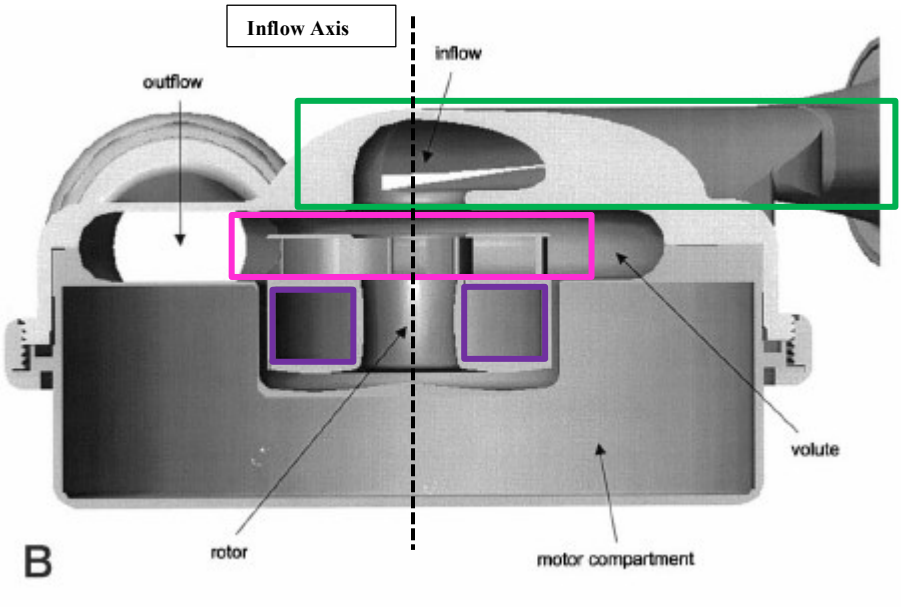
322. Bourque-2001 describes that the "rotor that includes an impeller and passively magnetic elements," and Figure 1B of Bourque-2001 illustrates the rigid coupling between the impeller (**pink**) and the passively magnetic element (**purple**).



Ex.1007 at 401, Fig. 1B (annotated).

323. As discussed for element [11C], for components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis") in space. The HeartMate III pump described in Bourque-2001 thus has an **inflow axis** that is configured in axial alignment with the **inflow tube** (e.g., "an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007 at 401) so as to provide the flow of blood to the **magnetically driven rotor** ("impeller" of the rotor, Ex.1007 at 401) that is *rigidly coupled and axially adjacent* to the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401).

324. For example, Figure 1B of Bourque-2001 depicts the impeller (**pink**) being *rigidly coupled* to the passively magnetic elements (**purple**), and both components being *axially adjacent* and *axially aligned* along the inflow axis (**black**) of the inflow tube (cannula) (**green**):



Ex.1007 at 401, Fig. 1B (annotated).

325. Accordingly, Bourque-2001 discloses "the **magnetically driven rotor** ("impeller") "*being rigidly coupled and axially adjacent to a* ***first magnetic device*** ("passively magnetic elements") *that is axially aligned with the* ***inflow axis***."

326. To the extent that Bourque-2001 does not expressly disclose the "impeller" and the "passively magnetic elements" "*axially aligned with the…inflow axis*," it would have been obvious to a POSITA as of February 27, 2007 to modify the inflow subassembly of the HeartMate III described in Bourque-2001 in view of Wampler-169 to axially align the LV cannula with the impeller and passively magnetic elements of the rotor for the same reasons discussed for element [11A], and for numerous reasons as discussed below in Section X.B.8. *See supra* [11A].

327. Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious "the **magnetically driven rotor** ("impeller") "*being rigidly coupled and axially adjacent to a* ***first magnetic device*** ("passively magnetic elements") *that is axially aligned with the* ***inflow axis***."

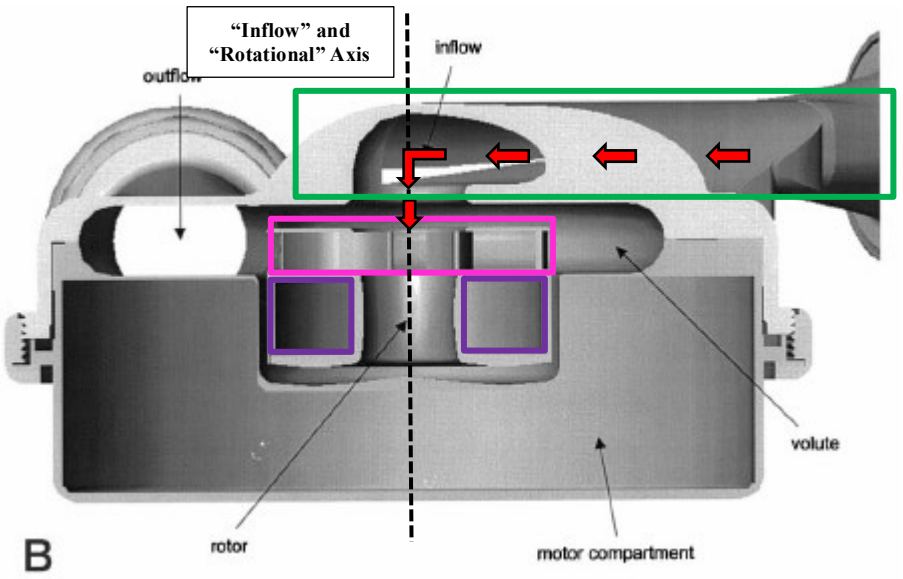
vi. [11E] the magnetically driven rotor and first magnetic device being rotatable about an axis of rotation aligned with the inflow axis to drive the blood flowing from the inflow tube

328. Bourque-2001 discloses "*the* ***magnetically driven rotor*** *and* ***first magnetic device*** *being rotatable about an axis of rotation aligned with the* ***inflow axis*** *to drive the blood flowing from the* ***inflow tube***."

329. By definition all centrifugal pumps have a rotor that rotates about a central axis. Indeed, Bourque-2001 discloses that the "pump's rotor" has a "rotational axis." Ex.1007 at 402. Further, "[t]he flow path is of circular cross-section through the inflow and outflow sections." Ex.1007 at 402. "An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller" and "exits the backswept blades of the impeller into a volute of uniformly increasing width." Ex.1007 at 402. Thus, the **magnetically driven rotor (e.g., "impeller")** and **first magnetic device** (e.g., "passively magnetic elements") are rotatable about an axis of rotation (e.g.,

"rotational axis") aligned with the **inflow axis** to drive the blood flowing from the **inflow tube** (e.g., "fluid leaving the inflow conduit [] enter[s] the impeller" and "exits the backswept blades of the impeller").

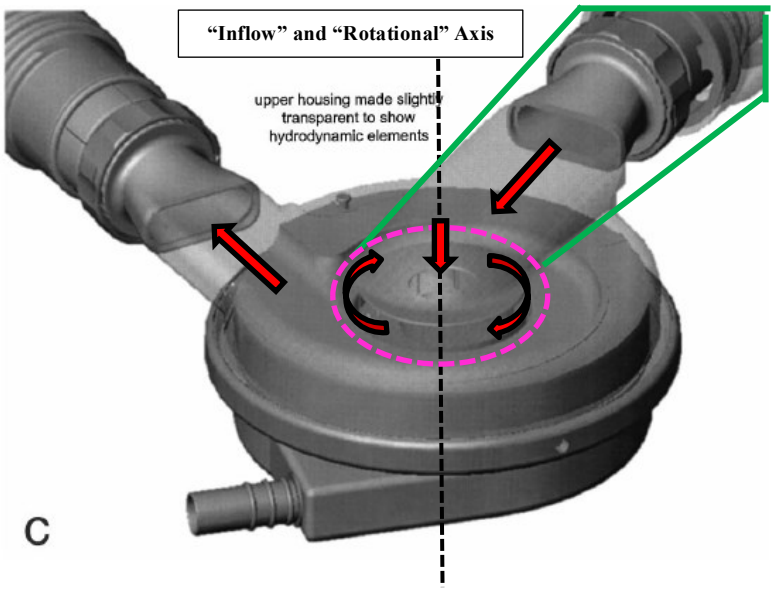
330. Figure 1B (annotated) illustrates a cross-sectional view of the HeartMate III in which the impeller of the rotor (**pink**) and the passively magnetic elements (**purple**) are *rotatable about an axis of rotation aligned with the inflow axis* (**black**) to drive blood (**red** arrows) "leaving the inflow conduit" (**green**):



Ex.1007 at Fig. 1B (annotated).

331. Similarly, Figure 1C (annotated) illustrates a view of the "flow paths" of blood (**red** arrows) through the HeartMate III in which the impeller of the rotor

(**pink**) is rotatable about a "rotational axis" (**black**) aligned with the "inflow axis" to drive blood received from the inflow subassembly (**green**):



Ex.1007, Fig. 1B (annotated).

332. To the extent that Bourque-2001 does not expressly disclose the "passively magnetic elements" "*axially aligned with the…inflow axis*," it would have been obvious to a POSITA as of February 27, 2007 to modify the inflow subassembly of the HeartMate III described in Bourque-2001 in view of Wampler-169 to axially align the LV cannula with the impeller and passively magnetic elements of the rotor for the same reasons discussed for element [11A], and for numerous reasons as discussed below in Section X.B.8. *See supra* [11A].

333. Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious "*the **magnetically driven rotor*** ("impeller") *and **first***

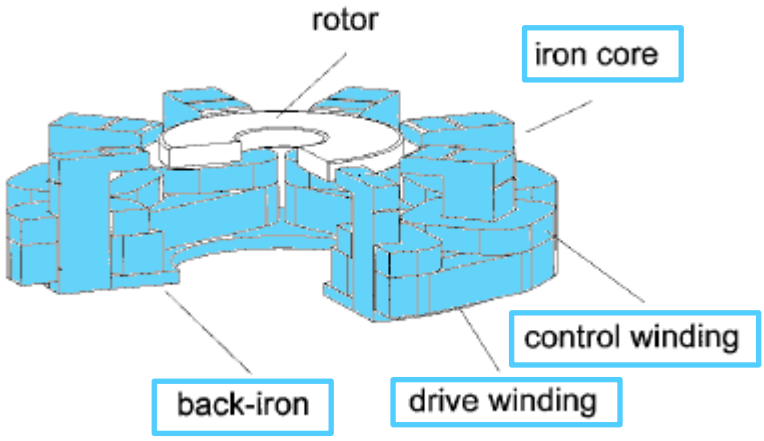
magnetic device ("passively magnetic elements") *being rotatable about an axis of rotation* ("rotational axis") *aligned with the* ***inflow axis*** *to drive the blood flowing from the* ***inflow tube*** ("an inflow subassembly")."

vii. [11F] a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis

334. Bourque-2001 discloses that "*a* ***magnetic drive system*** *comprising a* ***second magnetic device*** *axially aligned with the* ***inflow axis***."

335. Bourque-2001 discloses that "[t]he very simple main flow path is a consequence of the motor's "J" core configuration (i.e., the stator laminations are J shaped), which places an imaginary plane near the mid-height of the pump, below which are confined the motor and levitation elements, and above which the hydrodynamic elements are permitted free reign"). A "stator" is a commonly used component of an electric motor, typically made of iron or an electrically conductive coil, that remains static and creates a rotating magnetic field when an electric current is supplied, which thereby causes rotation of a rotor. The "motor" comprising the "stator laminations," "iron core," "drive winding," "control winding," and "back-iron" described in Bourque-2001 are a ***magnetic drive system*** comprising a ***second magnetic device*** as recited in Claim 11.

336. Figure 4 of Bourque-2001 depicts the "J" shaped stator laminations, control winding, drive winding, iron core, and back-iron comprising the "motor" (**light blue**) of the HeartMate III pump:

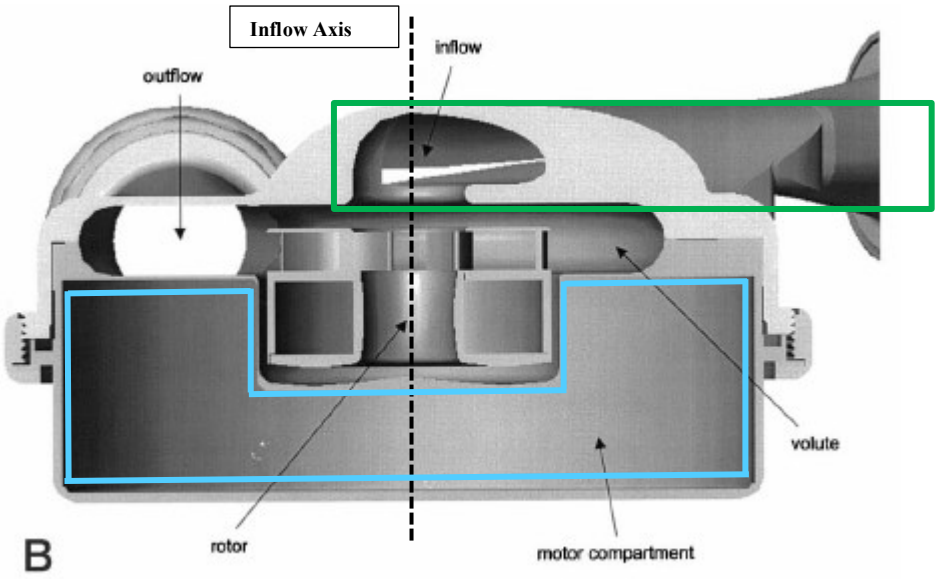


Ex.1007, Fig. 4 (annotated).

337. As discussed above with respect to element [11C], for components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis") in space. The HeartMate III pump described in Bourque-2001 has a ***magnetically driven rotor*** (e.g., "impeller" of the rotor, Ex.1007 at 401), which is driven by the electromagnetic interaction between the ***first magnetic device*** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401) and is in axial alignment with the ***second magnetic device*** (e.g., the "motor," Ex.1007 at 404, Fig. 4), all of which are aligned along the "inflow axis." *See infra* element [11H]; *supra* element [11D]. Bourque-2001 further teaches that

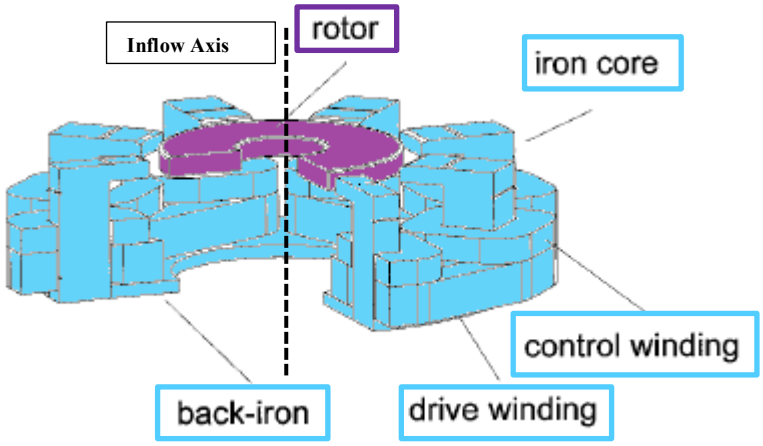
the HeartMate III comprises "drive and levitation in a single magnetic structure as shown in Figure 4. The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 403.

338. Figure 1B (annotated) illustrates the axial alignment of the motor (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") in the motor compartment with the inflow axis (**black**) of the "inflow subassembly (**green**):



Ex.1007 at Fig. 1B (annotated). Note that Figure 1B is a cross-sectional view of the HeartMate III and the stator laminations are understood to radially surround the passively magnetic elements of the rotor. The axial alignment of the components of

the motor (**light blue**) and the passively magnetic elements of the rotor (**purple**) (which is in turn axially aligned with the impeller of the rotor (*see supra* Section X.B.1.iv)) along the "inflow axis" (**black**) can be seen in Figure 4 (annotated):



Ex.1007, Fig. 4 (annotated).

339. To the extent that Bourque-2001 does not expressly disclose the "motor" "*axially aligned with the…inflow axis*," it would have been obvious to a POSITA as of February 27, 2007 to modify the inflow subassembly of the HeartMate III described in Bourque-2001 in view of Wampler-169 to axially align the LV cannula with the motor for the same reasons discussed for element [11A], and for numerous reasons as discussed below in Section X.B.8. *See also supra* [11A].

340. Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious "*a **magnetic drive system** comprising a **second***

magnetic device ("motor" with drive windings) *axially aligned with the* ***inflow axis***."

viii. [11G] and [the second magnetic device is] spaced apart from the magnetically driven rotor such that a wall of the one or more walls defining the chamber is positioned between the magnetically driven rotor and the second magnetic device

341. Bourque-2001 discloses that the ***second magnetic device*** is "*spaced apart from the* ***magnetically driven rotor*** *such that a wall of the* ***one or more walls*** *defining the* ***chamber*** *is positioned between the* ***magnetically driven rotor*** *and the* ***second magnetic device***."

342. For example, Bourque-2001 discloses that the HeartMate III's "rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely." Ex.1007 at 401. The HeartMate III has a "lower housing" that includes "a cavity for the rotor" and "in which the motor is enclosed." Ex.1007 at 401; *see also* Ex.1007 at 404 ("It was a fundamental goal of the HeartMate III mechanical design…to enclose a sophisticated motor."), 402 ("installing the motors in the pump lower housings").

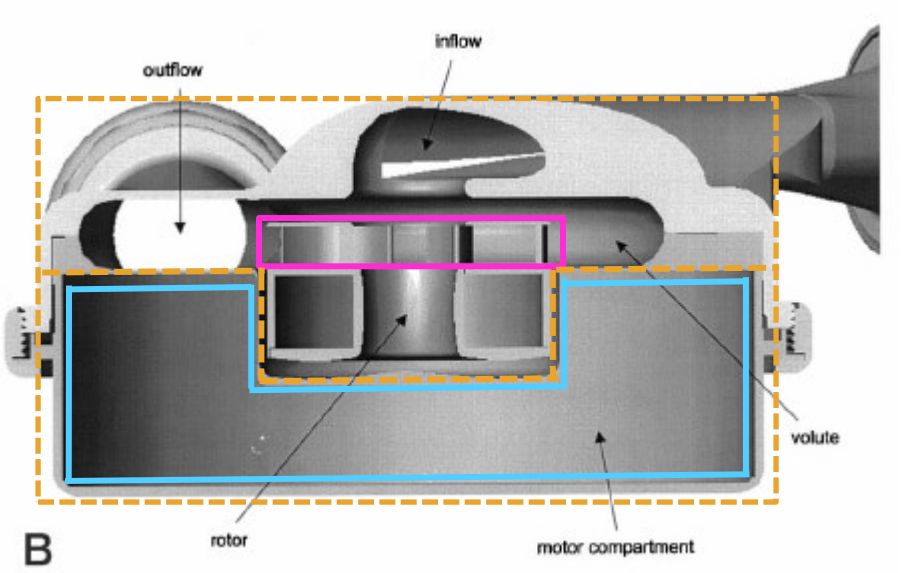
343. Bourque-2001 further discloses that the **second magnetic device** (e.g., the "motor") is sealed by "titanium surfaces…textured in the same way as the

HeartMate and HeartMate II,…intended to promote the development of a stable, adherent pseudoneointima immediately upon contact with blood, thereby insulating subsequent blood flow from contact with nonbiologic materials and reducing the risk of thromboembolism." Bourque-2001 at 401 (citations omitted).

344. In describing the blood flow path, Bourque-2001 discloses the "clearances above and below the rotor" which were "chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing.").

345. Thus, a wall of the ***one or more walls*** ("upper" and "lower housing") defining ***the chamber*** ("volute" and "cavity") is positioned between the ***second magnetic device*** ("motor" with drive windings) and the ***magnetically driven rotor*** ("impeller" of the rotor).

346. Figure 1B (annotated) illustrates that the motor (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") is *spaced apart* from the impeller of the rotor (**pink**) by a wall of the "upper" and "lower housing" (**orange**) positioned between the impeller and the motor:



Ex.1007 at Fig. 1B (annotated).

347. Figure 5 also illustrates the spacing between the "stator laminations" of the motor (**light blue**) and the passively magnetic elements of the rotor (**purple**):

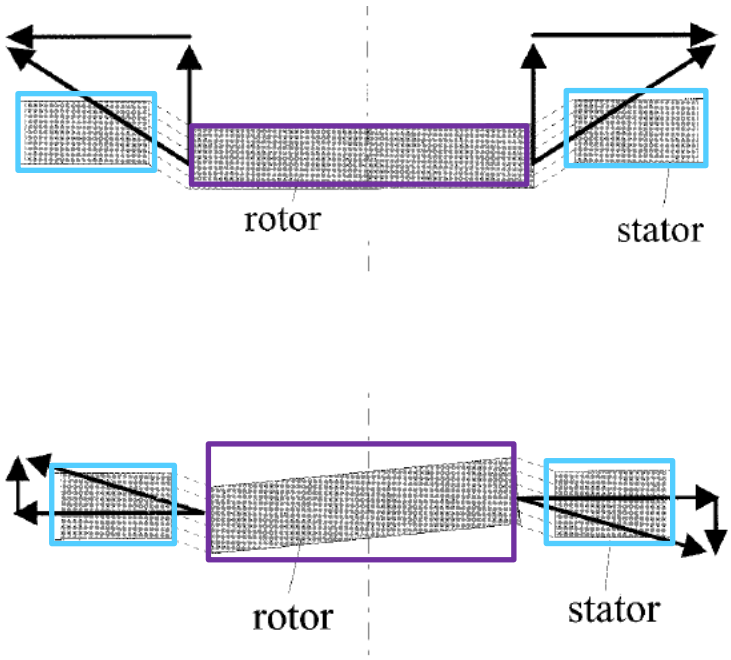


Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007, Fig. 5.

348. Accordingly, Bourque-2001 discloses that the ***second magnetic device*** ("motor" with drive windings) is "*spaced apart from the* ***magnetically driven rotor*** ("impeller") *such that a wall of the* ***one or more walls*** ("upper and lower housing") *defining the* ***chamber*** ("volute" and "cavity") *is positioned between the* ***magnetically driven rotor*** *and the* ***second magnetic device***."

ix. [11H] the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor so as to magnetically drive rotation of the magnetically driven rotor relative to the one or more walls via a magneto coupling with the first magnetic device; and

349. Bourque-2001 discloses that "*the **second magnetic device** positioned axially closer to the **first magnetic device** than to the **magnetically driven rotor** so as to magnetically drive rotation of the **magnetically driven rotor** relative to the one or more walls via a magneto coupling with the **first magnetic device**.*"

350. As discussed in Section VII.A.1, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating magnetic component to another rotating magnetic component via a magnetic field." *See supra* Section VII.A.1. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in parallel litigation) of "magneto coupling" to also include not only a transfer of torque from one rotating magnetic component to another rotating magnetic component, but also to include "a transfer of torque from one *stationary* magnetic component (i.e., a stator) to another rotating magnetic component using an *electro*magnetic field," is correct. *See* Ex.1019.

351. Accordingly, based on the Patent Owner's understanding of the term, Bourque-2001 describes a magneto coupling between the ***second magnetic device*** (e.g., the "motor," including the "stator laminations" and "windings," Ex.1007 at 404, Fig. 4) and the ***first magnetic device*** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401). For example, Bourque-2001 discloses that the HeartMate III's "rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely." Ex.1007 at 401. "The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 402-403. Bourque-2001 discloses that "[t]he very simple main flow path is a consequence of the motor's "J" core configuration (i.e., the stator laminations are J shaped), which places an imaginary plane near the mid-height of the pump, below which are confined the motor and levitation elements, and above which the hydrodynamic elements are permitted free reign").

352. Figure 5 (annotated) of Bourque-2001 illustrates the magneto coupling between the "passively magnetic elements" of the rotor (**purple**) and the "stator laminations" of the motor (**light blue**):

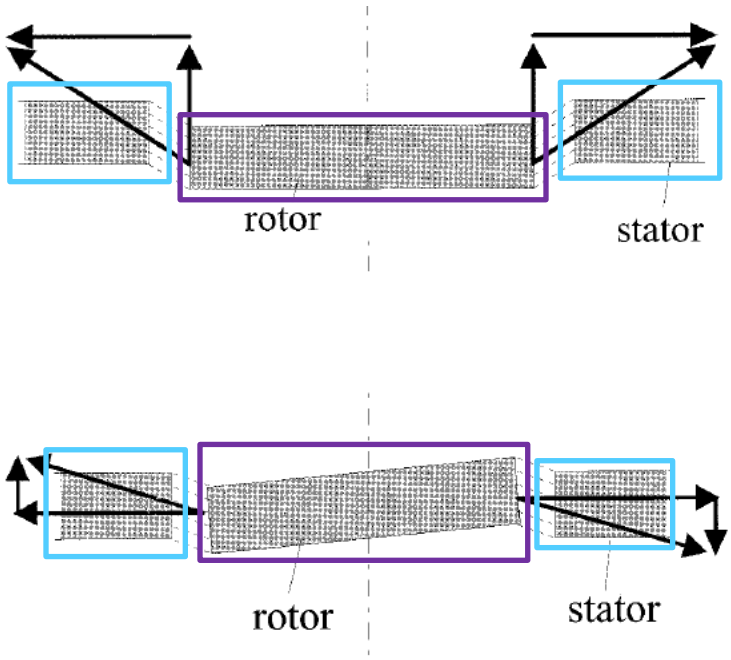


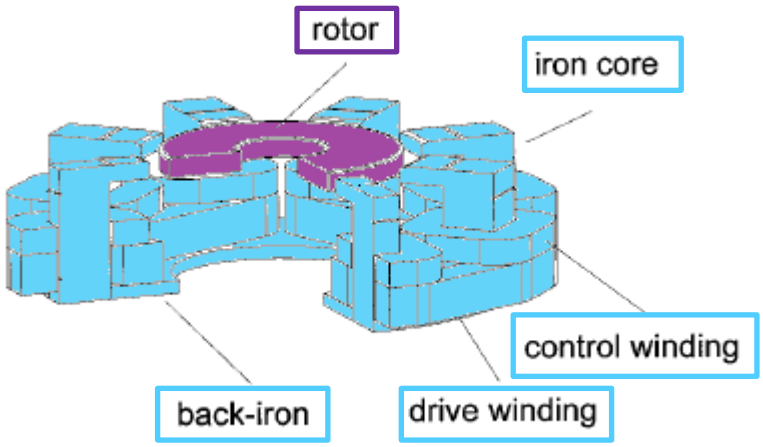
Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007, Fig. 5.

353. As discussed with respect to element [11D], the ***first magnetic device*** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401) is rigidly coupled to the ***magnetically driven rotor*** (e.g., the "impeller" of the rotor). Bourque-2001 further discloses how the motor impacts the rate of blood flow produced by the ***magnetically driven rotor*** (e.g., the "impeller" of the rotor), confirming that the ***second magnetic device*** (e.g., the "motor") of the HeartMate III is positioned to magnetically drive rotation of the ***magnetically driven rotor*** via the electromagnetic field applied to the ***first magnetic device*** (e.g., the "passively magnetic elements" of the rotor). Ex.1007 at 403 ("Note that the design point (7 L/min at 135 mm Hg)

occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability.").

354. As shown in Figure 4, "the motor's 'J' core configuration (i.e., the stator laminations are J shaped)" are *positioned to…drive rotation of the* **impeller** *via a magneto coupling* with the "**passively magnetic elements**":

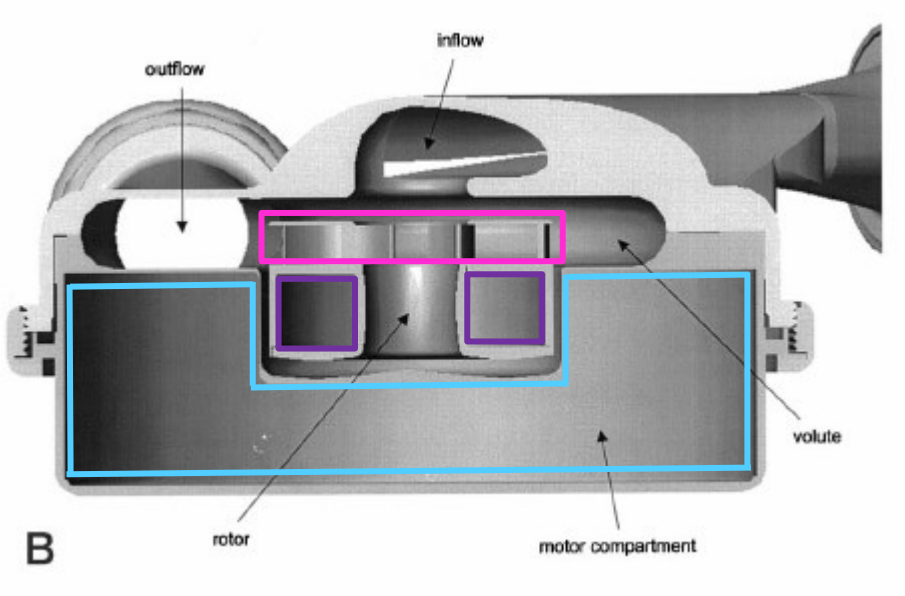


Ex.1007, Fig. 4, 402-404.

355. For the second magnetic device to be "axially closer" as recited in Claim 11, the components must be configured such that they are colinear, or in the same line (or "axis") in space. Additionally, the ***second magnetic device*** must be closer to the ***first magnetic device*** along that axis than it is to the ***magnetically driven rotor***. The **impeller** of the rotor of the HeartMate III pump described in Bourque-

2001 is in axial alignment with the ***second magnetic device*** (e.g., the "motor," Ex.1007 at 404, Fig. 4), all of which are aligned along the "inflow axis."

356. Figure 1B (annotated) illustrates that the motor (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") positioned axially closer to the passively magnetic elements of the rotor (**purple**) than to the impeller of the rotor (**pink**):



Ex.1007 at Fig. 1B (annotated).

357. In addition, as discussed with respect to element [11E], the **magnetically driven rotor** (e.g., the "impeller" of the rotor) the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401) are rotatable about an axis of rotation (e.g., "rotational axis"). *See supra* Section

X.B.1.vi. Bourque-2001 further discloses that the "lower housing" "includes the lower half of the volute and a cavity for the rotor." Ex.1007 at 401. Thus, the **magnetically driven rotor** (e.g., the "impeller" of the rotor) is driven in rotation about the "rotational axis" relative to the ***one or more walls*** (e.g., "upper housing" and "lower housing" forming the "volute" and "cavity").

358. Accordingly, Bourque-2001 discloses "*the **second magnetic device*** ("motor" with drive windings") *positioned axially closer to the **first magnetic device*** ("passively magnetic elements") *than to the **magnetically driven rotor*** ("impeller") *so as to magnetically drive rotation of the **magnetically driven rotor** relative to the **one or more walls*** ("upper housing" and "lower housing") *via a magneto coupling with the **first magnetic device***"

x. [11I] a blood outflow port positioned such that the blood driven by the magnetically driven rotor exits the chamber in a direction substantially perpendicular to the inflow axis

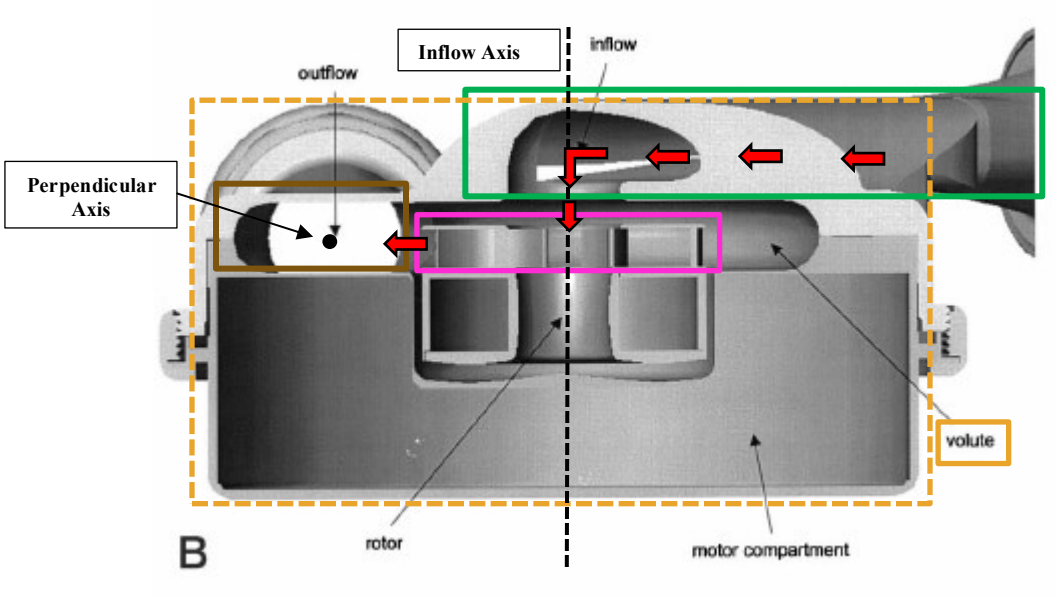
359. Bourque-2001 discloses "*a **blood outflow port** positioned such that the blood driven by the **magnetically driven rotor** exits the **chamber** in a direction substantially perpendicular to the **inflow axis***."

360. Bourque-2001 discloses that the HeartMate III includes an "outflow channel." Ex.1007 at 401. The "outflow channel" described in Bourque-2001 is a

blood outflow port as recited in Claim 11. Bourque-2001 further describes that "[t]he flow path is of circular cross-section through the inflow and outflow sections." Ex.1007 at 402. "An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller" and "exits the backswept blades of the impeller into a volute of uniformly increasing width, which terminates at a cutwater, peeling off most of the flow and directing it toward the outflow." Ex.1007 at 402. Thus, the **blood outflow port** (e.g., "outflow channel") is positioned such that blood driven by the **magnetically driven rotor** (e.g., the "impeller" of the rotor) exits the **chamber** (e.g., "volute") in a direction substantially perpendicular to the **inflow axis**.

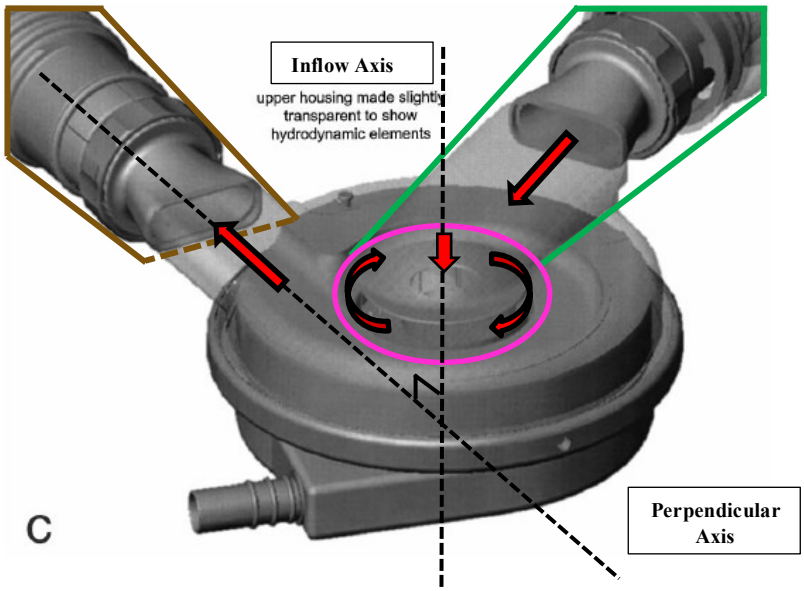
361. I note that in parallel litigation, the Patent Owner has asserted the blood outflow port of the "HeartMate 3" is positioned such that blood driven by the accused magnetically driven rotor exits the chamber in the same way as described above in Bourque-2001. *See e.g.*, Ex.1019, at 8-9 (Complaint, Ex. 11). For the purposes of my analysis, I also map the limitation that the **blood outflow port** (e.g., "outflow channel") is positioned such that blood driven by the **magnetically driven rotor** (e.g., the "impeller" of the rotor) exits the chamber ("volute") in a direction substantially perpendicular to the inflow axis in the same way.

362. Figure 1B (annotated) illustrates that the outflow channel (**brown**) is positioned such that the blood is driven (**red** arrows) by the impeller of the rotor (**pink**) exits the volute (**orange**) in a direction substantially perpendicular from the LV cannula of the inflow subassembly (**green**) along the inflow axis (**black**):



Ex.1007, Fig. 1B.

363. Similarly, Figure 1C (annotated) illustrates a view of the "flow paths" of blood (**red** arrows) through the HeartMate III in which blood is driven from the LV cannula of the inflow subassembly (**green**) by the impeller of the rotor (**pink**) to the outflow channel (**brown**) in a direction substantially perpendicular from the LV cannula of the inflow subassembly and the inflow axis (**black**):



Ex.1007, Fig. 1C (annotated).

364. To the extent that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 for the same reasons discussed in [11A] and below in Section X.B.8 that there would be "a 90-degree ['*perpendicular*'] redirection of the blood."

365. Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious "*a* ***blood outflow port*** ("outflow channel") *positioned such that the blood driven by the* ***magnetically driven rotor*** ("impeller") *exits the* ***chamber*** ("volute" and "cavity") *in a direction substantially perpendicular to the* ***inflow axis***."

xi. [11J] wherein the magneto coupling orients the magnetically driven rotor so that both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor,

366. Bourque-2001 discloses that "*the magneto coupling orients the **magnetically driven rotor** so that both the **magnetically driven rotor** and the **first magnetic device** remain spaced apart from the **one or more walls** by the blood in response to rotation of the **magnetically driven rotor**.*"

367. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls **by the blood** in response to rotation of the magnetically driven rotor" to mean that "in response to rotation of the magnetically driven rotor" refers to a hydrodynamic bearing such that "the blood" ***causes*** the "magnetically driven rotor and the first magnetic device" to "remain spaced apart from the one or more walls." *See* Section VII.A.2. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in parallel litigation) of "both magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation

of the magnetically driven rotor" to include not only hydrodynamic suspension of the rotor but also that it may be met by *exclusively* magnetic suspension, is correct. *See* Ex.1019.

368. Accordingly, based on the Patent Owner's understanding of the term and as discussed with respect to element [11H], Bourque-2001 discloses a magneto coupling between the ***second magnetic device*** (e.g., the "motor," Ex.1007 at 404) and the ***first magnetic device*** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401) to drive rotation of the ***magnetically driven rotor*** (e.g., "impeller"). For example, Bourque-2001 discloses that the HeartMate III's "rotor is magnetically suspended, ***eliminating contact between moving parts*** and consequently extending wear life indefinitely." Ex.1007 at 401. "The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 402-403.

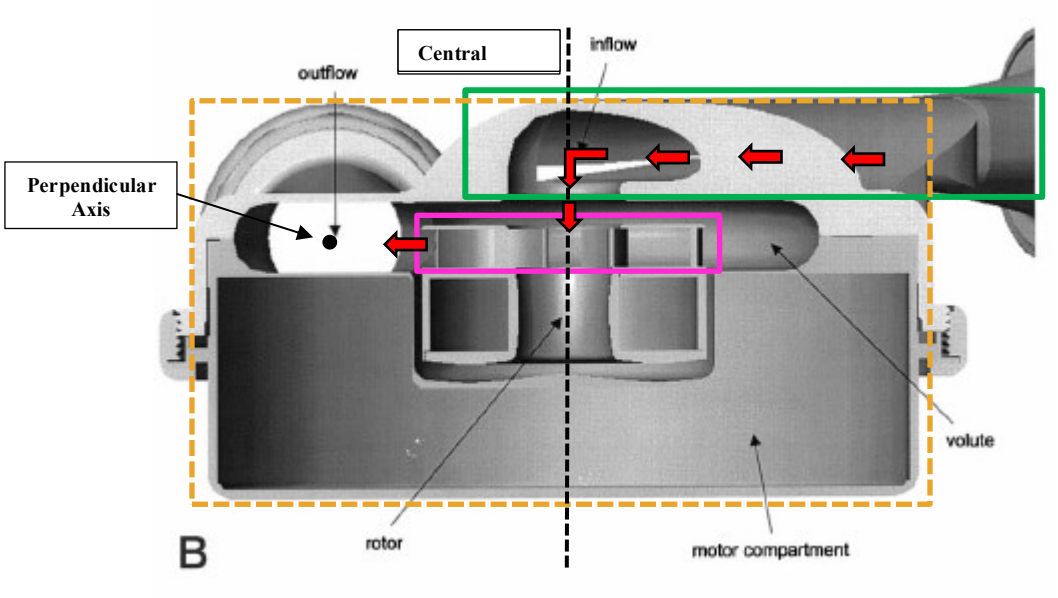
369. In addition, as discussed with respect to element [11D], the ***first magnetic device*** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401) is *rigidly coupled* to the ***magnetically driven rotor*** (e.g., the "impeller" of the rotor). Bourque-2001 further discloses how the motor impacts the rate of blood flow produced by the ***magnetically driven rotor*** (e.g., the "impeller" of the rotor),

confirming that the ***second magnetic device*** (e.g., "motor") of the HeartMate III is positioned to magnetically drive rotation of the ***magnetically driven rotor*** via the electromagnetic field applied to the ***first magnetic device*** (e.g., the "passively magnetic elements" of the rotor). Ex.1007 at 403 ("Note that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability.").

370. In describing the blood flow path, Bourque-2001 further discloses the "clearances above and below the rotor" which were "chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by

the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; **the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing**.").

371. Thus, the "magneto coupling" between the "passively magnetic elements" of the rotor and the "stator laminations" of the "motor" cause the rotor to be "magnetically suspended" such that, in response to rotation of the impeller of the rotor, the impeller is spaced apart from the "housing" by the blood flowing in the gap (e.g., "gaps permit up to 7× gravitational loads in any direction without contact ***between the rotor and housing***"). Figure 1B demonstrates gaps permitted between the magnetically levitated **impeller** and the **housing** to allow "flow" "above and below the rotor" (Ex.1007, 402) as shown:



Ex.1007, Fig. 1B.

372. Accordingly, Bourque-2001 discloses that "*the magneto coupling orients the* ***magnetically driven rotor*** ("impeller") *so that both the* ***magnetically driven rotor*** *and the* ***first magnetic device*** ("passively magnetic elements") *remain spaced apart from the* ***one or more walls*** *by the blood* ("without contact between the rotor and housing") *in response to rotation of the* ***magnetically driven rotor***."

xii. [11K] an external control unit configured to control operation of the second magnetic device based on a fixed value to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device,

373. Bourque-2001 discloses "*an* ***external control unit*** *configured to control operation of the* ***second magnetic device*** *based on a fixed value to thereby*

magnetically drive the rotation of the ***magnetically driven rotor*** *via the magneto coupling with the* ***first magnetic device***."

374. Bourque-2001 discloses connecting "electronics for power and control of the LVAD and for data acquisition" to the HeartMate III via an "electronic cable to be exteriorized percutaneously." Ex.1007 at 401, 403. Bourque-2001 further discloses that "[s]peed and motor parameters were set and controlled using software" and that the "motor drive and control electronics" were external, because they had not been "incorporat[ed]…within the pump." Ex.1007 at 405. Accordingly, the "electronics for power and control" described in Bourque-2001 are an **external control unit** as recited in Claim 11.

375. Bourque-2001 further discloses that during testing, "[t]he animals were continuously monitored for general welfare, and certain parameters such as arterial pressure, pump and pulmonary artery volume flow rates, pump speed, and blood chemistry (including plasma free hemoglobin) were periodically recorded. Ex.1007 at 403. In addition, during *in vitro* testing, "[s]peed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III." Ex.1007 at 403.

376. The "electronics for power and control" (or "power driver") of the HeartMate III pump drive the motor by providing an electric current to the "stator

laminations" of the "iron core" of the motor. Ex.1007 at 403, 404, Fig. 3, Fig. 4, Fig. 5. As discussed with respect to elements [11H] and [11J], the resulting magnetic field created by the "stators" of the motor causes the rotation and magnetic levitation of the "passively magnetic elements" of the rotor via a magneto coupling, and thereby drives the rotation of the "impeller" of the rotor. Ex.1007 at 403 ("Note that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability."), 404, Figure 4; *see also supra* Sections X.B.1.ix and .X.B.1.xi.

377. Figure 3 (annotated) illustrates the connection of the electronics for power and control (**lime green**) to the HeartMate III LVAD (**blue**):

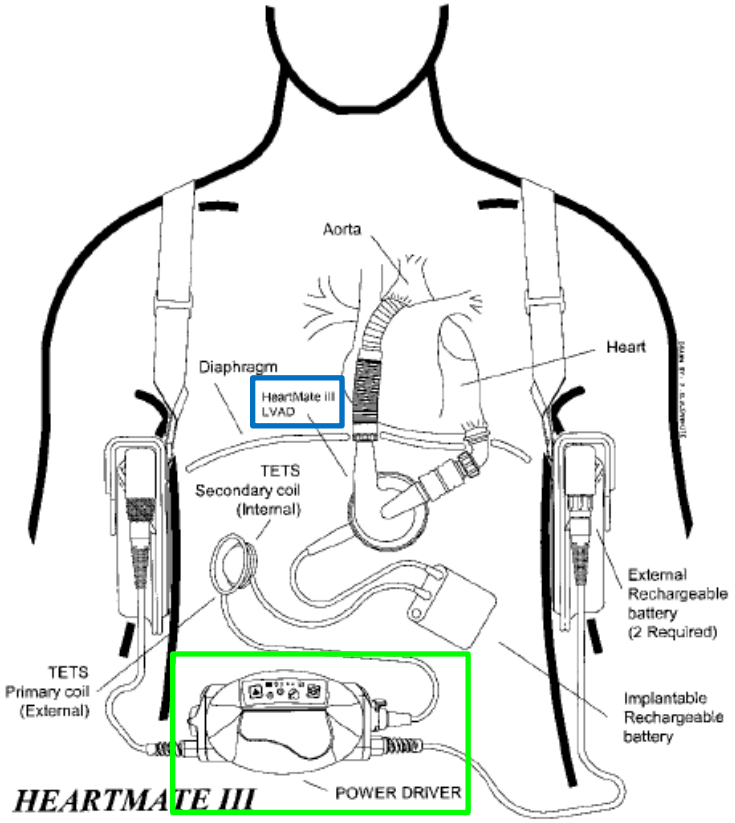


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3 (annotated).

378. Bourque-2001 further discloses that "[s]peed and ***motor parameters were set*** and controlled using software specifically designed to develop the HeartMate III." Ex.1001 at 403. Such "electronics for power and control of the LVAD and for data acquisition resided on a shelf." Ex.1007 at 403. During testing, "[t]he pump was prescribed to run at 3,500 rpm perioperatively, then gradually adjusted to maintain volume flow rates at 5 ± 1 L/min throughout the study."

Ex.1007 at 403. Further, volumetric flow rate and steady-state pump pressure were measured at various set pump speeds, as shown:

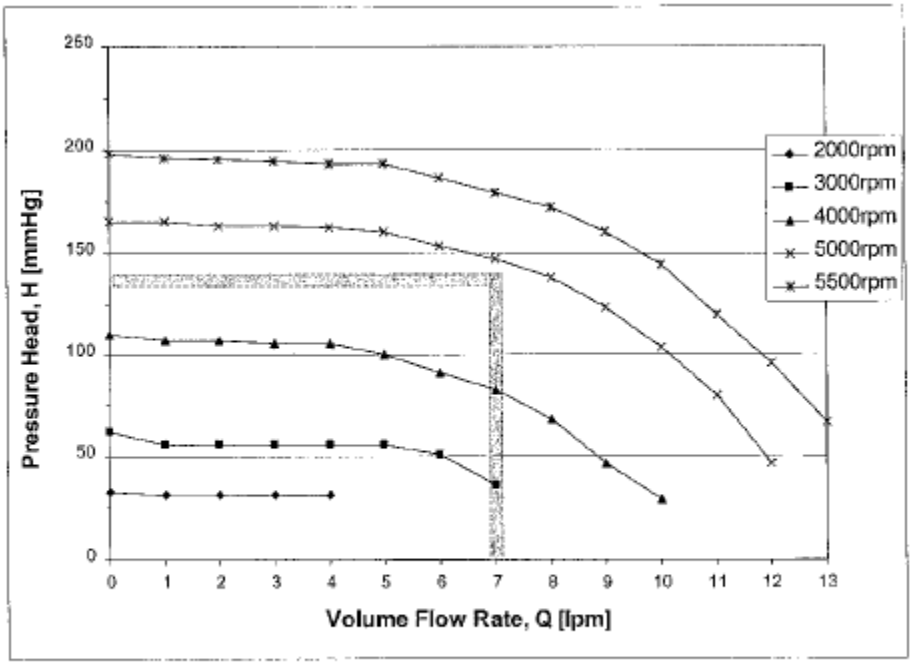


Figure 7. HeartMate III H-Q characteristic (the heavy, gray line indicates the design point).

Ex.1007 at 404; *see also* Ex.1007 at 403 ("The steady-state pump pressure head versus volume flow rate (H-Q) characteristic is shown in Figure 7. Note that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability.").

379. Thus, the HeartMate III's **external control unit** (e.g., "electronics for power and control") implementing software for setting "motor parameters" was configured to regulate operation of the **second magnetic device** (e.g., the "motor") based on a fixed value (e.g., "prescribed to run at 3,500 rpm perioperatively, then gradually adjusted," Ex.1007 at 403).

380. Accordingly, Bourque-2001 discloses "*an **external control unit*** ("electronics for power and control") *configured to control operation of the **second magnetic device*** ("motor" with drive windings) *based on a fixed value to thereby magnetically drive the rotation of the **magnetically driven rotor*** ("impeller") *via the magneto coupling with the **first magnetic device*** ("passively magnetic elements")."

2. Claim 12

a. [12] The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components.

381. Bourque-2001 discloses and/or renders obvious claim 12. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 11. I incorporate that discussion into my analysis for claim 12.

382. Bourque-2001 discloses that "*the **magnetically driven rotor** includes a guide surface to produce centrifugal flow components*." As discussed with respect

to element [11H], Bourque discloses that the **magnetically driven rotor** (e.g., "impeller" of the rotor) is rotated via a magneto coupling. *See supra* Section X.B.1.ix.

383. Bourque-2001 further discloses that the "impeller" of the rotor includes a "shroud (i.e., the cover across the top of the blades on the rotor)" and impeller "blades" having "leading edges" and "trailing edges." Ex.1007 at 402. Each of these components of the impeller is a "guide surface," which serves to direct the flow of blood within the centrifugal pump to the outflow subassembly. That is, "[a]n opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades." Ex.1007 at 402. "The flow exits the backswept blades of the impeller into a volute of uniformly increasing width, which terminates at a cutwater, peeling off most of the flow and directing toward the outflow." Ex.1007 at 402; *see also* Ex.1007 at 402 ("The pump components were designed to achieve the desired flow paths, accommodate the motor, and provide convenient, reliable connections in the simplest, most cost effective way.").

384. Indeed, the HeartMate III pump described in Bourque-2001 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis

towards the impeller and is cast out by centrifugal force along its circumference. Said another way, the production of centrifugal flow components by the components of the impeller are a characteristic feature of a centrifugal pump.

385. Accordingly, Bourque-2001 discloses that "*the **magnetically driven rotor*** ("impeller") *includes a guide surface to produce centrifugal flow components*."

3. Claims 14-15

a. [14], 15.

386. Bourque-2001 discloses and/or renders obvious claims 14-15. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 11. I incorporate that discussion into my analysis for claim 14.

387. Bourque-2001 discloses that "*the **one or more walls** and the **magnetically driven rotor** define a gap separating the **magnetically driven rotor** from the **one or more walls**, the gap configured to be occupied by the blood when the **second magnetic device** drives the rotation of the **magnetically driven rotor***." Bourque-2001 further discloses that "*wherein the gap surrounds the **magnetically driven rotor***."

388. As discussed with respect to element [11H], Bourque-2001 discloses a magneto coupling between the **second magnetic device** (e.g., "motor" with drive windings, Ex.1007 at 403) and the **first magnetic device** (e.g., "passively magnetic elements," Ex.1007 at 401) to drive rotation of the **magnetically driven rotor** (e.g., "impeller" of the rotor, Ex.1007 at 401). *See element* [11H]. In addition, as discussed with respect to element [11J], Bourque-2001 discloses that the magneto coupling orients the **magnetically driven rotor** (e.g., "impeller") to be spaced apart from the **one or more walls** (e.g., "upper" and "lower" housing," Ex.1007 at 401) by the blood in response to the rotation of the **magnetically driven rotor**. *See supra* element [11J].

389. In describing the blood flow path, Bourque-2001 further discloses the "clearances above and below the rotor" which were "chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an

accumulation of stagnant blood there, and relieving the upward thrust load on the rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; **the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing**.").

390. Thus, Bourque-2001 discloses that the **one or more walls** (e.g., upper" and "lower housing," Ex.1007 at 401) and the **magnetically driven rotor** (e.g., "impeller" of the rotor, Ex.1007 at 401) define a gap (e.g., "gaps," Ex.1007 at 402) configured to be occupied by the blood when the **second magnetic device** (e.g., "motor," Ex.1007 at 403) drives rotation of the **magnetically driven rotor** via the magneto coupling. *See supra* element [11H].

391. Accordingly, Bourque-2001 discloses that "*the **one or more walls*** ("housing") *and the **magnetically driven rotor*** ("impeller") *define a gap* ("gaps") *separating the **magnetically driven rotor*** ("impeller") *from **the one or more walls**, the gap configured to be occupied by the blood when the **second magnetic device*** ("motor") *drives the rotation of the **magnetically driven rotor**.*" Bourque-2001 further discloses that "*wherein the gap surrounds the **magnetically driven rotor***."

4. Claim 16

a. [16] The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis.

392. Bourque-2001 discloses and/or renders obvious claim 16. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claims 11 and 14. I incorporate that discussion into my analysis for claim 16.

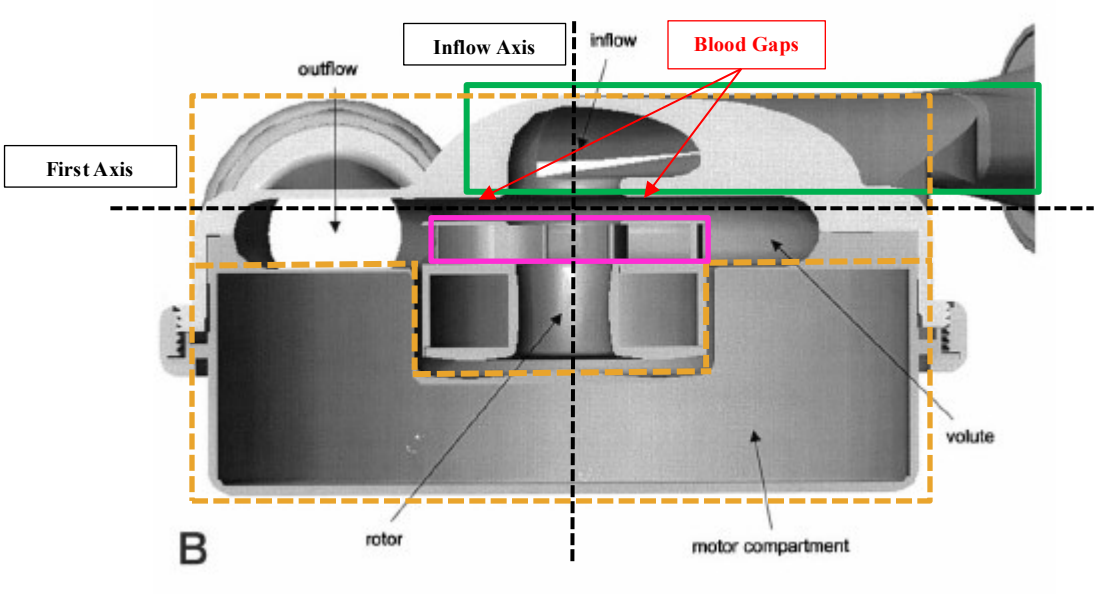
393. Bourque-2001 discloses that "*at least part of the gap extends along a first axis substantially perpendicular to the* ***inflow axis***."

394. Bourque-2001 discloses that the **one or more walls** (e.g., upper" and "lower housing," Ex.1007 at 401) and the **magnetically driven rotor** (e.g., "impeller" of the rotor, Ex.1007 at 401) define a gap (e.g., "gaps," Ex.1007 at 402) configured to be occupied by the blood when the **second magnetic device** (e.g., "motor," Ex.1007 at 403) drives rotation of the **magnetically driven rotor** via the magneto coupling. *See supra* element [11J]. In addition, as discussed with respect to element [11A], Bourque-2001 discloses the ***inflow tube*** (e.g., "an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007 at 401) defining a blood inflow path (e.g., "serves as the inflow cannula," Ex.1007, 401) along an

inflow axis so as to provide the flow of blood to the ***magnetically driven rotor*** ("impeller" of the rotor, Ex.1007 at 401).

395. In describing the blood flow path, Bourque-2001 further discloses the "clearances above and below the rotor" which were "chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; **the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing**.").

396. Figure 1B (annotated) of Bourque-2001 illustrates that at least part of the "gaps" occupied by blood (**red** arrows), defined when the "motor" drives the rotation of the impeller of the rotor (**pink**) via the magneto coupling, extends along a first axis (**black**, horizontal) substantially perpendicular to the inflow from the LV cannula of the inflow subassembly (**green**) along the inflow axis (**black**, vertical) of the pump:



Ex.1007, Fig. 1B (annotated).

397. Accordingly, Bourque-2001 discloses that "*at least part of the gap* ("gaps") *extends along a first axis substantially perpendicular to the* ***inflow axis***."

5. Claim 18

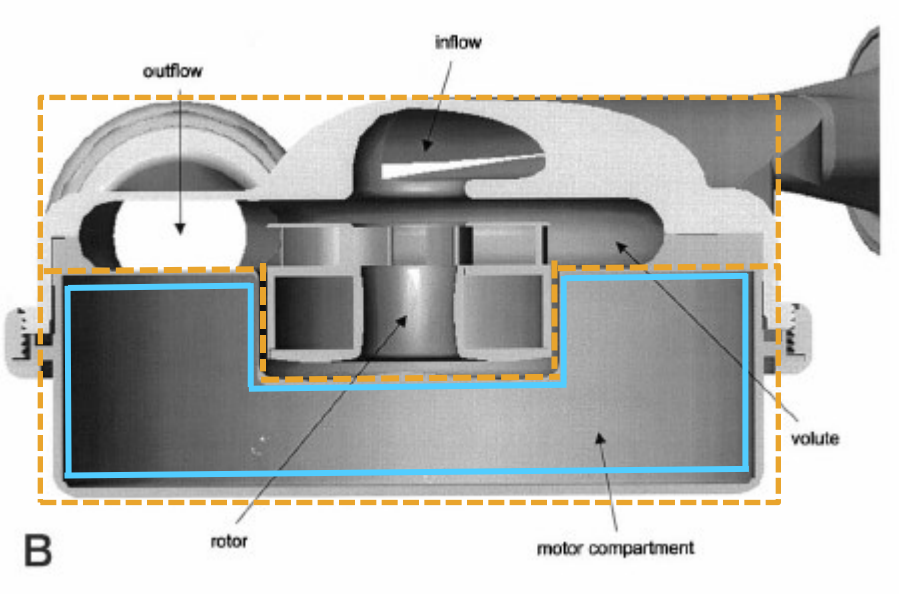
a. [18] The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.

398. Bourque-2001 discloses and/or renders obvious claim 18. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 11. I incorporate that discussion into my analysis for claim 18.

399. Bourque-2001 discloses that "*the **chamber** is a first chamber within which the **magnetically driven rotor** is positioned, and the **magnetic drive system** is positioned within a second chamber sealed from the first chamber*."

400. As discussed with respect to element [11B], the "upper housing" that includes "the upper half of the volute" and "a lower housing that includes the lower half of the volute and a cavity for the rotor" comprise "**one or more walls** at least partially defining a **chamber**" (Ex.1007 at 401) to receive blood from the **inflow tube** (e.g., "fluid leaving the inflow conduit … enter[s] the impeller," which is enclosed in the "housing," Ex.1007, 402). Thus, the "volute" and "cavity for the rotor" are a **first chamber** within which the **magnetically driven rotor** (e.g., "impeller" of the rotor) is positioned.

401. Figure 1B (annotated) of Bourque-2001 illustrates that the "motor" (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") within a "motor compartment" sealed from the "volute" and cavity for the rotor" by the walls of the "housing" (**orange**):



402. Thus, the **magnetic drive system** (e.g., "motor" with "drive windings," Ex.1007 at 403, Fig. 4) is positioned within a second chamber (e.g., "motor compartment," Ex.1007 at 402, Fig. 1A) sealed from the first chamber (e.g., "volute" and "cavity for the rotor," Ex.1007 at 401).

403. Accordingly, Bourque-2001 discloses that "*the **chamber*** ("volute" and "cavity for the rotor") *is a first chamber within which the **magnetically driven rotor*** ("impeller" of the rotor) *is positioned, and the **magnetic drive system*** ("motor" with

"drive windings") *is positioned within a second chamber* ("motor compartment") *sealed from the first chamber*."

6. Claim 19

a. [19] The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber.

404. Bourque-2001 discloses and/or renders obvious claim 19. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claims 11 and 18. I incorporate that discussion into my analysis for claim 19.

405. Bourque-2001 discloses that "*the wall of the* ***one or more walls*** *separates the first chamber from the second chamber.*"

406. As discussed with respect to element [11B] and [18], the "upper housing" that includes "the upper half of the volute" and "a lower housing that includes the lower half of the volute and a cavity for the rotor" comprise "**one or more walls** at least partially defining a **chamber**" (Ex.1007 at 401) which is a first chamber. For the same reasons, the "upper housing" and "lower housing" comprise "**one or more walls**" that separate the first chamber (e.g., "volute" and a cavity for the rotor") from the second chamber (e.g., "motor compartment").

407. Accordingly, Bourque-2001 discloses that "*the wall of the* ***one or more walls*** (“upper” and “lower housing”) *separates the first chamber* (“volute” and “cavity for the rotor”) *from the second chamber* (“motor compartment”).”

7. Claims 1-2, 4-5, 7-8, 20

408. In my opinion, claim 1 and dependent claims 2, 4-5, 7-8, and 20 recite elements that are identical or substantially analogous to independent claim 11 and dependent claims 12, 14, 16, 18-19, and are therefore rendered obvious for the same reasons. For instance, the “surrounding rotor housing” of claim 1 is essentially the same as the “one or more walls at least partially defining a chamber” of claim 11. Similarly, the “inflow tube,” “magnetically driven rotor,” and “first magnetic device” are all axially aligned with the “inflow axis” of claim 11 in essentially the same way that they are all aligned with the “central axis” of claim 1. The below chart maps the limitations of these claims to their analogous claim limitations that I’ve analyzed above. *Supra* Section X.B.

Claims 1-2, 4-5, 7-8, 20	Analogous Claim Limitations	Analogous Sections of Ground 2
[1PRE]	[11PRE]	§X.B.1.i
[1A]	[11A]	§X.B.1.ii
[1B]	[11C]	§X.B.5

[1C]	[11B], [11E]	§X.B.1.iii; §X.B.1.vi
[1D]	[11D]	§X.B.1.v
[1E]	[11F]	§X.B.1.vii
[1F]	[11H]	§X.B.1.ix
[1G]	[11G], [14]	§X.B.1.viii; §X.B.3
[1H]	[11I]	§X.B.1.x
[1I]	[11J]	§X.B.1.xi
[1J]	[11K]	§X.B.1.xii
[2]	[12]	§X.B.2
[4]	[18], [19]	§X.B.1.iii; §X.B.5-9
[5]	[14], [18]	§X.B.7.i; §X.B.3; §X.B.5
[7]	[18]	§X.B.5
[8]	[19]	§X.B.6
[20]	[11K]	§X.B.1.xii

i. *Claim 4*

409. Bourque-2001 discloses each and every element of claim [4] for the same reasons discussed in [11B] and Claims [18] and [19]. *See supra* [11B], [18]-[19]. Bourque-2001 further discloses "*a sealing wall positioned between the* ***second***

magnetic device (e.g., "motor") *and the* ***magnetically drive rotor*** (e.g., "impeller") so that "the motor is enclosed." Ex.1007, 402; *see supra* [11B] (analyzing "lower housing"); Ex.1008, [0070]).

ii. *Claim 20*

410. Bourque-2001 discloses each and every element of claim [20] for the same reasons discussed in [11K] and Claims [18] and [19]. *See supra* [11B], [18]-[19]. Bourque-2001 further discloses that "[s]peed and motor parameters [can be] set and controlled" for example, to be "prescribed to run at 3,500 rpm" and "gradually adjusted to maintain volume flow rates" including at "desired maximum flow (10 L/min at 135 mm Hg)" ("*based on a defined cardiac output*"). Ex.1007, 403.

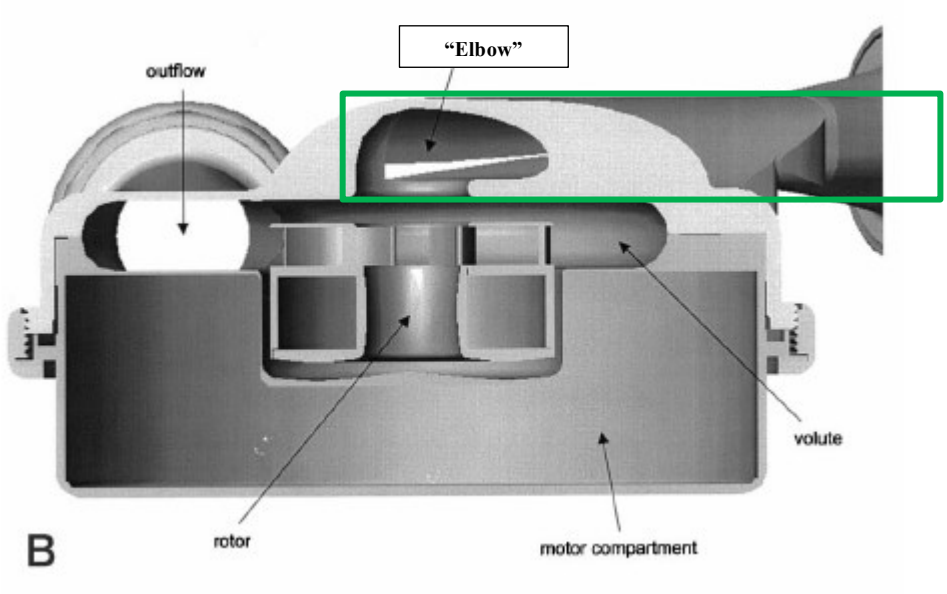
8. Motivation to Combine Bourque-2001 with Wampler-169

411. It would have been obvious to include Wampler-169's techniques related to use of an *inflow tube defining a blood inflow path along an inflow axis* in the Bourque-2001 device for the reasons explained below.

412. As discussed above, the Bourque-2001 device is "a centrifugal pump," and by definition of it being a centrifugal pump, the Bourque-2001 device already comprises an *inflow tube defining a blood inflow path along an inflow axis.* By

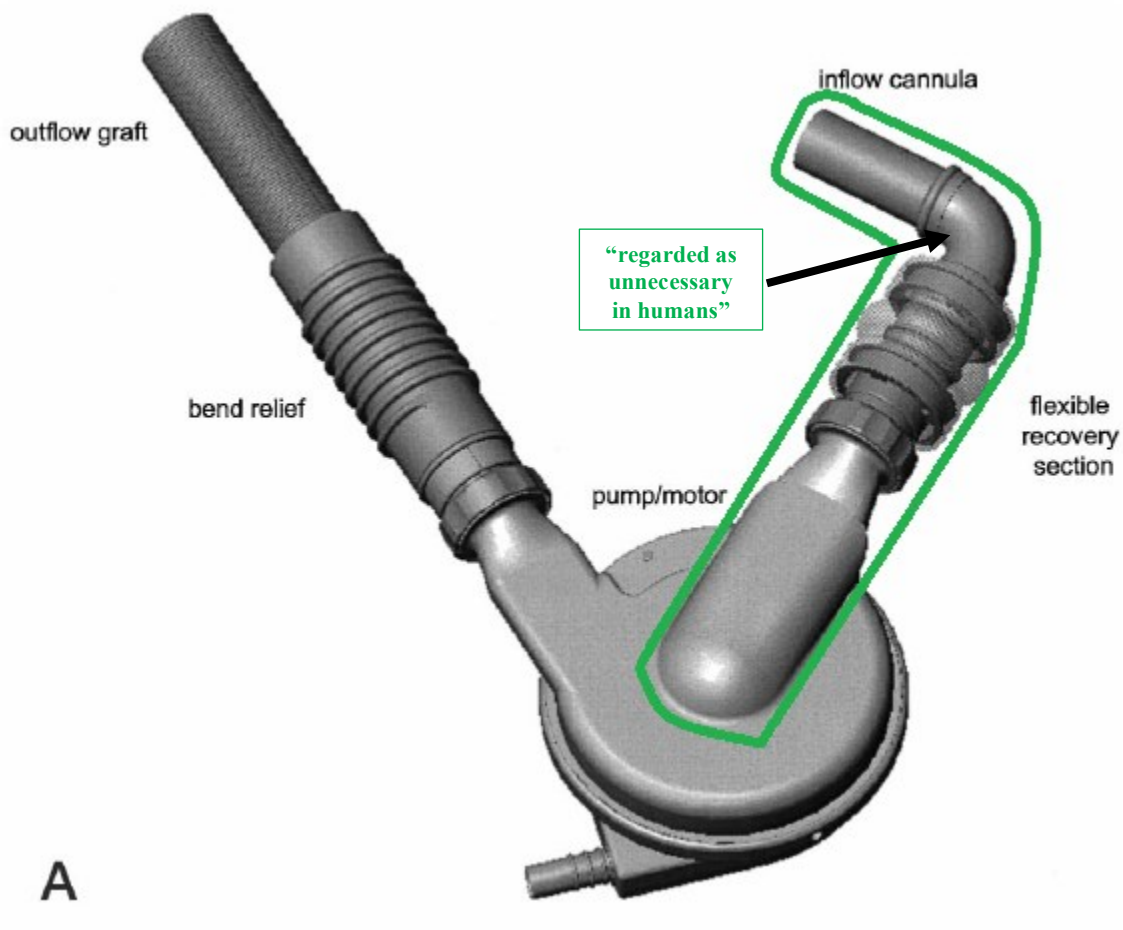
design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference.

413. The HeartMate III's ***inflow tube*** ("inflow subassembly that includes a left ventricular (LV) cannula"), however, also comprises an "elbow," as shown:



Ex.1007 at Fig. 1B (annotated).

414. Bourque-2001 describes that HeartMate III's ***inflow tube*** comprised another "elbow in the inflow segment, included to accommodate the bovine anatomy and presently regarded as unnecessary in humans," shown below in Figure 1A (annotated):



Ex.1007, Fig. 1A.

415. The HeartMate III's ***inflow tube*** is also illustrated in Figure 3 (annotated):

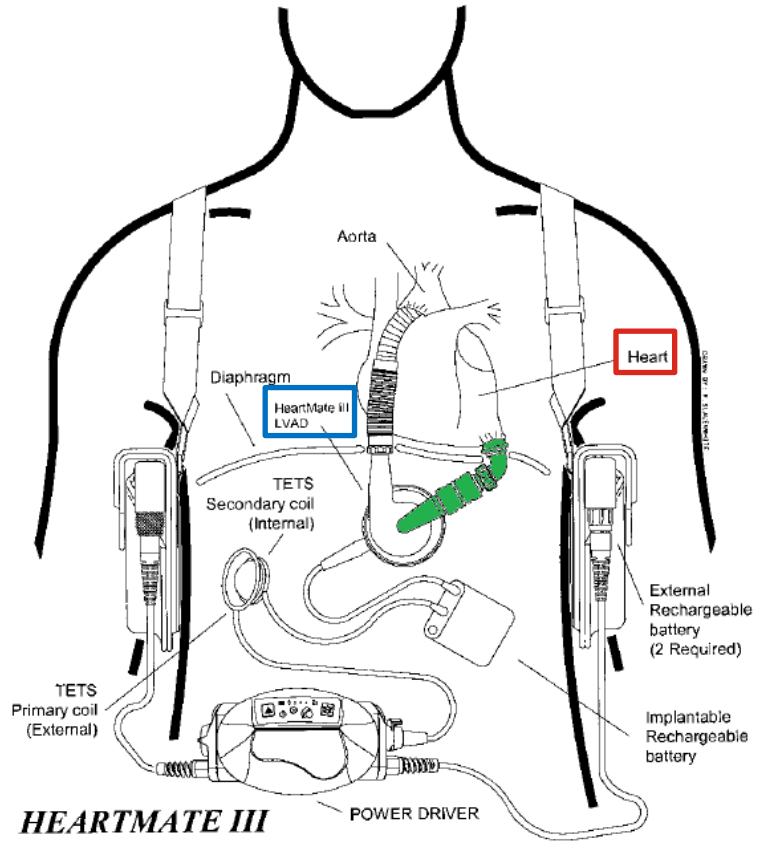
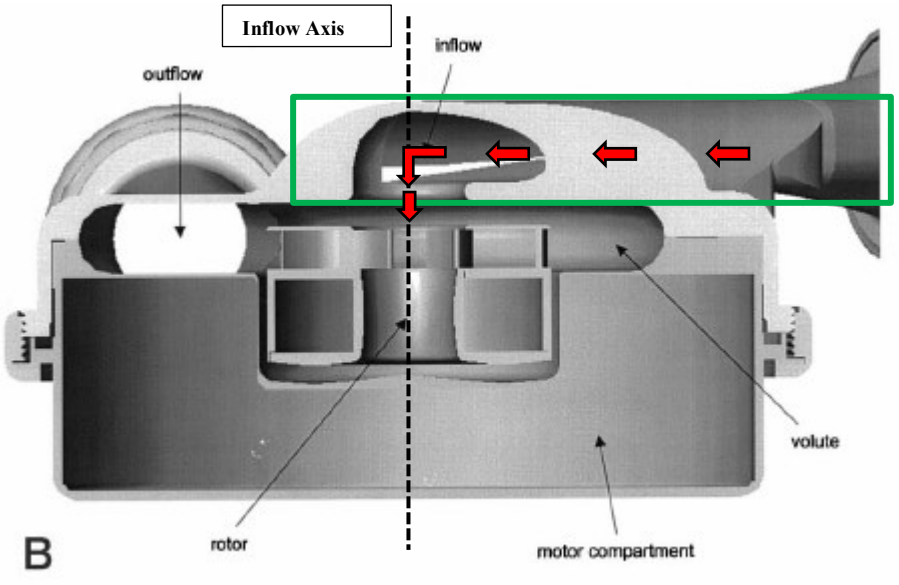


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3 (annotated).

416. The elbow ("sharp bend in the flow before it enters the impeller") was included in the Bourque-2001 device because "the rotational axis of the pump's rotor [is] perpendicular to the body's long axis" which "resulted in a sharp bend in the flow before it enters the impeller." Ex.1007 at 402. Figure 1B (annotated) below illustrates the inflow subassembly (**green**) of the Bourque-2001 HeartMate III along

the inflow axis (**black**) and the flow path of blood from the left ventricle of the heart (**red** arrows):



Ex.1007 at Fig. 1B (annotated).

417. Wampler-169, however, recognized that the use of an elbow, such as in the Bourque 2001 device, was not necessary when using a centrifugal pump. Ex.1008, [0076]. Like the Bourque 2001 device, Wampler-169 also employs "a centrifugal design of the pump." Ex.1008, [0076]. Wampler-169 appreciated that "[t]he centrifugal design of the pump allows a considerable amount of flexibility during implantation." Ex.1008, [0076]. "Owing to the axial inflow and radial outflow of the pump," which is a characteristic feature of centrifugal pumps including the Bourque 2001 device, Wampler-169 explains that "a 90 degree

redirection of the blood is effected **without the necessity of a flow-restrictive elbow fitting**." Ex.1008, [0076]. With this design, "[g]ood anatomic compatibility is possible since the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm." Ex.1008, [0076]. Consequently, "[t]he inlet tube 16 serves as the inflow cannula and is placed into the apex of the left ventricle 64," thereby eliminating the need for any elbow or additional inflow assembly, as shown below. Figure 5 (annotated) of Wampler-169 illustrates a representation of a human heart 63, showing the inlet tube 13 (**green**) of the pump 11 (**blue**) implanted within the left ventricle 64 (**red**) of the heart:

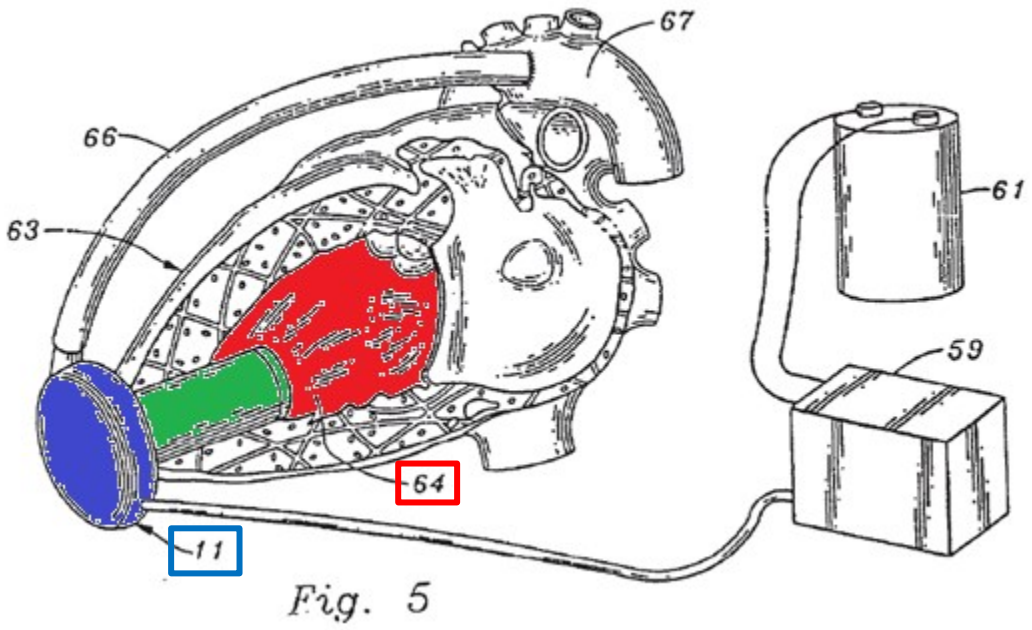


Fig. 5

Ex.1008, Fig. 5 (annotated).

418. In the combination of Bourque-2001 with the *inflow tube defining a blood inflow path along an inflow axis* technique of Wampler-169 (hereinafter Bourque/Wampler), the *inflow tube* would have been implemented *along an inflow axis* at the same location as the Bourque-2001 inflow tube so that "[t]he inlet tube…serves as the inflow cannula and is placed into the apex of the left ventricle" as taught by Wampler-169. Ex.1008, [0076].

419. Bourque-2001 and Wampler-169 are both analogous art to the 879 Patent for at least two reasons. *First*, Bourque-2001 and Wampler-169 are both directed toward **the same field of endeavor** of the 879 Patent—"to assist the performance of a heart with at least one pump that is formed as a rotary pump and driven via magneto coupling." Ex.1001, Abstract; 3:47-48 ("The embodiment to assist the performance of a heart according to the invention"). Bourque-2001 and Wampler-169 are within this same field of endeavor. Ex.1007 at 401 ("The HeartMate III…pump has no mechanical bearings [because] the rotor is magnetically suspended."); Ex.1008 at [0006], [0018] (An "implantable rotary sealless blood pump" that "advantageously" uses "magnets…in the pump drive system" such that "[t]orque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing.")

420. *Second*, Bourque-2001 and Wampler-169 are both reasonably **pertinent to a problem** described by the 879 Patent: reducing mechanical stress on the blood during pumping. *See, e.g.*, Ex.1001, 2:23-28 ("In particular, the fluid flow which is improved by the pump is to be developed in a way in which the mechanical stress of highly sensitive fluids, such as blood for example, can be kept as low as possible and nevertheless the corresponding improvement to circulation can be ensured at desired locations"). Both Bourque-2001 and Wampler-169 aim to address this problem. Ex.1007 at 401 ("The rotor is magnetically suspended, eliminating contact between moving parts" and resulting in "low hemolysis…and low thrombogenicity"); Ex.1008 at [0101] ("an improved sealless blood pump including magnetic bearings…to minimize thrombosis…[and] minimize hemolysis.").

421. It would have been obvious to combine Bourque-2001 with the *inflow tube defining a blood inflow path along an inflow axis* technique of Wampler-169 because to do so would have been the **arrangement of old elements** (substituting Bourque-2001's inflow assembly with Wampler-169's "inlet tube [which] serves as the inflow cannula and is placed into the apex of the left ventricle") with each performing the same function it has been known to perform (allowing blood to flow from the ventricle to the pump) and yielding no more than one would expect from such an arrangement (blood flowing from the ventricle to the pump) as Wampler-

169. Ex.1008 at [0075] ("The inlet tube 16 serves as the inflow cannula and is placed into the apex of the left ventricle 64.").

422. It would have also been obvious to combine Bourque-2001 with the *inflow tube…along an inflow axis* technique of Wampler-169 because a **POSITA would have been motivated** to do so based on the teachings of Wampler-169. For example, Wampler-169 teaches that a "centrifugal design…allows a considerable amount of flexibility during implantation" because "the axial inflow and radial outflow of the pump" means that "a 90-degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008 at [0076]. A POSITA would have recognized that, with the Wampler-169 configuration, "[g]ood anatomic compatibility is possible" so that the device "fit[s] well between the apex of the heart and the adjacent diaphragm." Ex.1008, [0076].

423. Further, a **POSITA would have been motivated** to combine Bourque-2001 with the *inflow tube…along an inflow axis* technique of Wampler-169 based on the teachings of Bourque-2001. First, Bourque 2001 recognized that its elbow was a "flow-restrictive elbow" that cased flow "losses in transition"—the exact type of elbow that Wampler-169 taught to eliminate. Ex.1007 at 402 (the orientation of the pump "resulted in a sharp bend in the flow before it enters the impeller" which caused "[flow] losses in this transition…through this elbow"). Second, Bourque

2001 taught that the number of components of its inflow assembly caused "clinical troubles." Ex.1007 at 405 ("[I]tems such as cannula, grafts, articulating mechanical joints, [and] connectors…can account for most of the propensity for clinical troubles when implanted."). Ex.1007 at 405. But Bourque-2001 also taught that "[i]t was a fundamental goal of the HeartMate III mechanical design to achieve optimal pumping performance and…in the simplest possible way." Ex.1007 at 404. Ex.1006 at 3 ("The advantages of the rotary blood pump are its compactness, simplicity, and low cost."). Consequently, a POSITA would have been motivated to reduce the "clinical troubles" by designing the pump "in the simplest possible way" and by eliminating the flow-restrictive elbow and other components of the inflow assembly—i.e., the *inflow tube…along an inflow axis* technique of Wampler-169.

424. It would have also been obvious to combine Bourque-2001 with the *inflow tube…along an inflow axis* technique of Wampler-169 because a **POSITA would have been motivated** to do so based on the teachings that placement of LVADs in the preperitoneal pocket position were associated with increased infections rates and decreasing the size of LVADs was associated with reduced infection rates. For example, as discussed above, the larger early-generation LVADs required "surgical dissection" to place the device in a "pump pocket," which was associated with increased risk of infection. Ex.1014 at 842. The "increased rates" of

infection signaled a "need for further improvements in…the design of the device." Ex.1012 at 1442. Because the second-generation devices were smaller "and d[id] not require a great deal of surgical dissection," they had a "low[er] infection rate." Ex.1014 at 842. Although the smaller pump pocket dissection was smaller, it was still considered a disadvantage. For example, it was recognized that although "the pocket dissection is smaller with the HeartMate II [second-generation device],…potentially introducing less risk of infection," the "preperitoneal pocket position" was a "disadvantage[]" due to the "increased risk of infection" and "[p]otential for prolonged pocket drainage." Ex.1013 at 25-26. Further, A POSITA would have further been motivated to reduce rates of infection by adhering to Wampler-169's focus on "[g]ood anatomic compatibility" over Bourque-2001's focus on "borrowing" from "presently available Heart-Mate systems" like the "HeartMate II." Ex.1007, 403, 405. The HeartMate III's "elbow" "resulted" from a design "deci[sion]" "[t]o orient the pump" below the "diaphragm" in a preperitoneal pocket position, as shown:

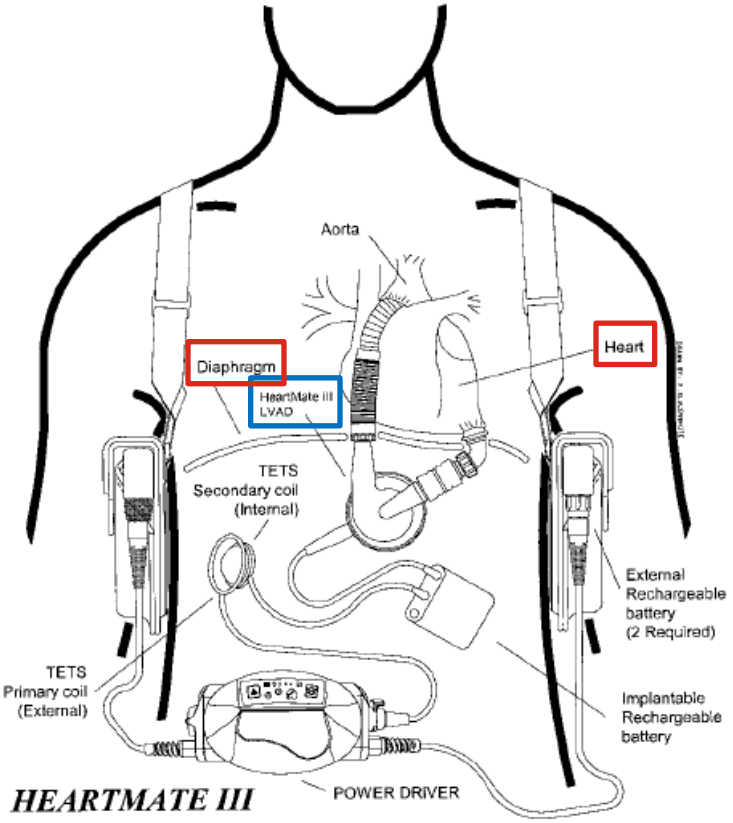


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3. This pocket position (below the diaphragm) resulted from Bourque-2001's aim to utilize the "peripheral hardware (i.e., inflow and outflow components)" of its predecessor "Heart-Mate systems." In addition to "borrowing" "inflow and outflow components" from the predecessor systems, Bourque-2001 also used similar "surgical techniques" for a "pump pocket dissection" as used to implant the "HeartMate II" below the diaphragm in a "preperitoneal pocket," as shown:

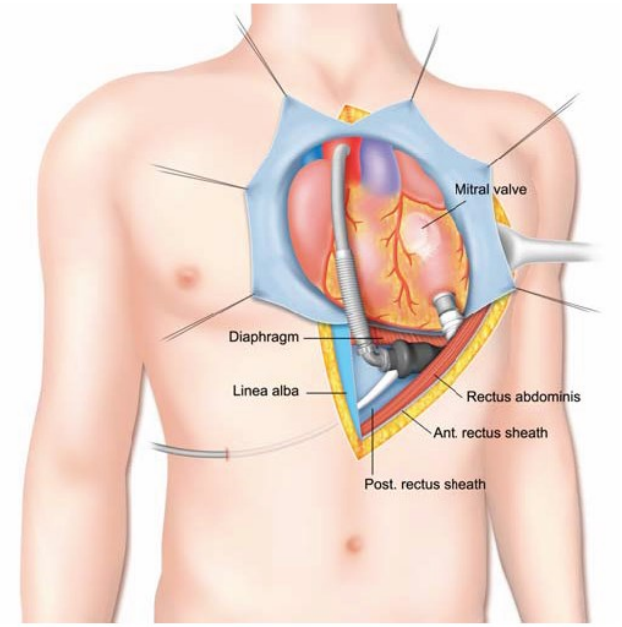


Figure 3: Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).

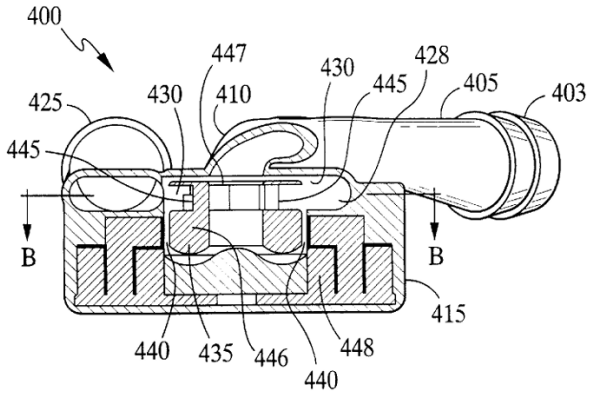
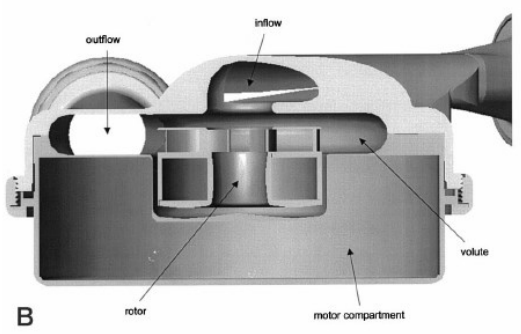
Ex.1013, 25. Indeed, both HeartMate II and III were "implanted…via left ventricular apical cannulation and anastomosis to the descending aorta." Ex.1007, 402, Ex.1013, 25, 57.

425. Bourque-2001 describes that its HeartMate III device would have been implanted in the same manner as "with presently available HeartMate systems," thus, a POSITA would have understood that it would have been placed at the preperitoneal pocket position. Ex.1007 at 405. A POSITA, however, would have recognized this to be a disadvantage with the Bourque-2001 device for the same reasons as recognized with the HeartMate I and HeartMate II systems described

above. Thus, a POSITA would have been motivated use the Bourque/Wampler combination, recognizing that such a configuration would enable the device to "fit[] well between the apex of the heart and the adjacent diaphragm" and eliminate the need for a dissection of and placement at the preperitoneal pocket position. Ex.1008, [0076]. Indeed, Wampler-169 is focused on "[a]natomical placement of the pump" and "[g]ood anatomic compatibility" so that the pump "fit[s] well between the apex of the heart and the adjacent diaphragm." Ex. 1008 at [0075]-[0076].

426. Further, a POSITA would have had a **reasonable expectation** that the Bourque/Wampler combination would be successful because the authors and engineers of Bourque-2001 taught that this specific modification was "not complex" and was "well-known in the art." Ex.1018 at 6:62-7:5. Victor L. Poirier is one of the engineers of Bourque-2001 HeartMate III device, co-author of Bourque-2001 reference, and also the inventor of U.S. Patent No. 6,050,975 (Ex.1018), assigned to Thoratec. The 975 patent issued on April 18, 2000, and is also prior art to the 879 Patent, and a POSITA exercising reasonable diligence could have located it. Further, Bourque-2001 and the 975 patent share common authors/inventors (and both worked for Thoratec), which is an additional reason that a POSITA would have looked to the teachings of the 975 patent.

427. The 975 Patent generally discloses two types of pumps, an axial flow blood pump (Fig. 1) and a centrifugal blood pump (Figs. 4-10). The HeartMate III design disclosed in Bourque-2001 is an embodiment of the 975 Patent's centrifugal blood pump (Figs. 4-10). For example, the following table illustrates a comparison between Figure 4B of the 975 Patent and the HeartMate III pump described in Bourque-2001:

975 Patent, Figure 4B	**Bourque 2001, Figure 1**
 FIG. 4B	

428. The 975 Patent's axial flow blood pump comprises an "inflow cannula apical tube 45, which is inserted into the apex of the left ventricle." Ex.1018, 4:43-46. The 975 Patent also describes that the centrifugal pump (e.g., Bourque-2001 HeartMate III) can be modified to use this inflow cannula from the axial flow blood pump:

> In the embodiment shown in FIGS. 4A-C, pump 400 can be attached to conventional tubing at adaptors 403 and 427 to connect it between the left ventricle and aorta to provide ventricular assistance. In another embodiment, pump 400 may be implemented using various components of pump 10 modified to function with pump 400. For example, pump 400 may be modified to incorporate… **inflow cannula apical tube 45**…**The modifications required are not complex and are well-known in the art.**

Ex.1018 at 6:62-7:5. Thus, a POSITA would have had a reasonable expectation that the Bourque/Wampler combination would be successful, because the 975 patent teaches that modifying the Bourque-2001 pump with "an inflow cannula apical tube 45, which is inserted into the apex of the left ventricle," like the Wampler-169 technique is "not complex" and is "well-known in the art."

429. Further, a POSITA would have had a **reasonable expectation** of success that the Bourque/Wampler combination would "fit[] well between the apex of the heart and the adjacent diaphragm." Ex.1008 at [0075]. The Bourque-2001 HeartMate III was already planned for "enhancements [to] continue the progression of this LVAD's development as a compact" device (i.e., enhancements to make the device smaller), which would help its placement at the cardiac apex. Ex.1007 at 405. A POSITA also would have had a reasonable expectation of success because numerous other similar devices had already shown that an LVAD could fit well at

that position. For example, in addition to Wampler-169, the Akamatsu-1999 device described above similarly uses an inflow tube that is inserted into the left ventricle and fits at the cardiac apex so that the device sits within the pericardial space. Ex.1006 at Fig. 1. Further, the HVAD, another third-generation type device, reported that its "small size" allowed for an "optimized fit" because "[t]he pump ha[d] a short integrated inflow cannula and an axial height less than one inch, thus, [t]he size of the device coupled with the perpendicular relationship of outflow to the inflow allow[ed] for intrapericardial pump placement and fast implantation." Ex.1015. The fact that all these devices with similar designs fit well in the position at the apex of the heart would have given a POSITA a reasonable expectation of success that the Bourque/Wampler combination would also fit well.

430. Moreover, the Bourque/Wampler combination would have also been **obvious to try**. At the time of the claimed invention, it was within the general knowledge of a POSITA that the implantation of LVADs presented a finite number (i.e, two) options—the device could be implanted at a preperitoneal pocket or at the cardiac apex. To implant the device at the cardiac apex, a POSITA would have used the Bourque/Wampler combination, because that was the well-known technique for implanting at that position. *See* Ex.1006 at Fig. 1; Ex.1008 at [0075]-[0076]; Ex.1015. In doing so, a POSITA would have had a reasonable expectation of success

in view of the Wampler-169, Akamatsu-1999, and HVAD devices described above. Ex.1006 at Fig. 1; Ex.1008 at [0075]-[0076]; Ex.1015.

431. Accordingly, it would have been obvious to modify the Bourque-2001 device to include Wampler's techniques related to use of an *inflow tube defining a blood inflow path along an inflow axis* to yield the Bourque/Wampler combination.

C. Ground 3: Akamatsu 1999 Renders Obvious Claims 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20 of the 879 Patent

1. Claim 11

i. [11PRE] A system for assisting blood circulation of a heart, the system comprising:

432. To the extent that the preamble is a limitation, Akamatsu-1999 discloses "*a system for assisting blood circulation of a* ***heart***."

433. For example, Akamatsu-1999 describes that at the time "[r]otary blood pumps, such as the axial flow pump and the centrifugal pump, [were] being developed worldwide as implantable ventricular assist systems (VAS)." Ex.1006 at 3. However, "the conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and the seal." Ex.1006 at 6. The study described in Akamatsu-1999 discusses the development of an improved blood pump, a "totally implantable left ventricular assist system (T-ILVAS)," which uses "a centrifugal pump with a magnetically suspended impeller

(MSCP)," which "operates completely contact-free without any material wear." Ex.1006 at 3, 7. The T-ILVAS, including the centrifugal pump (**blue**), in its implanted configuration with the inlet port placed in the left ventricle of the heart (**red**) of a body is illustrated in Figure 1, annotated:

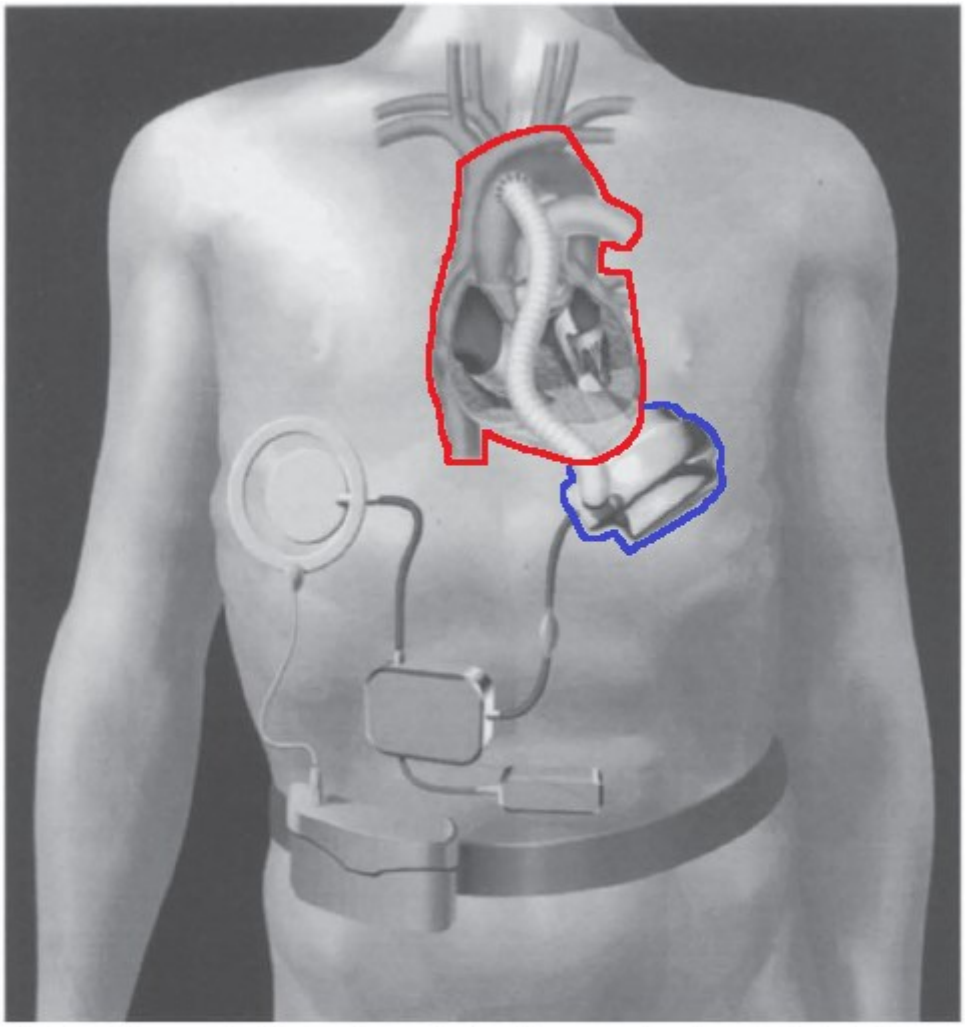


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

434. Accordingly, Akamatsu-1999 discloses "*a system for assisting the blood circulation of a* ***heart***."

ii. [11A] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;

435. Akamatsu-1999 discloses "*a* ***heart assist pump device*** *deliverable to the* ***heart*** *and comprising: an* ***inflow tube*** *defining a blood inflow path along an* ***inflow axis*** *and being insertable into* ***a left ventricle***."

436. The 879 Patent does not define the term "a heart assist pump device deliverable to the heart." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that assumes "a heart assist pump device" being "deliverable to the heart" includes inserting an inflow tube of the heart assist pump device into a left ventricle of a patient's heart. *See, e.g.*, Ex.1019, at 3-4 (Complaint, Ex. 11). For the purposes of my analysis, I adopt that construction of "a heart assist pump device deliverable to the heart."

437. Accordingly, Akamatsu-1999 discloses that the described "totally implantable left ventricular assist system (T-ILVAS)" includes a "sealless centrifugal pump." Ex.1006 at 3, 5. The T-ILVAS also includes an "inlet port" or "inflow conduit," which was "inserted into the left ventricle through a cuff sutured

to the left ventricular apex" during the *ex vivo* study performed on sheep. Ex.1006 at 4. During testing, "[t]he pump operated at a fixed rotational speed" and "aortic pressure and pump flow rate were continuously measured." Ex.1006 at 4. The pumps were "intrathoracically implanted" (i.e., implanted in the thorax) of the sheep. Ex.1006 at 5.

438. In addition, the **inflow tube** (e.g., "inlet port" or "inflow conduit," Ex.1006 at 4) of the centrifugal pump described in Akamatsu-1999 has an **"inflow axis**" so as to provide the flow of blood to the **magnetically driven rotor** (e.g., "impeller," Ex.1006 at 4) (discussed below for element [11B]).

439. Figure 2 (annotated) of Akamatsu-1999 illustrates a cross section of the centrifugal pump of the T-ILVAS, which includes an "inlet port" (**green**) of the defining a blood inflow path (arrows through the inlet port) along an inflow axis (**black**) from the left ventricle the heart (indicated by **red** arrow):

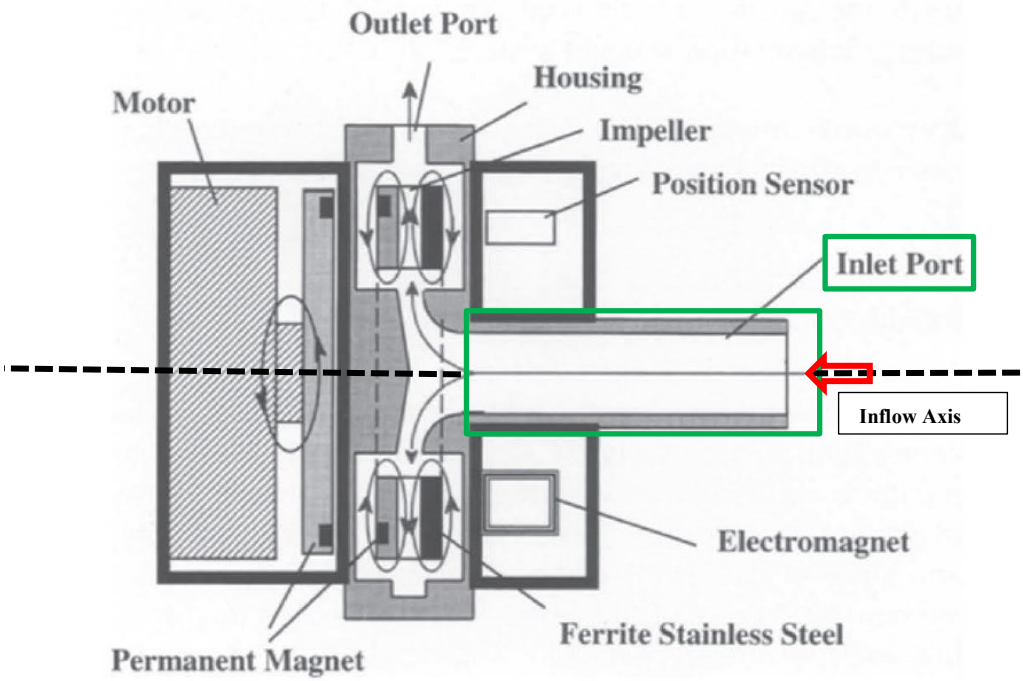


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated). Note that Figure 2 is a cross-sectional view of the centrifugal pump and the inlet port is understood to be in the shape of a tube that surrounds the inflow axis. Thus Figure 2 shows the inlet port as a rectangular cross sections.

440. Indeed, the pump described in Akamatsu-1999 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the rotating impeller and is accelerated by centrifugal force toward the circumference of the impeller, collected by a volute and then discharged through an outlet port. Said another way, an inflow tube defining a blood inflow path along an inflow axis is a characteristic feature of a centrifugal pump.

441. In addition, Figure 1 (annotated) illustrates the T-ILVAS, including the centrifugal pump (**blue**) delivered to a heart (**red**) such that the inlet port ['*inflow tube defining a blood inflow path*'] (**green**) of the T-ILVAS is inserted into the left ventricle of the heart:

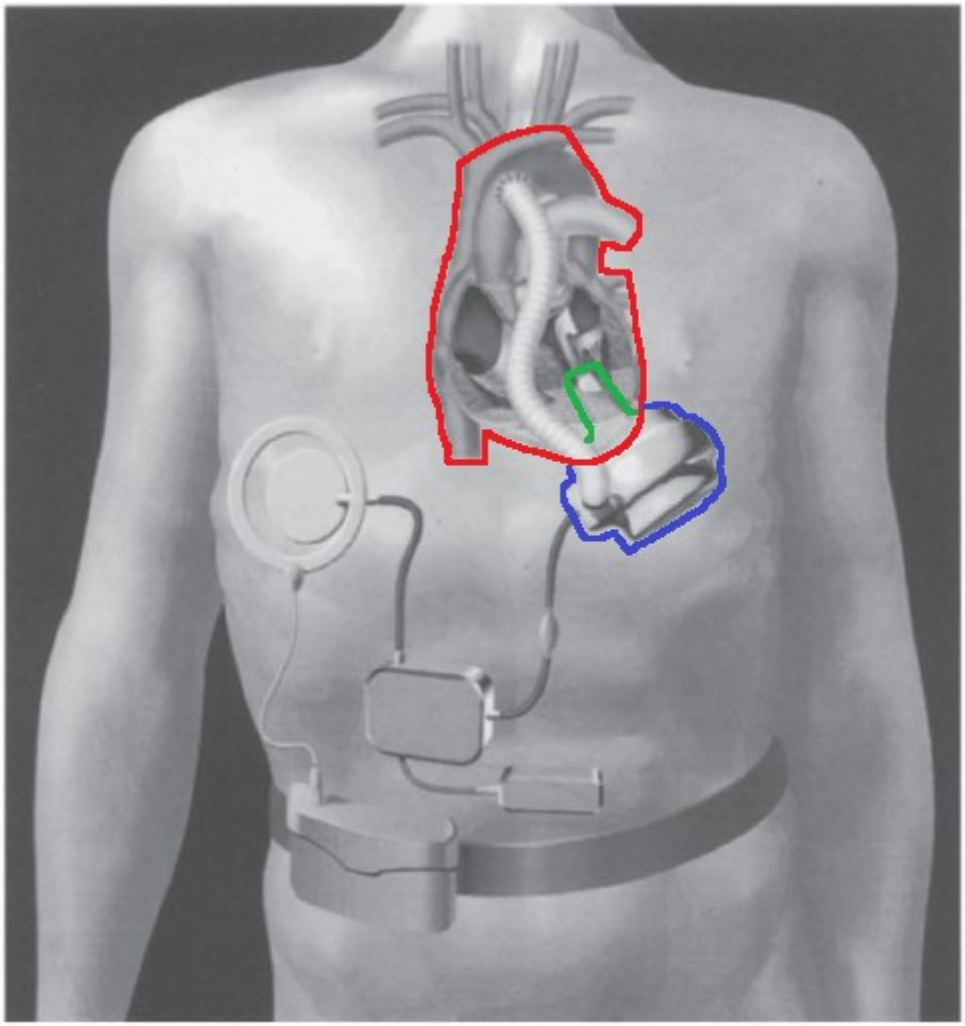


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

442. Accordingly, Akamatsu-1999 discloses "*a **heart assist pump device*** ("centrifugal pump") *deliverable to the **heart** and comprising: an **inflow tube*** ("inlet port") *defining a blood inflow path along an **inflow axis** and being insertable into **a left ventricle*** ("inserted into the left ventricle")."

iii. [11B] one or more walls at least partially defining a chamber to receive blood from the inflow tube,

443. Akamatsu-1999 discloses "***one or more walls*** *at least partially defining **a chamber** to receive blood from the **inflow tube**.*"

444. For example, Akamatsu-1999 discloses that the centrifugal pump includes a "housing." Ex.1006 at 5, Fig. 2; *see also* Ex.1006 at 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***."). Akamatsu-1999 further discloses that "[t]he impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1006 at 4; *see also* Ex.1006 at 6 ("We have developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear."), 3 ("Because the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material wear, it is

expected to be one of the most durable blood pumps."). Akamatsu-1999 further discloses that the pump includes a "blood chamber." Ex.1006 at 4.

445. Figure 2 (annotated) illustrates the "housing" the centrifugal pump having one or more walls (shown by the solid black line between the "impeller" and the "motor") defining a "blood chamber" (**orange**) to receive blood (**red** arrows) from the inlet tube 13 (**green**):

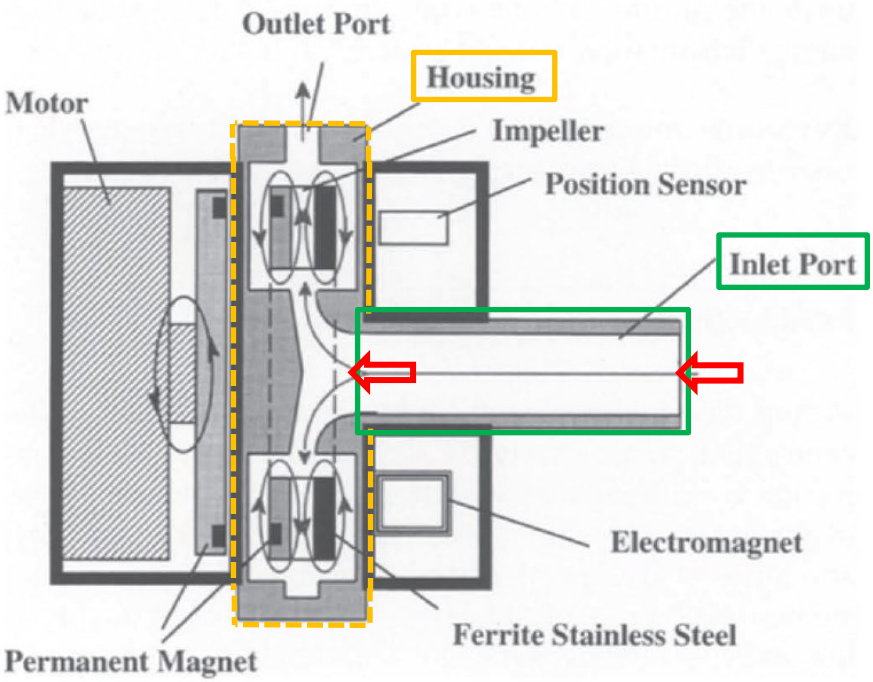
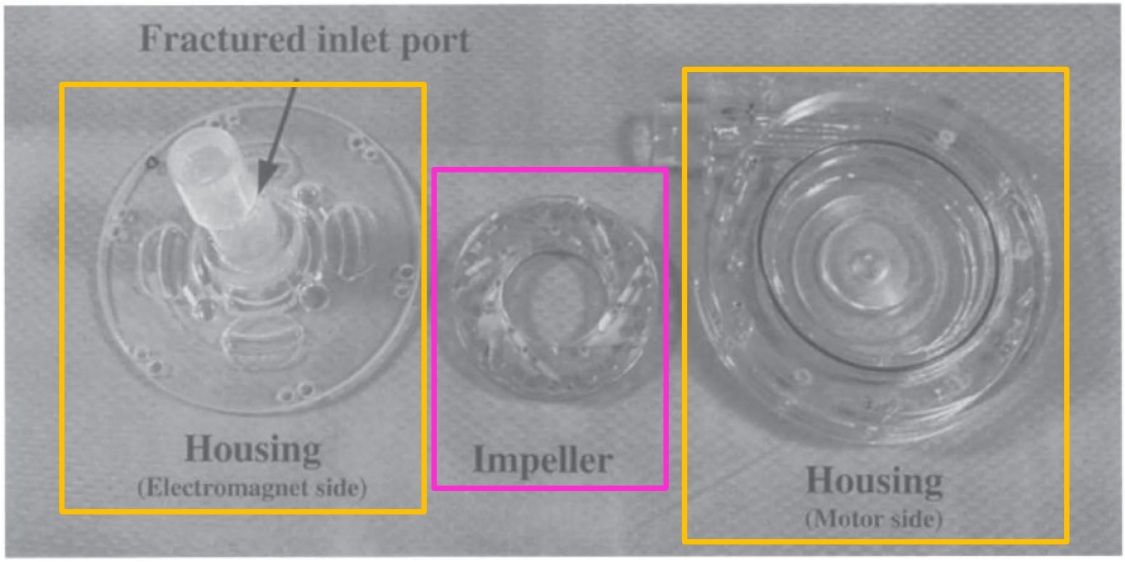


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

446. Figure 5 (annotated) illustrates a top view of the impeller (**pink**) (discussed below for element [11C]) and the "motor side" and "electromagnet side"

which form the one or more walls of the housing (**orange**) defining the "chamber" enclosing the impeller, in which each component was separated out after testing:



Ex.1006, Fig. 5 (annotated).

447. Thus, the **one or more walls** at least partially defining **a chamber** (e.g., "housing" forming a "blood chamber," Ex.1006 at 5, Fig. 2) of the centrifugal pump to receive blood from the **inflow tube** (e.g., "inlet port" or "inflow conduit," Ex.1006 at 4).

448. Accordingly, Akamatsu-1999 discloses "***one or more walls*** ("pump housing") *at least partially defining* ***a chamber*** ("blood chamber") *to receive blood from the* ***inflow tube*** ("inlet port")."

iv. [11C] a magnetically driven rotor axially aligned with the inflow axis

449. Akamatsu-1999 discloses "*a **magnetically driven rotor** axially aligned with the **inflow axis***."

450. For example, Akamatsu-1999 discloses that the T-ILVAS includes "a centrifugal blood pump with a magnetically suspended impeller (MSCP)." Ex.1006 at 3; *see also* Ex.1006 at 3 ("Because the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material, it is expected to be one of the most durable blood pumps."). "The impeller is suspended by a magnetic bearing, thus providing contact-free rotation of the impeller inside the pump." Ex.1006 at 3.

451. An "impeller" is a commonly used type of rotor that provides the pumping action when used in reference to a centrifugal pump, such as the "centrifugal pump" described in Akamatsu-1999. I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that maps the impeller portion of the "rotor" of the "HeartMate 3" to the "magnetically driven rotor" element recited in Claim 11. *See e.g.*, Ex.1019, at 5 (Complaint, Ex. 11). For the purposes of my analysis, I map the limitation of a "magnetically driven rotor" to the "impeller" described in Akamatsu-1999 in the same way.

452. Thus, based on the disclosures above, the "impeller" of the centrifugal pump described in Akamatsu-1999 is a "**rotor**."

453. Akamatsu-1999 further discloses that the "impeller" of the centrifugal pump is "**magnetically driven**" as recited in claim 11. For example, Akamatsu-1999 discloses that "[t]he impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1006 at 4; *see also* Ex.1006 at 6 ("We have developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear."). As illustrated in Figure 2 of Akamatsu-1999, the "DC brushless motor"[21] rotates a plate having embedded a "permanent magnet." Ex.1006, Fig. 2. The rotation of the motor's "permanent magnet" creates a torque on the impeller because of the attractive magnetic force between the permanent magnet

[21] The first "Brushless DC Motor" was invented in 1962 (Wilson, T. G., and P. H. Trickey. "DC machine with solid-state commutation." *Electrical Engineering* 81.11 (1962): 879-884) and has been commonly used for decades, for example, in household appliances like washing machines, computer equipment and many cordless tools. Brushless DC motor theory and practice would have been part of an undergraduate engineering course from about the 1980s, and therefore would have been well known to a POSITA at the time of the alleged invention on February 27, 2007. *See also* "Brushless DC Motors," National Aeronautics and Space Administration (NASA), NASA CR-2506, (January 1975) (accessed at https://ntrs.nasa.gov/api/citations/19750007247/downloads/19750007247.pdf).

embedded in the motor plate and the permanent magnet embedded in the impeller. Ex.1006 at 4, Fig. 2.

454. Thus, the impeller of the centrifugal pump described in Akamatsu-1999 is a **magnetically driven rotor** because it is a rotor driven by the magnetic force between the "permanent magnet" within the impeller and the "permanent magnet" of the DC brushless motor. *See infra* Section X.C.1.v; Ex.1006 at 4, Fig. 2, 5.

455. Figure 2 (annotated) illustrates a cross section of the centrifugal pump of the T-ILVAS, which includes a magnetically driven "impeller" (**pink**):

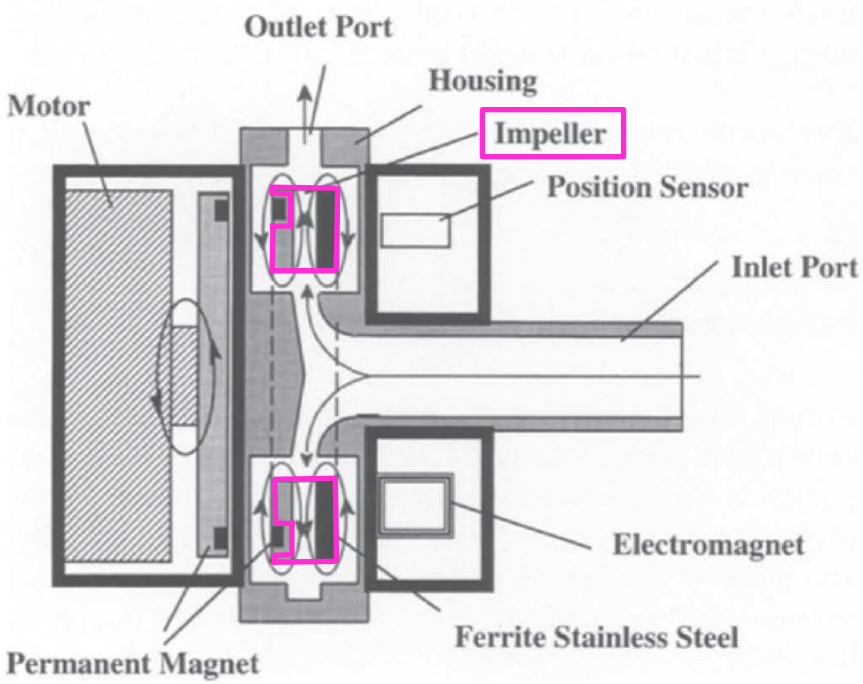
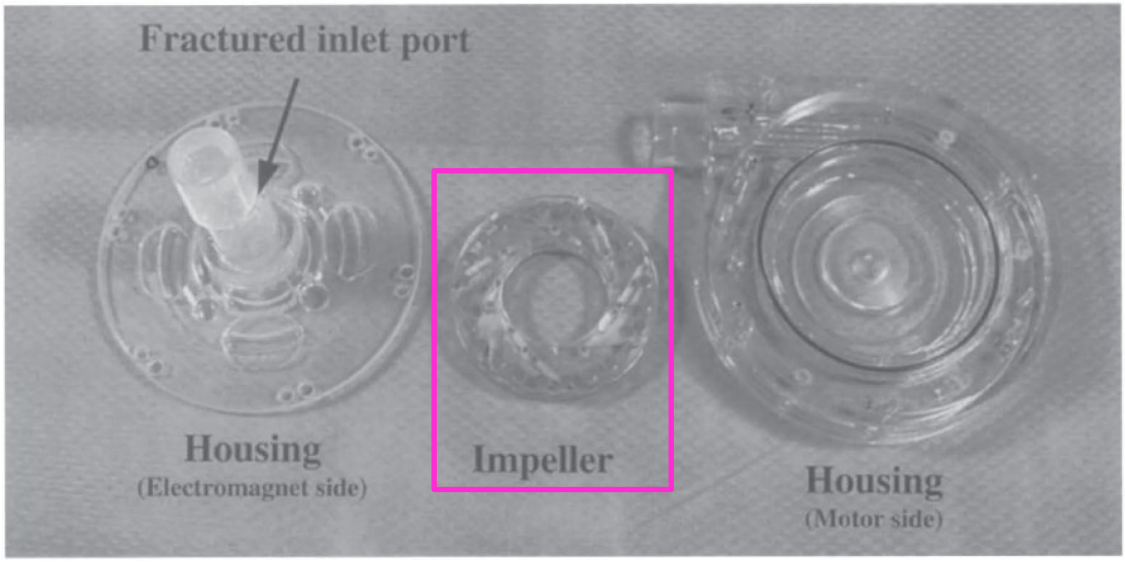


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

456. Figure 5 (annotated) illustrates a top view of the impeller (**pink**) separated from the housing of the pump after testing:



Ex.1006, Fig. 5 (annotated).

457. In addition, for components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis") in space. The centrifugal pump described in Akamatsu-1999 has an **inflow tube** (e.g., "inlet port" or "inflow conduit," Ex.1006 at 4) that provides the flow of blood to the **magnetically driven rotor** (e.g., "impeller," Ex.1006 at 4) such that each is "axially aligned" along an "inflow axis." For example, Figure 2 (annotated) of Akamatsu-1999 illustrates the alignment of the impeller (**pink**) and the inlet port (**green**) of the centrifugal pump along the inflow axis (**black**) and the flow path of blood from the left ventricle the heart (**red** arrows):

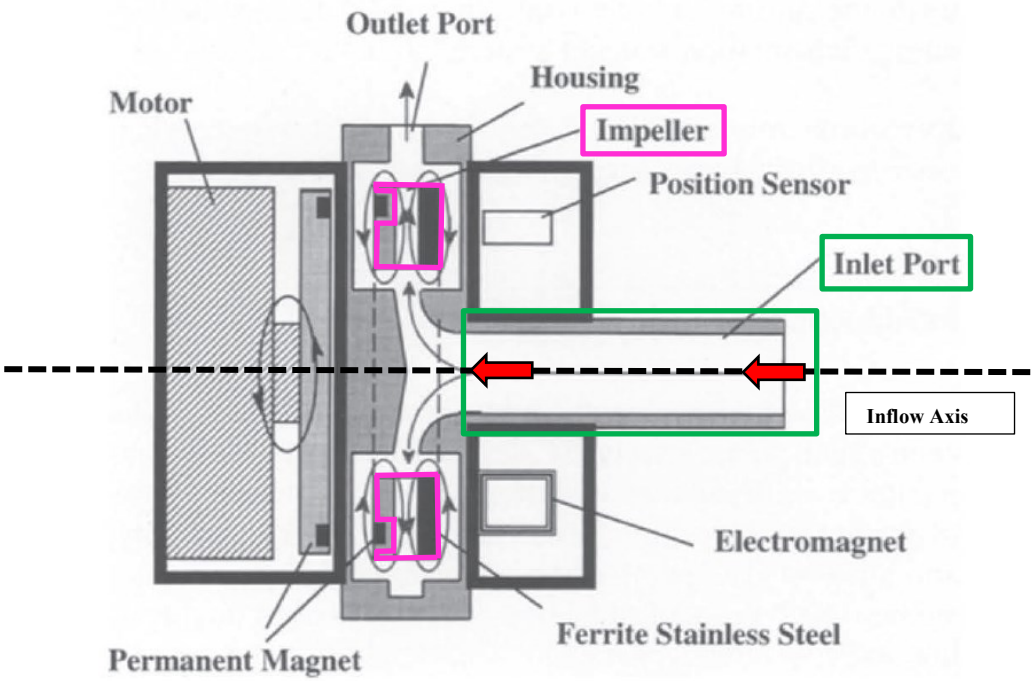


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated). As mentioned previously, note that Figure 2 is a cross-sectional view of the centrifugal pump and the inlet port is understood to be in the shape of a tube, and the impeller, including its embedded permanent magnets, is understood to be in the shape of a torus (donut shape), such that each surrounds the inflow axis. Thus Figure 2 shows the impeller as two rectangular cross sections and the inlet tube as one rectangular cross section.

458. Indeed, the pump described in Akamatsu-1999 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the rotating impeller and is accelerated by centrifugal force toward the circumference of the impeller, collected by a volute and then discharged through an outlet port. Said

another way, an inflow tube axially aligned with an impeller along an "inflow axis" is a characteristic feature of a centrifugal pump.

459. Accordingly, Akamatsu-1999 discloses that the "***magnetically driven rotor*** ("impeller") *axially aligned with the* ***inflow axis***."

v. [11D] and [the magnetically driven rotor] being rigidly coupled and axially adjacent to a first magnetic device that is axially aligned with the inflow axis

460. Akamatsu-1999 discloses the **magnetically driven rotor** "*being rigidly coupled and axially adjacent to a* ***first magnetic device*** *that is axially aligned with the* ***inflow axis***."

461. For example, Akamatsu-1999 discloses that the centrifugal pump "is composed of four parts: a magnetic bearing, an impeller, a housing, and a DC brushless motor." Ex.1006 at 4. "The impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1006 at 4. As illustrated in Figure 2 of Akamatsu-1999, the impeller has a "permanent magnet" located within it. Ex.1006, Fig. 2. As discussed with respect to element [11C], the "impeller" is a ***magnetically driven rotor***. *See* Section X.C.1.iv. The "permanent magnet" located within the impeller is a ***first***

magnetic device which is *rigidly coupled* to the ***magnetically driven rotor*** because it is located within the impeller.

462. As will be discussed with respect to elements [11G], [11H], and [11I], the "DC brushless motor" rotates a plate having a "permanent magnet." Ex.1006, Fig. 2. The rotation of the motor's "permanent magnet" creates a torque on the impeller because of the attractive magnetic force between the permanent magnet embedded in the motor plate and the permanent magnet embedded in the impeller. Ex.1006 at 4, Fig. 2; *see infra* Sections X.C.1.viii, X.C.1.ix, and X.C.1.x.

463. Figure 2 of Akamatsu-1999 depicts a cross-sectional view of the centrifugal pump having an impeller (**pink**), which includes rigidly coupled permanent magnets (**purple**):

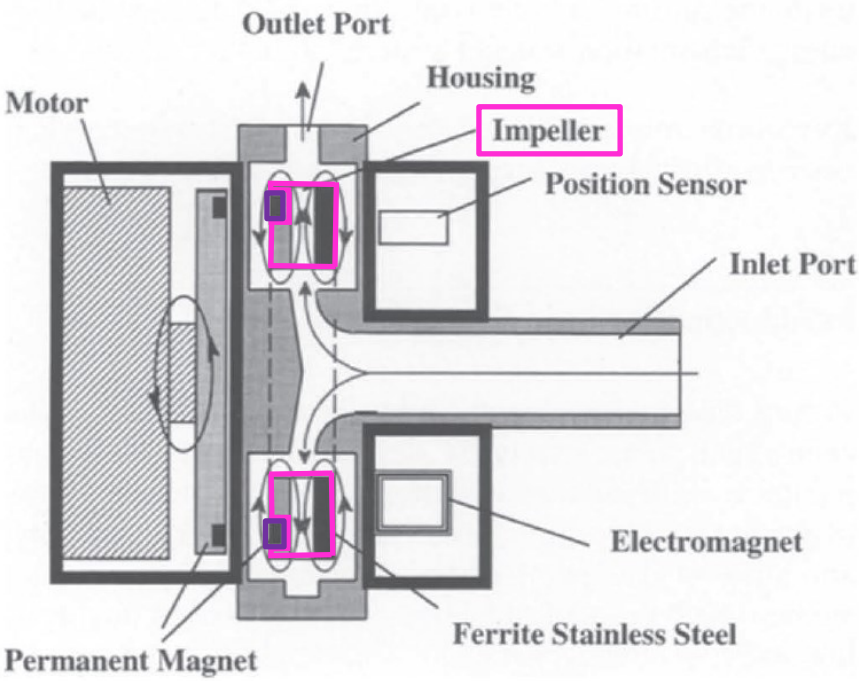


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

464. In addition, Akamatsu-1999 discloses that the "impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1006 at 4; *see also* Ex.1006 at 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***.").

465. Figure 2 (annotated) is a cross sectional view of the pump illustrating that the impeller (**pink**) and its "permanent magnet" (**purple**) are axially aligned with the inlet port (**green**) along the inflow axis (**black**):

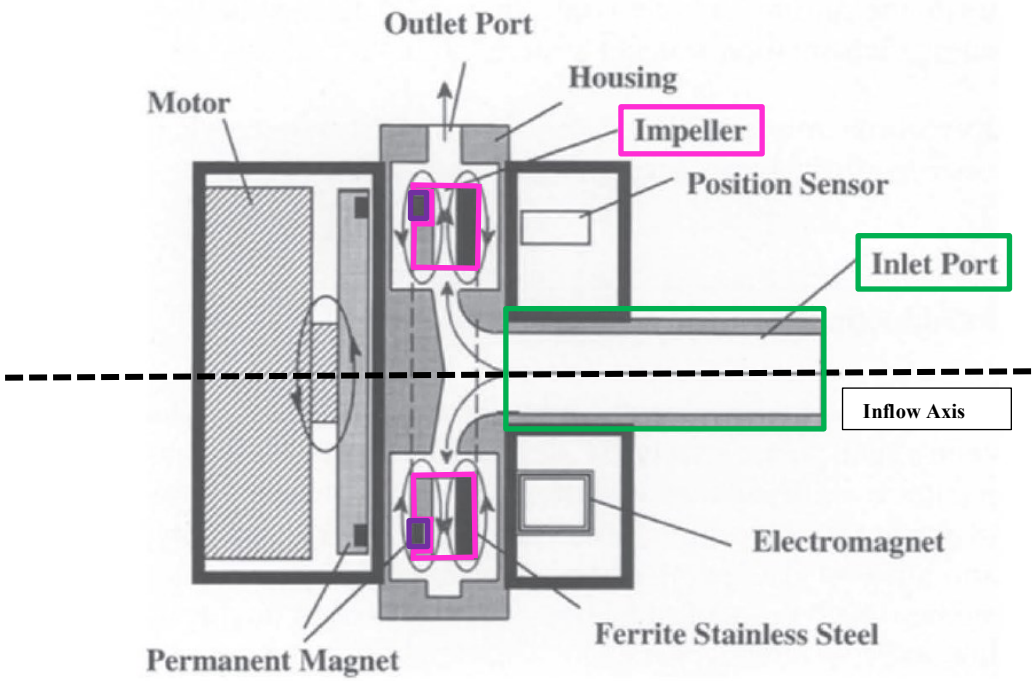


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

466. As mentioned previously, note that Figure 2 is a cross-sectional view of the centrifugal pump and the impeller, including its embedded permanent magnets, are understood to be in the shape of a torus (donut shape) that surrounds the inflow axis. Thus Figure 2 shows the impeller as two rectangular cross sections.

467. Accordingly, Akamatsu-1999 discloses the **magnetically driven rotor** ("impeller") *"being rigidly coupled and axially adjacent to a* ***first magnetic device*** (impeller's "permanent magnet") *that is axially aligned with the* ***inflow axis***."

vi. [11E] the magnetically driven rotor and first magnetic device being rotatable about an axis of rotation aligned with the inflow axis to drive the blood flowing from the inflow tube

468. Akamatsu-1999 discloses "*the **magnetically driven rotor** and **first magnetic device** being rotatable about an axis of rotation aligned with the **inflow axis** to drive the blood flowing from the **inflow tube**.*"

469. For example, Akamatsu-1999 discloses that the "impeller **rotates** by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1007 at 4; *see also* Ex.1006 at 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***.").

470. Figure 2 (annotated) is a cross sectional view of the pump illustrating that the impeller (**pink**) is rotatable about an axis of rotation that is aligned with the inflow axis (**black**), as indicated by the arrows circling the shaft of the motor driving the magnet:

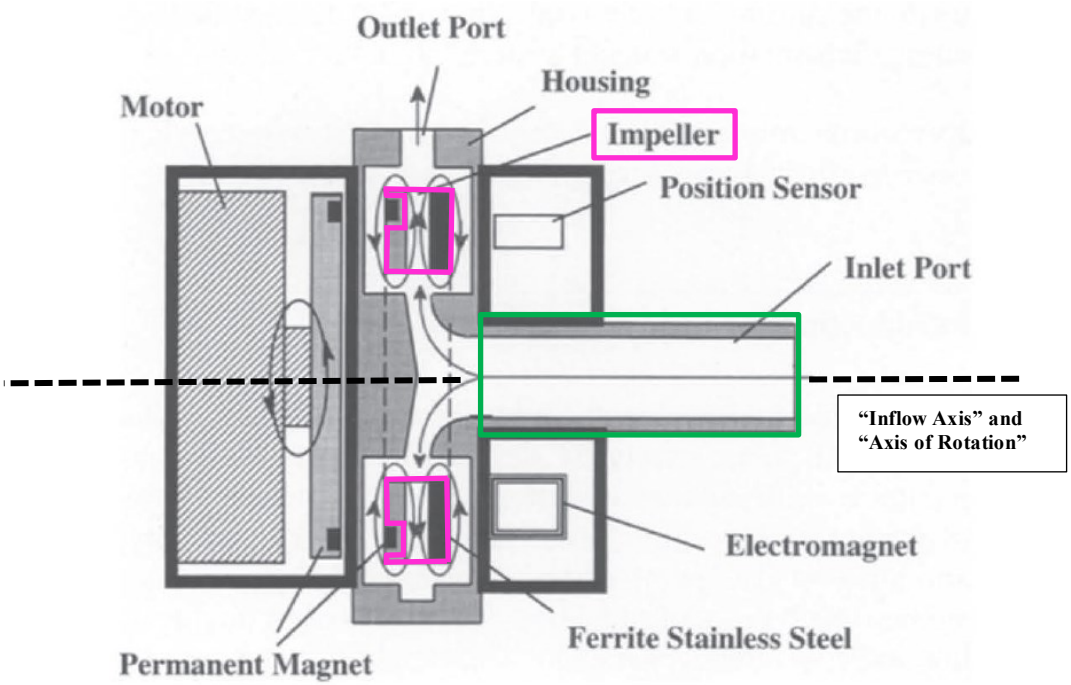
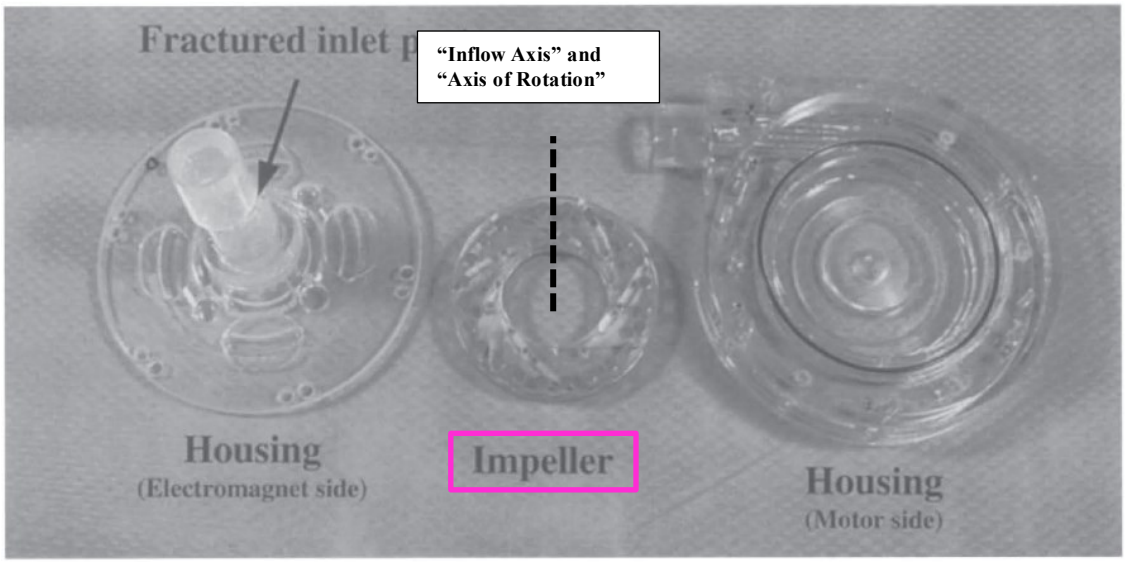


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

471. As mentioned previously, note that Figure 2 is a cross-sectional view of the centrifugal pump and the impeller, including its embedded permanent magnets, are understood to be in the shape of a torus (donut shape) that surrounds the inflow axis. Thus Figure 2 shows the impeller as two rectangular cross sections.

472. Figure 5 (annotated) also illustrates the donut shape of the impeller (**pink**), which is configured to rotate about an axis of rotation that is aligned with the inflow axis (**black**):



Ex.1006, Fig. 5 (annotated).

473. Accordingly, Akamatsu-1999 discloses "*the **magnetically driven rotor*** ("impeller") *and **first magnetic device*** (impeller's "permanent magnet") *being rotatable about an axis of rotation aligned with the **inflow axis** to drive the blood flowing from the **inflow tube*** ("inlet port")."

vii. [11F] a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis

474. Akamatsu-1999 discloses "*a **magnetic drive system** comprising a **second magnetic device** axially aligned with the **inflow axis***."

475. For example, Akamatsu-1999 discloses that the centrifugal pump includes a "DC brushless motor." Ex.1006 at 4. "The impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the

three electromagnets." Ex.1006 at 4. As shown in Figure 2, the "DC brushless motor" rotates a plate having embedded "permanent magnets." Ex.1006, Fig. 2. The "DC brushless motor," including its "permanent magnet," described in Akamatsu-1999 is a ***magnetic drive system comprising a second magnetic device*** as recited in Claim 11.

476. As will be discussed with respect to elements [11G], [11H], and [11I], the rotation of the motor's "permanent magnet" creates a torque on the impeller because of the attractive magnetic force between the permanent magnet in the motor plate and the permanent magnet within the impeller. Ex.1006 at 4, Fig. 2; *see infra* Sections X.C.1.viii, X.C.1.ix, and X.C.1.x.

477. Further, as discussed above with respect to element [11C], for components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis" of rotation) in space. *See supra* Section X.C.1.iv. The **heart assist pump device** (e.g., "centrifugal pump," Ex.1006 at 3-4) described in Akamatsu-1999 has an **inflow tube** (e.g., "inlet port" or "inflow conduit," Ex.1006 at 4) through which blood flows to the **magnetically driven rotor** (e.g., "impeller," Ex.1006 at 4), which is driven by the magnetic coupling between the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006, Fig. 2) and the **second magnetic device** (e.g., the "DC

brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 8). *See infra* element [11H].

478. Each of the impeller and its permanent magnet, and the DC brushless motor and its permanent magnet described in Akamatsu-1999 are axially aligned a with the **inflow axis** of the inlet port or inflow conduit. Ex.1006, Fig. 2. Indeed, the centrifugal pump described in Akamatsu-1999 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, an axially aligned inflow tube is a characteristic feature of a centrifugal pump.

479. Figure 2 (annotated) illustrates a cross-sectional view of the pump where the "DC brushless motor" (**light blue**), including its "permanent magnet," is axially aligned with the inflow axis (**black**) on which blood flows from the inlet port (**green**) to the impeller (**pink**):

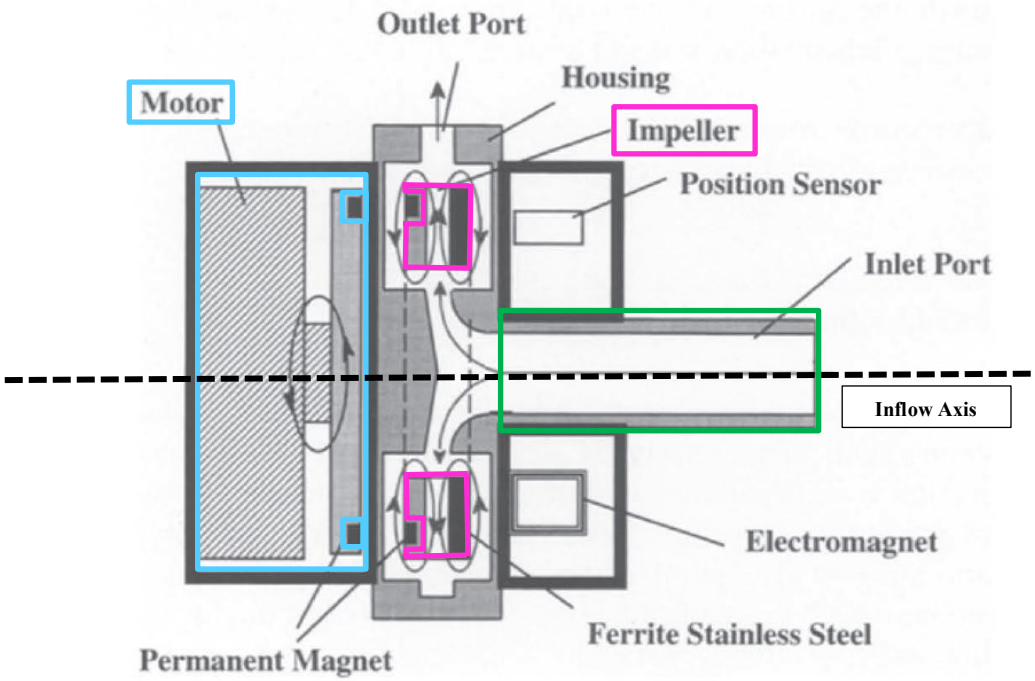


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

480. Akamatsu-1999 discloses "*a magnetic drive system* ("motor") *comprising a second magnetic device* (motor's "permanent magnet") *axially aligned with the* ***inflow axis***."

viii. [11G] and [the second magnetic device is] spaced apart from the magnetically driven rotor such that a wall of the one or more walls defining the chamber is positioned between the magnetically driven rotor and the second magnetic device

481. Akamatsu-1999 discloses the *second magnetic device* "*spaced apart from the magnetically driven rotor such that a wall of the one or more walls defining*

the chamber is positioned between the ***magnetically driven rotor*** *and the* ***second magnetic device***."

482. As discussed with respect to element [11B], Akamatsu-1999 discloses that the centrifugal pump includes an "impeller" and "housing." Ex.1006 at 5, Fig. 2; *see also* Ex.1006 at 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***."). As discussed with respect to element [11C], the "impeller" is a ***magnetically driven rotor***. *See supra* X.C.1.iv.

483. Akamatsu-1999 further discusses that "conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and seal." Ex.1006 at 6. As such, "the use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump." Ex.1006 at 6. And accordingly, Akamatsu "developed a ***sealless centrifugal pump*** with a magnetically suspended impeller (MSCP), which operates completely ***contact-free*** without any material wear." Ex.1006 at 6. Akamatsu-1999 further discusses the pump housing forms a "blood chamber." Ex.1006 at 5.

484. Thus, the ***second magnetic device*** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) is *spaced apart from the* ***magnetically***

driven rotor (e.g., "impeller," Ex.1006 at 4, Fig. 2) *such that a wall of the* ***one or more walls*** ("housing") *at least partially defining* ***a chamber*** (e.g., "blood chamber," Ex.1006 at 5, Fig. 2) *is positioned between the* ***magnetically driven rotor*** *and the* ***second magnetic device***.

485. Figure 2 (annotated) of Akamatsu-1999 illustrates a cross-sectional view of the centrifugal pump having a "DC brushless motor," including its "permanent magnet" (**light blue**) that is spaced apart from the "impeller" (**pink**) such that a wall of the "housing" defining the "blood chamber" (**orange**) is positioned between the impeller and the DC brushless motor and its permanent magnet:

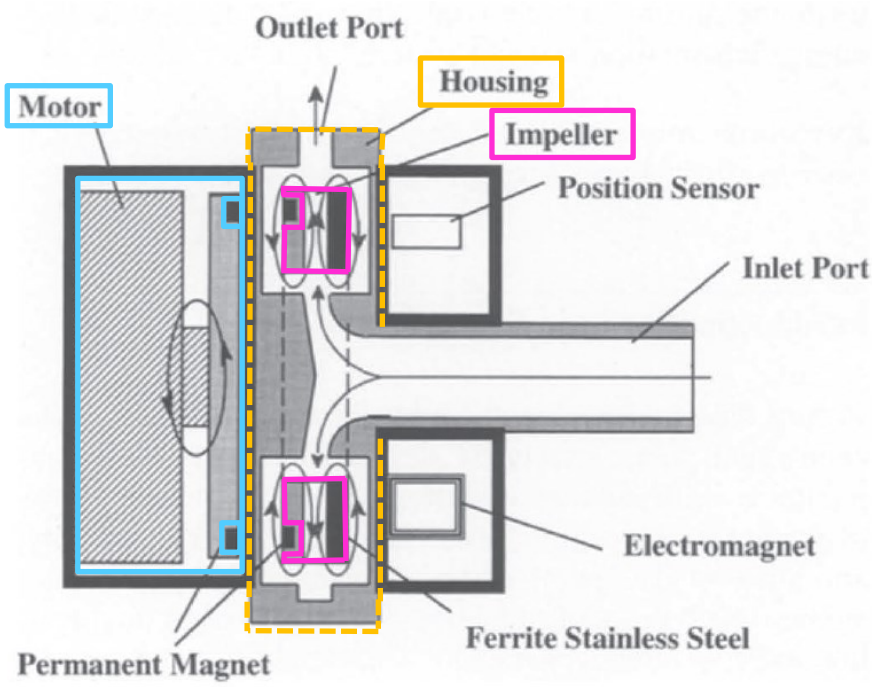


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

486. Accordingly, Akamatsu-1999 discloses that the ***second magnetic device*** (motor's "permanent magnet") "*spaced apart from the* ***magnetically driven rotor*** ("impeller") *such that a wall of the* ***one or more walls*** ("housing") *defining the* ***chamber*** ("blood chamber") *is positioned between the* ***magnetically driven rotor*** *and the* ***second magnetic device***."

ix. [11H] the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor so as to magnetically drive rotation of the magnetically driven rotor relative to the one or more walls via a magneto coupling with the first magnetic device; and

487. Akamatsu-1999 discloses "*the* ***second magnetic device*** *positioned axially closer to the* ***first magnetic device*** *than to the* ***magnetically driven rotor*** *so as to magnetically drive rotation of the* ***magnetically driven rotor*** *relative to the one or more walls via a magneto coupling with the* ***first magnetic device***."

488. As discussed in Section VII.A.1, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating magnetic component to another rotating magnetic component via a magnetic field." *See supra* Section VII.A.1. For the purposes of my analysis in this Ground, I assume that my narrower interpretation of

the plain and ordinary meaning is correct, and Patent Owner's apparent broader construction (in parallel litigation) of "magneto coupling" to also include not only a transfer of torque from one rotating magnetic component to another rotating magnetic component, but also to include "a transfer of torque from one *stationary* magnetic component (i.e., a stator) to another rotating magnetic component using an *electro*magnetic field," is incorrect. *See* Ex.1019.

489. Accordingly, based on my understanding of the term "magneto coupling," Akamatsu-1999 describes a magneto coupling between the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2). For example, Akamatsu-1999 discloses that the "impeller rotates by a ***magnetic coupling*** between the impeller and the motor." Ex.1006, [0072]; *see also* Ex.1006 at 3 ("Because the MSCP is a sealless rotary pump providing contact-free rotation of the impeller without any material wear it is expected to be one of the most durable blood pumps."). Akamatsu-1999 discusses that "conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and seal." Ex.1006 at 6. As such, "the use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as

nonthrombogenicity of a rotary blood pump." Ex.1006 at 6. And accordingly, Akamatsu "developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear." Ex.1006 at 6.

490. As shown in Figure 2, the T-ILVAS achieves this "contact-free" rotation of the impeller because the "DC brushless motor" rotates a plate having a "permanent magnet," which creates a torque on the impeller because of the attractive magnetic force (or "magnetic coupling") between the permanent magnet rotated by the motor and the permanent magnet within the impeller. Ex.1006 at 4, Fig. 2. That is, the rotation of the impeller is locked against relative rotation of the motor plate.

491. This "magnetic coupling" described in Akamatsu-1999 is the same type of transfer of torque using "magneto coupling" described in the 879 Patent. *See, e.g.*, Ex.1001, 4:53-58 ("The rotation of the paddle wheel 21 is regulated here accordingly by corresponding control of the fluid pressure in the lumen 22 serving for the supply of fluid, in which ***the [rotor] magnet 19, which is connected so as to be locked against relative rotation with the paddle wheel 21, is set into corresponding rotation***.").

492. Thus, the ***second magnetic device*** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) *magnetically drives rotation of the*

magnetically driven rotor ("impeller," Ex.1006 at 3) via a magneto coupling with and the ***first magnetic device*** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2).

493. Figure 2 (annotated) of Akamatsu-1999 illustrates that the "DC brushless motor", including its "permanent magnet" (**light blue**) is positioned axially closer to the permanent magnet (**purple**) than the impeller (**pink**) to magnetically drive rotation via the magneto coupling:

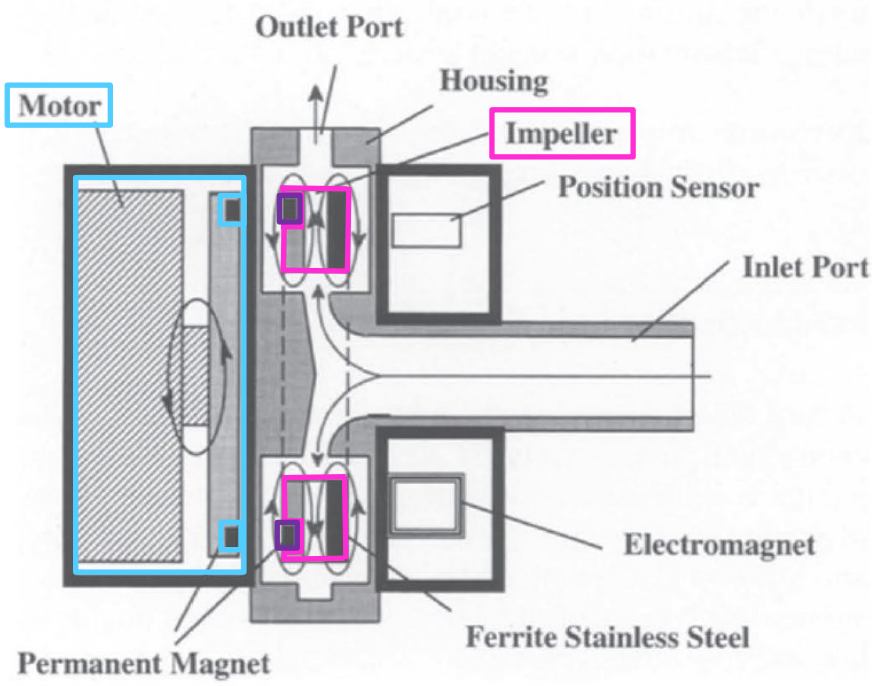


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

494. Note that Figure 2 is a cross-sectional view of the centrifugal pump and the impeller, including its permanent magnet, is understood to surround the inflow axis, essentially mirroring the rotation of the permanent magnet within the motor.

495. Finally, as discussed in element [11 Akamatsu-1999 discloses that the "impeller **rotates** by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1007 at 4; *see also* Ex.1006 at 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***."). Thus, the **magnetically driven rotor** (e.g., "impeller") rotates relative to the **one or more walls** ("housing").

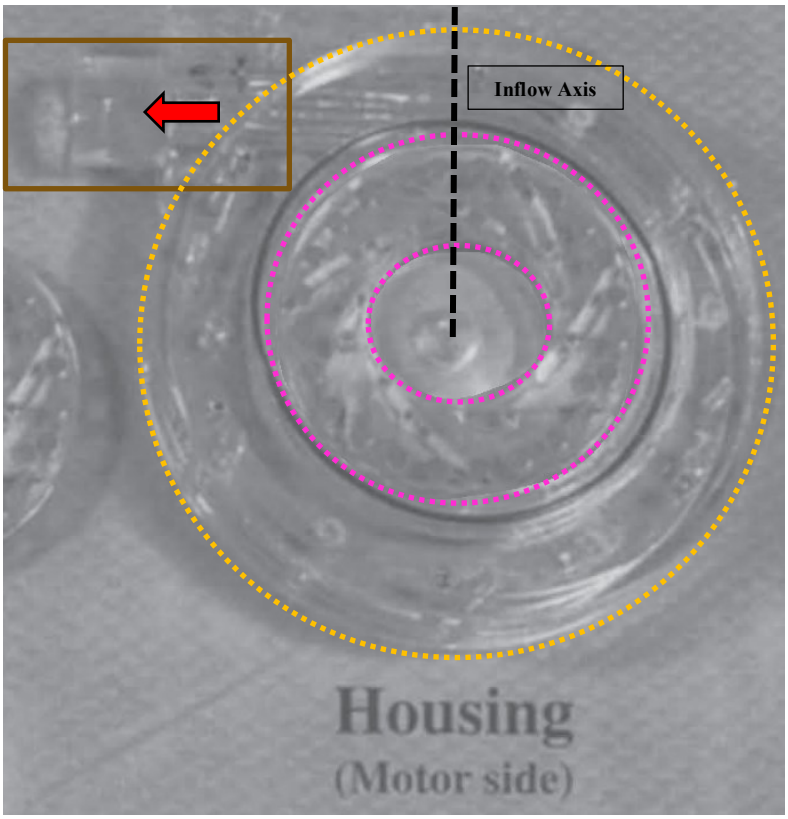
496. Accordingly, Akamatsu-1999 discloses that "*the **second magnetic device*** (motor's "permanent magnet") *positioned axially closer to the **first magnetic device*** (impeller's "permanent magnet") *than to the **magnetically driven rotor*** ("impeller") *so as to magnetically drive rotation of the **magnetically driven rotor** relative to the **one or more walls*** ('housing") *via a magneto coupling with the **first magnetic device***."

x. [11I] a blood outflow port positioned such that the blood driven by the magnetically driven rotor exits the chamber in a direction substantially perpendicular to the inflow axis

497. Akamatsu-1999 discloses "*a **blood outflow port** positioned such that the blood driven by the **magnetically driven rotor** exits the **chamber** in a direction substantially perpendicular to the **inflow axis**.*"

498. For example, Akamatsu-1999 discloses that the T-ILVAS includes an "outflow conduit" or "outlet port." Ex.1006 at 4, Fig. 1, 2, 3; *see also* Ex.1006 at 4 ("The Dacron outflow graft…was sutured to the descending aorta …). Akamatsu-1999 further discusses the pump housing forms a "blood chamber." Ex.1006 at 5. I note that in parallel litigation, the Patent Owner has asserted the blood outflow port of the "HeartMate 3" is positioned such that blood driven by the accused magnetically driven rotor exits the chamber in the same way as described above in Akamatsu-1999. *See e.g.*, Ex.1019, at 8-9 (Complaint, Ex. 11). For the purposes of my analysis, I also map the limitation that the **blood outflow port** (e.g., "outflow conduit") is positioned such that blood driven by the **magnetically driven rotor** (e.g., the "impeller") exits the chamber ("blood chamber") in a direction substantially perpendicular to the inflow axis in the same way.

499. Figure 5 (annotated) illustrates a top view of the motor side of the housing forming the chamber (**orange**) of the centrifugal pump, which shows the "outlet port" or "outflow conduit" (**brown**) is positioned such that blood driven (**red** arrow) by the impeller (**pink**) exits the chamber in a direction substantially perpendicular to the inflow axis:[22]



Ex.1006, Fig. 5 (annotated and altered).

[22] Note that for purposes of this analysis, the impeller in Figure 5 has been superimposed over the motor side of the housing for illustrative purposes to show how the impeller would be configured in operation.

500. I note that Figure 5 shows that when viewed from the top, the direction of the outlet port is offset from the axis of the inlet port as it does not intersect that axis. However, when viewed from the side, as shown in the cross-sectional view of Figure 2 (see below), the blood flows through the outlet port in a direction perpendicular from the inflow axis of the inlet port. Therefore, a POSITA would understand that blood is driven through the outlet port in a direction that is "substantially perpendicular" to the inlet port and the inflow axis of the impeller, as recited in Claim 11.

501. Thus, the ***blood outflow port*** (e.g., "outlet port" or "outflow conduit") is *positioned such that the blood driven by the* ***magnetically driven rotor*** (e.g., "impeller") *exits the* ***chamber*** (e.g., "blood chamber") *in a direction substantially perpendicular to the* ***inflow axis*** of the inlet port.

502. As another example, Figure 2 (annotated) illustrates a cross-sectional view of the centrifugal pump where the outlet port (**brown**) is positioned such that blood is driven (**red** arrows) by the impeller (**pink**) to exit the chamber (**orange**) formed by the housing in a direction substantially perpendicular to the inflow axis (**black**) of the inlet port (**green**):

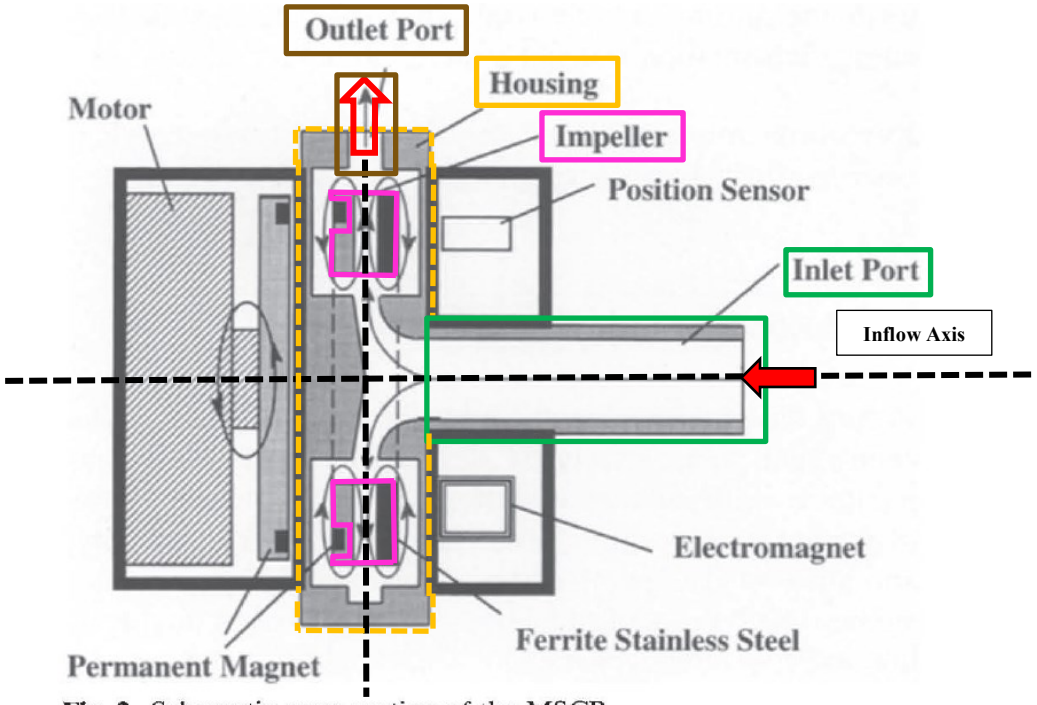


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

503. Another view of the outlet port (**brown**) and inlet port (**green**) is shown in Figure 3, which illustrates a side view of the centrifugal pump:

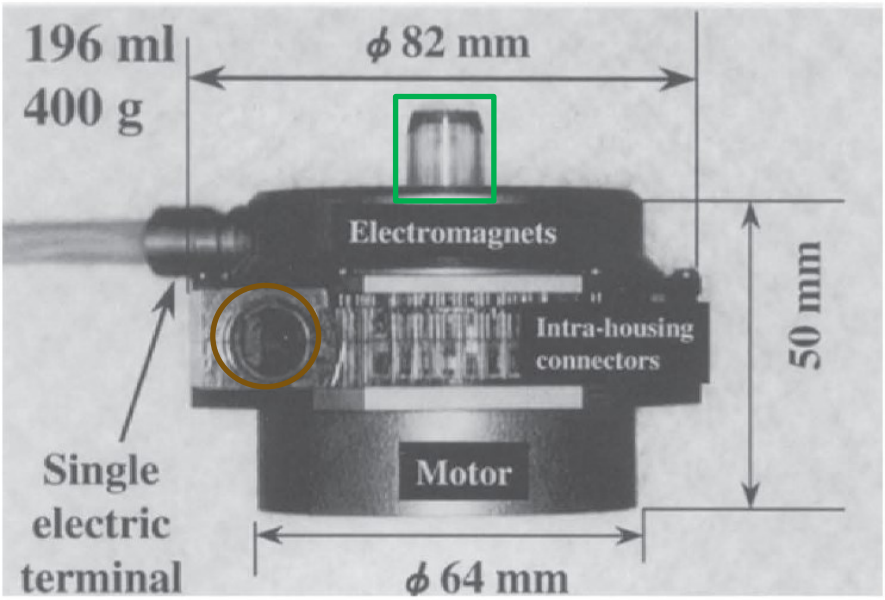


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3 (annotated).

504. Again, I note that Figure 3 shows that when viewed from this rotated side view, the axis of the outlet port is perpendicular to and offset from the axis of the inlet port. When viewed from the cross-sectional view of Figure 2 (see above), the blood flows through the outlet port in a direction perpendicular from the inflow axis of the inlet port. Therefore, a POSITA would understand that blood is driven through the outlet port in a direction that is "substantially perpendicular" to the inflow axis of the inlet port, as recited in Claim 11.

505. Accordingly, Akamatsu-1999 discloses "*a **blood outflow port*** ("outlet port") *positioned such that the blood driven by the **magnetically driven rotor***

("impeller") *exits the* ***chamber*** ("blood chamber" formed by the "housing") *in a direction substantially perpendicular to the* ***inflow axis***."

xi. [11J] wherein the magneto coupling orients the magnetically driven rotor so that both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor,

506. Akamatsu-1999 discloses that "*the magneto coupling orients the* ***magnetically driven rotor*** *so that both the* ***magnetically driven rotor*** *and the* ***first magnetic device*** *remain spaced apart from the one or more walls by the blood in response to rotation of the* ***magnetically driven rotor***."

507. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls **by the blood** in response to rotation of the magnetically driven rotor" to mean that "in response to rotation of the magnetically driven rotor" refers to a hydrodynamic bearing such that "the blood" ***causes*** the "magnetically driven rotor and the first magnetic device" to "remain spaced apart from the one or more walls." *See* Section VII.A.2. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in

parallel litigation) of "both magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor" to include not only hydrodynamic suspension of the rotor but also that it may be met by *exclusively* magnetic suspension, is correct. *See* Ex.1019.

508. Accordingly, based on the Patent Owner's understanding of the term and as discussed with respect to element [11H], Akamatsu-1999 discloses a magneto coupling between the ***second magnetic device*** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the ***first magnetic device*** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2). For example, Akamatsu-1999 discloses that the "impeller rotates by a magnetic coupling between the impeller and the motor." Ex.1006, [0072]. Figure 2 shows that the T-ILVAS achieves this "contact-free" rotation of the impeller because the "DC brushless motor" rotates a plate having a "permanent magnet," which creates a torque on the impeller because of the attractive magnetic force (or "magnetic coupling") between the permanent magnet within the motor and the permanent magnet within the impeller. Ex.1006 at 4, Fig. 2. That is, the rotation of the impeller is locked against relative rotation of the motor plate.

509. Therefore, the DC brushless motor is configured to orient the impeller to rotate within the housing via the magneto coupling. Akamatsu-1999 discusses that "conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and seal." Ex.1006 at 6. As such, "the use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump." Ex.1006 at 6. And accordingly, Akamatsu "developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear." Ex.1006 at 6.

510. Akamatsu-1999 discloses that the impeller "is suspended magnetically by the three electromagnets" which comprise the "magnetic bearing." Ex.1006 at 4. "The electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4; *see also* Ex.1006 at 3 ("Because the MSCP is a sealless rotary pump providing ***contact-free rotation*** of the impeller without any material wear it is expected to be one of the most durable blood pumps."). The V-ILVAS Model II used during testing "had a single electric wire, with the intrahousing connectors between the motor and the electromagnets." Thus, in response to the rotation of the impeller

by motor via the magneto coupling, the impeller and its permanent magnet remain spaced apart from the housing using the electromagnets, which interact with the "ferrite stainless steel" portion of the impeller, as shown in Figure 2.

511. For example, Figure 2 (annotated) illustrates that the magneto coupling orients the impeller (**pink**) such that in response to the rotation of the impeller (shown by the circular arrows surrounding the shaft of the motor driving the plate holding the permanent magnets), the impeller (and its permanent magnet) is spaced apart from the housing (**orange**) by the blood flowing (**red** arrows) to the outlet port (**brown**) using the electromagnets which interact with the "ferrite stainless steel" portion of the impeller:

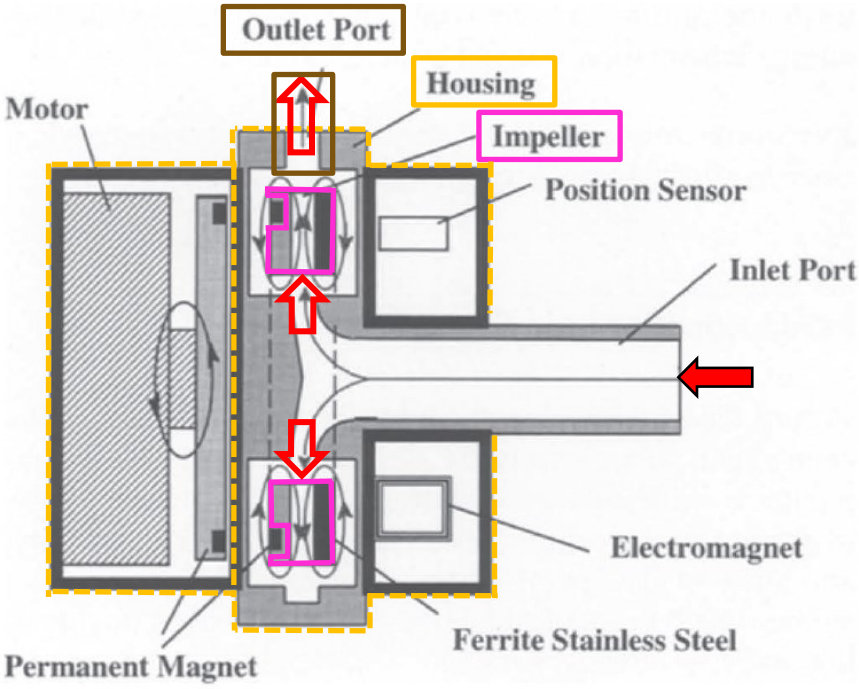


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

512. Accordingly, Akamatsu-1999 discloses that "*the magneto coupling orients the **magnetically driven rotor*** ("impeller") *so that both the **magnetically driven rotor** and the **first magnetic device*** (impeller's "permanent magnet") *remain spaced apart from the **one or more walls*** ("housing") *by the blood in response to rotation of the **magnetically driven rotor**.*"

xii. [11K] an external control unit configured to control operation of the second magnetic device based on a fixed value to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device,

513. Akamatsu-1999 discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a fixed value to thereby magnetically drive the rotation of the **magnetically driven rotor** via the magneto coupling with the **first magnetic device**.*"

514. For example, Akamatsu-1999 discloses a "controller" (shown to be externally worn in Figure 1) used to provide "electric current" to the "DC brushless motor" and the "electromagnets" located within the centrifugal pump via electric wires. Ex.1006 at 3, 4. The "Model I" and the "modified Model II" had "dual electric wires separately connect to the motor and electromagnets," while the "Model II"

version of the T-ILVAS "had a single electric wire, with the intrahousing connectors between the motor and the electromagnets." Ex.1006 at 4. Akamatsu-1999 further discloses that during testing, "[t]he pump was operated at a fixed rotational speed" and "***[t]he pump was percutaneously driven***," i.e., via the electric wire through the skin. Ex.1006 at 4, 5. In addition, "[a]ortic pressure and pump flow rate were continuously measured throughout the experiments." Ex.1006 at 4, 5.

515. Thus, the "controller" disclosed in Akamatsu-1999 is an **external control unit** as recited in Claim 11 which is configured to control operation of the **second magnetic device** (e.g., "DC brushless motor" and its "permanent magnet," Ex.1006 at 3, 4) based on a fixed value (e.g., "fixed rotational speed," Ex.1006 at 4, 5) to thereby magnetically drive the rotation of the **magnetically driven rotor** (e.g., "impeller," Ex.1006 at 3, 4) via the magneto coupling with the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2). *See supra* Sections X.C.1.iv and X.C.1.ix.

516. The configuration of the external control unit's connection (**lime green**) via an electric wire to the centrifugal pump to control the DC brushless motor (**light blue**) is shown in Figure 3 (annotated):

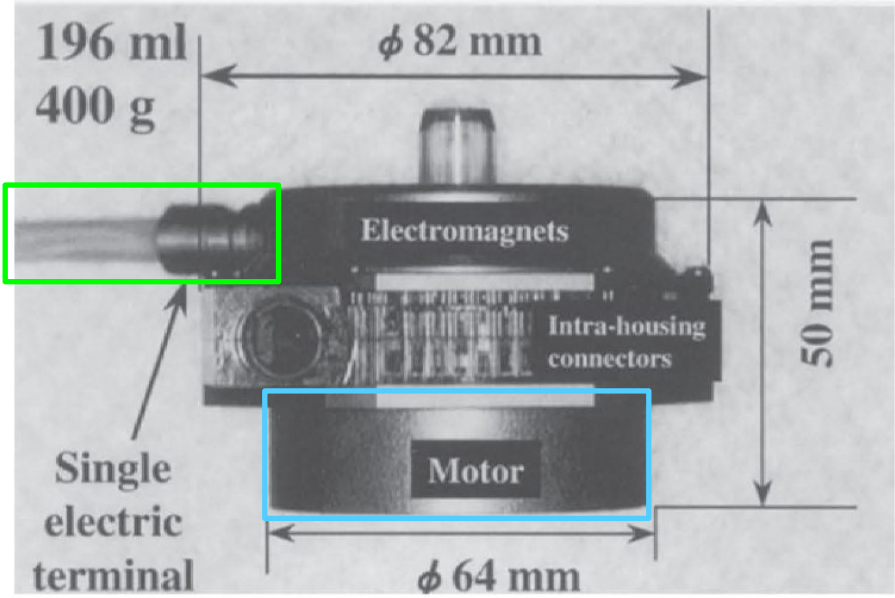


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3 (annotated).

517. Figure 1 (annotated) also illustrates the connection of the external controller (**lime green**) to the centrifugal pump (**blue**), in which the DC brushless motor and the impeller are enclosed:

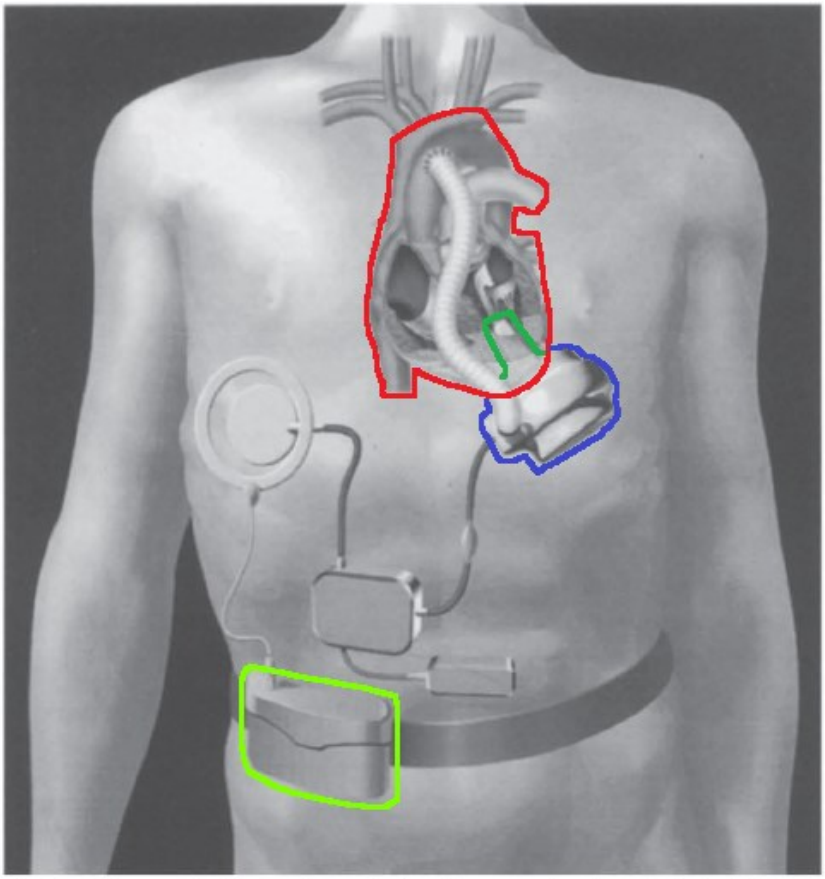


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

518. Accordingly, Akamatsu-1999 discloses "*an* ***external control unit*** ("controller") *configured to control operation of the* ***second magnetic device*** (motor's "permanent magnet") *based on a fixed value* ("fixed rotational speed") *to thereby magnetically drive the rotation of the* ***magnetically driven rotor*** ("impeller") *via the magneto coupling with the* ***first magnetic device*** (impeller's "permanent magnet")"

2. Claim 12

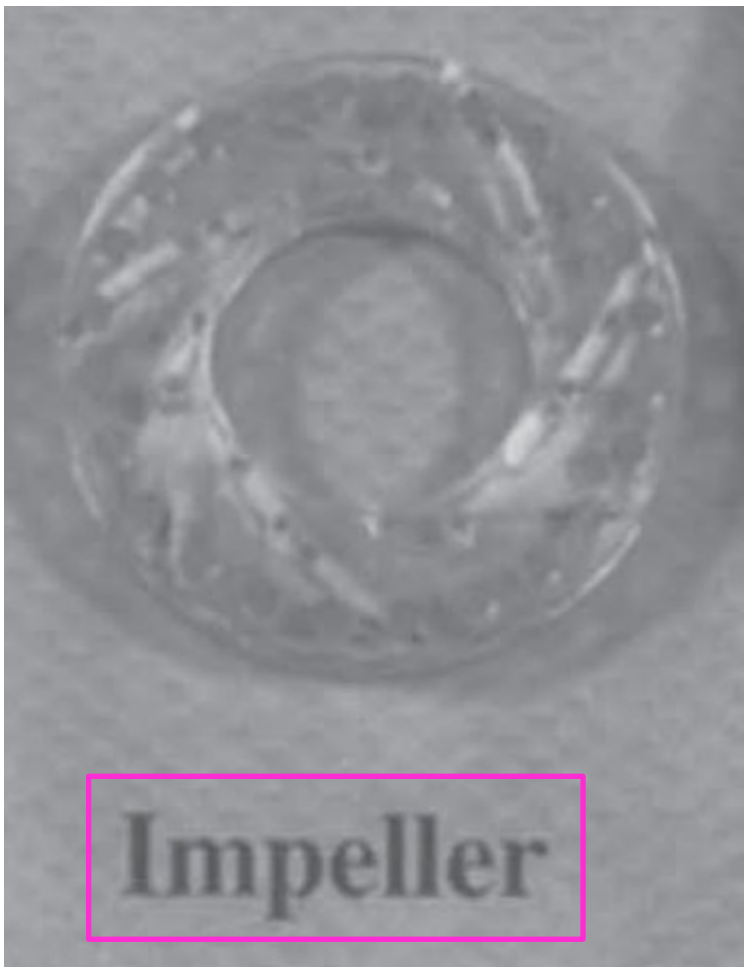
a. [12] The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components.

519. Akamatsu-1999 discloses and/or renders obvious claim 12. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claim 11. I incorporate that discussion into my analysis for claim 12.

520. Akamatsu-1999 discloses that "*the **magnetically driven rotor** includes a guide surface to produce centrifugal flow components*."

521. As discussed with respect to element [11H], Akamatsu-1999 discloses a magneto coupling between the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2). *See supra* Section X.C.1.ix.

522. An isolated portion of Figure 5 (annotated) of Akamatsu-1999 shows a top view of the impeller (**pink**) removed from the housing and having guide surfaces that produce "centrifugal flow components":



Ex.1006, Fig. 5 (annotated).

523. Indeed, the pump described in Akamatsu-1999 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. *See, e.g.*, Ex.1006 at 3 ("***Rotary blood pumps***, such as the axial flow pump and the ***centrifugal pump***, are being developed worldwide ventricular assist systems (VAS)."). An impeller has blades or edges (i.e., "guide surfaces") which push fluid radially, imparting kinetic

energy to the fluid resulting in increased pressure. Said another way, the production of centrifugal flow components by the guide surfaces of the impeller are a characteristic feature of a centrifugal pump.

524. Accordingly, Akamatsu-1999 discloses that "***magnetically driven rotor*** ("impeller") *includes a guide surface to produce centrifugal flow components*."

3. Claims 14-15

a. [14], [15].

525. Akamatsu-1999 discloses and/or renders obvious claims 14-15. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claims 11. I incorporate that discussion into my analysis for claim 14.

526. Akamatsu-1999 discloses that "***one or more walls*** *and the* ***magnetically driven rotor*** *define a gap separating the* ***magnetically driven rotor*** *from the* ***one or more walls****, the gap configured to be occupied by the blood when the* ***second magnetic device*** *drives the rotation of the* ***magnetically driven rotor***." Akamatsu-1999 further discloses that "*wherein the gap surrounds the* ***magnetically driven rotor***."

527. As discussed with respect to element [11D], Akamatsu-1999 discloses that the centrifugal pump includes ***one or more walls*** ("housing"). *See supra* Section X.C.1.v; Ex.1006 at 5, Fig. 2.

528. Akamatsu-1999 discloses that the centrifugal pump includes a "housing." Ex.1006 at 5, Fig. 2; *see also* Ex.1006 at 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***."). Akamatsu-1999 further discloses that "[t]he impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1006 at 4; *see also* Ex.1006 at 6 ("We have developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear."), 3 ("Because the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material wear, it is expected to be one of the most durable blood pumps."), 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***."). Akamatsu-1999 further discloses that the pump includes a "blood chamber." Ex.1006 at 4.

529. Figure 2 (annotated) of Akamatsu-1999 illustrates a cross-sectional view of the centrifugal pump where the "housing" defining the "blood chamber"

(**orange**) and the "impeller" (**pink**) define a *gap occupied by blood* (as shown by the black arrows) separating the impeller from the walls of the housing when the "DC brushless motor," including its "permanent magnet" (**light blue**) drives rotation of the "impeller":

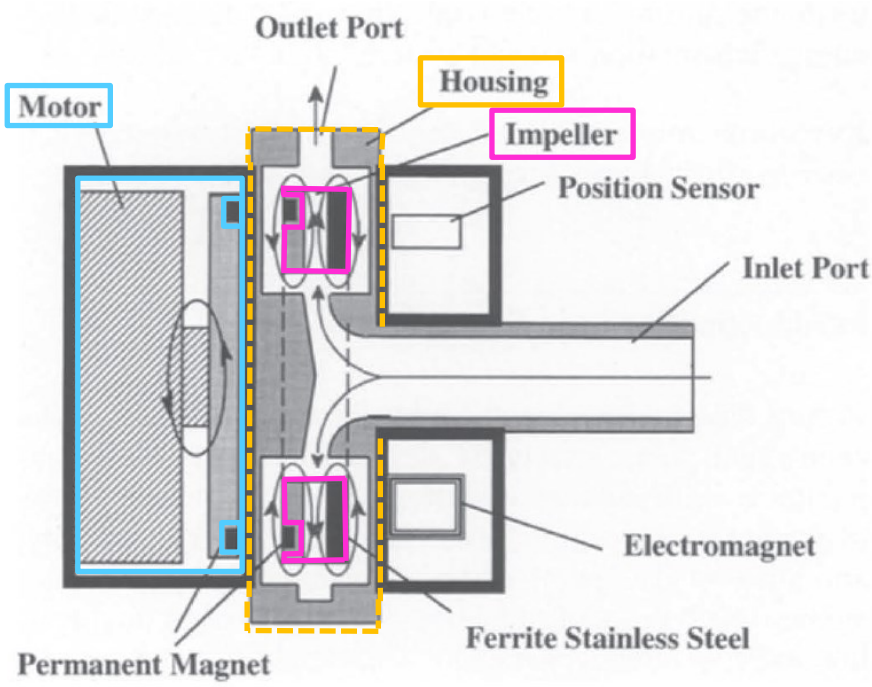


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

530. Accordingly, Akamatsu-1999 discloses that "***one or more walls*** *and the* ***magnetically driven rotor*** ("impeller") *define a gap separating the* ***magnetically driven rotor*** ("impeller") *from the* ***one or more walls****, the gap configured to be occupied by the blood when the* ***second magnetic device*** (motor's "permanent

magnet") *drives the rotation of the* ***magnetically driven rotor***." Akamatsu-1999 further discloses that "*wherein the gap surrounds the* ***magnetically driven rotor***."

4. Claim 16

a. [16] The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis.

531. Akamatsu-1999 discloses and/or renders obvious claim 16. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claims 14 and 11. I incorporate that discussion into my analysis for claim 16.

532. Akamatsu-1999 discloses that "*at least part of the gap extends along a first axis substantially perpendicular to the* ***inflow axis***."

533. As with respect to claim [14], Akamatsu-1999 discloses the "housing" and the "impeller" define a "gap" occupied by the blood during rotation of the impeller. *See supra* Section X.C.3. Figure 2 further illustrates that at least part of the gap, defined when the "motor" and its permanent magnet (**light blue**) drive the rotation of the impeller (**pink**) via the magneto coupling, extends along a first axis substantially perpendicular to the inflow axis of the pump, allowing the blood to exit via the outlet port:

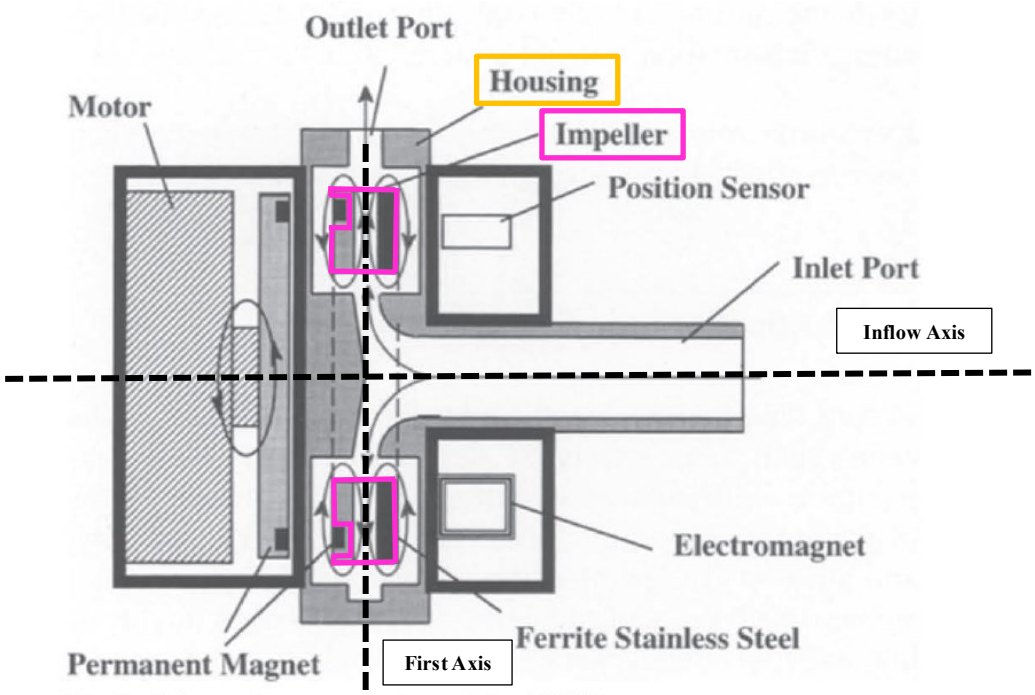


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

534. Accordingly, Akamatsu-1999 discloses that "*at least part of the gap extends along a first axis substantially perpendicular to the* ***inflow axis***."

5. Claim 18

a. [18] The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.

535. Akamatsu-1999 discloses and/or renders obvious claim 18. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and

every element of claims 11. I incorporate that discussion into my analysis for claim 18.

536. Akamatsu-1999 discloses that "*the **chamber** is a first chamber within which the **magnetically driven rotor** is positioned, and the **magnetic drive system** is positioned within a second chamber sealed from the first chamber*."

537. As demonstrated in [11B] and [11G], the **impeller** is positioned in the **chamber** (e.g., "blood chamber") of the **one or more walls** ("pump housing"), while the **magnetic drive system** ("motor" and its "permanent magnet") is positioned within a separate compartment ("a second chamber"), as indicated by the solid black line separating the below:

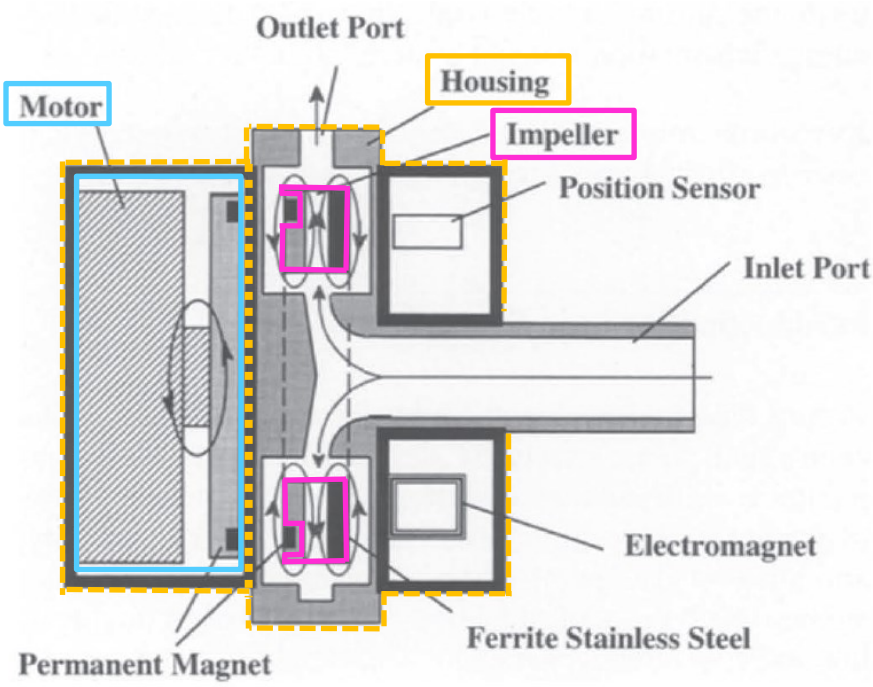


Fig. 2. Schematic cross section of the MSCP

Ex.1006, 4 Fig. 2; *see also* Fig. 5 (depicting motor housing). Akamatsu-1999 also discloses sealing the device to prevent "leakage of blood into the…motor." Ex.1006, 5. For the same reasons, because the "permanent magnets" are rigidly coupled to the "impeller," the "permanent magnets" rotate together with the "impeller" relative to and within the housing providing "contact-free rotation." Ex.1006 at 4, 6.

538. Accordingly, Akamatsu-1999 discloses that "*the **chamber*** ("housing") *is a first chamber within which the **magnetically driven rotor*** ("impeller") *is positioned, and the **magnetic drive system*** ("motor" and its "permanent magnet") *is positioned within a second chamber sealed from the first chamber*."

6. Claim 19

a. [19] The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber.

539. Akamatsu-1999 discloses and/or renders obvious claim 19. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claims 18 and 11. I incorporate that discussion into my analysis for claim 19.

540. Akamatsu-1999 discloses that "*the wall of the **one or more walls** separates the first chamber from the second chamber.*"

541. For the same reasons discussed in [18], Akamatsu-1999 discloses that the wall of the **one or more walls** ("pump housing," Ex.1006 at 4) separates the first chamber ("blood chamber," Ex.1006 at 5) from the second chamber ("motor's" compartment to effectuate "contact-free rotation," Ex.1006 at 4, 6).

542. Accordingly, Akamatsu-1999 discloses that "*the wall of the **one or more walls*** ("pump housing") *separates the first chamber from the second chamber*."

7. Claims 1-2, 4-5, 7-8, 20

543. In my opinion, claim 1 and dependent claims 2, 4-5, 7-8, and 20 recite elements that are identical or substantially analogous to independent claim 11 and dependent claims 12, 14, 16, 18-19, and are therefore rendered obvious for the same reasons. For instance, the "surrounding rotor housing" of claim 1 is essentially the same as the "one or more walls at least partially defining a chamber" of claim 11. Similarly, the "inflow tube," "magnetically driven rotor," and "first magnetic device" are all axially aligned with the "inflow axis" of claim 11 in essentially the same way that they are all aligned with the "central axis" of claim 1. The below chart maps the limitations of these claims to their analogous claim limitations that I've analyzed above. *Supra* Section X.C.

Claims 1-2, 4-5, 7-8, 20	Analogous Claim Limitations	Analogous Sections of Ground 3
[1PRE]	[11PRE]	§X.C.1.i
[1A]	[11A]	§X.C.1.ii
[1B]	[11C]	§X.C.5
[1C]	[11B], [11E]	§X.C.1.iii; §X.C.1.vi
[1D]	[11D]	§X.C.1.v
[1E]	[11F]	§X.C.1.vii
[1F]	[11H]	§X.C.1.ix
[1G]	[11G], [14]	§X.C.1.viii; §X.C.3
[1H]	[11I]	§X.C.1.x
[1I]	[11J]	§X.C.1.xi
[1J]	[11K]	§X.C.1.xii
[2]	[12]	§X.C.2
[4]	[18], [19]	§X.C.1.iii; §X.C.5-9
[5]	[14], [18]	§X.C.7.i; §X.C.3; §X.C.5
[7]	[18]	§X.C.5
[8]	[19]	§X.C.6
[20]	[11K]	§X.C.1.i

i. *Claim 4*

544. Akamatsu-1999 discloses each and every element of claim [4] for the same reasons discussed in [11B] and Claims [18] and [19]. *See supra* [11B], [18]-[19]. Akamatsu-1999 further discloses "*a sealing wall positioned between the **second magnetic device*** (e.g., "motor") *and the **magnetically drive rotor*** (e.g., "impeller") to prevent "leakage of blood into the…motor." Ex.1006, 5.

ii. *Claim 20*

545. Akamatsu-1999 discloses each and every element of claim [20] for the same reasons discussed in [11K] and Claims [18] and [19]. *See supra* [11B], [18]-[19]. Akamatsu-1999 further discloses that "[t]he pump was operated at a fixed rotational speed" and that "[a]ortic pressure and pump flow rate were continuously measured" ("*based on a defined cardiac output*"). Ex.1006, 4, 5.

D. Ground 4: Schima in view of Akamatsu-1999 Renders Obvious Claims 1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20 of the 879 Patent

1. Claim 11

i. [11PRE] A system for assisting blood circulation of a heart, the system comprising:

546. To the extent that the preamble is a limitation, Schima discloses "*a system for assisting blood circulation of a **heart***."

547. For example, Schima discloses "a rotary pump for moving blood ["*assisting the blood circulation*"] and other shear-sensitive liquids with a rotor journaled hydraulically and, if necessary, magnetically in a housing." Ex.1005, [0001]. For example, a POSITA would have understood that the publication classification codes published with Schima indicate that it is rotary blood pump for assisting a heart in a body. *See, e.g.*, Schima at "Publication Classification."

548. In addition, Schima discloses that its "rotary pump" is for *assisting…a heart in a body* through its disclosure that the object of the invention is to overcome disadvantages with prior art heart assist pump devices. As discussed below in connection with element [11A], Schima is silent regarding its placement in the body, but Schima describes "disadvantages" with a number of existing heart assist pump devices that were in development at the time, and then states that "[t]he present invention therefore has the object of overcoming the[] disadvantages" with those other heart assist pump devices. *See* Ex.1005, [0004] - [0009].

549. Accordingly, Schima discloses "*a system for assisting the blood circulation of a* ***heart***."

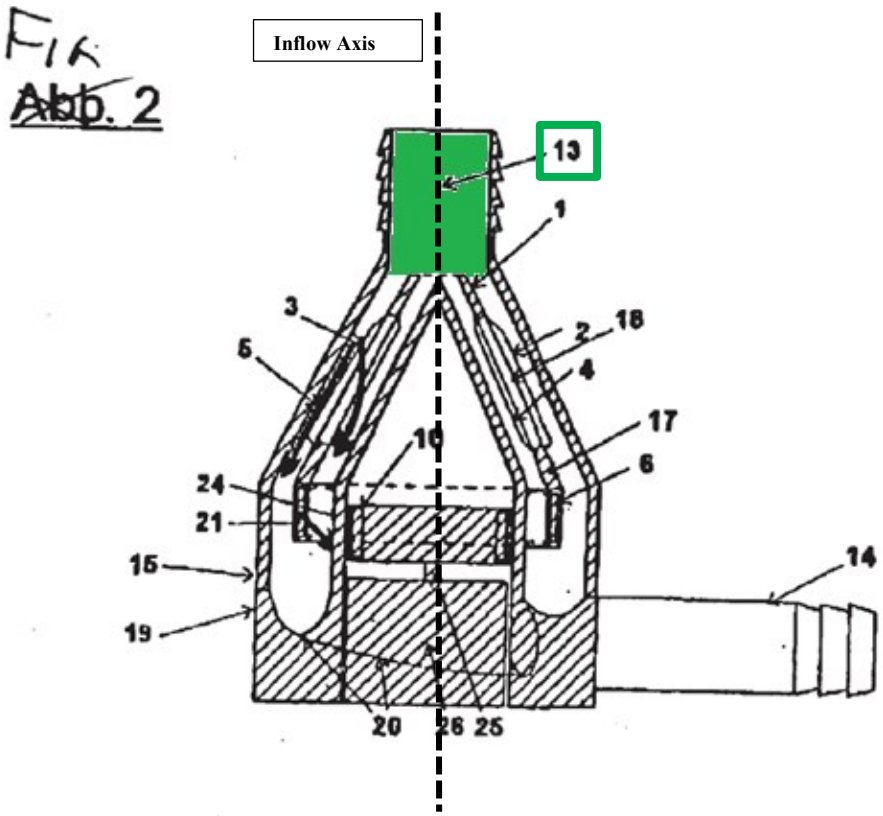
ii. [11A] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle,

550. Schima discloses "*a **heart assist pump device** deliverable to the **heart** and comprising: an **inflow tube** defining a blood inflow path along an **inflow axis** and being insertable into **a left ventricle**.*"

551. The 879 Patent does not define the term "a heart assist pump device deliverable to the heart." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that assumes "a heart assist pump device" being "deliverable to the heart" includes inserting an inflow tube of the heart assist pump device into a left ventricle of a patient's heart. *See, e.g.*, Ex.1019, at 3-4 (Complaint, Ex. 11). For the purposes of my analysis, I adopt that construction of "a heart assist pump device deliverable to the heart."

552. Schima discloses a "rotary pump for moving blood [*a heart assist pump device*]" Ex.1005, [0001], Abstract. Schima further discloses that "[t]he rotor 1 has at an inlet 13 ["*an inflow tube*"] an inlet opening 36 that distributes the incoming liquid to both sides of the rotor and against the point of the cone-shaped middle part 16" ['*defining a blood inflow path along an inflow axis*']. Ex.1005, [0012], *see also* Ex.1005, Claim 1. For example, Figure 2 (annotated) of Schima illustrates a cross

section of the described "pump" (not labeled but refers to the entire structure shown in Figure 2) having an "inlet 13" (**green**) distributing blood along an inflow axis (**black**):



Ex.1005, Fig. 2 (annotated).

553. A POSITA would have understood that the "pump" described in Schima is a "***heart assist pump device***" designed to be deliverable to the heart such that the inlet tube 13 ["*an inflow tube*"] *defin[es] a blood inflow path and … is insertable into a ventricle of the heart*, because "the object of" "[t]he present invention" of Schima was directed at "overcoming…disadvantages" with previously

known heart assist pump devices designed to be delivered to the heart. Ex.1005, [0009].

554. For example, Schima describes "overcoming" a number of existing heart assist pumps that were in development at the time. *See* Ex.1005, [0004], [0005], [0006], [0007], [0008]. Each of the heart assist pumps described in those publications were *deliverable to the heart* such that *an inflow tube of the heart assist pump device* is *insertable into a left ventricle* of the heart.

555. For example, Schima identifies a disadvantage with the centrifugal pump described in an "Akamatsu" publication. Ex.1005, [0004] (citing Akamatsu et al (*see e.g. Artificial Organs* 1997, Vol. 21, No. 7, pp. 645-638)). The same pump described in the Akamatsu article cited in article cited is described elsewhere, for example, in Akamatsu-1999, which I detail above in Ground 3. Ex.1006, [0004]. That pump described by Akamatsu is a "totally implantable left ventricular assist system (T-ILVAS)," which uses "a centrifugal pump with a magnetically suspended impeller (MSCP)," which "operates completely contact-free without any material wear." Ex.1006 at 3, 7. The T-ILVAS described in Akamatsu-1999 includes an "inlet port" or "inflow conduit," which was "inserted into the left ventricle ["*inflow tube ... insertable into a left ventricle*"] through a cuff sutured to the left ventricular apex"

during the *ex vivo* study performed on sheep. Ex.1006 at 4; *see also* Ex.1006 at Fig. 1 (illustration of *inflow tube insertable into a left ventricle*).

556. Similarly, Golding (U.S. Pat. No. 5,324,177, referenced in Schima, [0007]) describes "capable for use as heart or blood pumps, or ventricular assist devices ["*deliverable to the heart*"] that "can be sized for implantation within a living body, and is preferably employed as an assist device for humans. It is to be noted that the pump can be sized so as to even be implantable within a heart chamber ["*inflow tube… being insertable into a left ventricle*"]. Ex.1027 (Golding), 1:9-11; 4:27-39.

557. Allaire (*Prototype Continuous Flow Ventricular Assist Device*, J. Artificial Organs 1996, Vol. 20, No. 7, pp.582-690 (Ex.1028), referenced in Schima, [0006], describes a prototype "Continuous Flow Ventricular Assist Device Number 2 (CFVAD2) system" that has "expected use…in an adult human." Ex.1028 at 583. Allaire further describes that "the pump itself will be implanted in the abdominal cavity ['*deliverable to the heart*']." Ex.1028 at 583. "The inlet to the CFVAD2 is a 14 mm internal diameter (ID) cannula that collects blood from the apex of the left ventricle ["*an inflow tube…being insertable into a left ventricle*"] and returns it through the outlet near the root of the aortic arch. Ex.1028 at 583.

558. Finally[23], Kung and Hart (*Design Considerations for Bearingless Rotary Pumps*, J. Artificial Organs 1997, Vol. 21, No. 7, pp. 645-650, Ex.1029), referenced in Schima [0005], describes another "rotary blood pump" used for "implantable cardiac support applications ["*a heart assist pump device deliverable to the heart*"]." Ex.1029 at 645.

559. Because Schima describes that "[t]he present invention therefore has the object of overcoming these" heart assist pump devices described above (Akamatsu, Golding, Allaire, Kung and Hart), Schima is describing that its "present invention" is also a "*heart assist pump device*," designed to be *deliverable to a heart* such that the "inlet tube 13 ['*an inflow tube*']" "*is inserted into a left ventricle*."

560. Accordingly, Schima discloses "*a **heart assist pump device*** ("pump") *deliverable to the **heart** and comprising: an **inflow tube defining a blood inflow path*** ("inlet 13") *along an **inflow axis** and being insertable into **a left ventricle***."

---

[23] Schima also identifies another heart assist pump device as described in "Woodward et al (WO 00/12587)." Schima [0008]. However, I could not find an application with that publication number listing Woodward. I note, however, that a Jonathan Woodard is listed as an inventor to several patents assigned to Thoratec which also relate to heart assist pump devices delivered to a heart, which would be consistent with the others. *See, e.g.*, US 2005/0196293.

561. To the extent one asserts that Schima's "rotary pump for moving blood" is not delivered to the heart so that the inlet 13 is inserted into a ventricle of a heart, it would have been obvious to a POSITA as of February 27, 2007 that Schima's pump was designed for such delivery. As discussed above, Schima describes a number of existing heart assist pumps that were in development at the time. *See* Ex.1005, [0004], [0005], [0006], [0007], [0008]. For example, the "totally implantable left ventricular assist system (T-ILVAS)" described in Akamatsu-1999 includes an "inlet port" or "inflow conduit," which was "inserted into the left ventricle through a cuff sutured to the left ventricular apex ['*an inflow tube ... insertable into a left ventricle*']" during the *ex vivo* study performed on sheep. Ex.1006 at 4.

562. As I detail below in Section X.D.8 and incorporated by reference here, a POSITA would have been motivated to deliver the "pump" described in Schima to a heart as described in Akamatsu-1999 because the disclosures are directed to the same problems faced in existing blood pumps at the time—the improvement of rotary blood pumps used to assist the circulation of blood in the heart. Therefore, a POSITA would have had a reasonable expectation of successfully addressing those problems in doing so. Delivering the "pump" to a heart would have required merely using a known component (an inlet tube) in a known way by inserting the inlet tube

13 into the left ventricle of the heart, as described in Akamatsu-1999. For example, Figure 1 (annotated) illustrates the Akamatsu-1999 T-ILVAS, including the centrifugal pump (**blue**) delivered to a heart (**red**) such that the inflow conduit (**green**) of the T-ILVAS is "*insertable into a left ventricle*:"

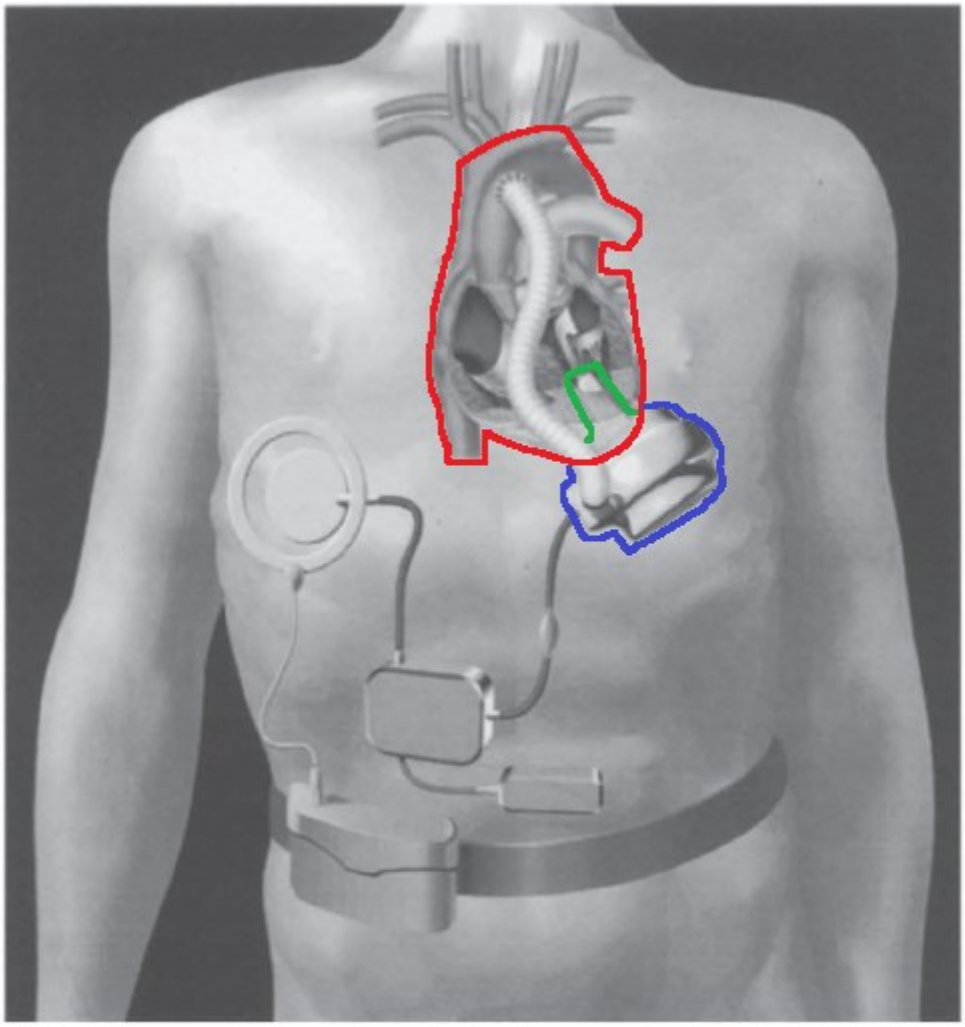


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

563. Therefore, it is my opinion that the resultant combination of Schima and Akamatsu-1999 would have been predictable, and a POSITA would have been motivated and had a reasonable expectation of success because the delivery of an LVAS was well known and developed in the field for the reasons stated below in Section X.D.8. Thus, implementing the combination would have been well within the ordinary skillset of a POSITA at the time.

564. Accordingly, Schima in view of Akamatsu-1999 renders obvious "*a **heart assist pump device*** ("pump") *deliverable to the **heart** and comprising: an **inflow tube defining a blood inflow path*** ("inlet 13") *along an **inflow axis** and being insertable into **a left ventricle*** ("inserted into the left ventricle," Ex.1006)."

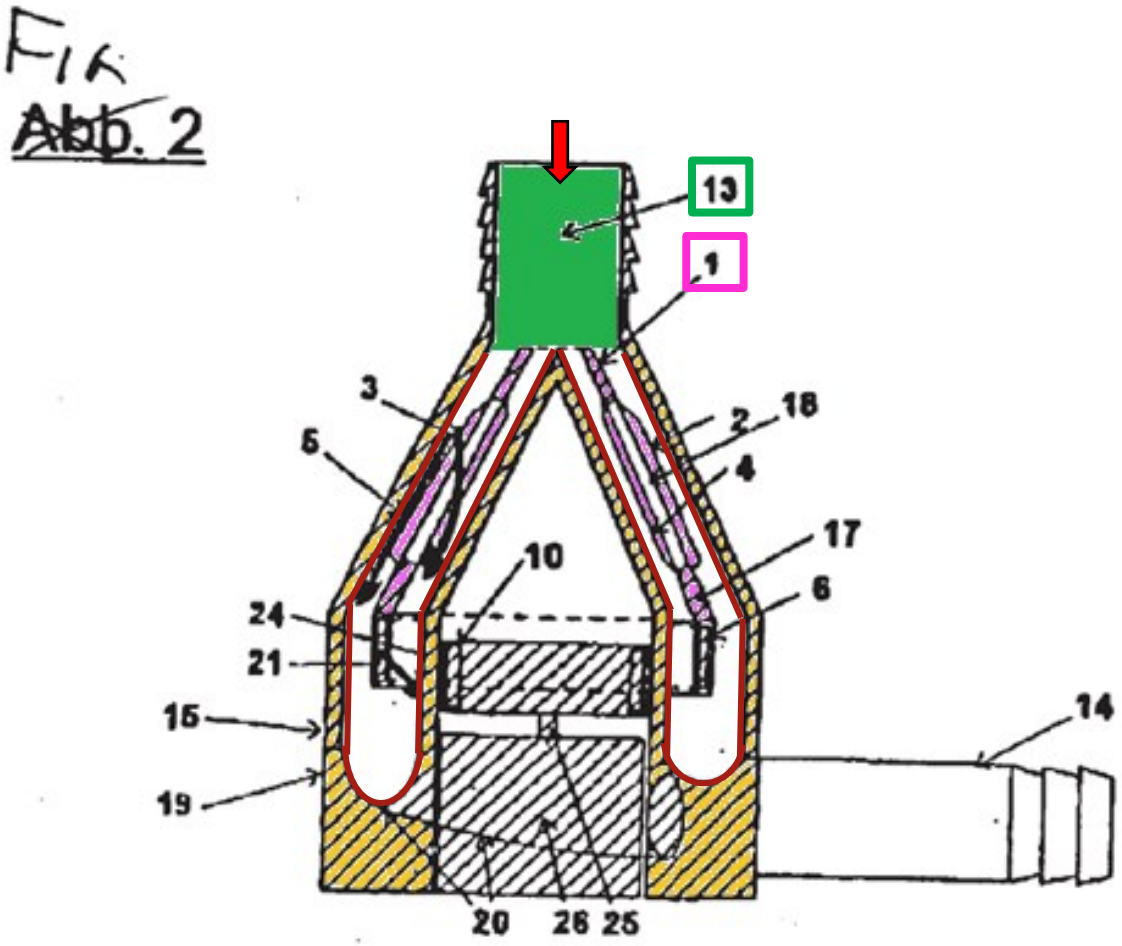
iii. [11B] one or more walls at least partially defining a chamber to receive blood from the inflow tube,

565. Schima discloses "***one or more walls*** *at least partially defining a **chamber** to receive blood from the **inflow tube***."

566. For example, Schima describes that the pump includes "hollow conical rotor 1 rotat[ing] in a pump housing 30 comprised of a housing lower part 19 with a conical middle part 16 and a hollow conical upper part 15 ['***one or more walls at least partially defining a chamber***'], centering of the hollow conical rotor in the middle part 16 of the housing lower part 19 being effected by the flow components

5 directed against the housing, this flow being preferably axially against the conical upper surface of the middle part 16" ['*to receive blood from the inflow tube*'] Ex.1005, [0012]. Schima further discloses that the "inlet 13" "distributes the incoming liquid to both sides of the rotor and against the point of the cone-shaped middle part 16." Ex.1005, [0012].

567. Figure 2 (annotated) of Schima illustrates that the rotor 1 (**pink**) rotates within the pump housing 30 (**orange**, labeled in Figure 1), such that it rotates in the space defined between the "hollow conical upper part 15" and "the middle part 16" (**maroon**) of the housing (labeled in Figure 1), to receive blood flowing (**red** arrow) from the inlet 13 (**green**) toward the rotor:



Ex.1005, Fig. 2 (annotated); Fig. 1.

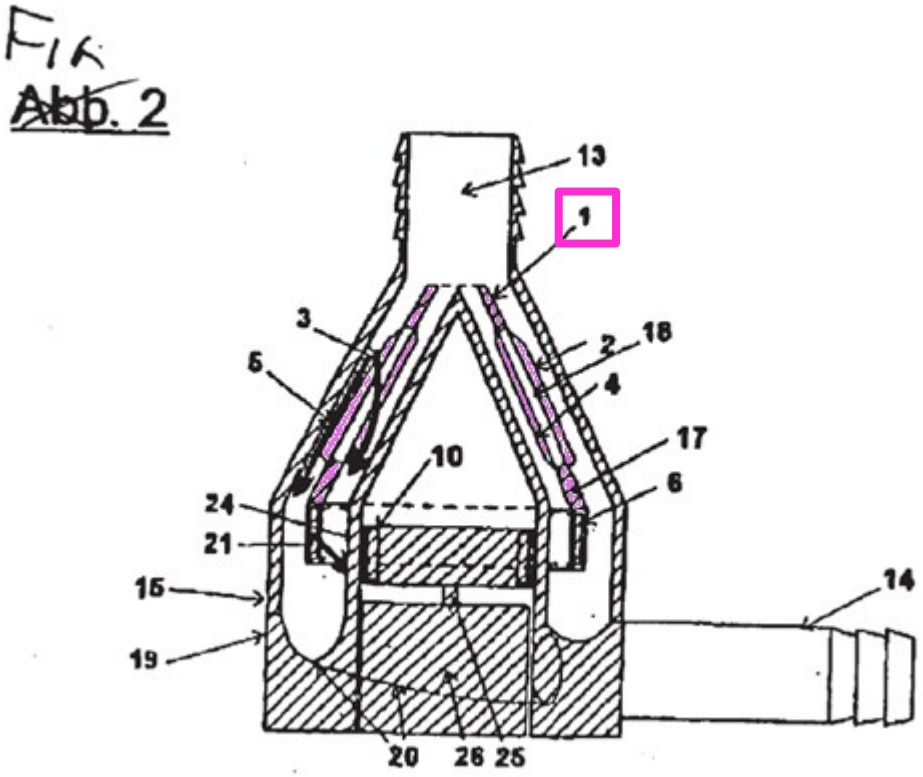
568. Accordingly, Schima discloses "***one or more walls*** ("housing 30") *at least partially defining a* ***chamber*** (space between "hollow conical upper part 15" and "the middle part 16") *to receive blood from the* ***inflow tube*** ("inlet 13," Ex.1005)."

iv. [11C] a magnetically driven rotor axially aligned with the inflow axis

569. Schima discloses that the "***magnetically driven rotor*** *axially aligned with the* ***inflow axis***."

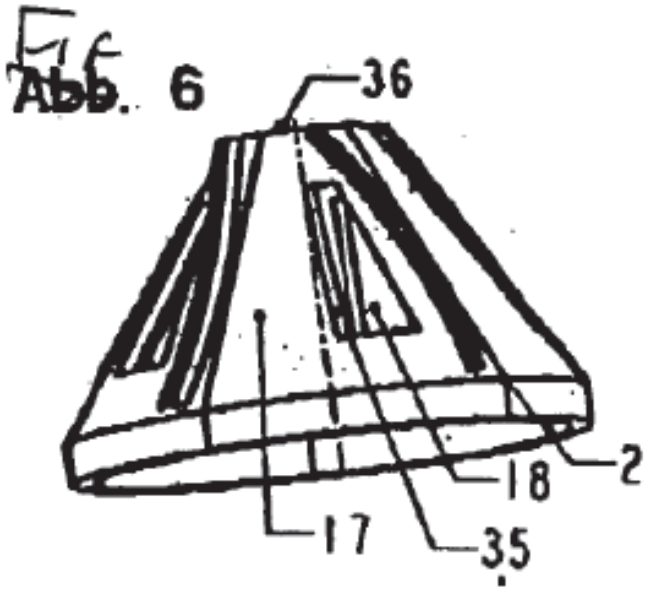
570. For example, the "pump" described in Schima includes a "rotor 1 [***rotor***]" that "holds rotor magnets 6 that preferably transfer rotation energy and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. Further, Schima discloses that "the drive can…be an electric motor 26 which drives a rotating disk 24 with magnets 10 ['***magnetically driven***']." Ex.1005, [0013]. Thus, the "rotor 1" described in Schima is a "***magnetically driven rotor***" as recited in claim 11.

571. Figure 2 (annotated) of Schima illustrates the rotor 1 (**pink**) of the pump:



Ex.1005, Fig. 2 (annotated).

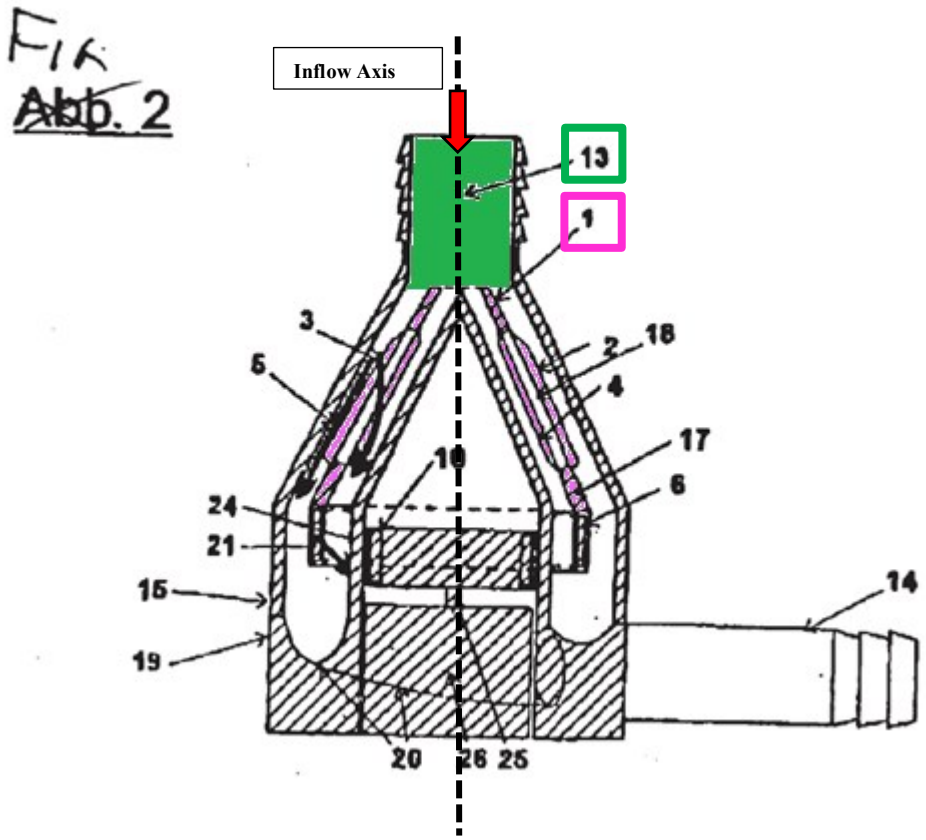
572. Figure 6 of Schima shows an oblique view of the "rotor 1" separated from the pump for clarity:



Ex.1005, Fig. 6.

573. In addition, for components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis") in space. The blood pump described in Schima has an inflow axis that is configured in axial alignment with the **inflow tube** (e.g., "inlet tube 13," Ex.1005, [0012]) so as to provide the flow of blood to the **magnetically driven rotor** (e.g., "rotor 1," Ex.1005, [0012]). Specifically, Schima states that the "flow [from *the inflow tube*]" is "preferably axially against ['*axially aligned*'] the conical upper surface of the middle part 16" of the pump housing 30." Ex.1005, [0012].

574. For example, Figure 2 (annotated) of Schima illustrates the alignment of the rotor 1 (**pink**) and the inlet 13 (**green**) of the pump along an inflow axis and the flow path of blood from the left ventricle the heart (**red** arrow):



Ex.1005, Fig. 2 (annotated).

575. Indeed, the pump described in Schima is a *centrifugal* pump (producing "centrifugal flow components," Ex.1005, [0012]) and by design, fluid enters a centrifugal pump along its axis towards the rotor and is accelerated by centrifugal force toward the circumference of the impeller, collected by a volute (the "spiral shaped outlet passage 20," Ex.1005, [0012]) and then discharged through an outlet

14. Thus, by definition of it being a centrifugal pump, the "*magnetically driven rotor is axially aligned with the inflow axis*."

576. Accordingly, Schima discloses that ***magnetically driven rotor*** ("rotor 1") *axially aligned with the* ***inflow axis***."

v. [11D] and [the magnetically driven rotor] being rigidly coupled and axially adjacent to a first magnetic device that is axially aligned with the inflow axis

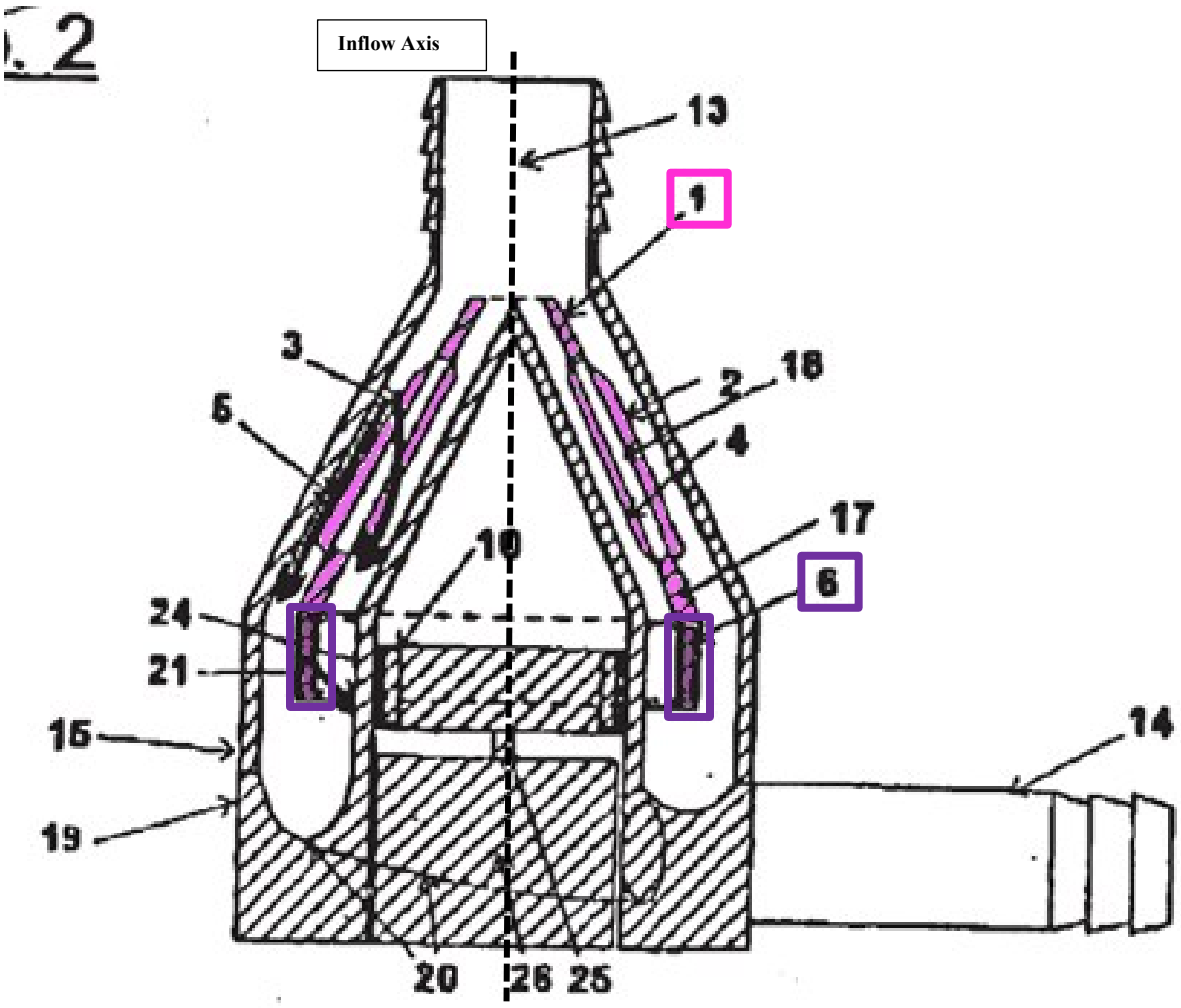
577. Schima discloses the **magnetically driven rotor** "*being rigidly coupled and axially adjacent to a* ***first magnetic device*** *that is axially aligned with the* ***inflow axis***."

578. For example, "[t]he rotor holds ['*coupled to*'] **rotor magnets 6** that preferably transfer rotation energy and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. As discussed with respect to element [11C], the "rotor 1" is a **magnetically driven rotor**. *See supra* Section X.D.1.iv. The "rotor magnets 6" which transfer rotation energy to the rotor 1 are a **first magnetic device** which is rigidly coupled to the **magnetically driven rotor** because the rotor magnets 6 are held by the rotor 1.

579. As will be discussed with respect to elements [11G], [11H], and [11I], the "drive" for the "*magnetically driven*" rotor can be an "electric motor 26 which

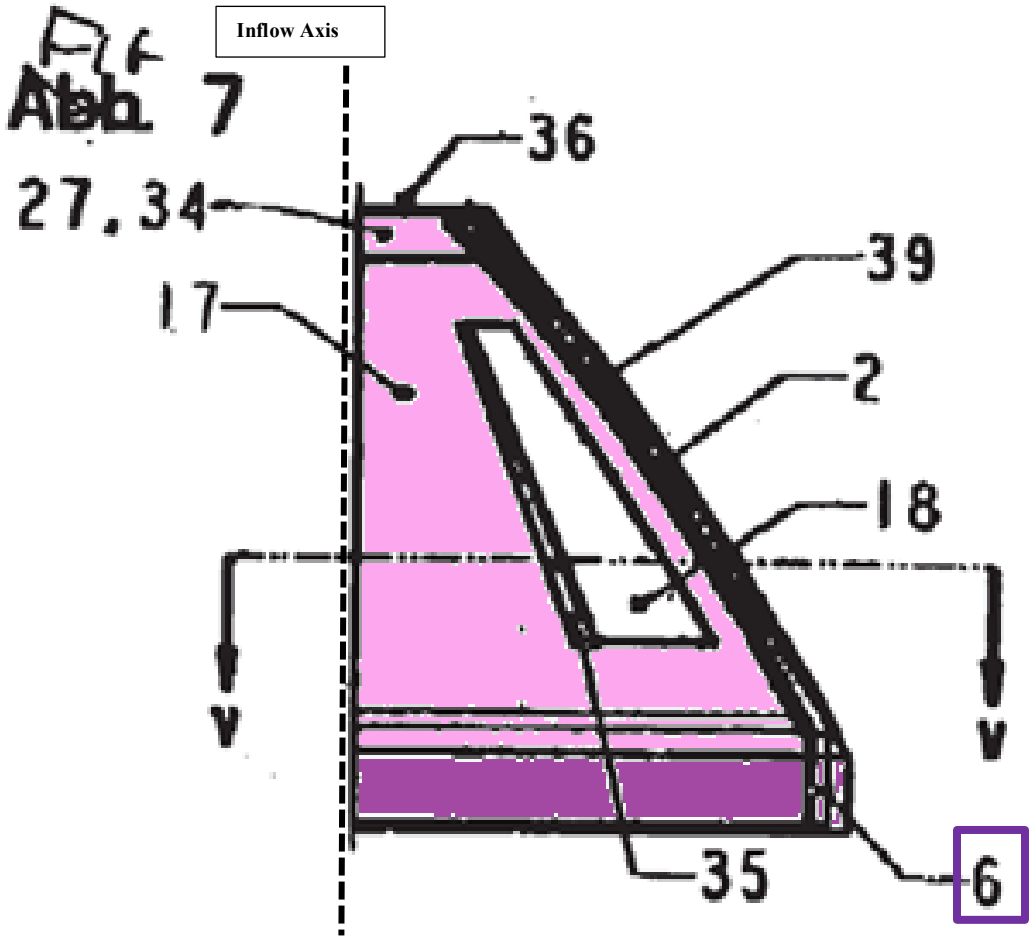
drives a rotating disk 24 with magnets 10 by means of a shaft 25," thereby creating a "magnetic force 21" with the "rotor magnets 6." Ex.1005, [0012], [0013]; *see infra* Sections X.D.1.viii, X.D.1.ix, X.D.1.x. In addition, as discussed for element [11C], the **inlet 13** "distributes the incoming liquid to both sides of the **rotor**" so as to "center[] the…rotor in the…housing" ['*axially aligned with the inflow axis*']. Ex.1005, [0012].

580. Figure 2 (annotated) of Schima illustrates that the rotor magnets 6 (**purple**) are rigidly coupled to the rotor 1 (**pink**), and each are "axially aligned" along the inflow axis (**black**):



Ex.1005, Fig. 2 (annotated); *see also* Fig. 1.

581. Figure 7 (annotated) of Schima shows a side view of the rotor 1 (**pink**) removed from the pump for clarity, which holds rotor magnets 6 (**purple**), which "can be formed by a continuous magnetic ring," where each component is "axially aligned" along the "inflow axis":



Ex.1005, Fig. 7 (annotated).

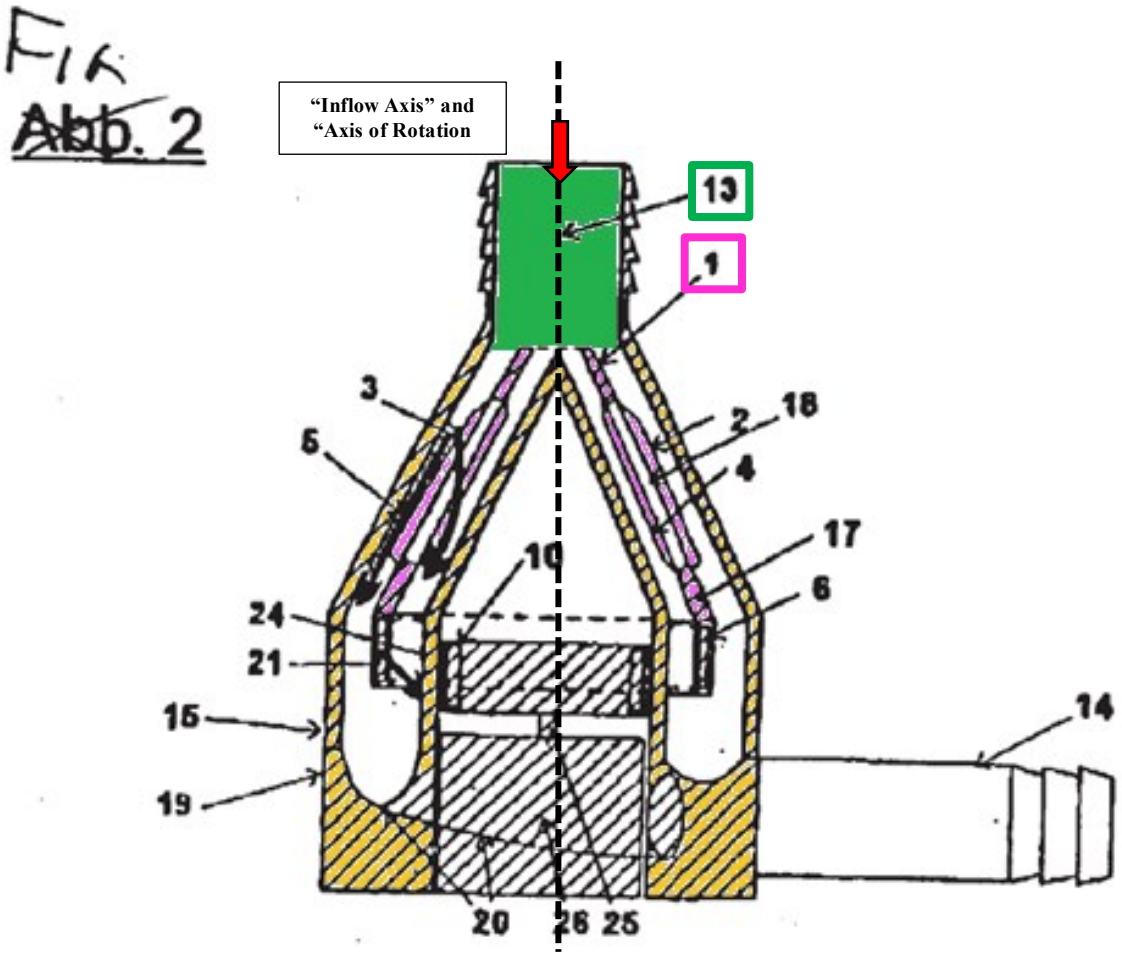
582. Accordingly, Schima discloses the **magnetically driven rotor** ("rotor 1") *"being rigidly coupled and axially adjacent to a* ***first magnetic device*** ("rotor magnets 6") *that is axially aligned with the* ***inflow axis***."

vi. [11E] the magnetically driven rotor and first magnetic device being rotatable about an axis of rotation aligned with the inflow axis to drive the blood flowing from the inflow tube

583. Schima discloses "*the **magnetically driven rotor** and **first magnetic device** being rotatable about an axis of rotation aligned with the **inflow axis** to drive the blood flowing from the **inflow tube***."

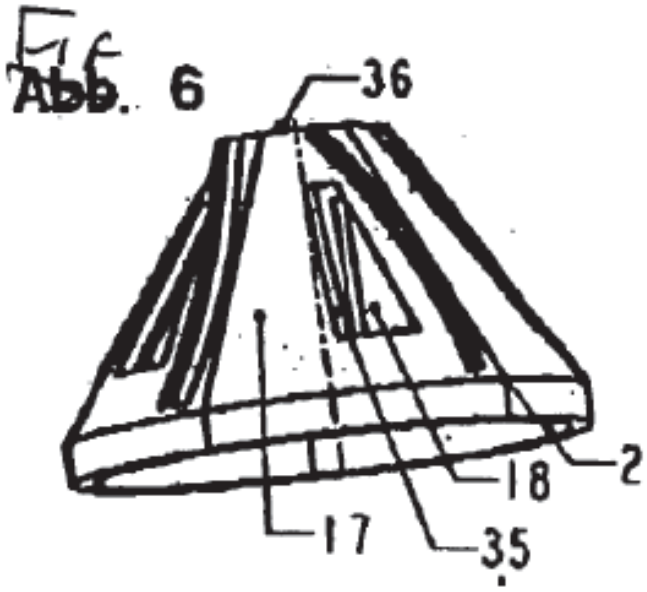
584. For example, Schima describes that the "hollow conical rotor 1 rotates in a pump housing 30 ['*rotatable about an axis of rotation*'] comprised of a housing lower part 19 with a conical middle part 16 and a hollow conical upper part 15 …" Ex.1005, [0012]. In addition, Schima states that the "flow" is "preferably axially against the conical upper surface of the middle part 16" of the pump housing 30." Ex.1005, [0012]. Further, the rotor 1 "holds rotor magnets 6 that preferably ***transfer rotation energy*** and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. Finally, "**inlet 13**" "distributes the incoming liquid to both sides of the rotor" ['*to drive the blood flowing from the inflow tube*'] such that there is "axial…stabilizing of the rotor." Ex.1005, [0012].

585. Figure 2 (annotated) of Schima illustrates that the rotor 1 (**pink**) and its rotor magnets 6 (**purple**) are rotatable about an axis of rotation that is aligned with the inflow axis (**black**) of the inlet 13 (**green**):



Ex.1005, Fig. 2; Fig. 1. Further, because Schima is a "centrifugal blood pump[]," the rotor is by definition "*rotatable about an axis of rotation.*"

586. Figure 6 of Schima also shows an oblique view of the "rotor 1" separated from the pump for clarity that shows the conical shape the rotor, which therefore is "*rotatable about an axis of rotation*":



Ex.1005, Fig. 6.

587. Accordingly, Schima discloses "*the **magnetically driven rotor*** ("rotor 1") *and **first magnetic device*** ("rotor magnets 6") *being rotatable about an axis of rotation aligned with the **inflow axis** to drive the blood flowing from the **inflow tube*** ("inlet 13")."

vii. [11F] a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis

588. Schima discloses "*a magnetic drive system comprising a second magnetic device axially aligned with the **inflow axis***."

589. Schima discloses that the "drive" for moving the rotor 1 can be "an electric motor 26 which drives a rotating disk 24 with ***magnets 10*** by means of a

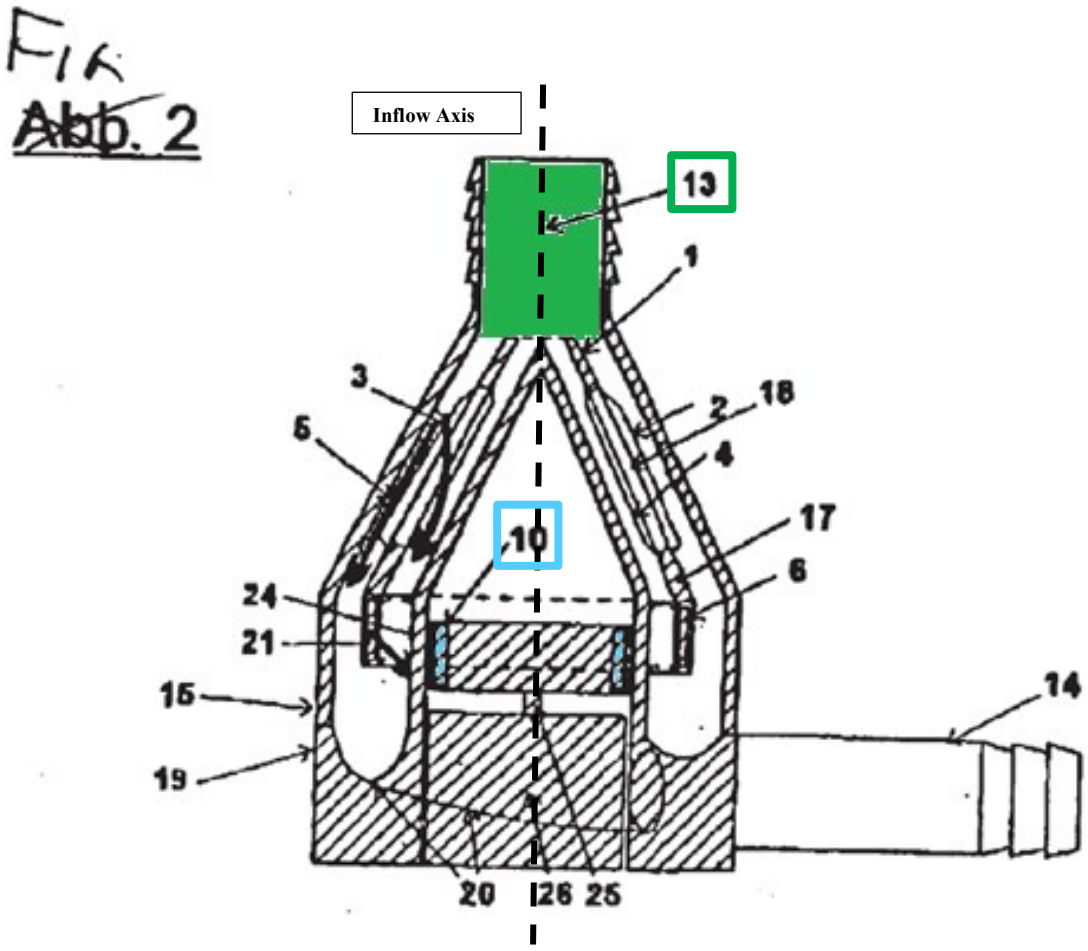
shaft 25. This embodiment has the advantage that no electrical energy is used to journal the rotor and as a result the axial offset of the disk 24 ensures an axial component for the magnetic force 21." Ex.1005, [0013]. The "magnets 10" within the rotating disk 24" driven by "electric motor 26" described in Schima are a ***magnetic drive system comprising a second magnetic device*** as recited in Claim 11.

590. As discussed above with respect to element [11C], for components to be "axially aligned" as recited in Claim 11, the components are configured such that they are colinear, or in the same line (or "axis" of rotation) in space. *See supra* Section X.D.1.ii. The ***heart assist pump device*** (e.g., "pump," Ex.1005, [0012]) described in Schima has an ***inflow tube*** (e.g., "inlet 13," Ex.1005, [0012]) through which blood flows to the ***magnetically driven rotor*** (e.g., "rotor 1," Ex.1005, [0012]), which is driven by the magnetic coupling between the ***first magnetic device*** (e.g., the "rotor magnets 6," Ex.1005, [0012]) and the ***second magnetic device*** (e.g., "magnets 10" within "rotating disk 24", Ex.1005, [0013]). *See infra* element [11G].

591. Each of the rotor 1, rotor magnets 6, and the magnets 10 within the rotating disk 24 driven by the electric motor 26 are "*axially aligned*" with the inflow axis of the inlet 13. Ex.1005, Fig. 2. Indeed, the pump described in Schima is a *centrifugal* pump (producing "centrifugal flow components," Ex.1005, [0012]) and by design, fluid enters a centrifugal pump along its axis towards the rotor and is

accelerated by centrifugal force toward the circumference of the impeller, collected by a volute and then discharged through an outlet.

592. Figure 2 (annotated) illustrates a cross-sectional view of the pump where the "magnets 10" (**light blue**) within rotating disk 24 are axially aligned with the inflow axis (**black**) of the inflow (**green**):



Ex.1005, Fig. 2 (annotated).

593. Accordingly, Schima discloses "***a magnetic drive system*** ("electric motor 26") ***comprising a second magnetic device*** ("magnets 10") *axially aligned with the* ***inflow axis***."

viii. [11G] and [the second magnetic device is] spaced apart from the magnetically driven rotor such that a wall of the one or more walls defining the chamber is positioned between the magnetically driven rotor and the second magnetic device

594. Schima discloses that the ***second magnetic device*** is "*spaced apart from the* ***magnetically driven rotor*** *such that* ***a wall*** *of the* ***one or more walls*** *defining* ***the chamber*** *is positioned between the* ***magnetically driven rotor*** *and the* ***second magnetic device***."

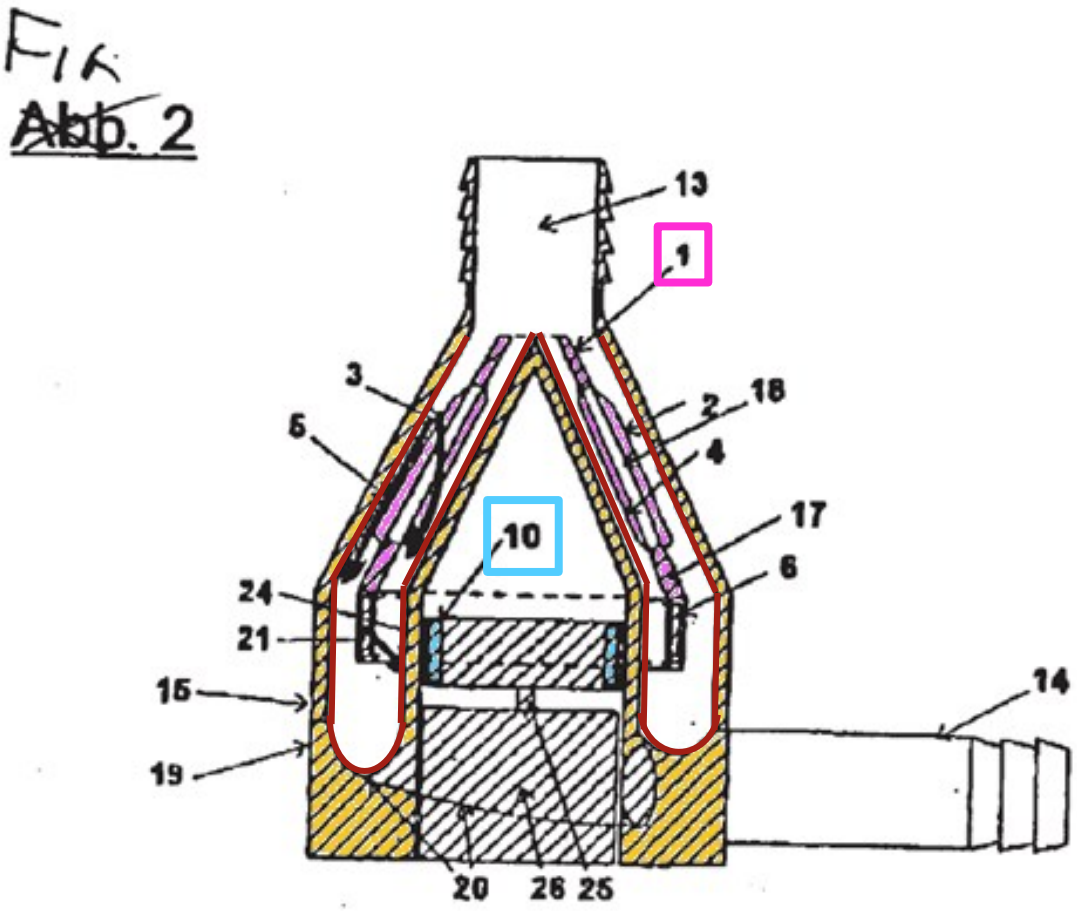
595. Schima describes that its invention relates to a rotary pump, that has a rotor 1 that is able to rotate "contact-free" ["*spaced apart*"] from the housing. Ex.1005, [0010], Abstract, Claim 1. Indeed, existing "conventional axle-type pumps" used at the time had an "axle…mounted in a standard seal, for example in a needle bearing in the pump chamber, so as to produce regions of high shear, friction and also often of low flow velocity near the axle." Ex.1005, [0003]. However, because of the seal required for those pumps, "low-flow and dead-water areas" could

create deposits, which is "referred to as thrombosis- or clot-forming." Ex.1005, [0002].

596. According to Schima, "therefore solutions have been suggested to provide pumps without axles or mechanical bearings." Ex.1005, [0004]. The invention in Schima "is characterized in that the rotor has flow-control surfaces for producing centrifugal flow components and flow components directed against the housing, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for contact-free ['*spaced apart*'] journaling and stabilizing of the rotor in the housing." Ex.1005, [0010].

597. As will be discussed for element [11G], this contact-free spacing is accomplished in Schima by the use of the "magnets 10" within "rotating disk 24" driven by electric motor 26, which drive rotation of rotor magnets 6 by the "magnetic force 21," without the need for contact between the magnetic devices. *See infra* Section X.C.1.viii. Thus, *the* ***second magnetic device*** ("magnets 10") are *spaced apart* such that a wall ("conical middle part 16") of the **one or more walls** ("housing 30") is positioned between the ***magnetically driven rotor*** ("rotor 1") and *the* ***second magnetic device*** ("magnets").

598. Figure 2 (annotated) of Schima illustrates a cross-sectional view of the pump having magnets 10 (**light blue**) being *spaced apart* from the rotor (**pink**) such that the "conical middle part 16" (not labeled) of the housing 30 (**orange**) is positioned between the rotor and the magnets 10:



Ex.1005, Fig. 2 (annotated); *see also* Fig. 1 embodiment labeling conical middle part 16.

599. Accordingly, Schima discloses that the ***second magnetic device*** ("magnets 10") is "*spaced apart from the* ***magnetically driven rotor*** ("rotor 1') *such that* ***a wall*** ("conical middle part") *of the* ***one or more walls*** ("housing 30") *defining* ***the chamber*** (space between "hollow conical upper part 15" and "the middle part 16") *is positioned between the* ***magnetically driven rotor*** *and the* ***second magnetic device***."

ix. [11H] the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor so as to magnetically drive rotation of the magnetically driven rotor relative to the one or more walls via a magneto coupling with the first magnetic device,

600. Schima discloses "*the* ***second magnetic device*** positioned *axially closer to the* ***first magnetic device*** *than to the* ***magnetically driven rotor*** *so as to magnetically drive rotation of the* ***magnetically driven rotor*** *relative to the* ***one or more walls*** *via a magneto coupling with the* ***first magnetic device***."

601. As discussed in Section VII.A.1, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating magnetic component to another rotating magnetic component via a magnetic field." *See supra* Section VII.A.1. For the purposes of my analysis in this Ground, I assume that the plain and ordinary meaning

is correct, and Patent Owner's apparent broader construction (in parallel litigation) of "magneto coupling" to also include not only a transfer of torque from one rotating magnetic component to another rotating magnetic component, but also to include "a transfer of torque from one *stationary* magnetic component (i.e., a stator) to another rotating magnetic component using an *electro*magnetic field," is incorrect. *See* Ex.1019.

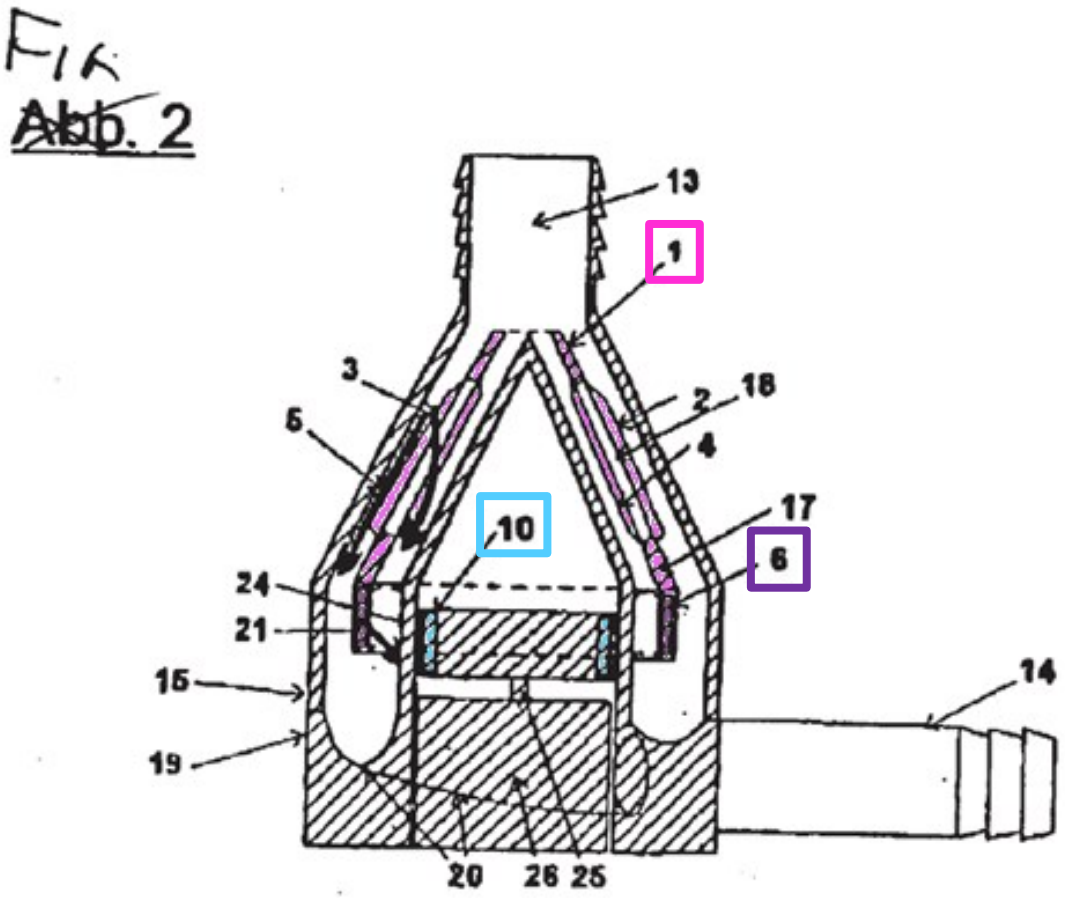
602. Schima, however, discloses "magneto coupling" under both constructions, thus the claims are invalid under any interpretation.

603. Based on my understanding of the plain and ordinary meaning of the term "magneto coupling," Schima describes a *magneto coupling* between the ***second magnetic device*** (e.g., "magnets 10" within "rotating disk 24," Ex.1005, [0013]) and the ***first magnetic device*** (e.g., the "rotor magnets 6" held by the rotor 1, Ex.1005, [0012]). For example, Schima discloses that the "rotor holds rotor magnets 6 that preferably **transfer rotation energy** and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. "As shown in FIG. 2, the drive can also be an electric motor 26 which drives a rotating disk 24 with magnets 10 by means of a shaft 25. This embodiment has the advantage that no electrical energy is used to journal the rotor and as a result the axial offset of the disk 24 ensures an axial component for the **magnetic force 21**." Ex.1005, [0013]; *see also* Ex.1005, Claim 9

(The pump according to one of the preceding claims, characterized in that in the region of the lower edge (41) the rotor (1) is provided with **a plurality of rotor magnets (6)** or a magnetic ring **that cooperates with magnets (10, 12)** in the housing (30) and/or with a magnetic drive.").

604. Thus, the ***second magnetic device*** (e.g., "magnets 10" within "rotating disk 24," Ex.1005, [0013]) is positioned to drive rotation of the ***magnetically driven rotor*** (e.g., "rotor 1," Ex.1005, [0012]), via the magneto coupling with the ***first magnetic device*** (e.g., the "rotor magnets 6" held by the rotor 1, Ex.1005, [0012]).

605. Figure 2 (annotated) illustrates that the "magnets 10" (**light blue**) with rotating disk 24 are positioned *axially closer* to the rotor magnets 6 (**purple**) than to the rotor 1 (**pink**) so as to magnetically drive rotation via a *magneto coupling* ("transfer rotation energy" using the "magnetic force 21"):



Ex.1002, Fig. 2 (annotated).

606. Note that Figure 2 is a cross-sectional view of the pump and the rotor holding rotor magnets 6 is understood to surround the inflow axis, essentially mirroring the rotation of the magnets 10 within rotating disk 24, which is rotated by electric motor 26.

607. Schima also discloses "*magneto coupling*" under the Patent Owner's apparent construction. To the extent that the term "*magneto coupling*" is interpreted broadly according to Patent Owner's apparent construction, Schima also discloses

an embodiment of the rotor 1 where the "rotor magnets work as shown in FIG. 1 with a stator 12 inside the housing lower part 19 having coils 9 creating a rotating magnetic field. An axial offset of the rotor magnets 6 and stator 8 causes the coupling force 21 to be effective at an angle and provide an axial component for additional stabilizing of the rotor 1." Ex.1005, [0012].

608. Thus, under either interpretation of the term, Schima discloses that a ***second magnetic device*** (either "magnets 10" in the first embodiment, or "stator 12" in the second embodiment), is positioned axially closer to the rotor magnets 6 to magnetically drive rotation of the rotor 1 via a magneto coupling.

609. Finally, Schima discloses that its "rotor 1 rotates in a pump housing 30" and thus the ***magnetically driven rotor*** is driven in rotation *relative to the* ***one or more walls***. Ex.1005, [0012].

610. Accordingly, Schima discloses that "*the* ***second magnetic device*** ("magnets 10") *positioned axially closer to the* ***first magnetic device*** ("rotor magnets 6") *than to the* ***magnetically driven rotor*** ("rotor 1") *so as to magnetically drive rotation of the* ***magnetically driven rotor*** *relative to the* ***one or more walls*** ("housing 30") *via a magneto coupling with the* ***first magnetic device***."

x. [11I] and a blood outflow port positioned such that the blood driven by the magnetically driven rotor exits the chamber in a direction substantially perpendicular to the inflow axis

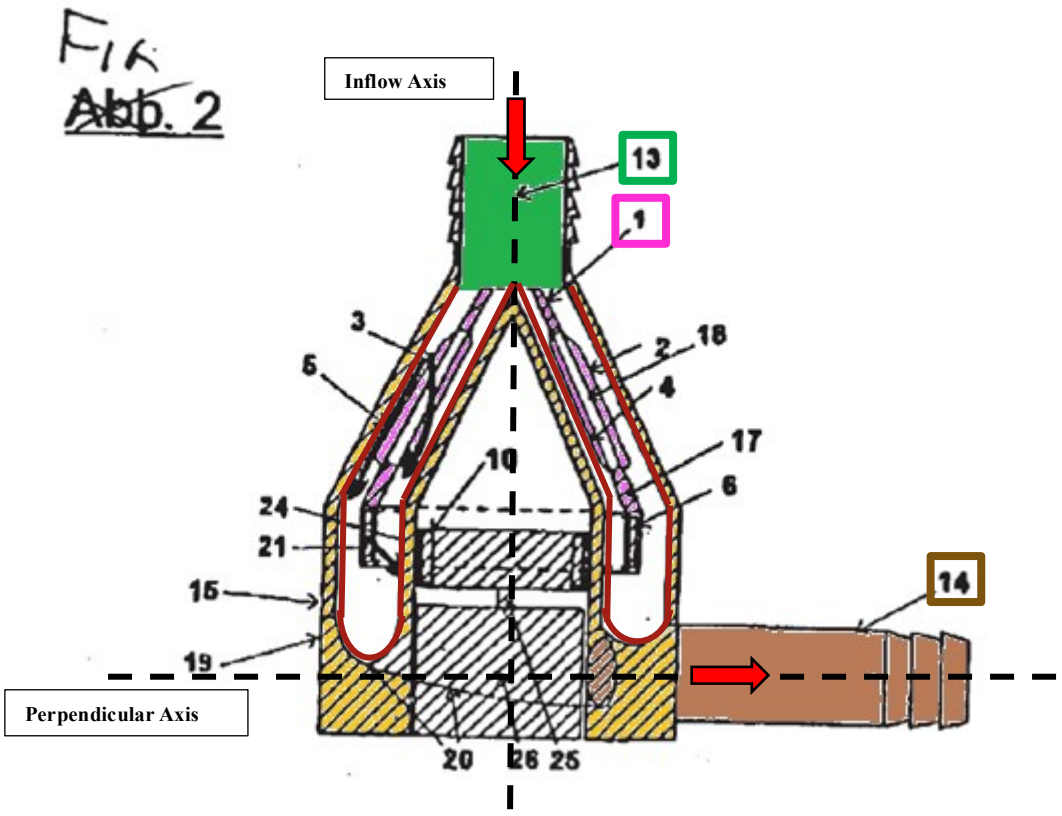
611. Schima discloses a "***blood outflow port*** *positioned such that the blood driven by the* ***magnetically driven rotor*** *exits the* ***chamber*** *in a direction substantially perpendicular to the* ***inflow axis***."

612. For example, Schima discloses that "[a] spiral-shaped outlet passage 20 in the lower housing part 19 leads to an outlet 14." Ex.1005, [0012]. Given the "spiral shape[]" of the outlet passage leading to the "outlet 14" as shown in Figure 2, the "outlet 14" is *a* ***blood outflow port*** *positioned radially adjacent the* ***magnetically driven rotor*** ("rotor 1").

613. I note that in parallel litigation, the Patent Owner has asserted the blood outflow port of the "HeartMate 3" is positioned such that blood driven by the accused magnetically driven rotor exits the chamber in the same way as described above in Schima. *See e.g.*, Ex.1019, at 8-9 (Complaint, Ex. 11). For the purposes of my analysis, I also map the limitation that the **blood outflow port** (e.g., "outlet 13") is positioned such that blood driven by the **magnetically driven rotor** (e.g., the "rotor 1") exits the **chamber** (space between "hollow conical upper part 15" and

"the middle part 16" formed by "housing 30") in a direction substantially perpendicular to the inflow axis in the same way.

614. Figure 2 (annotated) of Schima illustrates a cross-sectional view of the pump showing that the outlet 14 (**brown**) is positioned such that blood driven (**red** arrows) by the rotor 1 (**pink**) exits the space between conical middle part 16 and conical upper part 15 (**maroon**) of the "housing 30" (**orange**), in a direction substantially perpendicular from the inflow axis (**black**) of the inlet 13 (**green**) and of rotor 1:



Ex.1005, Fig. 2 (annotated). Thus, this cross-sectional view shows *that blood driven by the magnetically driven rotor* (**red** arrows moving in direction of centrifugal flow components 3 and 5) *is configured to exit* ***chamber*** (space between "hollow conical upper part 15" and "the middle part 16" formed by "pump housing 30") *in a direction substantially perpendicular to the inflow axis* (**black**).

615. Accordingly, Schima discloses a "***blood outflow port*** ("outlet 14") *positioned such that the blood driven by the* ***magnetically driven rotor*** ("rotor 1") *exits the* ***chamber*** (space between "hollow conical upper part 15" and "the middle part 16" formed by "pump housing 30") *in a direction substantially perpendicular to the* ***inflow axis***."

xi. [11J] wherein the magneto coupling orients the magnetically driven rotor so that both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor,

616. Schima discloses that "*the magneto coupling orients the* ***magnetically driven rotor*** *so that both the* ***magnetically driven rotor*** *and the* ***first magnetic device*** *remain spaced apart from the* ***one or more walls*** *by the blood in response to rotation of the* ***magnetically driven rotor***."

617. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls **by the blood** in response to rotation of the magnetically driven rotor" to mean that "in response to rotation of the magnetically driven rotor" refers to a hydrodynamic bearing such that "the blood" ***causes*** the "magnetically driven rotor and the first magnetic device" to "remain spaced apart from the one or more walls." *See* Section VII.A.2. For the purposes of my analysis in this Ground, I assume that the plain and ordinary meaning of this phrase is correct. *See* Ex.1019. However, whether this limitation is interpreted broadly (to include *exclusively* magnetic suspension) or narrowly (to require the blood flowing to cause suspension of the rotor), my interpretation would in any event be included within the Patent Owner's broader interpretation.

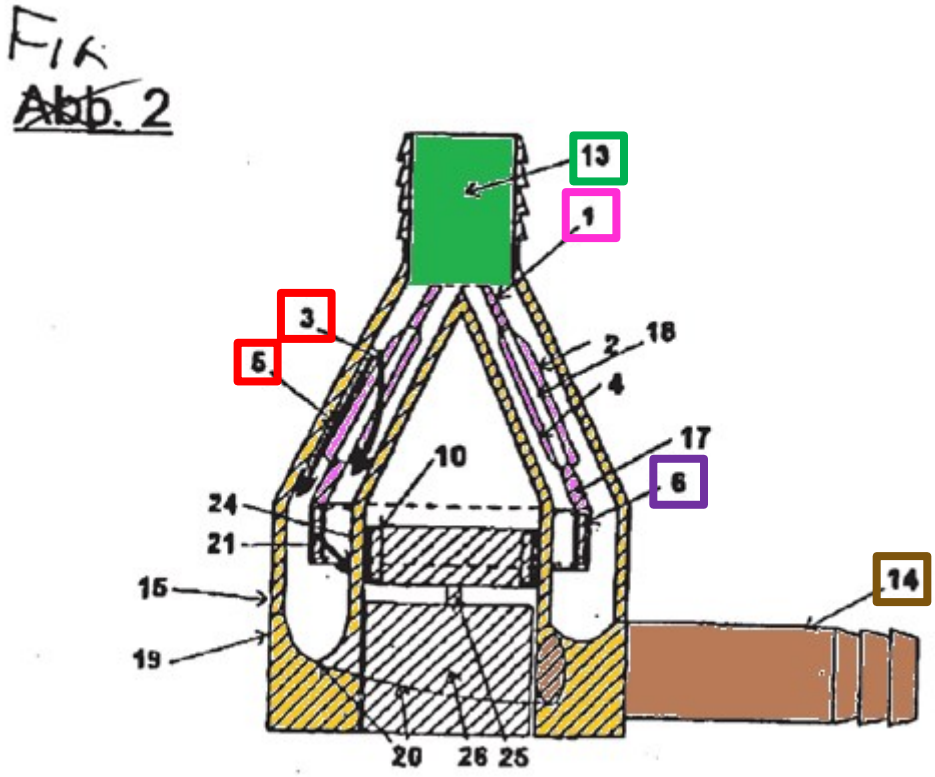
618. Accordingly, based on my understanding of this limitation, Schima discloses that the *magneto coupling orients the* ***magnetically driven rotor*** ("rotor 1") *so that, so that both the* ***magnetically driven rotor*** *and the* ***first magnetic device*** ("rotor magnets 6") *remain spaced apart from the* ***one or more walls*** ("housing 30") *by the blood in response to rotation of the* ***magnetically driven rotor***."

619. For example, Schima describes that its contact free journaling is achieved by a hydrodynamic bearing—"[t]he rotor 1 has as flow surfaces 2 and 4 vanes that produce **centrifugal flow components** 3 and flow components 5 directed against the housing. To this end these flow surfaces 2 and 4 are formed on a conical base 17 which has rotor openings 18 for flow to the inner vanes 4. Ex.1005, [0012]. *See also* Ex.1005, [0010] ("The invention is characterized in that the rotor has flow-control surfaces for producing **centrifugal flow components and flow components directed against the housing**, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for **contact-free journaling and stabilizing of the rotor in the housing.**"); Claim 1 ("… the flow components (**5**) directed against the housing serving mainly for **contact free journaling and stabilizing of the rotor in the housing**").

620. In particular, Schima discloses that "[t]his hollow conical **rotor 1 rotates** in a pump housing 30 ['*magneto coupling orients the magnetically driven rotor'*] comprised of a housing lower part 19 with a conical middle part 16 and a hollow conical upper part 15, **centering of the hollow conical rotor in the middle part 16** ['*both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls*'] of the housing lower part 19 being

effected by the flow components 5 directed against the housing [‘*by the blood’*], this flow being preferably axially against the conical upper surface of the middle part 16. This centering can however also be wholly or additionally effected by flow components (5) directed against the housing or centrifugally (3) against the hollow conical upper part 15.” Ex.1005, [0012].

621. Figure 2 (annotated) illustrates the centrifugal flow components 3 and 5 (**red**, included in the original Figure 2) of the blood flowing to the outlet 14 (**brown**), which are produced during by the rotation of the rotor 1 (**pink**), and directed against the housing 30 (**orange**) so as to create a “contact free journaling and stabilizing of the rotor in the housing”:



Ex.1005, Fig. 2 (annotated). Thus, this cross-sectional view shows that magneto coupling orients the magnetically driven rotor ("**rotor 1 rotates**") so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor and the first magnetic device are spaced apart from the one or more walls ("**housing 30**") by the blood flowing (**the "centrifugal flow components" 3 and 5**) so as to create a "contact free journaling and stabilizing" when the rotor 1 is in rotation. Ex.1005, [0010], [0012].

622. Accordingly, Schima discloses that "*the magneto coupling orients the **magnetically driven rotor*** ("rotor 1") *so that both the **magnetically driven rotor** and*

*the **first magnetic device*** ("rotor magnets 6") *remain spaced apart from the **one or more walls*** ("housing 30") *by the blood in response to rotation of the **magnetically driven rotor***."

xii. [11K] an external control unit configured to control operation of the second magnetic device based on a fixed value to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device,

623. While Schima does not explicitly disclose "*an **external control unit** configured to control operation of the **second magnetic device** based on a fixed value to thereby magnetically drive the rotation of the **magnetically driven rotor** via the magneto coupling with the **first magnetic device***" it would have been obvious to a POSITA at the time of the invention on February 27, 2007 to do so.

624. As I detail below in Section X.D.8 and incorporated by reference here, "*an external control unit configured to control operation of the second magnetic device*" is taught by Schima in view of Akamatsu-1999 because Akamatsu-1999 expressly discloses a "controller" to "operate[]" "the pump…at a fixed rotational speed" and that "[t]he pump was percutaneously driven." Ex.1006 at 5 and 7 (discussing plans to make the external controller "an implantable controller"). Figure

1 (annotated) of Akamatsu-1999 illustrates the connection of the external control unit (**lime green**) to the centrifugal pump (**blue**):

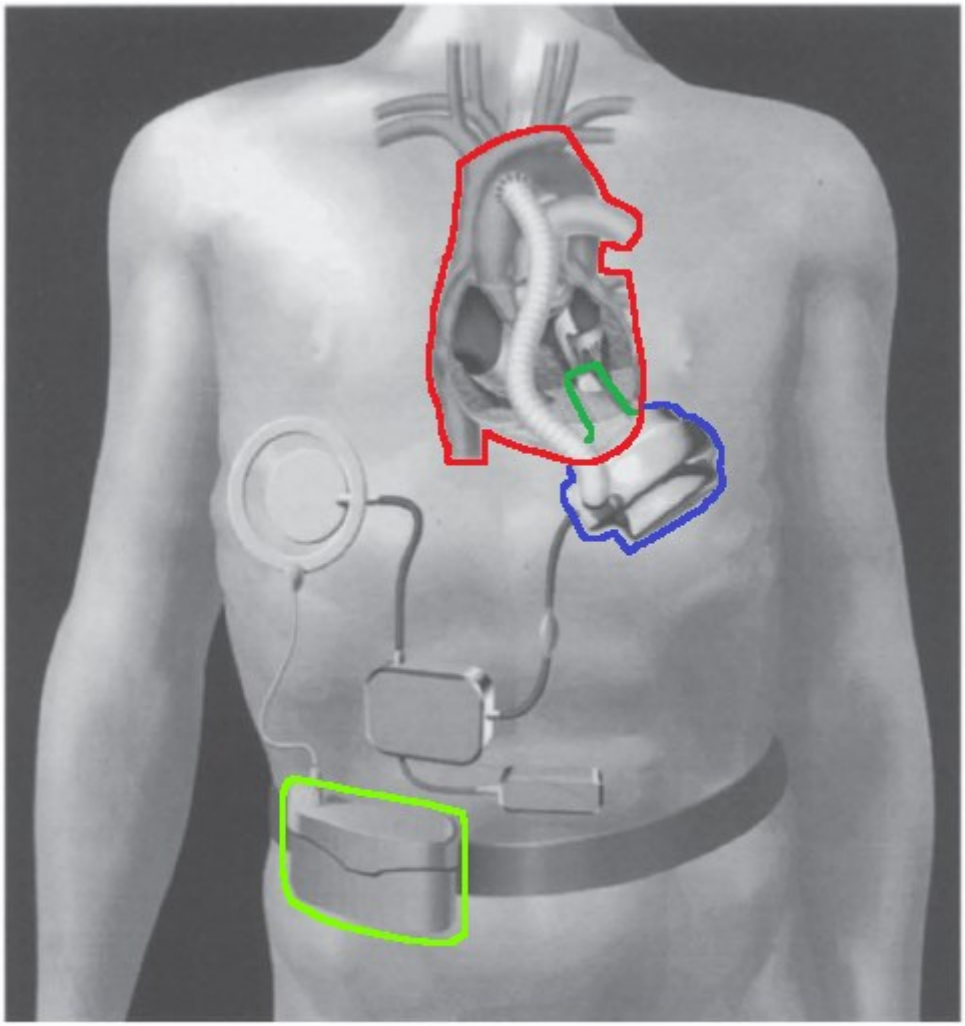


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated). It would have been obvious to a POSITA that Schima pump could be operated based on the teachings of Akamatsu-1999 such that Schima's "electric motor 26" and its "magnets 10" (i.e., "*the second magnetic*

device") could be connected to a "controller" (i.e., "*external control unit*") as taught by Akamatsu-1999. Thus, it would have been obvious to a POSITA that Schima's "electric motor 26" could be connected to and regulated by "*an external control unit*" for the reasons explained below. *See supra* Section X.D.8.

625. In addition, it would have been obvious to combine Schima's pump with Akamatsu-1999's ***external control unit***,…to *control operation of the* ***second magnetic device*** *based on a fixed value*. As demonstrated in Ground 3, Akamatsu-1999 discloses a "**controller"** to *control* the "**motor**" so that "[t]he pump was operated at a fixed rotational speed" ("*a fixed value*"). Ex.1006, 3-4.

626. Accordingly, Schima in view of Akamatsu-1999 renders obvious "*an* ***external control unit*** ("controller," Ex.1006, 3-4) *configured to control operation of the* ***second magnetic device*** ("magnets 10") *based on a fixed value* ("fixed rotational speed," Ex.1006, 3-4) *to thereby magnetically drive the rotation of the* ***magnetically driven rotor*** ("rotor 1") *via the magneto coupling with the* ***first magnetic device*** ("rotor magnets 6")."

2. Claims 12

a. [12] The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components.

627. Schima discloses claim 12. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 11. I incorporate that discussion into my analysis for claim 12.

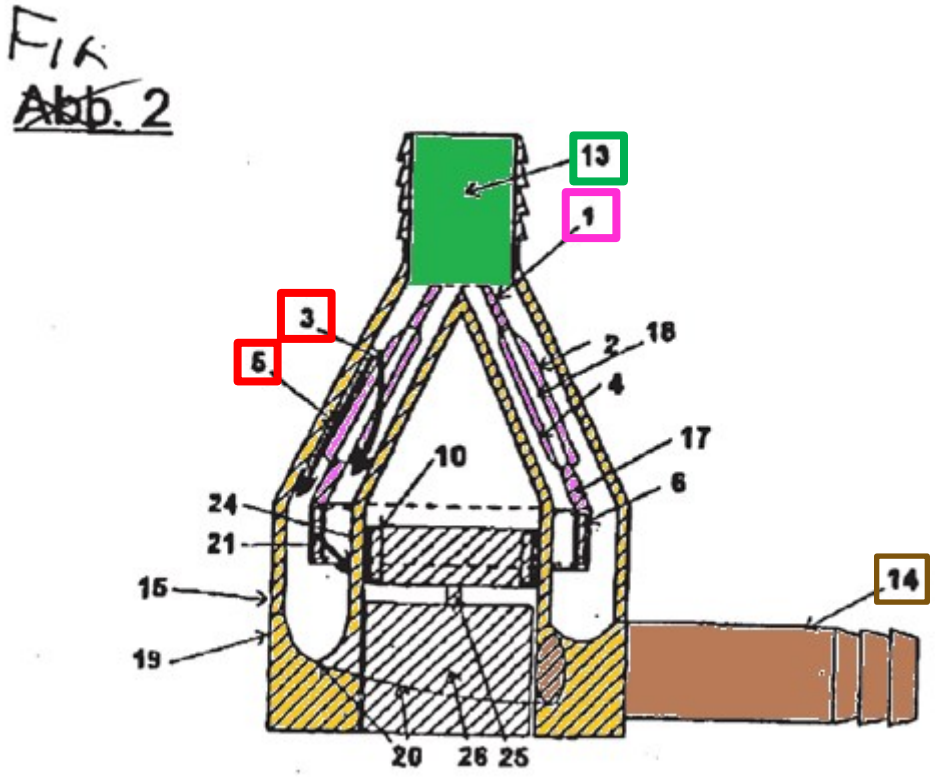
628. Schima discloses that "*the **magnetically driven rotor** includes a guide surface to produce centrifugal flow components*." As discussed with respect to element [11H], Schima discloses a magneto coupling between the **second magnetic device** (e.g., "magnets 10" within "rotating disk 24," Ex.1005, [0013]) and the **first magnetic device** (e.g., "rotor magnets 6," Ex.1005, [0012]) to drive rotation of the rotor 1 by the "magnetic force 21." *See supra* Section X.D.1.ix.

629. Schima further discloses that "[t]he rotor 1 has as **flow surfaces 2 and 4 vanes that produce centrifugal flow components 3 and flow components 5** directed against the housing." Ex.1005, [0012]; *see also* Ex.1005, [0010] ("The invention is characterized in that the rotor has flow-control surfaces for producing **centrifugal flow components and flow components directed against the housing**, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving

mainly for **contact-free journaling and stabilizing of the rotor in the housing**."), Claim 1 ("… the flow components (**5**) directed against the housing serving mainly for **contact free journaling and stabilizing of the rotor in the housing**").

630. A POSITA would understand the "flow surfaces 2 and 4 vanes" are "*guide surfaces*" as recited in Claim 12, that "*produce centrifugal flow components* 3 and flow components 5 directed against the housing." Ex.1005, [0012].

631. Figure 2 (annotated) illustrates the *centrifugal flow components* 3 and 5 (**red**, included in the original Figure 2) of the blood flowing from the inlet 13 (**green**) to the outlet 14 (**brown**), which are produced in response to the rotation of the magnetically driven rotor (**pink**), and directed against the housing 30 (**orange**) so as to create a "contact free journaling and stabilizing of the rotor in the housing":



Ex.1005, Fig. 2 (annotated).

632. Accordingly, Schima discloses that "*the* ***magnetically driven rotor*** ("rotor 1") *includes a guide surface* ("flow surfaces 2 and 4") *to produce centrifugal flow components* ("centrifugal flow components 3")."

3. Claims 14-15

a. [14], [15]

633. Schima discloses and/or renders obvious claims 14-15. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders

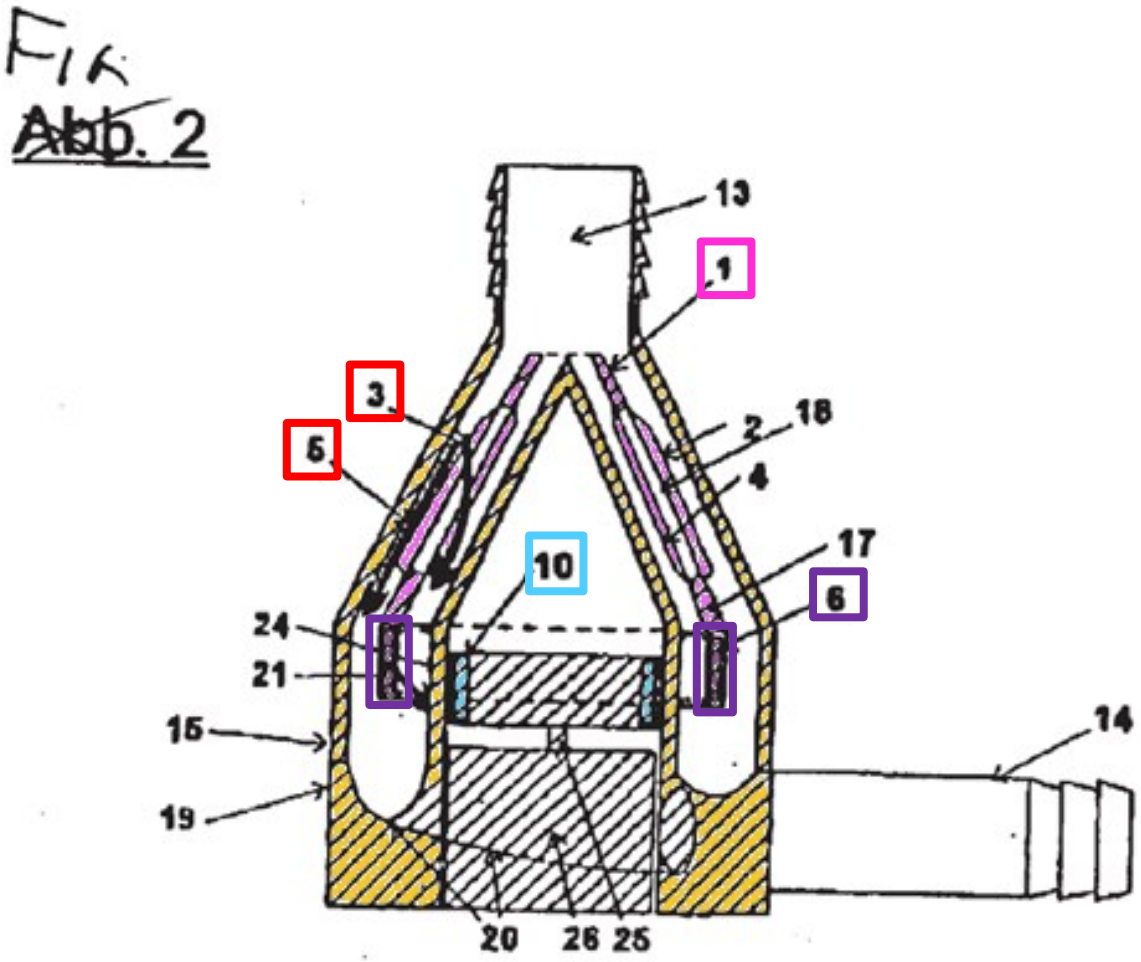
obvious each and every element of claim 11. I incorporate that discussion into my analysis for claim 14.

634. Schima discloses that "*the **one or more walls** and the **magnetically driven rotor** define a gap separating the **magnetically driven rotor** from the **one or more walls**, the gap configured to be occupied by the blood when the **second magnetic device** drives the rotation of the **magnetically driven rotor**.*" Schima further discloses that "*wherein the gap surrounds the **magnetically driven rotor**.*"

635. For example, Schima discloses that "[t]he rotor 1 has as **flow surfaces 2 and 4 vanes that produce centrifugal flow components 3 and flow components 5** directed against the housing." Ex.1005, [0012]; *see also* Ex.1005, [0010] ("The invention is characterized in that the rotor has flow-control surfaces for producing **centrifugal flow components and flow components directed against the housing**, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for **contact-free journaling and stabilizing of the rotor in the housing**."), Claim 1 ("… the flow components (**5**) directed against the housing serving mainly for **contact free journaling and stabilizing of the rotor in the housing**").

636. A POSITA would understand the "centrifugal flow components 3 and flow components 5 directed against the housing" create a *gap…occupied by the blood* between the "rotor 1" and the "housing 30." Ex.1005, [0012].

637. Thus, Schima discloses "contact-free" "journaling and stabilizing of the rotor in the housing" effectuated by the "centrifugal flow components 3 and 5" against the housing. Ex.1005, [0010], [0012]. In addition, Schima discloses the **inlet 13** "distributes the incoming liquid to both sides of the rotor and against the point of the cone-shaped middle part 16". Ex.1005, [0012]. Figure 2 illustrates the *gap* formed by the centrifugal flow components 3 and 5 (**red**, included in the original Figure 2) directed against the housing 30 (**orange**), and separating the housing from the rotor 1 (**pink**) when the magnets 10 (**light blue**) drives rotation of the rotor 1:



Ex.1005, Fig. 2 (annotated).

638. Accordingly, Schima discloses that "*the* ***one or more walls*** ("housing 30") *and the* ***magnetically driven rotor*** ("rotor 1") *define a gap separating the* ***magnetically driven rotor*** *from the* ***one or more walls*** ("housing 30"), *the gap configured to be occupied by the blood when the* ***second magnetic device*** ("magnets 10") *drives the rotation of the* ***magnetically driven rotor***." Schima further discloses that "*wherein the gap surrounds the* ***magnetically driven rotor***."

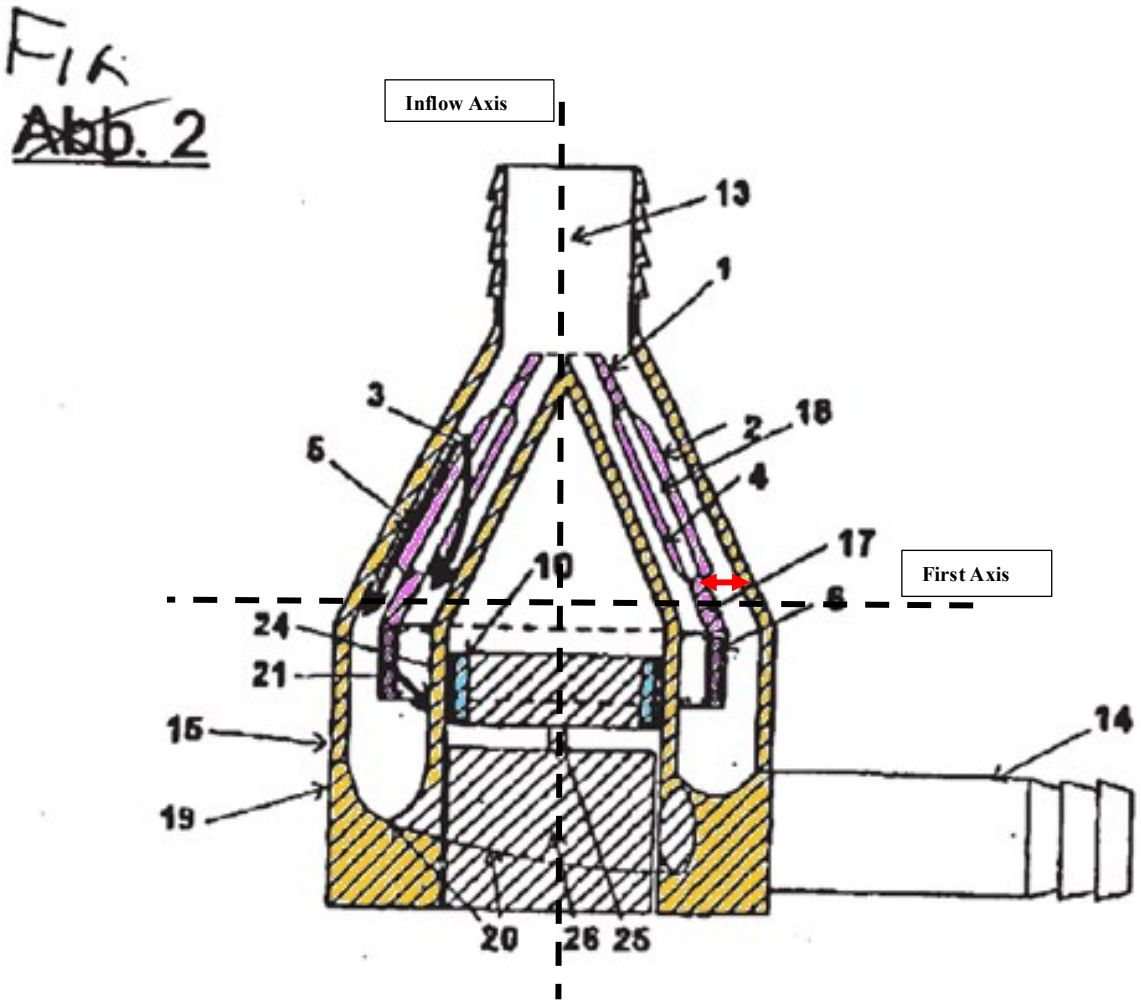
4. Claim 16

a. [16] The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis.

639. Schima discloses and/or renders obvious claim 16. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claims 11 and 14. I incorporate that discussion into my analysis for claim 16.

640. Schima discloses that "*at least part of the gap extends along a first axis substantially perpendicular to the* ***inflow axis***."

641. Schima discloses that the "contact-free" ['*gap*'] "journaling and stabilizing of the rotor in the housing" is a result of "centrifugal flow components 3 and flow components 5 directed against the housing" and therefore at least part of the *gap occupied by the blood* extends *along an axis substantially perpendicular to the* ***inflow axis*****"** in the direction of the housing to effectuate the "contact-free" "journaling." Ex.1005, [0012]. Figure 2 (annotated) illustrates that at least part of the *gap* created as a result of "centrifugal flow components 3 and flow components 5" directed against the housing (**orange**) extends along an axis (**black**, "first axis") substantially perpendicular to the inflow axis (**black**, "inflow axis"):



Ex.1005, Fig. 2.

642. Accordingly, Schima discloses that "*at least part of the gap extends along a first axis substantially perpendicular to the* ***inflow axis***."

5. Claim 18

a. [18] The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.

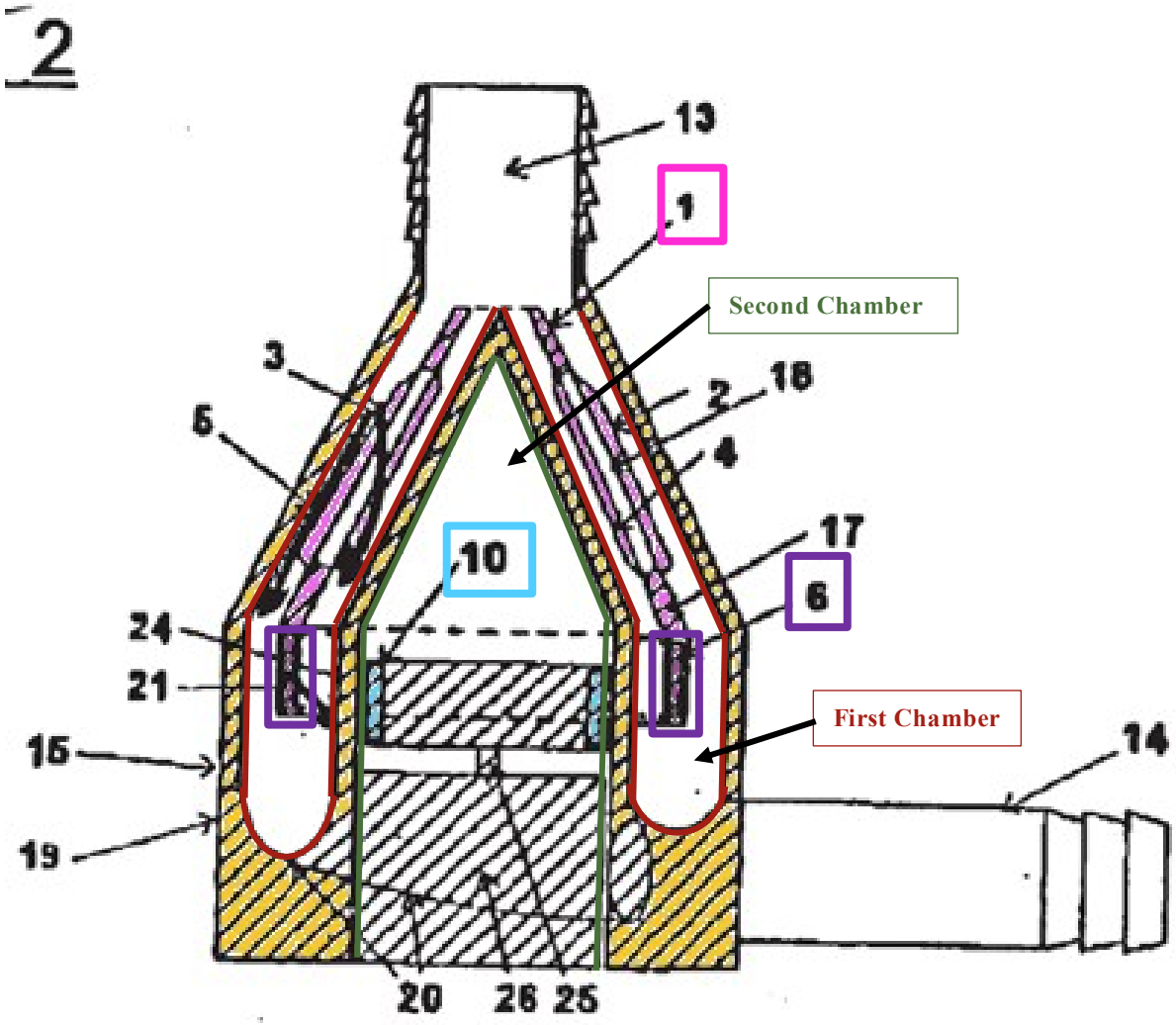
643. Schima discloses and/or renders obvious claim 18. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 11. I incorporate that discussion into my analysis for claim 18.

644. Schima discloses that "*the **chamber** is a **first chamber** within which the **magnetically driven rotor** is positioned, and the **magnetic drive system** is positioned within a **second chamber** sealed from the **first chamber**.*"

645. As demonstrated in [11B], the space between the "conical middle part 16 and a hollow conical upper part 15" of the "housing 30" define a **first chamber** within which **magnetically driven rotor** ("rotor 1") "rotates" and is "center[ed]." Ex.1005, [0012]. Schima further discloses the **magnetic drive system** (e.g., "electric motor 26" including "magnets 10") "resides inside the housing lower part 19" (**a second chamber**). Ex.1005, [0012], Fig. 2, Fig. 1.

646. Figure 2 (annotated) illustrates the "electric motor 26" including "magnets 10" (**light blue**) "resides inside the housing lower part 19" (**dark green**)

such that the motor is *sealed* from the space between the "conical middle part 16 and a hollow conical upper part 15" of the "housing 30" (**maroon**) in the which "rotor 1 [**pink**] rotates" with its rotor magnets 6 (**purple**):



Ex.1005, Fig. 2; *see also* Fig. 1 (showing "stator 12" resides "inside the housing lower part 19" in the same way).

647. Accordingly, Schima discloses that "*the **chamber*** (space between "conical middle part 16 and a hollow conical upper part 15") *is a **first chamber** within which the **magnetically driven rotor*** ("rotor 1") *is positioned, and the **magnetic drive system*** ("magnets 10"; "stator 12" Ex.1005) *is positioned within a **second chamber*** ("inside the housing lower part 19") *sealed from the **first chamber***."

6. Claim 19

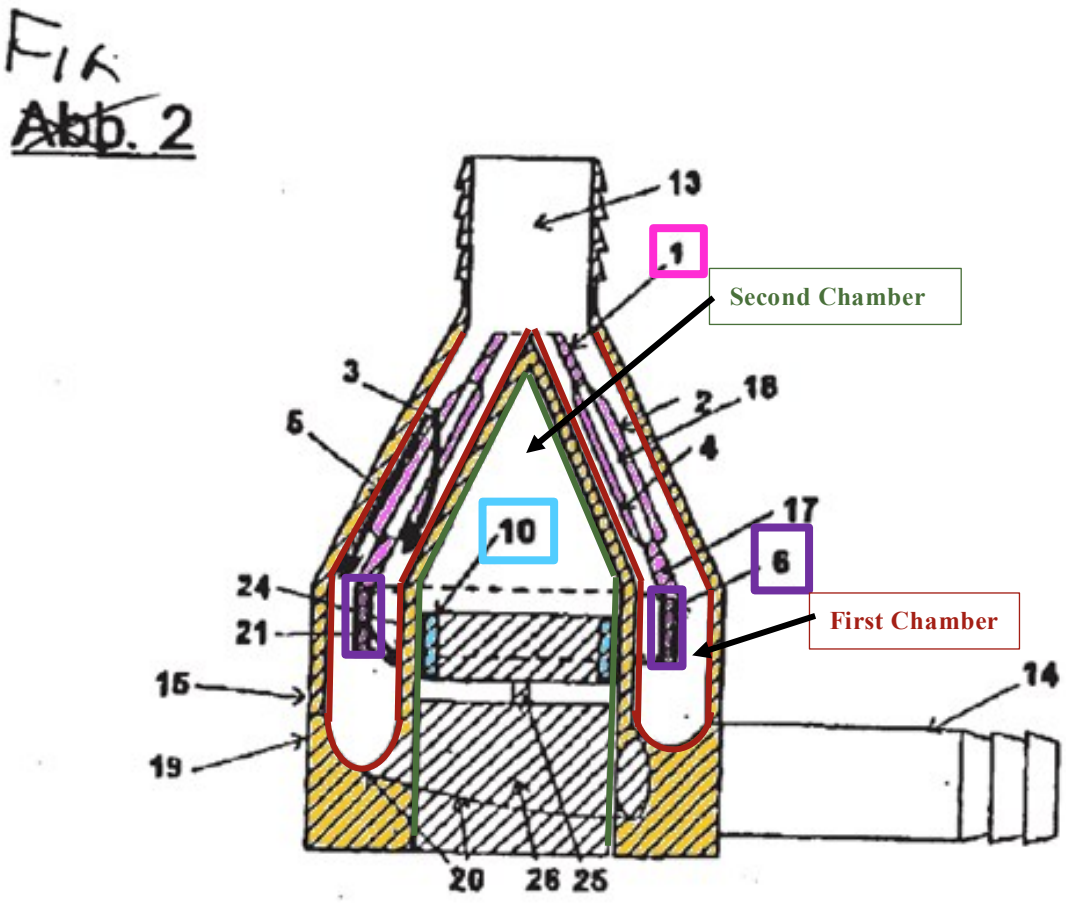
a. [19] The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber.

648. Schima in view of Akamatsu-1999 renders obvious claim 19. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claims 18 and 11. I incorporate that discussion into my analysis for claim 19.

649. Schima discloses that "*the wall of the **one or more walls** separates the **first chamber** from the **second chamber***."

650. For the same reasons discussed for [11B] and [18], the **wall** ("conical middle part 16") of the **one or more walls** ("housing 30") *separates* the **first chamber** (space between the "conical middle part 16 and a hollow conical upper part 15") from the "inside [of] the housing lower part 19" (**dark green**) in which the

"drive" components, e.g., magnets 10 or "stator 12" (**light blue**) reside (Ex.1005, [0011]-[0012]):



Ex.1005, Fig. 2 (annotated); *see also* Fig. 1 (showing "stator 12" resides "inside the housing lower part 19" in the same way).

651. Accordingly, Schima discloses that "*the wall* ("conical middle part 16") *of the* ***one or more walls*** ("housing 30") *separates the* ***first chamber*** (space between

the "conical middle part 16 and a hollow conical upper part 15") *from the* ***second chamber*** ("inside the housing lower part 19")."

7. Claims 1-2, 4-5, 7-8, 20

652. In my opinion, claim 1 and dependent claims 2, 4-5, 7-8, and 20 recite elements that are identical or substantially analogous to independent claim 11 and dependent claims 12, 14, 16, 18-19, and are therefore rendered obvious for the same reasons. For instance, the "surrounding rotor housing" of claim 1 is essentially the same as the "one or more walls at least partially defining a chamber" of claim 11. Similarly, the "inflow tube," "magnetically driven rotor," and "first magnetic device" are all axially aligned with the "inflow axis" of claim 11 in essentially the same way that they are all aligned with the "central axis" of claim 1. The below chart maps the limitations of these claims to their analogous claim limitations that I've analyzed above. *Supra* Section X.D.

Claims 1-2, 4-5, 7-8, 20	Analogous Claim Limitations	Analogous Sections of Ground 4
[1PRE]	[11PRE]	§X.D.1.i
[1A]	[11A]	§X.D.1.ii
[1B]	[11C]	§X.D.5
[1C]	[11B], [11E]	§X.D.1.iii; §X.D.1.vi

[1D]	[11D]	§X.D.1.v
[1E]	[11F]	§X.D.1.vii
[1F]	[11H]	§X.D.1.ix
[1G]	[11G], [14]	§X.D.1.viii; §X.D.3
[1H]	[11I]	§X.D.1.x
[1I]	[11J]	§X.D.1.xi
[1J]	[11K]	§X.D.1.xii
[2]	[12]	§X.D.2
[4]	[18], [19]	§X.D.1.iii; §X.D.5-9
[5]	[14], [18]	§X.D.7.i; §X.D.3; §X.D.5
[7]	[18]	§X.D.5
[8]	[19]	§X.D.6
[20]	[11K]	§X.D.1.i

i. *Claim 4*

653. Schima discloses each and every element of claim [4] for the same reasons discussed in [11B] and Claims [18] and [19]. *See supra* [11B], [18]-[19]. For the same reasons, Schima discloses "*a sealing wall positioned between the*

second magnetic device ("magnets 10" or "stator 12") *and the* ***magnetically driven rotor*** ("rotor 1")." Ex.1005, [0012].

ii. *Claim 20*

654. Schima in view of Akamatsu-1999 renders obvious each and every element of claim [20] for the same reasons discussed in [11K] and Claims [18] and [19]. *See supra* [11K], [18]-[19]. *See* elements [11K], [18]-[19]; *see also* Ground 3 (Akamatsu-1999), claim [20] (Section X.C.7.ii).

8. Motivation to Combine Schima with Akamatsu-1999

655. It would have been obvious to use Schima's pump in the configuration described by Akamatsu-1999 (i.e., "*an inflow tube … is insertable into a left ventricle*") with an *external control unit* disclosed in Akamatsu-1999 for the reasons explained below (hereinafter the Schima/Akamatsu combination).

a. The Akamatsu-1999 configuration ("*inflow tube … insertable into a left ventricle*")

656. Schima is silent regarding implanting its pump in the body. However, it would have been readily apparent to a POSITA for the reasons below that Schima's pump would be implanted in the same way as Akamatsu's T-ILVAS device—Schima's "inlet 13" of the pump would be *insert[ed] into a left ventricle* of the heart to collect blood from the left ventricle.

657. Akamatsu-1999 and Schima are analogous art to the 879 Patent for several reasons. First, Akamatsu-1999 and Schima are both directed toward the **same field of endeavor** of the 879 Patent—"to assist the performance of a heart with at least one pump that is formed as a rotary pump and driven via magneto coupling." Ex.1001, Abstract; 3:47-48 ("The embodiment to assist the performance of a heart according to the invention"). Both Akamatsu-1999 and Schima are within this same field of endeavor. Ex.1006, at 3 ("a [r]otary blood pumps, such as…the centrifugal pump, are being developed worldwide as implantable ventricular assist systems (VAS)"); Ex.1005, at [0001] ("The present invention relates to a rotary pump for moving blood and other shear-sensitive liquids with a rotor journaled hydraulically and, if necessary, magnetically in a housing.").

658. Second, Akamatsu-1999 and Schima are **reasonably pertinent to a problem** described by the 879 Patent: reducing mechanical stress on the blood during pumping. *See, e.g.*, Ex.1001, 2:23-28 ("In particular, the fluid flow which is improved by the pump is to be developed in a way in which the mechanical stress of highly sensitive fluids, such as blood for example, can be kept as low as possible and nevertheless the corresponding improvement to circulation can be ensured at desired locations"). Both Akamatsu-1999 and Schima aim to address this problem. Ex.1006, at 8 ("all of these pumps are subject to mechanical wear. Among these, the

use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump."); Ex.1005, [0002], [0009] ("The present invention relates to a rotary pump for moving blood and other shear-sensitive liquids with a rotor journaled hydraulically and, if necessary, magnetically in a housing.").

659. It would have also been obvious to combine Schima and Akamatsu-1999 by using Schima's pump in the configuration described in Akamatsu-1999 because to do so would have been the **arrangement of old elements.** In fact, Schima already discloses its pump design would be suitable for use with the arrangement of old elements taught by Akamatsu. For example, Schima states:

> Akamatsu et al (see e.g. *Artificial Organs* 1997, Vol. 21, No. 7, pp. 645-638) proposes a pump where the rotor of a centrifugal pump is driven from one side by a standard motor and is stabilized by a controlled electromagnet. This pump above all is of complex construction and there is a small gap between the rotor and the housing for proper electrical operation
>
> …
>
> The present invention therefore has the object of overcoming these disadvantages. Mechanical depositions, dead-water zones or zones of reduced flow velocity and

> small gaps are to be avoided. The number of parts should be small and the construction simple.

Ex.1005, [0004]. Schima cites to a 1997 article by Akamatsu et al. (Ex 1017), but this is substantively the same device I describe above in connection with Akamatsu-1999 (Ex.1006). Thus, Schima identified some "disadvantages" with the Akamatsu design, but none of these disadvantages relate to Akamatsu's implantation of "*an inflow tube of the heart assist pump device…inserted into a ventricle of the heart*" nor use of an "*external control unit*." Instead, Schima teaches that its pump could be used to "overcome" "dead-water zones…and small gaps" identified with Akamatsu configuration, but the Schima pump could otherwise be implanted and controlled in the same way as the Akamatsu configuration.

660. This configuration would have merely required arranging Schima's "inlet 13" as taught by the configuration of Akamatsu. For example, the "totally implantable left ventricular assist system (T-ILVAS)" described in Akamatsu-1999 includes an "inlet port" or "inflow conduit," which was "inserted into the left ventricle through a cuff sutured to the left ventricular apex ['*insertable into a left ventricle*']." Ex.1006 at 4. Figure 1 (annotated) illustrates the T-ILVAS, including the centrifugal pump (**blue**) delivered to a heart (**red**) such that the inflow conduit (**green**) of the T-ILVAS is "*insertable into a left ventricle*:"

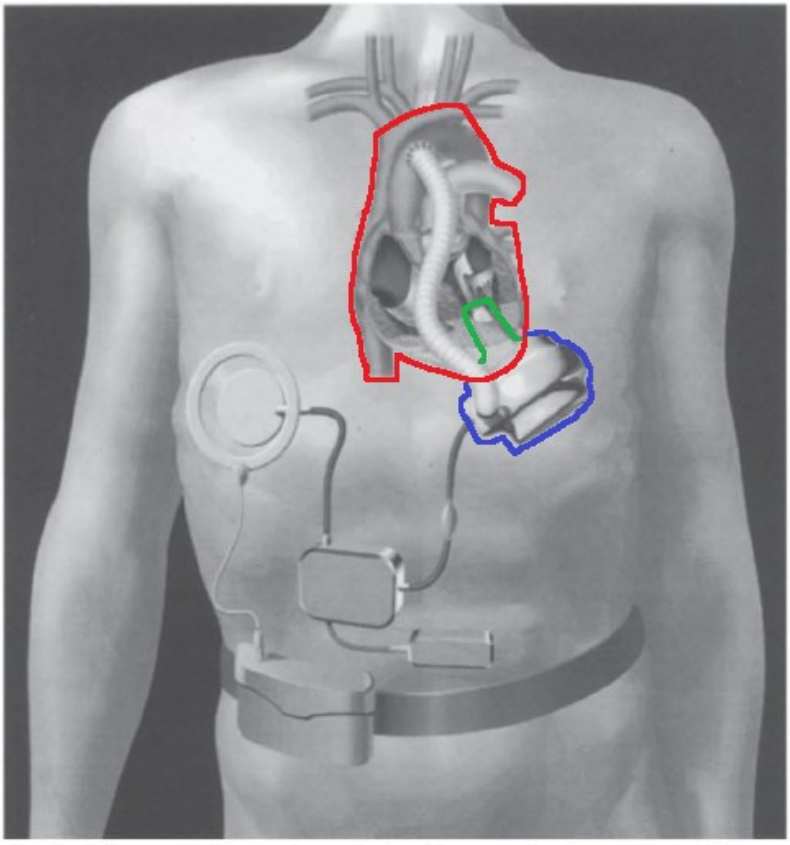


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated). Thus, the Schima pump would be placed in the configuration as taught by Akamatsu (i.e., delivering Schima's "inlet 13" so that it *is insertable into a left ventricle* in the same way as the Akamatsu-1999 inlet) with the pump performing the same function it has been known to perform (allow blood to flow from the heart through the *inflow tube* toward the *magnetically driven rotor*) and yielding no more than one would expect from such an arrangement (*assisting blood circulation of a heart*) as Schima demonstrates. Ex.1005, at [0009], [0010].

661. Such a combination would have **yielded predicable results**. A POSITA could have combined Schima's improved pump design with Akamatsu-1999's described configuration where the inlet tube is inserted in the left ventricle using known methods, and such a method would merely perform the same function—assisting with blood flow, which is entirely predictable.

662. A POSITA would have been **motivated to combine** Schima and Akamatsu-1999 so as to use Schima's pump and corresponding rotor design in the configuration shown in Akamatsu where the device is delivered to a heart for at least the reasons specifically discussed in Schima—the "[Akamatsu] pump above all is of complex construction and there is a small gap between the rotor and the housing" and those disadvantages can be "overcome[e]" by the rotor design of Schima's pump. Ex.1005, [0004], [0009] – [0010]. Thus, as Schima teaches, its pump would offer an advantageous design compared to the Akamatsu-1999 device because "[t]he number of parts [is] small and the construction simple," while being used to pump blood in the same way described in Akamatsu-1999. Ex.1005, [0009]. And because Schima did not identify any disadvantages with the Akamatsu-1999 configuration as implanted in the body, a POSITA would have been motivated to implant the Schima pump using the Akamatsu-1999 configuration.

663. Further, a POSITA would have had a **reasonable expectation of success** that the Schima/Akamatsu-1999 combination could deliver a pump to the left ventricle of a heart to improve blood flow to the aorta, because this design was well known and commonly used in the prior art. For example, Wampler-169 also employed a similar configuration as Akamatsu-1999 and reported that "[g]ood anatomic compatibility is possible since the [Wampler] pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm," so that when placed at the cardiac apex, an inlet tube and is placed into the apex of the left ventricle and an outlet to the aorta. Ex.1008, [0075] - [0076]; Fig 5. Indeed, these third-generation type devices could be "implanted with routine surgical techniques via left ventricular apical cannulation and anastomosis to the descending aorta" leading to the "successful performance" of the pump in the animal studies. Ex.1007 at 403, 405. Thus, the implantation method for using a pump to improve blood flow described in Akamatsu-1999 was well-known at the time and a POSITA would have had a reasonable expectation of success in implanting Schima's pump according to Akamatsu's teaching. As such, it would also have been straightforward for a POSITA to implant Schima's pump according to Akamatsu-1999's teaching by inserting the inlet into the left ventricle of the heart and directing the outlet to the aorta and that such a system would work.

b. The Akamatsu-1999 *external control unit*

664. Schima is silent regarding how its "electric motor" is operated and controlled. It would have been obvious to combine Schima and Akamatsu-1999 by using an *external control unit* as described in Akamatsu-1999 to control the operation of Schima's pump.

665. As an initial matter, Akamatsu-1999 discloses different pumps that use either an internal or an external control unit. The "Model I" and "Model II" pumps used a controller *exterior* to the body while future development plans for a "Model III" pump involved "an implantable controller." Ex.1006 at 4, 7 ("For the next phase, we have developed the Model III system, consisting of a prototype MSCP with a sensorless motor and dual electric wires and an implantable controller …"). For instance, Akamatsu-1999 further discloses that during testing of the Model 1 and Model II "[t]he pump was percutaneously driven," i.e., via an external electric wire inserted through the skin. Ex.1006 at 4, 5. Figure 1 (annotated) of Akamatsu-1999 illustrates the connection of the external controller (**lime green**) to the centrifugal pump (**blue**):

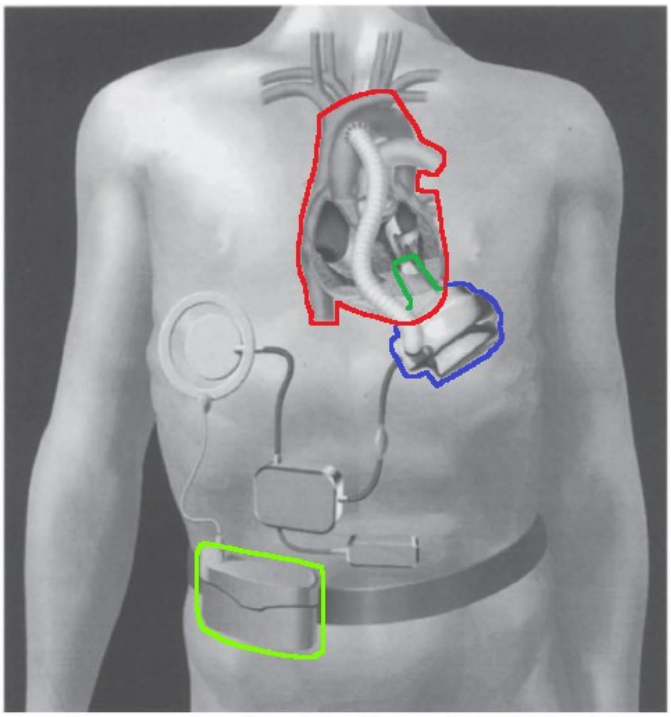


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated). Thus, the "controller" disclosed in Akamatsu-1999 is an ***external control unit*** as recited in Claim 11.

666. Using Akamatsu-1999's *external control unit* with the Schima pump would have been obvious, because, as explained above, Akamatsu-1999 and Schima are both directed toward the **same field of endeavor** of the 879 Patent and are **reasonably pertinent to a problem** described by the 879 Patent.

667. Further, using an *external control unit* as described in Akamatsu-1999 to control the operation of Schima's pump would have merely been the **arrangement of old elements**.

668. Akamatsu-1999 discloses the use of a "controller" (i.e., "*external control unit*") connected to the motor and the "the intra-housing connectors" by an "electric wire." Ex.1006 at 4 (describing that "an implantable controller" would be featured in future Model III devices but that Model I and II devices used external controllers), at 5 ("The pump was percutaneously driven"), Figs. 1-3. In addition, "[a]ortic pressure and pump flow rate were continuously measured throughout the experiments." Ex.1006 at 4, 5. Thus, Schima/Akamatsu combination would have used the same arrangement of elements by connecting the Akamatsu-1999 "controller" (i.e., "*external control unit*") to the Schima pump using an electric wire as taught by Akamatsu-1999.

669. Further, a POSITA would have known that using this arrangement of old elements—the Akamatsu-1999 "controller" (i.e., "*external control unit*") to control the operation of Schima's pump to "*regulat[e] operation*" of the "electric motor" in Schima's pump—would not have altered how Schima's pump works. Rather, the speed of the "electric motor 26" would necessarily be controlled by a user in some way in order to operate the pump properly. Ex.1005 at [0013], [0017]. Incorporating a "controller" with Schima's pump so that the pump is "percutaneously driven," i.e., via an electric wire through the skin, as described in Akamatsu-1999 would therefore be an obvious and easy to implement design choice

that would have required merely using a known external "controller" in a known way to control the speed of an electric motor. Ex.1006 at 4, 5.

670. Thus, this arrangement of old elements would have performed the same function they had been known to perform. The Akamatsu-1999 controller (i.e., "*external control unit*") is "*configured to control operation of the second magnetic device based on a fixed value.*" Ex.1006 at 4 ("The pump was operated at a fixed rotational speed."). The Schima "position sensors" would have determined "[t]he position (running characteristic) of the rotor," which is the same function the position sensors had in Akamatsu-1999 "to maintain the impeller free-floating at the center of the pump housing." Ex.1005 at [0017]; Ex.1006 at 4.

671. Further, this arrangement of old elements also would have yielded no more than one would expect from such an arrangement. The Akamatsu-1999 controller (i.e., "*external control unit*") yielded the ability to "operate[] "the pump…at a fixed rotational speed, i.e., "*control operation of the second magnetic device based on a fixed value to thereby magnetically drive the rotation of the magnetically driven rotor*." Ex.1006 at 4 ("The pump was operated at a fixed rotational speed.").

672. Moreover, a POSITA would have been **motivated to combine** the external control unit as described in Akamatsu to control the operation of Schima's

pump, because such a configuration was a routine and well-known way to control operation of a pump, as evidenced by pumps with sensors and external controllers like Akamatsu-1999 (Ex.1006 at 4), Wampler (Ex.1008 at [0070] ("it is contemplated that controller 59 and power supply 61 may be worn externally by the user …"); and Bourque 2001 (Ex.1007 at 403). For example, the Bourque 2001 external controller allows for "regulating operation" because it controls the pump speed (rpm) to be "gradually adjusted to maintain volume flow rates." Ex.1007 at 403.

673. Such a combination would have **yielded predicable results** because using *an external control unit configured to regulate operation of a second magnetic device* was well known in the field of heart assist pumps at the time of the invention. A POSITA could have combined Akamatsu-1999's "*external control unit*" with Schima's pump design using known methods, such as by connecting an "electric wire" to the pump "percutaneously" as described in Akamatsu-1999, and such a method would merely perform the same function—"*control operation*," and these known methods were entirely predictable. *See* Akamatsu-1999, (Ex.1006 at 5 ("The pump was percutaneously driven.")); Wampler-169 (Ex.1008 at [0070] ("a brushless rotor motor 53…[is] interconnected by means of percutaneous wires to a controller 59")); Bourque 2001 (Ex.1007 at 401, 405 ("The pumps…had

percutaneous leads" and "an electronic cable to be exteriorized percutaneously")). While Akamatsu-1999 uses position sensors for a purpose not needed in Schima, the results would have predictably been the same to provide the position and distance of the rotor from the housing to the controller in order regulate the speed of the motor so as to maintain contact-free rotation as described in Schima.

674. A POSITA would have had a **reasonable expectation of success** because the use of external "controllers" in the field of heart assist pump devices was well known. For example, Bourque-2001 describes that in the *in vivo* testing of the HeartMate III, "electronics for power and control of the LVAD and for data acquisition resided on a shelf" and the test subjects were "continuously monitored for…certain parameters such as arterial pressure, pump and pulmonary artery volume flow rates, pump speed, and blood chemistry (including plasma free hemoglobin) were periodically recorded." Ex.1007 at 403. Likewise, Wampler-169 describes a rotary blood pump that includes a "controller 59" that "may include circuitry as simple as variable voltage or current control, manually adjusted or programed to determine the running rate of [the] pump" and may also "have interactive and automatic capabilities." Ex.1008, [0071]. For example, Wampler's "controller 59" may be "interconnected to sensors…to tailor operation of the pump to the user's physical activity and condition." Ex.1008, [0071]. Thus, implementing

the combination would have been straightforward and well within the ordinary skillset of a POSITA at the time.

675. Moreover, using Akamatsu's controller (i.e., "*external control unit*") with Schima's pump design would have been **obvious to try**. At the time of the claimed invention, it was within the general knowledge of a POSITA that the location of an LVAD's controller presented a finite number (i.e., two) options—a controller could be external or implanted (i.e., internal). Both techniques were well-known—in fact, Akamatsu-1999 discloses a Model III pump with inclusion of "an implantable controller" and a Model II pump using an external controller. Ex.1006 at 7 ("For the next phase, we have developed the Model III system, consisting of a prototype MSCP with a sensorless motor and dual electric wires and an implantable controller …"). In using an external controller, a POSITA would have had a reasonable expectation of success in view of the numerous other similar devices that also employed an external controller. *See* Ex.1006 at 7; Ex.1007 at 203 ("control of the LVAD…resided on a shelf"); Ex.1008 at [0070] ("it is contemplated that controller 59 and power supply 61 may be worn externally by the user …").

XI. CONCLUSION

I declare 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 that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1101 of Title 18 of the United States Code.

Dated: Friday, November 22, 2024
At: Aarhus, Denmark

Peter Crosby

Peter Crosby