UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,

Petitioner,

v.

MIRACOR MEDICAL SA,

Patent Owner.

IPR2025-00112
Patent 11,351,357

DECLARATION OF BORIS LESCHINSKY IN SUPPORT OF PATENT OWNER MIRACOR MEDICAL SA'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW

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LIST OF EXHIBITS

Exhibit No.	Description
2001	Certification of Todd G. Vare
2002	Corrected Certification of Todd G. Vare
2003	Kenneth K. Liao et al., *End-Stage Congestive Heart Failure in the Adult Population: Ventricular Assist Devices*, Handbook of Cardiac Anatomy, Physiology, and Devices 725–732 (2015)
2004	Howard M. Loree II et al., *The HeartMate III: Design and In Vivo Studies of a Maglev Centrifugal Left Ventricular Assist Device*, 25 Artificial Organs 386–391 (2001)
2005	Greg W. Burgreen et al., *Computational Fluid Dynamics Analysis of a Maglev Centrifugal Left Ventricular Assist Device*, 28 Artificial Organs 874–880 (2004)
2006	David J. Farrar et al., *Design Features, Developmental Status, and Experimental Results With the Heartmate III Centrifugal Left Ventricular Assist System With a Magnetically Levitated Rotor*, American Society of Artificial Internal Organs (ASAIO) Journal 310–315 (2007)
2007	Abbott, *A Father of HeartMate 3 Wants A Bigger Family*, available at https://www.abbott.com/corpnewsroom/products-and-innovation/a-father-of-heartmate-3-wants-a-bigger-family.html (December 16, 2021)
2008	Kevin Bourque et al., *Design Rationale and Preclinical Evaluation of the HeartMate 3 Left Ventricular Assist System for Hemocompatibility*, American Society of Artificial Internal Organs (ASAIO) Journal 375–383 (2016)
2009	U.S. Patent No. 10,500,321 to Bourque (issued December 10, 2019)

Exhibit No.	Description
2010	American Heart Association News, *The past, present and future of the device keeping alive Carew, thousands of HF patients*, available at https://www.heart.org/en/news/2018/06/13/the-past-present-and-future-of-the-device-keeping-alive-carew-thousands-of-hf-patients (June 13, 2018)
2011	Chart of Petitioner's Reliance on Pleadings from Parallel Litigation for Claim Construction
2012	Reserved
2013	Donald Esmore et al., *VentrAssist Left Ventricular Assist Device: Clinical Trial Results and Clinical Development Plan Update*, 32 European Journal of Cardio-Thoracic Surgery 735–744 (2007)
2014	Transcript of Deposition of Peter Crosby (September 4, 2025)
2015	Declaration of Boris Leschinsky
2016	Curriculum Vitae of Boris Leschinsky
2017	Declaration of Dr. Robert Gallegos
2018	Curriculum Vitae of Dr. Robert Gallegos
2019	Richard Wampler et al., *A Sealless Centrifugal Blood Pump with Passive Magnetic and Hydrodynamic Bearings*, 23 Artificial Organs 780–784 (1999)
2020	Trever Symalla et al., *Choosing the Appropriate Left Ventricular Assist Device for Your Patient*, 36 (Suppl 2) Indian Journal of Thoracic and Cardiovascular Surgery S256–S264.
2021	Milad Hosseinipour et al., *Rotary Mechanical Circulatory Support Systems*, 4 Journal of Rehabilitation and Assistive Technologies Engineering, 1–24 (2017)

Exhibit No.	Description
2022	Martin Stoiber et al., *A Passive Magnetically and Hydrodynamically Suspended Rotary Blood Pump*, 33 Artificial Organs 250–257 (2009)

CHALLENGED CLAIMS

Claim No.	Claim Language
[1PRE]	A system for assisting the blood circulation of a heart, comprising:
[1A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path;
[1B]	a magnetically driven rotor axially aligned with the inflow tube,
[1C]	and being rotatable within a surrounding rotor housing to act upon blood flowing from the inflow tube toward the magnetically driven rotor,
[1D]	the magnetically driven rotor being rotatable about a central axis
[1E]	and [the magnetically driven rotor] being rigidly coupled to a first magnetic device
[1F]	that [the first magnetic device] is located within the surrounding rotor housing
[1G]	wherein both the magnetically driven rotor and the first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor;
[1H]	a magnetic drive system comprising: a second magnetic device axially aligned with the central axis of the magnetically driven rotor
[1I]	and [the second magnetic device] spaced apart from the magnetically driven rotor such that a wall of the surrounding rotor housing is positioned between the magnetically driven rotor and the second magnetic device,
[1J]	the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor so as to provide a magneto coupling with the first magnetic device to drive rotation of the magnetically driven rotor;

Claim No.	Claim Language
[1K]	a blood outflow port positioned radially adjacent the magnetically driven rotor such that blood driven by the magnetically driven rotor is configured to exit the surrounding rotor housing in a direction substantially perpendicular from the blood inflow path and the central axis of the magnetically driven rotor,
[1L]	wherein the magneto coupling orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor is spaced apart from the surrounding rotor housing by the blood flowing in the gap and to the blood outflow port; and
[1M]	an external control unit configured to regulate operation of the second magnetic device, the external control unit connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device.
[2]	The system of claim 1, wherein the magnetically driven rotor comprises guide surfaces to produce centrifugal flow components.
[3]	The system of claim 2, wherein the first magnetic device rotates together with the magnetically driven rotor relative to the surrounding rotor housing.
[10]	The system of claim 1, wherein the magnetically driven rotor is positioned axially side-by-side with the first magnetic device and rotates together with the first magnetic device within the surrounding rotor housing.
[11]	The system of claim 10, further comprising one or more sensors that deliver feedback signals to the external control unit.
[14]	The system of claim 1, wherein the external control unit is configured to regulate operation of the second magnetic device based on a fixed control value.

Claim No.	Claim Language
[17]	The system of claim 1, wherein the heart assist pump device is a catheter device.

I, Boris Leschinsky, declare as follows:

I. INTRODUCTION

1. I have been retained as a technical expert by counsel for Patent Owner Miracor Medical SA ("Miracor") to address certain issues regarding U.S. Patent No. 11,351,357 ("the '357 patent") to Mohl et al.

2. I am being compensated at my usual consulting rate for time spent working on issues in this matter. I am also being reimbursed for reasonable and customary expenses associated with my work on this matter. My compensation does not depend on the outcome of this matter or the opinions I express.

3. If called as a witness, I could and would testify completely and truthfully with regard to the matters set forth herein.

II. BACKGROUND AND QUALIFICATIONS

4. I am an engineer and inventor with over 35 years of experience in the development of medical devices. I have extensive experience in cardiovascular and endovascular devices, with a focus on heart assist devices, percutaneous catheters, balloons, vascular closure products, and delivery systems. I have a comprehensive understanding of surgical and interventional treatments of various heart diseases and deep knowledge of cardiovascular anatomy, physiology, and pathophysiology. I have invented and designed a variety of heart assist devices, including

implantable and short-term heart assist products. Examples of such circulatory assist devices that I have worked on include intra-aortic balloon pumps, expandable intravascular blood pumps, and direct cardiac compression heart assist devices.

5. I earned a Master's degree in Mechanical Engineering from Moscow State Technical University in 1987. I was recruited out of college by the Scientific Institute for Transplantology and Artificial Organs in Moscow, where I became a lead biomedical engineer in their artificial heart laboratory. While at the Scientific Institute, I developed new concepts for centrifugal blood pumps, including new concepts for impellers aimed at improving hemocompatibility and reducing hemolysis. I have also worked on prototypes for several artificial heart devices, including their bench testing and chronic studies evaluation, in large animals. I further participated as a member of a surgical team implanting various VADs, and worked on the clinical trials of the first Russian artificial heart.

6. From 1990 through 2009, I worked in various positions with Datascope Corp., a diversified medical device company based in Montvale, NJ with major product lines in intra-aortic balloon pumping, patient monitoring, vascular sealing, and vascular grafts. I began my tenure with Datascope as an Engineer and was eventually promoted to Scientific Director and then corporate

Vice President, Technology. As Scientific Director, I was responsible for advanced development of new generations of products primarily in the fields of counterpulsation, vascular closure, and endovascular aneurysm treatment devices. As Vice President, Technology, I was responsible for directing the research and development activities of all four of the company's divisions. At Datascope, among many other technologies that I developed, I invented a key concept for a new catheter-based heart assist device combining low-profile insertion with full-flow assist capability. The Percutaneous Heart Assist (PHP) project was a result of 7 years of development and pioneered a concept of an expandable intravascular blood pump designed to be implanted in a compact state to allow for a percutaneous insertion, and yet expand *in-vivo* to support full flow for unloading the heart of a patient. This project was bought by Abbott in 2016.

7. From 2009 to 2013, I worked as the Chief Technology Officer of Cerus Endovascular Inc., where I was responsible for leading a start-up team in developing proprietary, non-invasive devices for treating brain aneurysms.

8. In 2009, in addition to working at Cerus Endovascular, I co-founded LifeCuff Technologies Inc. I have served as LifeCuff's Chief Technology Officer on a part-time basis from its founding through the present time. At LifeCuff, I

developed (and am named as an inventor on several patents relating to) technologies relating to automated devices for remote ischemic conditioning.

9. Since 2013, I have worked as the Vice President of Product Development for Corinnova Inc., which is a medical device start-up company. At Corinnova, I am responsible for leading the engineering team in developing a minimally invasive, non-blood contacting direct cardiac compression cardiac assist device for acute and chronic heart failure treatment. The device is designed to conform to the external surface of the heart and increase cardiac output through the use of a pneumatic driver that gently squeezes the heart by using minimal air pressure. The device has a control system that uses sensors to detect the heart's EKG signal, which enables monitoring of the heart's performance, and which controls the inflation and deflation of the device in synchrony with the heart's beating. The device is positioned in the pericardial space immediately surrounding the heart and through this work I have developed expertise related to delivering cardiac assist devices to this space that is relevant to this proceeding.

10. I am a Registered Patent Agent with the U.S. Patent and Trademark Office, and I am an inventor on 58 U.S. patents and numerous international patents and patent applications, including the ones listed in the table below.

Patent	Title
US 5,342,181	Single roller blood pump and pump/oxygenator system using same
US 5,413,549	Devices and methods for efficient intra-aortic balloon pumping
US 5,429,486	Single roller blood pump and oxygenator system
US 5,439,448	Bubble-free connector for liquid carrying tubing
US 5,716,373	Support member for reduced diameter balloon catheter, and intra-aortic balloon catheter using the same
US 5,817,001	Method and apparatus for driving an intra-aortic balloon pump
US 5,910,103	Device and method for an IAB assist with multiple balloons
US 5,928,132	Closed chest intra-aortic balloon based ventricular assist device
US 6,146,372	Apparatus and method for the percutaneous insertion of a pediatric intra-aortic balloon catheter
US 6,191,111	Method and device for enhancing of biobypass by increasing the coronary blood flow
US 6,238,382	Intra-aortic balloon catheter having a tapered Y-fitting
US 6,241,706	Fast response intra-aortic balloon pump
US 6,245,008	Fast response intra-aortic balloon pump
US 6,346,092	Intra-aortic balloon catheter and insertion sheath
US 6,602,270	Reduced size intra-aortic balloon catheter

Patent	Title
US 7,393,181	Expandable impeller pump
US 7,841,976	Heart assist device with expandable impeller pump
US 7,927,068	Expandable impeller pump
US 8,376,707	Expandable impeller pump
US 8,485,961	Impeller housing for percutaneous heart pump
US 8,992,163	Expandable impeller pump
US 9,364,592	Heart assist device with expandable impeller pump
US 9,364,593	Heart assist device with expandable impeller pump
US 9,717,833	Heart assist device with expandable impeller pump
US 9,833,318	Self-expanding heart assist device
US 9,833,551	Fully implantable direct cardiac and aortic compression device
US 10,149,932	Heart assist device with expandable impeller pump
US 10,215,187	Expandable impeller pump
US 10,463,496	Self-expanding heart assist device
US 10,507,271	Fully implantable direct myocardium assist device
US 10,864,309	Heart assist device with expandable impeller pump
US 10,865,801	Expandable impeller pump
US 11,428,236	Expandable impeller pump
US 11,434,921	Expandable impeller pump

Patent	Title
US 11,511,102	Cardiac compression device having passive and active chambers
US 11,708,833	Heart assist device with expandable impeller pump
US 12,404,858	Catheter blood pump heart assist device

11. A true and correct copy of my curriculum vitae, which includes a list of cases in which I have provided expert declarations/reports and/or testimony, is included as Ex. 2016.

III. BASIS OF OPINIONS

12. I have been retained by Barnes & Thornburg LLP on behalf of Miracor to provide various analyses and opinions. Among other tasks, I have been asked to address the technology claimed in the '357 patent and to evaluate whether certain claims of the '357 patent would have been obvious to a person of ordinary skill in the art at the time of the invention.

13. All of the opinions I express in this Declaration have been made from the standpoint of a person of ordinary skill in the relevant art ("POSA") at the time of the invention of the '357 patent, which I am informed is the claimed priority date of February 27, 2007.

14. My opinions are based on my experience and knowledge and the information I have reviewed as of the date of this Declaration. In connection with my analysis, I have reviewed the exhibits and other documents cited herein.

IV. LEGAL STANDARDS

15. For the purposes of this Declaration, counsel for Barnes & Thornburg LLP informed me of the following legal standards.

A. Level of Ordinary Skill in the Art

16. I understand that my analysis herein must be from the perspective of a POSA as of the date of the invention.

17. I understand that the POSA is a hypothetical person who is presumed to have known the relevant art at the time of the invention. By "relevant," I understand that is relevant to the claims of the '357 patent.

18. I understand that factual indicators of the level of ordinary skill in the art include the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field. Thus, in assessing the level of skill of a POSA, I consider the type of problems encountered in the art, the prior solutions to those problems found in the prior art references, the rapidity with which innovations are

made, the sophistication of the technology, the level of education of active workers in the field, and my own experience working with those of skill in the art at the time of the invention.

B. Claim Construction

19. I understand that patent claims are to be interpreted in light of a patent's specification and prosecution history. I am informed that claim construction starts with the plain language of the claims as understood by a POSA at the time the patent application was filed.

C. Anticipation

20. I understand that a patent claim is unpatentable as anticipated if a single prior art reference discloses each and every limitation of the claimed invention, either expressly or inherently.

21. I understand that a prior art reference inherently discloses a claim limitation only when that reference necessarily includes the limitation that is not expressly disclosed.

22. I understand that a prior art reference can only anticipate a claimed invention if it describes the claimed invention in sufficient detail to enable a POSA to carry out the claimed invention.

D. Obviousness

23. I understand that a patent claim is unpatentable if the claimed invention would have been obvious to a POSA at the time of the purported invention.

24. I understand that an obviousness analysis involves comparing a claim to the prior art to determine whether the claimed invention would have been obvious to a POSA at the time of the invention in view of the prior art and in light of the general knowledge in the art at that time, as a whole. I also understand that obviousness is ultimately a legal conclusion based on underlying facts of four general types, all of which must be considered: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of non-obviousness, including any praise of the invention.

25. I also understand that obviousness may be established under certain circumstances by combining or modifying the teachings of the prior art. Specific teachings, suggestions, or motivations to combine a first prior art reference with a second prior art reference can be explicit or implicit, but must have existed before the date of purported invention. I understand that prior art references themselves may be one source of a specific teaching or suggestion to combine features of the

prior art, but that such suggestions or motivations to combine art may come from the knowledge that a POSA would have had.

26. I understand that a reference may be relied upon for all that it teaches, including uses beyond its primary purpose, but also including teachings that lead away from the invention. I understand that a reference may be said to teach away from a particular development path when a POSA, upon reading the reference, would be discouraged from following the path set out in the reference, although the mere disclosure of alternative designs does not teach away.

27. I understand that in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis, the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.

28. I further understand that whether there is a reasonable expectation of success in combining references in a particular way is also relevant to the analysis.

29. I understand that it is improper to use hindsight—namely, using the claims as a guide—to combine references or elements of references to reconstruct the invention.

30. I understand that to render a claim obvious, the prior art, taken as a whole, must enable a POSA to make and use the claimed invention. I understand

that in the absence of other supporting evidence to enable a POSA to make the claimed invention, a standalone prior art reference must enable the portions of its disclosure being relied upon.

31. I am not offering any legal opinions in this declaration. I only consider such legal standards in framing my opinions and conclusions. Additionally, from a subject matter perspective, I understand that the petitioner always has the burden of persuasion regarding a challenge of patentability of an invention under an *Inter Partes* Review.

V. TECHNICAL BACKGROUND

32. Rather than include a dueling but parallel technical background, I offer the following opinions on the technical background of Left Ventricular Assist Devices ("LVADs") provided by Mr. Crosby in his declaration. Ex. 1003 ¶¶ 40–65. In general, I believe Mr. Crosby's summary is overly limiting in certain respects and mischaracterizes the teachings of certain references in service of Petitioner's positions. I also note that every LVAD represents a delicate balance of many design choices that reflect different, and sometimes contradictory, goals. Each particular LVAD embodies one example of this balance and a POSA would not find it trivial to change or swap various portions, as suggested by Petitioner.

This is because even small changes can have unpredictable and potentially outsized consequences by upsetting the balance achieved by a particular device.

33. For example, Mr. Crosby's definition of an LVAD or Left Ventricular Assist System ("LVAS") provided in Ex. 1003 ¶ 42 is, in my opinion, overly limiting to include only blood pumps. Such a definition excludes other traditional LVAD configurations such as direct cardiac compression devices, intra-aortic balloons, aortic counterpulsation devices, etc., as well as certain alternative LVAD configurations, such as an inflow cannula placed in the left atrium rather than the left ventricle. This example highlights how Mr. Crosby continually adopts overly limiting definitions to serve his and Petitioner's positions, definitions that are inconsistent with what a POSA would have understood at the time of the invention.

34. When describing the evolution of LVADs, it is my opinion that Mr. Crosby mischaracterizes the references he relies on to support his positions. For example, in Ex. 1003 ¶ 48, Mr. Crosby suggests that the smaller size of second-generation LVADs produced lower infection rates. (citing Ex. 1014 at 842). While size may have been one factor at play, Mr. Crosby omits mention of many other factors mentioned in the cited reference, such as the absence of "compliance chambers, polyurethane membranes, or prosthetic valves" found on earlier "pulsatile devices." Ex. 1014 at 842. The Ex. 1014 reference describes that the

differences in blood-facing components within the pump, along with the smaller surgical dissection to place the devices in a preperitoneal pocket, "collectively may explain the low infection rate." Ex. 1014 at 842. It is also the case that the medical arts advance over time in myriad ways, any number of which may be at play in the observed reduction in infection rates. In my opinion, it is not correct to attribute a lower infection rate to a reduction in size alone.

35. Mr. Crosby again oversimplifies description of the technical field when describing third-generation LVADs and noting that they achieved smaller size that allowed for intrapericardial pump placement. In particular, Mr. Crosby points to the HVAD as an example third-generation device with a size, including an axial height of less than one inch, that allowed for intrapericardial pump placement. Ex. 1003 ¶ 52 (citing Ex. 1015). As noted in Ex. 1015, however, the HVAD was an exceptionally small device and the first LVAD that could be placed at the apex of the heart. For example, it weighed 145 grams and displaced a 50 cc volume. Ex. 1015. As explained in more detail below, this means the pump was significantly smaller than any of the pumps disclosed in the prior art references relied on to allegedly invalidate the challenged claims of the '357 patent. In addition, there are a number of other factors that influence the ability to utilize intrapericardial pump placement beyond the size of the pump alone. For example,

patient size plays an important role because placement of a given pump may be possible in a large male patient but impossible in a relatively smaller female patient (indeed, even today only around 25% of LVAD implantations are in women despite an equal rate of heart failure with men). Accordingly, it is my opinion that Mr. Crosby and Petitioner significantly oversimplify the state of the art at the time of the invention when contending that a POSA would have found it obvious to implant the much larger pumps disclosed in the relied-upon prior art references at the apex of the heart. Such a contention draws false equivalence between certain third-generation LVADs, like the HVAD, and larger devices like those in the relied-upon prior art.

36. Mr. Crosby also misleads when suggesting that third-generation pumps could be driven by either "magnetic coupling" or by "magnetic levitation." Ex. 1003 ¶ 53. It is my opinion that "magnetic coupling" is a broader term that includes "magnetic levitation" technology as well as simpler couplings that utilize magnetic fields solely to apply torque to a rotor across a sealed boundary.

37. To support his contention regarding a distinction between "magnetic coupling" and "magnetic levitation," Mr. Crosby cites to examples where rotating magnets are utilized to transmit torque to a rotor. Ex. 1003 ¶¶ 53–54 (citing Ex. 1011, 1; Ex. 1016, 36; and Ex. 1006, Fig. 2). Based on these examples, Mr. Crosby

concludes that "'magnetic coupling' uses a motor to rotate a permanent magnet, which in turn rotates another permanent magnet on the impeller." Ex. 1003 ¶ 55. In my opinion, this conclusion is overly limiting. A coupling using rotating magnets is just one example of a "magnetic coupling" that can be used to generate a rotating magnetic field. In my opinion, a POSA would have understood other ways to achieve the transmission of torque via magnetic forces, including by generating a rotating magnetic field with a stator and rotor, in the same way as other common electric motors. As an example, the relied upon Schima reference shows both rotating magnets and a stator that generates a rotating magnetic field, thereby showing different manners of achieving a "magnetic coupling" to drive a rotor. Ex. 1005, Figs. 1 and 2.

38. In contending that smaller, third-generation LVADs could be placed at the cardiac apex within the pericardial space, Mr. Crosby uses as an example the Wampler publication and, in particular, its Fig. 5 that shows the embodiment of Figs. 1–8 implanted in a heart. Ex. 1003 ¶ 62 (citing Ex. 1008, [0076] and Fig. 5, Petitioner's annotated version of which is reproduced below). As explained in more detail below, it is important to note that this placement in Wampler was the result of a particular construction that used a rotor 17 including a shaft 18 that extended into the inlet tube 13 and included a magnetic bearing to assist in

positioning the rotor relative to the housing (for example, see Wampler's Fig. 2, reproduced below). Including this structure extending into the inlet tube 13 allowed minimizing the size of the disc-shaped housing 12 that would occupy extracardiac space so the device could fit in the pericardial space. As disclosed in a later paper by Wampler about its pump, the disc-shaped housing displaced only 28 cc (the total pump displaced 43 cc) and the pump weighed 195 grams. Ex. 2019 at 781. This is much smaller than the pumps described in the other references relied upon in this proceeding. For example, the pump disclosed in Bourque-2001 weighed 475 grams and displaced 175 ml—more than twice as much weight and several times more volume of displacement! Ex. 1007 at 401. These pumps were not of comparable size and, as explained in more detail below, I believe a POSA would have immediately recognized the practical impossibility of implanting a pump like the one disclosed in Bourque-2001 at the apex of the heart due to its large size and weight.

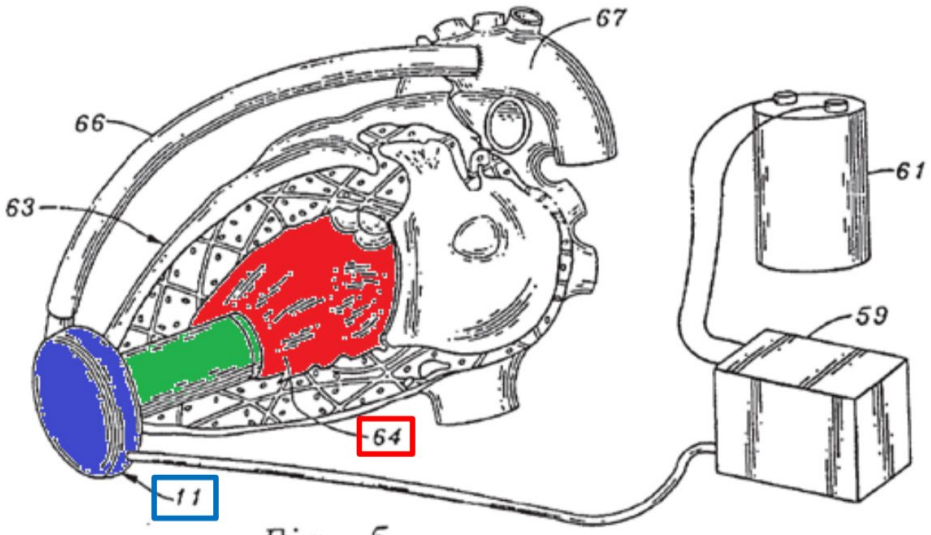


Fig. 5

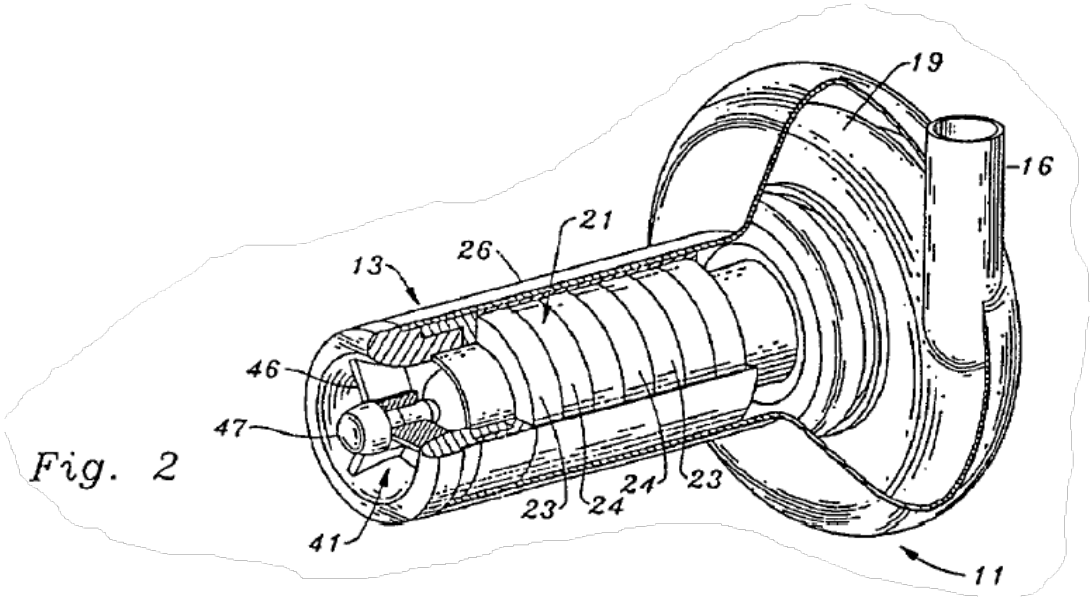


Fig. 2

39. Mr. Crosby also points to another allegedly similar example, the HeartWare HVAD. Ex. 1003 ¶ 63 (citing Ex. 1015). This device was the first LVAD to be implanted at the apex of the heart in practice, and in my opinion a main reason for this was the very small size of the device relative to the pumps

disclosed in the other references relied on in this proceeding. For example, the HeartWare HVAD had a weight of around 145 grams and displaced a volume of 50 ml. Ex. 2021 at 12. Compared to, for example, the pump disclosed in Bourque-2001, the HVAD was less than half the weight and less than a third the size/volume. As with the comparison to Wampler noted above, I believe a POSA would have immediately recognized the practical impossibility of implanting a pump like the one disclosed in Bourque-2001 at the apex of the heart, like the HVAD, due to its large size and weight relative to that device.

40. I also note that device size is just one parameter used by doctors to determine whether to implant an LVAD and, if so, which LVAD to utilize. Risk of thrombosis is another example consideration and one that may not be addressed simply by use of a smaller pump.

41. Mr. Crosby goes on to acknowledge that the pump disclosed in Bourque-2001 was implanted in a preperitoneal pocket rather than in the pericardial space, but notes that the device 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." Ex. 1003 ¶ 64 (citing Ex. 1007 at 405). I believe this statement is misleading, however, as a POSA would have appreciated that the pump disclosed in Bourque-2001 was not

nearly equivalent to the above-mentioned pumps intended for implantation at the apex of the heart. The pump of Bourque-2001 was over twice the weight and size of these pumps, and a POSA would have appreciated that such a device was not nearly appropriate for implantation in the pericardial space. Further, the "enhancements" mentioned in Ex. 1007 that are referenced by Mr. Crosby as support for enabling placement at the cardiac apex do not appear to be so intended. In particular, Ex. 1007 notes the "enhancements" include "incorporation of motor drive and control electronics within the pump, and integration of a TETS (transcutaneous energy transmission system) to eliminate the percutaneous drive line." Ex. 1007 at 405. I believe Mr. Crosby has made too large of a leap from this language to the idea that Bourque-2001 intended to implant its pump at the apex of the heart.

42. Moreover, we know from later work by Bourque that six years after the publication of Bourque-2001 the disclosed pump still had the same general physical characteristics (e.g., a noted weight of 500 grams) and, as a result, was still implanted in a preperitoneal pocket. Ex. 2006 at 310–311. Still further, and as explained in more detail below, we know from other publications by Bourque that significant work was done to redesign the prototype HeartMate III device from Bourque-2001 and ultimately develop the much smaller clinical HeartMate 3

device that was capable of implantation at the apex of the heart. Ex. 2007. Indeed, Bourque was able to secure a patent on certain of the innovations that allowed the prototype HeartMate III device from Bourque-2001 to transform into the clinical HeartMate 3 device capable of implantation at the apex of the heart. Ex. 2007 at 7–8; Ex. 2009.

43. Mr. Crosby makes another misleading statement when listing the pump of Akamatsu as "another example" of a pump, like the HVAD, that was compact enough to allow "it to be implanted in patients at the cardiac apex 'even those of small body size.'" Ex. 1003 ¶ 63 (citing Ex. 1006 at 3). Akamatsu does not make such a statement. The reference states that implantable ventricular assist devices are being developed that include advantages like "compactness, simplicity, and low cost. The pump can be implanted in both men and women, even those of small body size, with better quality of life and cost-effectiveness." Ex. 1006 at 3. Nowhere does Akamatsu disclose that implantation is at the apex of the heart, especially not in the quoted language. Furthermore, and as discussed in more detail below, I believe a POSA would have immediately understood that the pump of Akamatsu could not have been implanted at the apex of the heart due to its size, which was similar to the pump disclosed in Bourque-2001. In particular, Akamatsu discloses that its pump weighed 400 grams and displaced 196 ml. Ex. 1006 at 4.

This is, like the pump of Bourque-2001, at least twice the weight and size/volume of a pump like the HeartWare HVAD that was capable of implantation at the apex of the heart.

44. Generally speaking, it is my opinion that Mr. Crosby's description of the technology glosses over important contextual details in an attempt to draw equivalence between very different pumps. As reviewed above, a central example is the relative sizes of the pumps in the references being relied upon in this proceeding. In particular, the pumps disclosed in Bourque-2001 and Akamatsu were very large compared to, for example, the pump disclosed in Wampler for implantation in the heart or any of the devices that were later actually implanted at the apex of the heart. In my opinion, a POSA would have immediately appreciated this issue and understood that there was no way the larger pumps could be delivered to the heart in the contended manner. As discussed in more detail below, doing so would be practically impossible and, if done, would pose potentially grave risks to the patient by placing such a large device in the pericardial space and attaching such a heavy weight directly to the moving heart.

45. I believe that Petitioner and Mr. Crosby also overreach when suggesting that a POSA would have implanted the pump of Schima at all, much less at the apex of the heart. As explained in more detail below, the pump disclosed

in Schima is configured for extracorporeal use and is not intended for implantation. This would have been clear to a POSA from the teachings of the Schima reference alone, e.g., because of recognition of features not suitable for implantation, such as barbed hose fittings and sharp edges on the pump housing. Beyond this, however, the Schima pump is similar to other known extracorporeal pumps and a POSA would have appreciated this similarity at the time of the invention. E.g., Ex. 1011. Still further, later work by Schima makes clear the intention for extracorporeal use of the pump, as explained below. E.g., Ex. 2022.

VI. THE '357 PATENT

46. The '357 patent is one of a series of U.S. continuation and divisional applications claiming priority back to U.S. Appl. No. 12/449,632, filed on August 18, 2009 (issued as U.S. Patent No. 8,255,050), which is the U.S. national phase of International Application PCT/IB2008/000421, filed on February 27, 2008. This International Application claims the benefit of AT A 306/2007, filed February 27, 2007. Ex. 1001, 1:7–23. I assume that February 27, 2007, is the effective filing date of the '357 patent.

47. I have reviewed the file history of the '357 patent, including the earlier applications to which the '357 patent claims priority.

48. The claims of the ‘357 patent that are being challenged and that I have been asked to evaluate are claims 1–3, 10, 11, 14, and 17. These claims are reproduced above.

49. I have reviewed the descriptions of the ‘357 patent provided by Mr. Crosby and the PTAB in its Institution Decision. Ex. 1003, ¶¶ 27–39; Paper 13, 2–5. I offer the following opinions regarding these descriptions:

50. Generally speaking, it is my opinion that these descriptions of the ‘357 patent are overly restrictive and characterize the teachings of the ‘357 patent too narrowly based on its disclosure of an example embodiment that is a catheter device having a fluid-driven rotary pump. I believe a POSA would not have viewed the disclosure of the ‘357 patent so narrowly and would have understood that other embodiments are within the scope of the invention described in the ‘357 patent.

51. For example, I disagree with Petitioner and Mr. Crosby’s characterization that the ‘357 patent is directed to a catheter device that is altogether distinct from an LVAD like Abbott’s HeartMate 3, as contended, for example, in Paper 1, 1–3 and Ex. 1003 ¶¶ 30–36 and 40. It is true that the ‘357 patent discloses one embodiment of its “device to assist the performance of a heart” that is built around a catheter, but this is an example embodiment and would

not have been understood by a POSA as limiting the scope of the disclosure or its claims. Ex. 1001, Title.

52. As counter examples, I note that the Abstract of the '357 patent does not mention a "catheter," instead noting that the invention is directed to "a method and device 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. In addition, a "catheter" is not recited in the claims until dependent claims 17 and 19, which would have suggested to a POSA that the scope of the invention as described in at least the other claims is broader in this respect and can encompass both catheter devices and those that are not so limited.

53. The disclosure of the '357 patent also describes improvements relative to prior art that are not dependent on the device being "a catheter device." For example, the '357 patent focuses on the idea that its disclosed device is implantable to provide the benefit of dispensing with an external pump that was required with prior devices. Ex. 1001, 1:39–2:26.

54. Mr. Crosby repeatedly focuses on the specifics of the example embodiment disclosed in the '357 patent, for example, the use of "a paddle wheel operated hydraulically or pneumatically" via a "fluid pump" and a "driving fluid." Ex. 1003, ¶¶ 33–36. This arrangement, however, represents just one example

configuration for causing rotation of a rotor and would not have been understood by a POSA as required in every embodiment of the invention.

55. Furthermore, I disagree with Petitioner's contention that the '357 patent admits the claimed pump design was known in the prior art. Petitioner alleges that there is a concession in the '357 patent that "the claimed pump design was known in the prior art," but offers for support a quote from the '357 patent noting that "the rotor itself can follow design principles" found in an earlier reference and subsequently elaborating on features that the "known design" *of the rotor* can include. Paper 1, 7 (citing Ex. 1001, 3:18–28). This statement in the '357 patent that features of the "rotor itself" can borrow from earlier work is not a statement conceding that the "claimed pump design" was known in the prior art.

56. Petitioner's expert, Mr. Crosby, limits himself more to the language of the '357 patent in noting that the reference to the earlier work is with regard to rotor design in particular but, in my opinion, overreaches by suggesting that this disclosure "supports…that there was nothing novel disclosed in the '357 patent's specification about the design of the rotor." Ex. 1003 ¶¶ 37–38. Just because a rotor design may include features from a prior work does not mean, for example, that there are no additional features included, or that there are no new features associated with how the rotor is packaged and used in a device or method. Indeed,

as explained in more detail below, the reference cited in the '357 patent for disclosure of rotor features involved an extracorporeal pump not suitable for use in the body, just like the Schima reference relied upon by Petitioner and Mr. Crosby to allegedly render the '357 patent invalid. A POSA would not have understood such a pump to be no different from the device disclosed in the '357 patent that is suitable for use in the body.

VII. LEVEL OF SKILL IN THE ART

57. I understand that Petitioner has asserted that a POSA would be a person with "at least a bachelor's degree in engineering; knowledge and experience in human circulatory system anatomy and physiology; and at least five years' experience designing and developing implantable medical devices." Paper 1, 6 (citing Ex. 1003 ¶ 18). I also understand that the Patent Trial and Appeal Board ("PTAB") found, for purposes of deciding to institute this proceeding, that "the '357 patent and the cited prior art references reflect the appropriate level of skill at the time of the claimed invention and that the level of skill reflected in these references and in the '357 patent is consistent with the definition of a person of ordinary skill in the art proposed by Petitioner." Paper 13, 18–19.

58. As noted above, I understand that the POSA is a hypothetical person who is presumed to have known the relevant art at the time of the invention. By

"relevant," I understand that is relevant to the claims of the '357 patent. And in assessing the level of skill of a POSA, I consider the type of problems encountered in the art, the prior solutions to those problems found in the prior art references, the rapidity with which innovations are made, the sophistication of the technology, the level of education of active workers in the field, and my own experience working with those of skill in the art at the time of the invention.

59. Based on my experience, I believe a POSA would have a more specifically-focused level of skill than has been articulated by Petitioner. In particular, I believe that the '357 patent and cited prior art references reflect the complicated and critical nature of cardiac assist devices. As a result, I believe a POSA would be better characterized as having at least a bachelor's degree in engineering, knowledge and experience in human circulatory system anatomy and physiology, and at least five years' experience designing and developing implantable cardiac assist devices in particular. This more tailored level of experience—versus experience designing and developing any implantable medical device—is warranted because of the level of complication involved in developing cardiac assist devices and the critical, life-supporting nature of the heart and associated circulatory system that makes the field very high risk.

60. Indeed, throughout this declaration I question many conclusions and contentions of Petitioner's expert, Peter Crosby, as contrary to what a POSA at the time of the invention would have understood was possible or advisable. I believe certain of Mr. Crosby's incorrect contentions may result from a lack of experience in the actual design and development of rotary pump cardiac assist devices in particular. Mr. Crosby appears to have spent solely around 4 years working as the Chief Operating Officer and Chief Executive Officer of a company developing such a device, but I believe this C-suite participation in the company has left him with an underdeveloped appreciation for the complexities of actually engineering a rotary pump cardiac assist device and the practices that would have governed behavior of a POSA in this field at the time of the invention.

61. I believe I satisfy both Petitioner's definition of a POSA and the modified definition I have proposed above. In particular, I have a Master's degree in mechanical engineering and significant work experience exceeding the thresholds noted above specifically with regard to the design and development of implantable cardiac assist devices.

VIII. CLAIM CONSTRUCTION

62. I have been instructed to apply the plain and ordinary meaning of all claim terms.

A. "Magneto Coupling"

63. I understand from the Institution Decision that the Board has adopted the broader of two constructions for the term "magneto coupling" advanced by Petitioner. Paper 13 at 22. In particular, the Board has adopted a construction for the term "magneto coupling" that encompasses generating a rotating magnetic field either by rotating magnets or by an electromagnet, e.g., a stator. Paper 13 at 22.

64. I agree with the construction adopted by the Board in the Institution Decision and believe it is consistent with how a POSA would have understood the term "magneto coupling" at the time of the invention in view of the disclosure of the '357 patent.

65. More particularly, it is my opinion that a POSA at the time of the invention would not have limited the definition of "magneto coupling" to the narrower construction advanced by Petitioner in view of the disclosure of the '357 patent. Instead, it is my opinion that a POSA would have understood that the term "magneto coupling" refers more generally to coupling movement of two components via magnetic fields, and that there are a number of ways to achieve such coupling commonly known in the art, including both the use of rotating magnets and electromagnets, e.g., a stator.

66. For example, I note that the ‘357 patent does not contain any language or indication that its disclosure of an example embodiment with dual rotating magnets is intended to be anything other than a non-limiting example of magnetic coupling. As a result, I believe a POSA would have understood the ‘357 patent to use “magneto coupling” to generally describe a way to couple the rotor to the drive component and transfer torque via a magnetic field to enable sealing the rotor from the drive component and avoiding a direct mechanical coupling to the drive component of the pump.

67. In addition, I note that the original priority application for the ‘357 patent is in German and uses the term “MagnetKupplung,” which translates to “magnetic coupling.” It does not appear that this term has any special meaning or limitation that would exclude one type of “magnetic coupling” while allowing another, as Petitioner’s narrower construction does.

68. Further, there are examples in the field of both types of magnetic coupling being used interchangeably. One such example is the Schima reference cited by Petitioner (Ex. 1005). This reference discloses similar embodiments where the difference is the use of either an electromagnet or a rotating permanent magnet to drive rotor movement. Ex. 1005 at Figs. 1–4 and [0012]–[0016]. I believe this reference supports my view that a POSA at the time of the invention would have

understood both of these example magnetic couplings to fall within the meaning of the term "magneto coupling," as used in the '357 patent.

69. Mr. Crosby's declaration reviews several references, including Schima (Ex. 1005), in an attempt to show a distinction in the art between types of magnetic couplings. Ex. 1003 ¶¶ 74–81. I disagree with Mr. Crosby's conclusions and believe that, to the extent a given reference discloses a particular type of magnetic coupling, it is provided as an example and not an acknowledgement of any commonly-understood distinction in the meaning of magnetic couplings to a POSA at the time of the invention. And certain of the references reviewed, such as Schima, appear to reach the opposite conclusion as Mr. Crosby. As noted above, for example, in my opinion Schima shows that both rotating magnets and an electromagnet were understood as different types of a magnetic coupling or, as used in the '357 patent, a "magneto coupling."

B. "<u>By the Blood Flowing</u>"

70. I understand from the Institution Decision that the Board has adopted the broader of two constructions for the term "by the blood flowing" advanced by Petitioner. Paper 15 at 22–23. In particular, the Board has adopted a construction for the term "by the blood flowing" that encompasses both a hydrodynamic bearing and a magnetic bearing. Paper 15 at 23.

71. I agree with the construction adopted by the Board in the Institution Decision and believe it is consistent with how a POSA would have understood the term "by the blood flowing" at the time of the invention in view of the disclosure of the '357 patent.

72. More particularly, it is my opinion that a POSA at the time of the invention would not have limited the definition of "by the blood flowing" to the narrower construction advanced by Petitioner in view of the disclosure of the '357 patent. Instead, it is my opinion that a POSA would have understood the term to mean that the rotor is spaced apart from the housing and is surrounded by the flowing blood, which would encompass different manners of achieving that spacing to allow for surrounding flowing blood, including both the use of hydrodynamic bearings and magnetic bearings.

73. I do not believe that a POSA at the time of the invention would have understood "by the blood flowing" to require that the flowing blood solely causes the separation of the rotor and housing, such that the presence of only magnetic or only hydrodynamic forces would be involved. Instead, the '357 patent describes the complete separation of the rotor from the housing, which is not limited to one type of bearing to achieve the separation.

74. Further, the ‘357 patent, and independent claim 1 in particular, make clear that it is the magnetic coupling that orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains spaced apart from the surrounding rotor housing. The magnetic coupling is therefore involved in determining the spacing of the rotor relative to the housing. Where the magnetic coupling is involved in orienting the rotor and determining its position in space, it is my opinion that a POSA would have understood that use of a magnetic bearing is included. I therefore disagree with Mr. Crosby’s contention that use of a hydrodynamic bearing is the “only logical interpretation” of claim 1 of the ‘357 patent. Ex. 1003 ¶ 91.

75. Mr. Crosby relies on disclosure in Schima (Ex. 1005) that was referenced in the ‘357 patent to suggest that the term “by the blood flowing” requires use of hydrodynamic bearings like those disclosed in Schima. Ex. 1003 ¶¶ 92–94. I disagree with this analysis for several reasons, including the fact that Schima is referenced in the ‘357 patent for the possible incorporation of “design principles” of its rotor in particular. This does not mean incorporation of its rotor is required, much less its system for suspending or orienting the rotor. In addition, Schima discloses several different embodiments of its pump as examples and discloses that its rotor can be “journaled hydraulically and if necessary

magnetically in a housing," so I do not agree that Schima limits itself to use of hydrodynamic bearings. Ex. 1005, Claim 1. Instead, it is my opinion that a statement like this in Schima shows that it contemplates use of either or both hydrodynamic and magnetic positioning of its rotor.

76. It is therefore my opinion that the term "by the blood flowing," taken in proper context of the disclosure of the '357 patent, would have been understood by a POSA at the time of the invention to require only that the rotor is spaced apart from the housing and surrounded by flowing blood, and not that the manner of achieving such positioning was limited to only a hydrodynamic bearing. My understanding is therefore consistent with the broader construction of this term adopted by the Board in the Institution Decision.

C. "<u>Axially Closer</u>"

77. I understand from the Institution Decision that the Board has adopted a construction for the term "axially closer" as requiring each of the components to be "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." Paper 13 at 23–24. The Institution Decision also requests input regarding "whether only a portion of the second magnetic device need be 'positioned *axially closer* to the first magnetic device than

to the magnetically driven rotor' to satisfy claim 1." Paper 13 at 25 (emphasis in original).

78. It is my opinion that it is possible to rely on a distance between only a portion of a first component and a second component but, in a situation where different portions of a first component have different distances from a second component measured along an axis, a minimum of those distances should be used to compare whether the two components are positioned "axially closer" to one another than one of them is to a third component. When determining which components are relatively "closer," i.e., separated by a minimum distance, I believe logic would dictate utilizing the minimum possible value to use in the comparison. To do otherwise would allow for selectively ignoring a portion of a component to arrive at what would be an artificially inflated measure of distance between two components. I do not believe a POSA would appreciate any reason to do this and would instead follow the logic described here.

IX. PRIOR ART

A. Wampler

79. Wampler discloses a "rotary blood pump [that] includes a housing and a pump rotor." Ex. 1008 ¶ [0012]. The reference further discloses that "a centrifugal pump impeller is attached to an impeller support shaft, or spindle, to

form the pump rotor." Ex. 1008 ¶ [0012]. The rotor is disposed within a pump housing that includes "an elongate inlet tube surrounding the shaft, and a scroll-shaped casing, or volute, with a discharge outlet, enclosing the impeller." Ex. 1008 ¶ [0012].

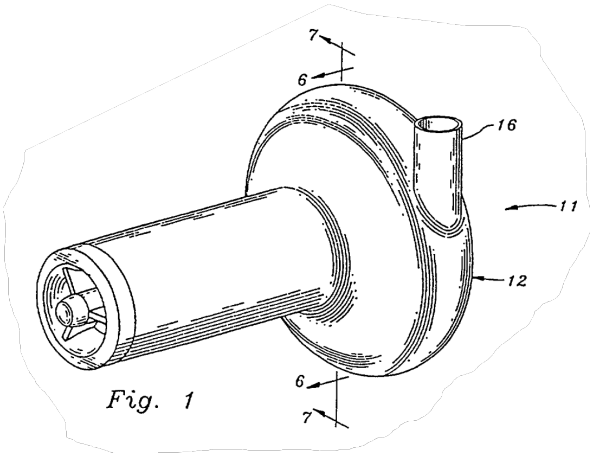


Fig. 1

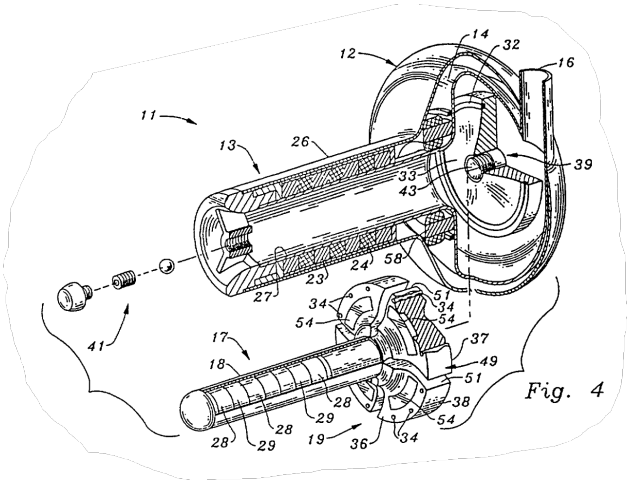
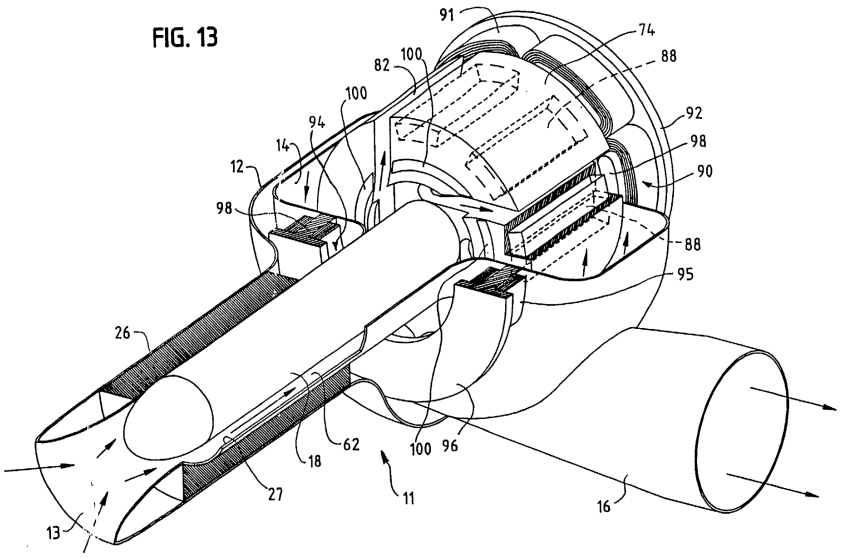


Fig. 4

80. The rotor of Wampler is disclosed as suspended within the pump housing using radial magnetic bearings that "maintain the support shaft and the impeller about a rotational axis." Ex. 1008 ¶ [0013]. Further, the rotor is "axially restrained by a [*sic*] magnetic and hydrodynamic forces in combination with mechanical thrust bearings, or touchdowns." Ex. 1008 ¶ [0014].

81. The rotor impeller is disclosed as having "sealed, hollow chambers…provided within the thick impeller blades" that "house magnets used in the pump drive system." Ex. 1008 ¶¶ [0017] and [0018]. The rotor is rotated 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].

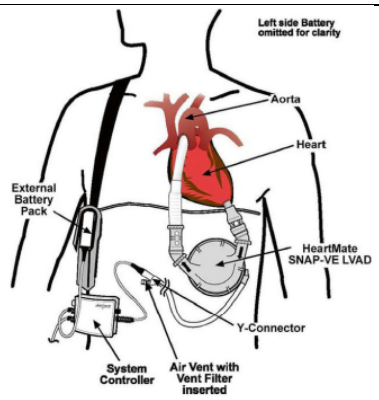
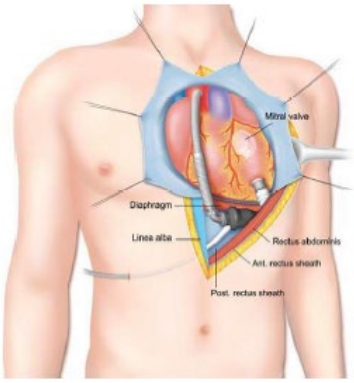
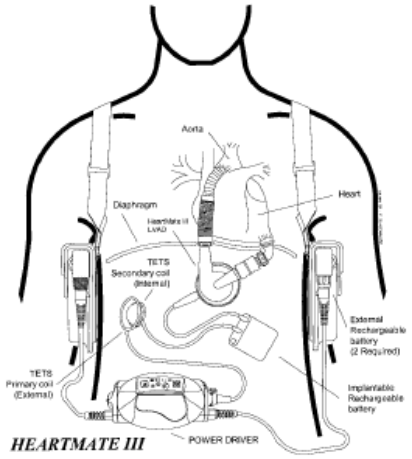


82. Wampler discloses different embodiments of blood pumps, including a first embodiment shown in FIGS. 1–8 and alternative embodiments shown in FIGS. 11–20. Wampler illustrates only the first embodiment implanted in a heart and including elements like a power supply and controller. Ex. 1008 at FIG. 5. There is no illustration or disclosure of the alternative embodiments implanted in a heart or including ancillary components for driving the disclosed pumps.

B. <u>Bourque-2001</u>

83. Borque-2001 discloses an early design concept for a centrifugal blood pump—which is distinct from the later-developed clinical HeartMate 3 device—that was intended to become the HeartMate III product to replace the prior

HeartMate XVE and HeartMate II. Ex. 1007 at 401. The prototype HeartMate III pump, like the earlier two products, is disclosed as being implanted in a preperitoneal or abdominal pocket located below the heart. Ex. 1007 at Fig. 3; Ex. 1013 at 25 (describing the similar implantation position of the HeartMate XVE device and Heartmate II devices). Implanting in this location provides more room to accommodate a larger pump, in contrast to a pericardial placement where the pump would be placed against the heart in the thoracic cavity. Bourque-2001 describes that the preperitoneal position of the pump was the "least obtrusive position (i.e., in the human configuration, as in Figure 3)." Ex. 1007 at 402. The pump in Bourque-2001 was not implanted in humans, but the disclosed layout was the same as the earlier HeartMate devices. Ex. 1007 at Fig. 3. This placement was the same as the earlier devices because this is the only place where a device the size of the Bourque-2001 pump would fit in a human.

HeartMate XVE	HeartMate II	HeartMate III
 Ex. 2003 at 725–732, 727	 Ex. 1013 at 25	 Ex. 1007 at Fig. 3, 403

84. A flexible inflow cannula is disclosed as connecting the pump, disposed at the above-noted remote location, to the apex of the left ventricle. Ex. 2004 at 387, also authored by Bourque, describes the same prototype HeartMate III device as having a "flexible cannula [that] is fitted upstream of the pump in-flow to improve anatomical fit, to decouple the pump from cardiac motion, and to provide a point for clamping and ligation for pump explant."

85. In order to fit the pump in the disclosed position, the rotational axis of the pump's rotor is perpendicular to the longitudinal axis of the patient's body. Ex. 1007 at 402. This also creates a sharp bend in the flow before it enters the impeller of the pump. Ex. 1007 at 402. Bourque's description of the configuration can be seen in the following annotated version of Figure 3 showing the body's long axis

in blue, the heart in red, and the diaphragm in orange. As illustrated, the rotational axis of the rotor (extending straight out of the page) is perpendicular to the body's long axis, as Bourque describes. Ex. 2014 at 59–60. Because the pump is displaced from the heart, the flexible recovery section extends in the plane of the page from the pump to the heart, as explained above.

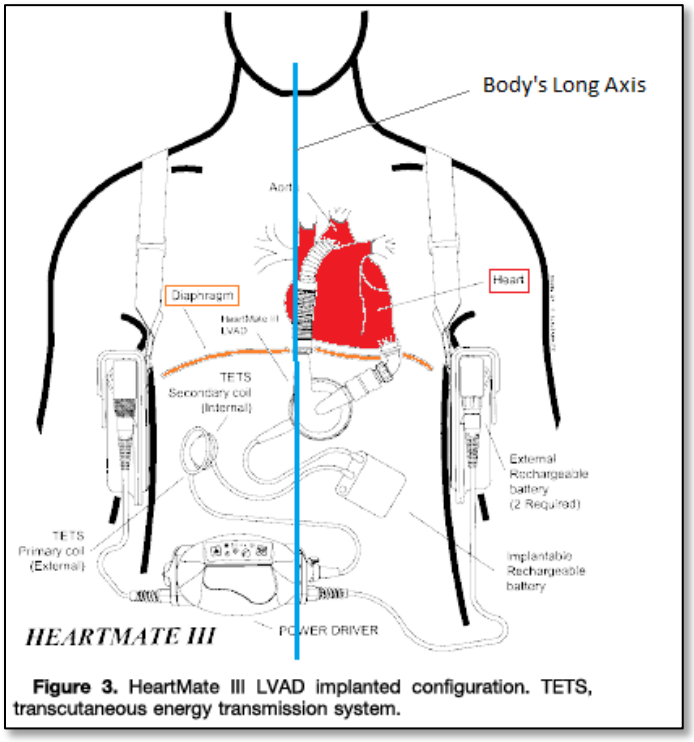


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

86. The pump disclosed in Bourque-2001 had a mass of 475 grams (535 grams if including the inflow cannula, recovery section, outflow graft, bend relief, and associated connecting hardware). Ex. 1007 at 401. The pump displaced 175 ml, had a diameter of 69 mm at its puck shaped portion, and this same portion had a height of 30 mm. Ex. 1007 at 401. As explained in more detail below, this device

was far too large for implantation in the pericardial space. The pump disclosed in Bourque-2001 was multiple times larger and heavier than the ultimate HeartMate 3 clinical device, which was introduced years after the Bourque-2001 reference (and the priority date of the '357 patent) and was implanted in the pericardial space.

C. Akamatsu

87. Akamatsu describes work to develop "an implantable left ventricular assist system (T-ILVAS) featuring a centrifugal blood pump with a magnetically suspended impeller (MSCP)." Ex. 1006 at 3. Akamatsu addresses efforts related to three prototype MSCPs: "the paracorporeal Model I, the implantable Model II (Fig. 3), and the modified Model II." Ex. 1006 at 4. Finally, there is disclosure of a "Model III system," "for the next phase," that includes "a prototype MSCP…and an implantable controller," as well as "further developments…under way" regarding "a totally implantable LVAS, including a transcutaneous energy and information transfer system and internal/external batteries." Ex. 1006 at 7. Akamatsu includes a conceptual illustration of such a "totally implantable LVAS" in its FIG. 1, which is reproduced below.

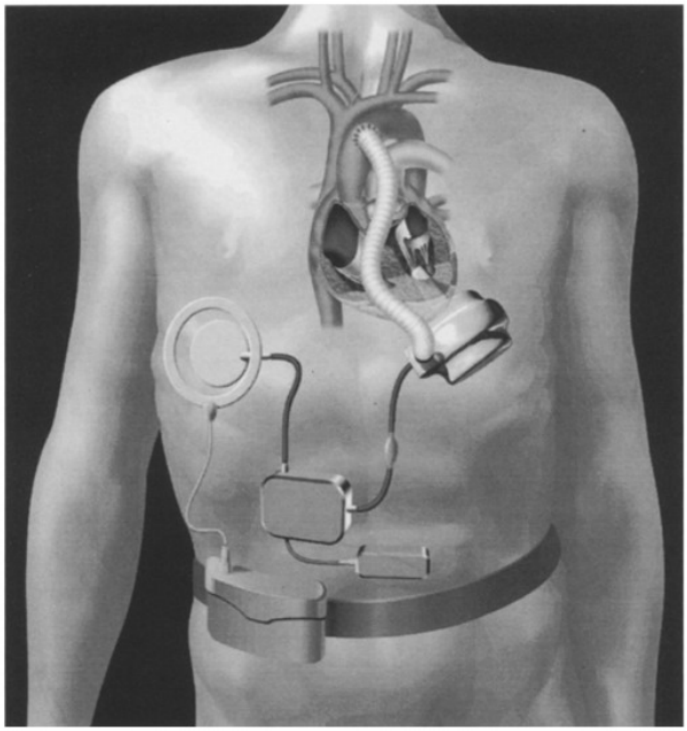


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

88. Akamatsu discloses "ex vivo" studies that evaluated the MSCP paracorporeally "for long-term durability and nonthrombogenicity in a chronic sheep left heart bypass model," including valuation of Model I in one sheep and Model II in two sheep. Ex. 1006 at 1. Akamatsu also discloses "intrathoracic implantation of the MSCP" Model II and modified Model II prototypes in two sheep. Ex. 1006 at 5. In the implantation examples, "the pump was percutaneously driven," though no additional details are provided regarding what exactly this means. Ex. 1006 at 5.

89. Regarding the prototype MSCPs, Akamatsu discloses that "the MSCP is composed of four parts: a magnetic bearing, an impeller, a housing, and a DC brushless motor," and refers to its FIG. 2 schematic. Ex. 1006 at 4.

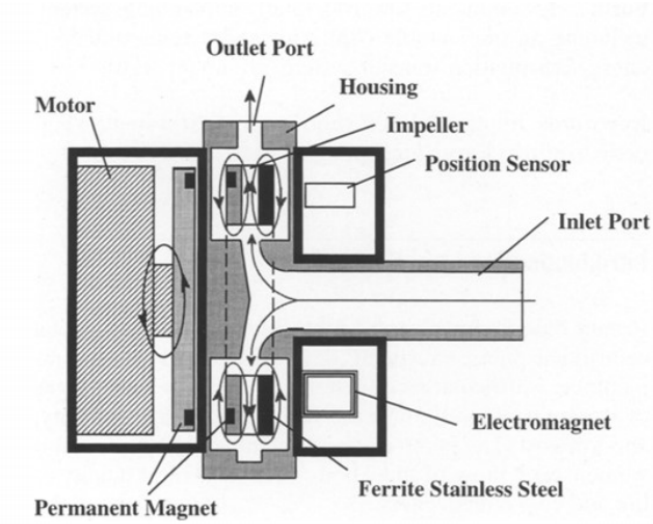


Fig. 2. Schematic cross section of the MSCP

90. Akamatsu notes that "the impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by…three electromagnets." Ex. 1006 at 4. Electric current of the electromagnets is "controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing." Ex. 1006 at 4.

91. The pump disclosed in Akamatsu had a mass of 400 grams and displaced 196 ml. Ex. 1006 at 4. At its widest point, the pump was about 82 mm in diameter and it had a height of about 50 mm. Ex. 1006 at 4. These dimensions are on par with the pump disclosed in Bourque-2001 and, like that pump, the pump

disclosed in Akamatsu was far too large for implantation in the pericardial space. For example, and as explained in more detail below, this device was multiple times larger and heavier than the first device, the HeartWare HVAD, that was clinically implanted in the pericardial space years after the publication of Akamatsu (and the priority date of the '357 patent).

D. Schima

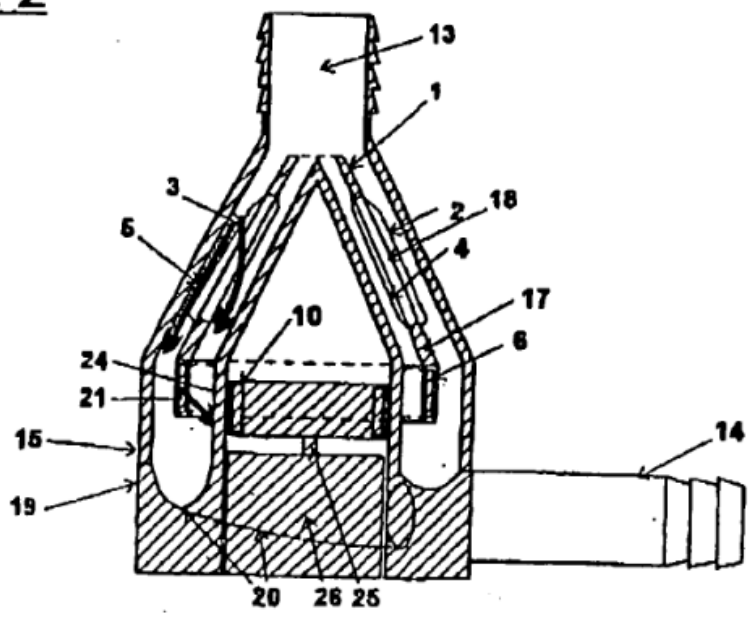
92. Schima discloses a "rotary pump for moving blood and other shear-sensitive liquids with a rotor journaled hydraulically and, if necessary, magnetically in a housing." Ex. 1005 at [0001]. Schima's disclosed goal is to overcome disadvantages of prior devices by avoiding "mechanical depositions, dead-water zones or zones of reduced flow velocity and small gaps," while favoring a "small" number of parts and "simple" construction. Ex. 1005 at [0009].

93. Schima discloses about a dozen different embodiments of rotary pumps, and describes that its "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." Ex. 1005 at [0010]. The flow surfaces are disclosed as vanes formed on the rotor that produce the various flow components. Ex. 1005 at [0012].

94. Schima does not teach or suggest any practical implementation of its disclosed pump and instead discloses only details regarding the pump itself. In FIG. 2, Schima discloses a pump with a rotor 1 driven by "an electric motor 26 which drives a rotating disk 24 with magnets 10 by means of a shaft 25." Ex. 1005 at [0013].

Fig.
~~Abb.~~ 2



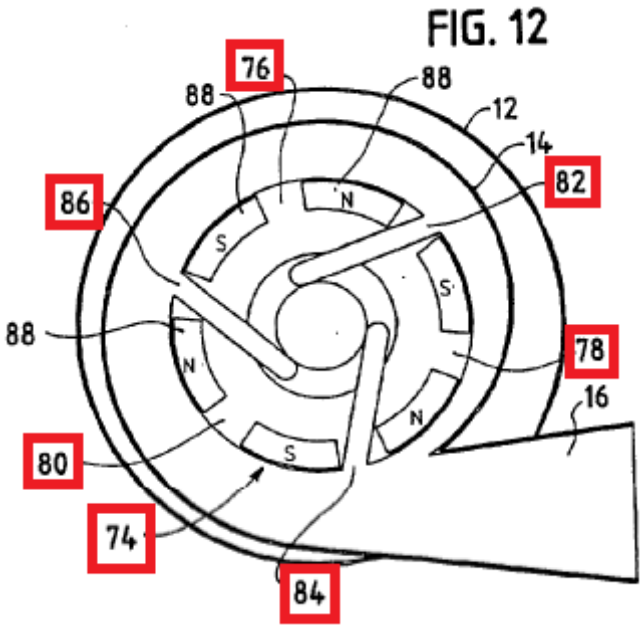
X. GROUND 1—ALLEGED OBVIOUSNESS OF CLAIMS 1–3, 10, 11, 14, AND 17 OVER WAMPLER

A. Claim 1

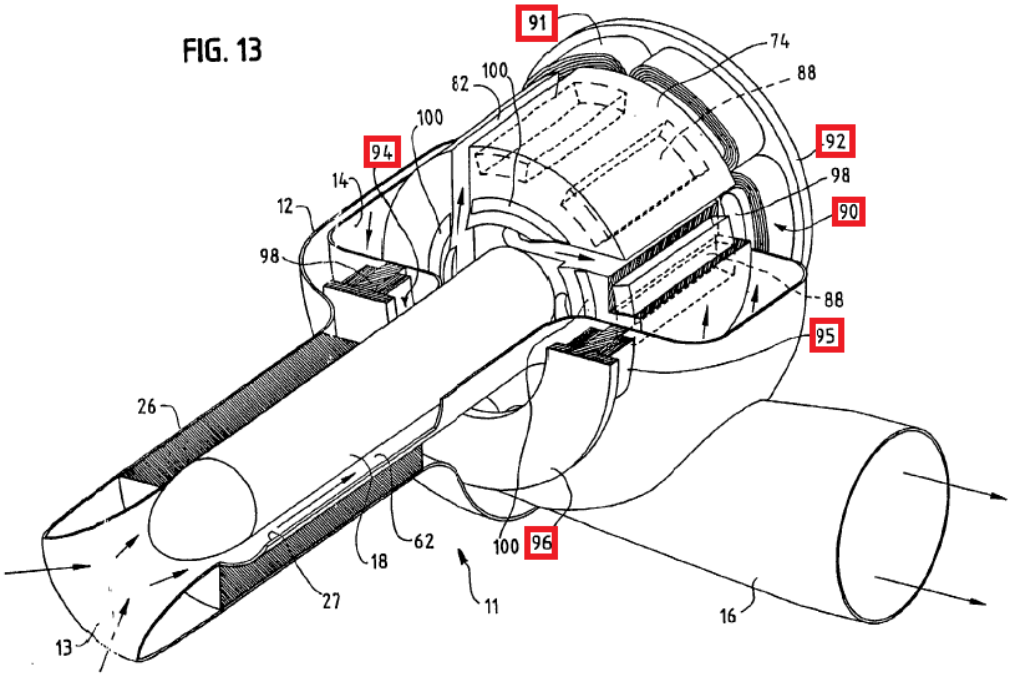
1. [1J] *The second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor*

95. As noted above in Section VIII.C regarding claim construction of "axially closer," the Board has adopted a construction requiring the second magnetic device, magnetically driven rotor, and first magnetic device to be "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." Paper 13 at 23–24.

96. Petitioner contends Wampler's impeller 74 is the "magnetically driven rotor." Paper 1 at 17, 31. As shown in Figure 12 of Wampler (shown below), the impeller 74 includes three "blade sectors" 76, 78, 80 that are separated by slots 82, 84, 86. Ex. 1008, ¶ [0078]; Paper 1 at 23, 25, 38. Petitioner identifies the six motor rotor magnets 88, illustrated in Figure 12 as the claimed "first magnetic device." Paper 1 at 21–23, 31.



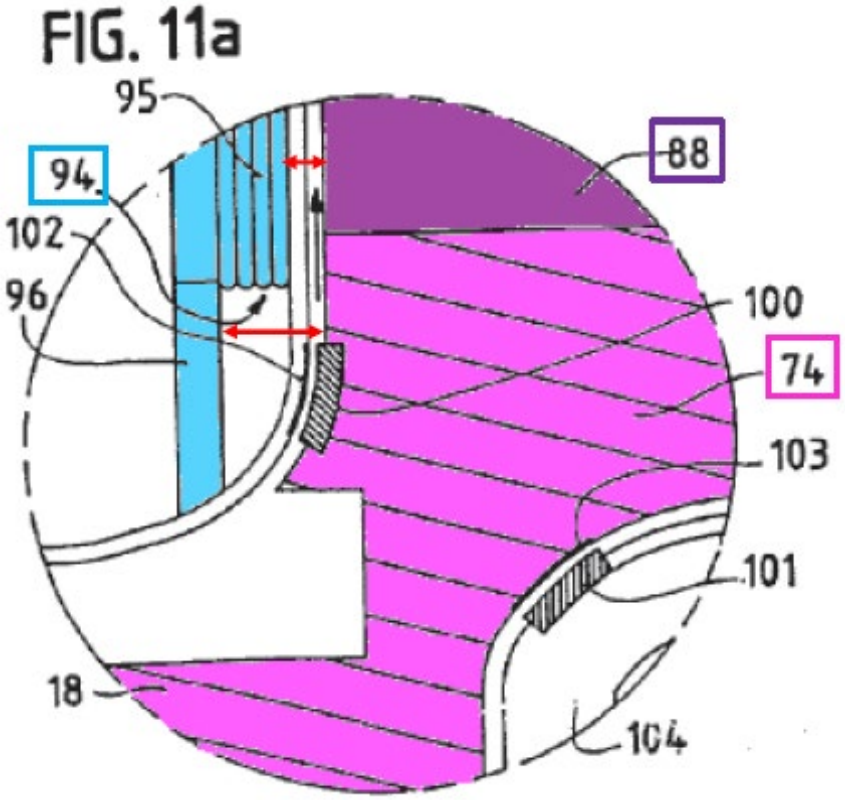
97. For the "second magnetic device," Petitioner contends the two motor stators 90, 94 meet this feature. Paper 1 at 27, 31. Figure 13 (shown below) illustrates that the two motor stators 90, 94 are located on opposite sides of the impeller 74. Ex. 1008, ¶¶ [0084]–[0085]. One motor stator 90 includes windings 91 and a back iron 92. The second motor stator 94 includes winding 95 and a back iron 96. The purpose of each back iron is to "complete a magnetic circuit." *Id*.



98. Petitioner then states without explanation that the "axially closer" claim element is met. Paper 1 at 31. I disagree with this contention. At the outset, I note that Wampler discloses its permanent magnet segments are "imbedded within each impeller blade sector," suggesting that the impeller surrounds the magnets 88. Ex. 1008 at [0018]. Accordingly, it appears that the second magnetic device cannot be positioned axially closer to the first magnetic device at least because the magnetically driven rotor (impeller 74) surrounds the first magnetic device (magnets 88).

99. Petitioner's analysis goes on and, in my opinion, defies logic. They provide an annotated version of Fig. 11a (reproduced below) in which they contend that the "back iron 96" is farther from the magnetically driven rotor 74 than the

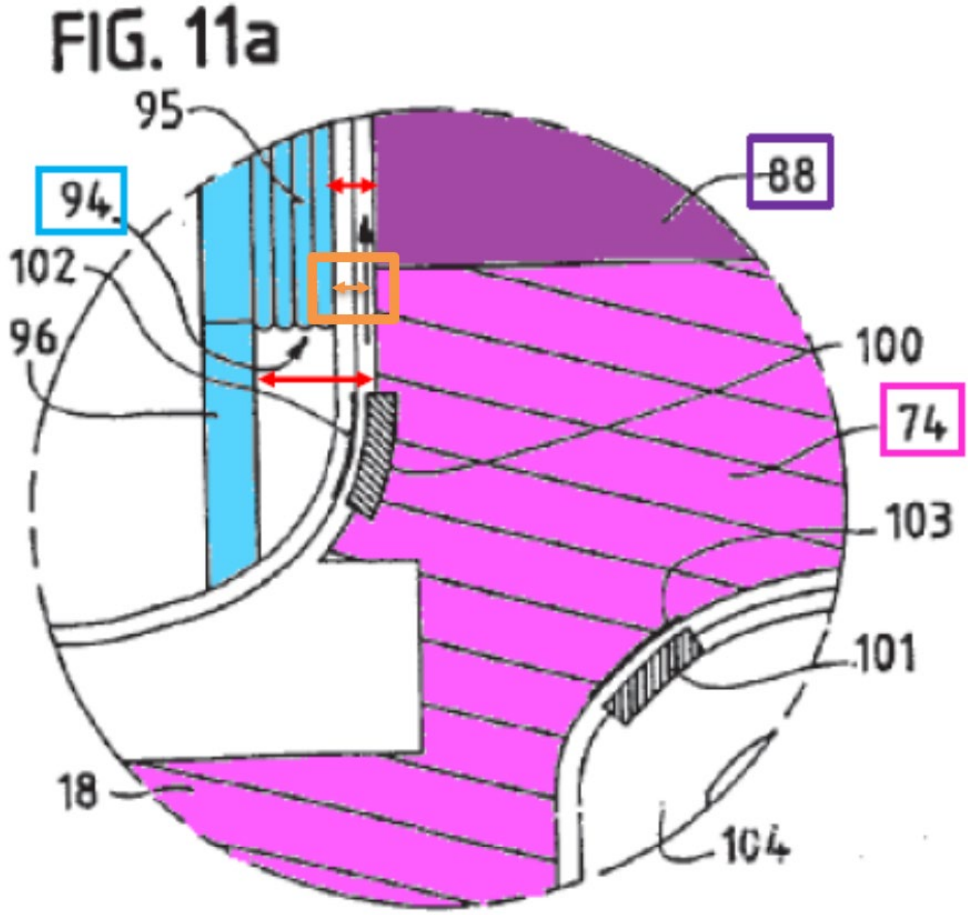
stator coil 95 is from the rotor magnet 88. Paper 1 at 32–34. The figure then uses the two red arrows to show different distances between the second magnetic device (94/96) and (a) the first magnetic device (88), as well as (b) the magnetically driven rotor (74). Paper 1 at 33.



100. In the figure above, Petitioner defines the second magnetic device in two different ways in order to make the claimed configuration work, but I think this is incorrect. In my opinion, making the comparison to correctly determine "closeness" when different portions of the second magnetic device are at different distances relative to the magnetically driven rotor requires utilizing a minimum

distance between the two components. I think that comparing minimum distances between components is the logical decision when faced with a situation where different portions of a component are at different axial distances from another component. To proceed otherwise involves selectively ignoring a portion of a component and utilizing an artificially inflated measurement of distance between the two components. Petitioner provides no rationale for doing so, and I do not think a POSA would have done this.

101. A better measurement of axial closeness is provided in the image below, where an orange arrow (highlighted within an orange box) shows that the second magnetic device is the same distance from the magnetically driven rotor and the first magnetic device.



102. Petitioner goes on to argue that it would have been obvious to position the motor stators 90 and 94 closer to the magnets 88 such that they would meet element [1J]. Paper 1 at 34; Ex. 1003 ¶ 223. This would have been done, argues Petitioner, to allow the stators to interact with the magnets and provide more torque to the impeller. Paper 1 at 34; Ex. 1003 ¶ 223. The magnetic interaction between the stator 94 and the magnet 88, however, has nothing to do with the impeller 74, such that I do not believe it implicates anything regarding the relative

distance of between the stator 94 and magnet 88, versus the stator 94 and impeller 74.

103. Mr. Crosby further argues that there would be a motivation to make this modification because "the 'motor stators' act upon the 'magnetic pieces'—positioning those elements closer to each other would facilitate that action." Ex. 1003 ¶ 223. Here again, however, I note that even if the positioning of these components mattered to their operation, it does nothing to motivate a POSA to change the relative distance between the stator and the magnet with respect to the stator and the impeller.

104. I therefore do not believe that Wampler teaches or suggests element [1J].

2. [1L] ***The magneto coupling orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor is spaced apart from the surrounding rotor housing by the blood flowing in the gap and to the blood outflow port***

105. Petitioner switches between different disclosed embodiments in Wampler in an inappropriate manner to suit their positions and without analysis of why a POSA would have combined the different disclosed embodiments in the contended manner. For claim elements [1A] and [1M], for example, Petitioner relies on the pump embodiment shown in Wampler's Figs. 1–8. Paper 1 at 15–17,

41–42. This is necessary because only the first embodiment of Wampler is illustrated and described as being implanted in a heart and including controller 59 and power supply 61 that "may be worn external by the user." Ex. 1008 at [0070], [0075], Fig. 5. Petitioner's expert has admitted that Wampler discloses multiple distinct embodiments of a pump and contends they are relying only on the embodiment shown in Fig. 11, however. Ex. 2014 at 34–35. Indeed, for claim elements [1B]–[1L], Petitioner cites to the pump embodiment shown in Wampler's Figs. 11–14. Paper 1 at 17–41.

106. Petitioner cannot rely on Wampler's first embodiment (Figs. 1–8) for claim element [1L] because that embodiment includes thrust bearings 39 and 41 to maintain positioning of the rotor 17 relative to the housing 12. Ex. 1008 at [0058]–[0062], FIG. 7. Given that the thrust bearings 39, 41 involve contact with the rotor 17, this embodiment cannot satisfy the recitation of element [1L] that the magnetically driven rotor remains spaced apart from the surrounding rotor housing in response to rotation of the rotor.

107. A POSA would have understood that the first embodiment and the second embodiment of the pumps disclosed in Wampler are different and that the respectively disclosed features are not necessarily combinable.

3. [1M] ***An external control unit configured to regulate operation of the second magnetic device, the external control unit connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device***

108. In contending that this claim element is obvious over Wampler, Petitioner again mixes teachings from distinct embodiments in ways that I do not believe a POSA would have found obvious to do. In particular, Petitioner and Mr. Crosby rely again on the first embodiment of a pump disclosed in Wampler; they must do so because the only disclosure of an external controller in Wampler is with regard to Fig. 5 showing the first pump embodiment. Paper 1 at 41–42; Ex. 1003 ¶ 248–249. As noted above, however, Petitioner relies on the second embodiment of Fig. 11 to teach other elements of claim 1. There is no disclosure, however, of the second embodiment pump being utilized with the controller of the first embodiment pump shown in Fig. 5.

109. Further, a POSA would not have simply interchanged a pump and controller combination in view of the specialized nature of this pairing. Each cardiac assist pump has specific requirements for control and safe operation, and its associated controller is specifically tailored to suit. A POSA would not have understood that it was obvious to swap a pump and controller pairing.

110. The different pump embodiments in Wampler operate in different manners. This includes the pump of the second embodiment utilizing different electromagnet drivers (e.g., the dual stators 90, 94 of the second embodiment) to position the rotor relative to the first embodiment (e.g., utilizing thrust bearings). A POSA would not have found it obvious to utilize the controller shown in Fig. 5 and disclosed as operating the first embodiment pump (e.g., that does not require control of dual stators 90, 94) with the second embodiment pump of Fig. 11 due to these differences. As noted above, each particular LVAD embodiment represents a complex balance of many factors and a POSA would not have found it obvious to simply swap components or change the configuration of a particular LVAD embodiment due to the potentially significant follow-on effects such a chance can have.

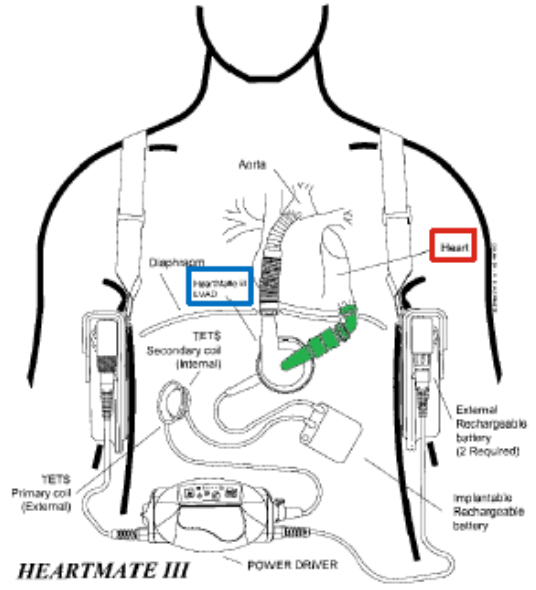
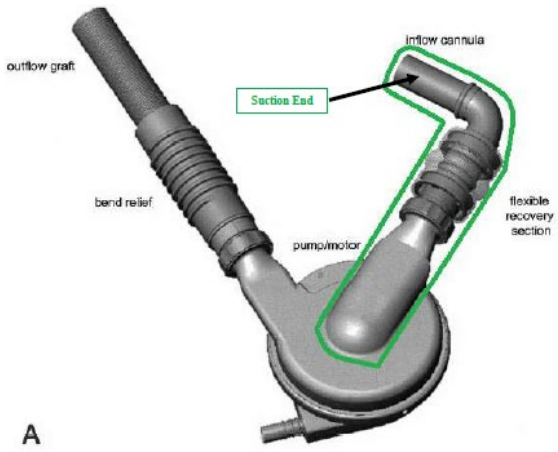
XI. GROUND 2—ALLEGED OBVIOUSNESS OF CLAIMS 1–3, 10, 11, 14, AND 17 OVER BOURQUE-2001 IN VIEW OF WAMPLER

A. Bourque-2001 Alone Does Not Teach or Suggest Claim 1[C] *The magnetically driven rotor is axially aligned with the inflow tube*

111. I understand that, in the Institution Decision, the Board agreed with Patent Owner that the challenged claims are not obvious over Bourque-2001 alone, in particular because the reference does not teach or suggest a rotor "axially aligned" with an inflow tube. I agree with this determination.

112. Claim 1 recites "a suction end of an inflow tube of the heart assist device is inserted into a ventricle of the heart" and that "the magnetically driven rotor is axially aligned with the inflow tube." Ex. 1001 at 5:29–33. It is my opinion that Bourque-2001 does not have this configuration.

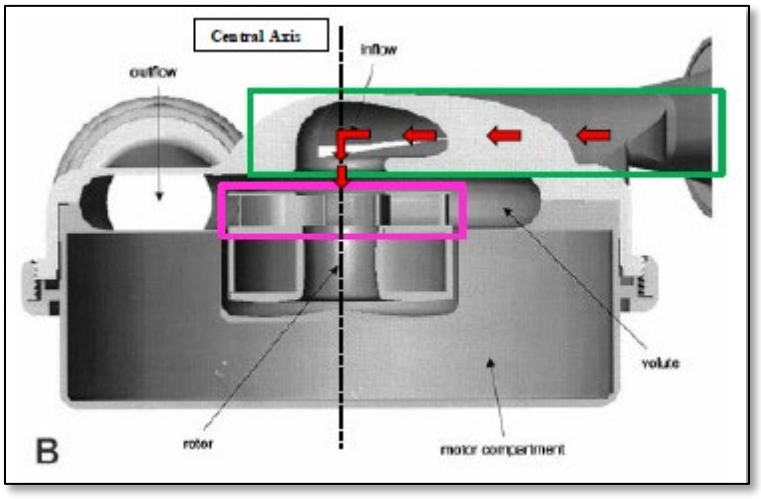
113. Petitioner defines the "flexible recovery section" or "inflow cannula" to be the "inflow tube" that is "defining a blood inflow path." Paper 1 at 46–48; Ex. 1003 ¶¶ 290–294. Petitioner highlights this structure in green in the images below.

 **Figure 3.** HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.	
Paper 1 at 48	Paper 1 at 47

114. The rotor axis in Bourque-2001 is perpendicular to this inflow cannula. That is, the rotor axis extends out of the plane of the page in Fig. 3 from

Bourque-2001 shown above at left. Bourque-2001 recognizes this in describing that this perpendicular arrangement "resulted in a sharp bend in the flow before it enters the impeller." Ex. 1007 at 402.

115. Petitioner annotates another Bourque-2001 image, shown below, with red arrows to supposedly show blood flow. They contend that the flow becomes axially aligned just prior to entering the impeller. Paper 1 at 49–50. I disagree with this contention.



116. The claim recites that the *inflow tube* and the rotor are axially aligned—not that the flow of blood and the rotor are axially aligned. This means that showing the red arrows as aligned with the rotor axis just before entering the impeller does not show that the claim language is met. Instead, we must look to the structure that is the inflow tube, and this is clearly not axially aligned with the rotor. It instead extends perpendicular to the rotor axis along a top surface of the

pump, as shown in Petitioner's annotated image above. In comparison, the '357 patent includes an inflow tube 9 that is axially aligned with a magnetically driven rotor 18. Ex. 1001 at Fig. 2 (shown below).

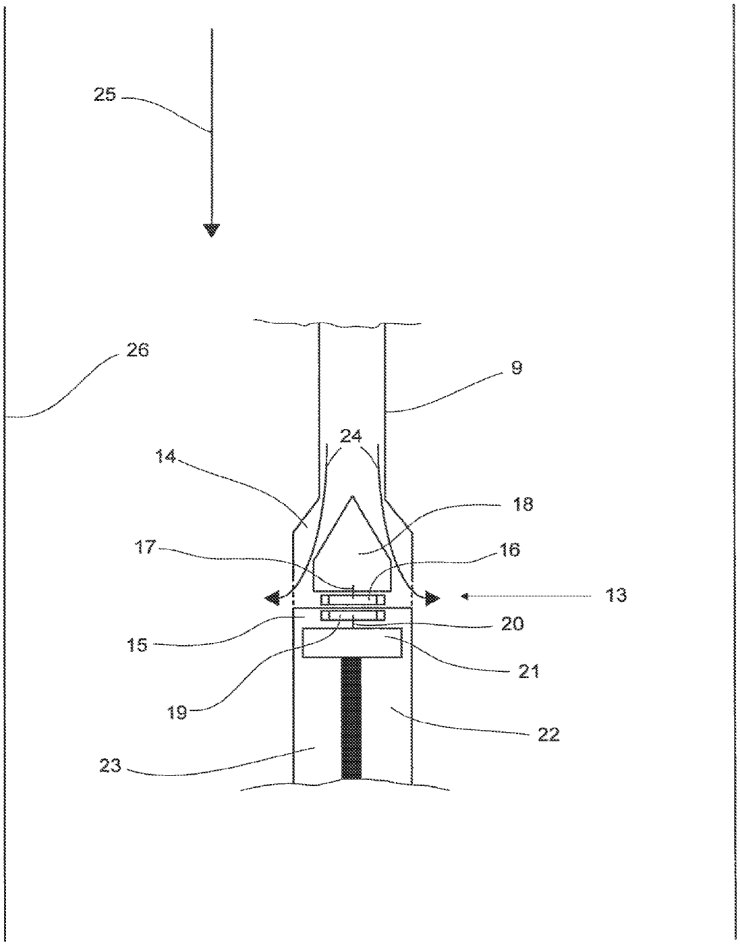


Fig. 2

117. Petitioner's red arrows in the annotated image from Bourque-2001 above are also an oversimplification of the blood flow and not technically correct. The flow does not simply make a 90 degree turn as the arrows contend. Instead, the

flow is complex and extends at various angles throughout its passage through the inflow cannula and into the pump body.

118. The complicated nature of the blood flow in the pump of Bourque-2001 is shown in a computational fluid dynamics analysis of the prototype HeartMate III pump by Mr. Bourque. Ex. 2005 at 874. That analysis shows that the blood does not flow straight down along the central axis like Petitioner's red arrows contend, but curves into the pump at angles. An example image showing the various flow angles is reproduced below from Ex. 2005 at 878.

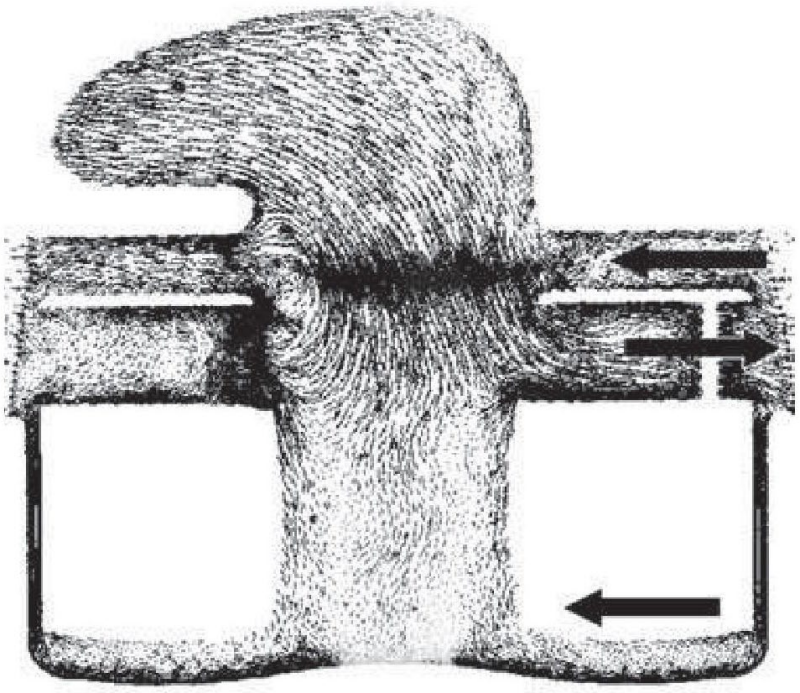
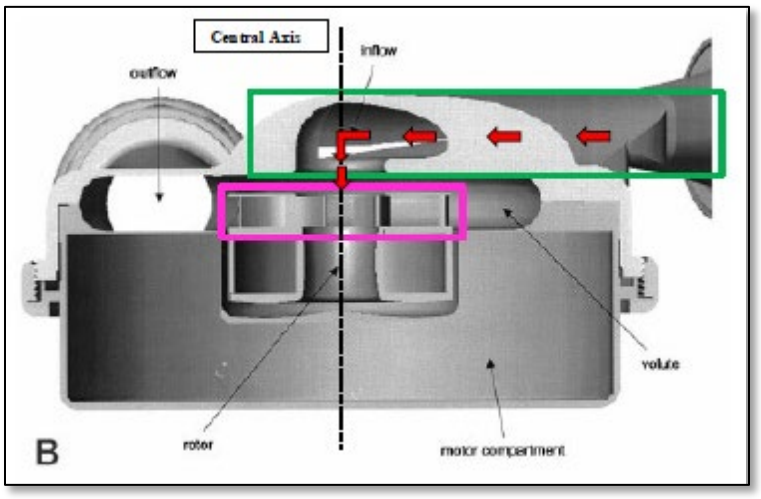


FIG. 6. Planar cut through middle of pump. Arrows indicate local flow directions.



119. Further, the computational fluid dynamics analysis also "reveals a slight degree of swirling flow in the elbow," including "a small pocket of preswirl [that] is induced from the impeller and migrates upward into the elbow." Ex. 2005 at 878. Bourque's own computational fluid analysis of the prototype HeartMate III device from Bourque-2001 therefore shows that the flow is far more complex—and different—than Petitioner's red arrows imply, and that it is not axially aligned as Petitioner contends via its red arrows (e.g., compare Fig. 6 above showing flow from the Bourque computational fluid dynamics study to the Petitioner's annotated image B from Bourque-2001 showing their oversimplified red arrows).

B. A POSA Would Not Have Been Motivated to Combine Bourque-2001 and Wampler As Petitioner Contends

120. Petitioner's answer to the above-noted deficiency of Bourque-2001 regarding an axially aligned inflow tube, among others, is to combine it with

Wampler to deliver the Bourque-2001 pump to the heart with an axially aligned inflow tube, as shown in Wampler's Fig. 5. Paper 1 at 50–51; Ex. 1003 ¶¶ 304–306.

121. There are a number of problems with this contention, perhaps most important among them is that this combination would not have been possible due to the size of the pump disclosed in Bourque-2001. The pump disclosed in Bourque-2001 weighed 475 grams (and totaled 535 grams if including its inflow cannula, recovery section, outflow graft, bend relief, and connecting hardware) and displaced 175 ml. Ex. 1007 at 401. This size and weight of pump is too large to be delivered to the heart as shown in Wampler, i.e., positioned in the pericardial space and coupled directly to the beating heart. In my opinion, a POSA would have appreciated this from the disclosure of Bourque-2001 and other art available at the time of the invention.

122. Wampler describes a pump that is much smaller than the pump of Bourque-2001, but provides only a conceptual illustration of its implantation in Fig. 5. The Wampler pump was never implanted. Further, at the time of these publications, there was no LVAD that fit well at the apex of the heart.

123. Another paper by Wampler describes how it was not ready for implantation even years after the priority date of the cited reference. Ex. 2019 at

783. In addition, this paper cautions that pumps like the one disclosed in Bourque-2001 that include a "complete suspension with active magnetic bearings" have significant downsides, including greater power requirements and the need for additional components, such as proximity sensors and servo circuits, that can increase complexity and compromise reliability. Ex. 2019 at 780. Perhaps most important, however, pumps like the one in Bourque-2001 utilizing active magnetic rotor suspension "add significant volume and weight, making these pumps large and heavy when compared to other rotary pump concepts," like the one shown in Fig. 5 of Wampler. Ex. 2019 at 780.

124. It is my opinion that, even if the proposed combination to modify the inflow subassembly of the pump in Bourque-2001 to axially align the inflow cannula with the impeller of the rotor were undertaken, it would still not be possible to deliver the resulting pump to the heart as shown in Wampler because it would be far too large and heavy.

125. As a counter example, the HeartWare HVAD, which was the first device to be commonly implanted at the apex of the heart—it received FDA approval for this years after the priority date of the '357 patent—was a far smaller device than the pump of Bourque-2001. The HVAD weighed only 145 grams and displaced only 50 cc. Ex. 1015. This means the Bourque-2001 pump was over

three times heavier and larger than the HVAD. Such a device could not have been positioned in the pericardial space in the manner of the HVAD.

126. Bourque-2001 appreciates this fact and discloses that its preperitoneal placement below the diaphragm is the "least obtrusive position" in a human. Ex. 1007 at 402. Further, Bourque-2001 states that "clinical experience has suggested that some freedom of movement between the native heart and pump ameliorates stresses imposed on the heart by an imperfectly placed pump, subdues unnecessary pump motion and potential tissue trauma caused by cardiac motion." Ex. 1007 at 405. As explained in more detail below, coupling a large and heavy pump directly to the heart can have serious negative effects on a patient's health because the pump can interfere with movement and physiological operation of the heart, i.e., anchoring the heart and resisting its beating motion while also impinging on the pericardial space, as well as the lungs.

127. Moreover, the authors of Bourque-2001 published other papers showing the importance of preperitoneal positioning and that implantation at the apex of the heart was not an option for this pump. For example, a 2001 publication by Mr. Bourque, among others, describes that the early HeartMate III device includes a "flexible cannula [that] is fitted upstream of the pump inflow to improve anatomical fit, to decouple the pump from cardiac motion [emphasize this, it is

key], and to provide a point for clamping and ligation for pump explant." Ex. 2004 at 387.

128. The concept of decoupling the pump from cardiac motion is an important one. A pump weighing as much as the one disclosed in Bourque-2001 can create serious negative consequences for operation of the heart if it were to be directly coupled such that it moved with the heart. It would essentially become an anchor on the heart that limits its movement and, thereby, its effectiveness at moving blood within the body. Below I address in more detail why it is important to allow the heart to move, even when using an LVAD. Bourque was expressing an understanding of this importance in the quoted statement from Ex. 2004 noted immediately above, and it supports why a POSA—and Bourque himself—understood that the pump disclosed in Bourque-2001 could not be attached directly to the heart.

129. In still another paper authored by Mr. Bourque, this one from around the time of the priority date of the '357 patent, the relationship between the prototype HeartMate III pump and a patient's heart was discussed. Ex. 2006 at 310. The article notes that, despite over 6 years of development following Bourque-2001, the pump was still "attached to the heart and circulatory system by a flexible inflow cannula inserted into the left ventricular apex." Ex. 2006 at 311.

That is, Mr. Bourque still viewed the preperitoneal placement, spaced apart from the heart and coupled thereto by a flexible cannula, to be the appropriate placement. It is furthermore my opinion that this placement was the only possible position given the size of the pump.

130. Conversely, Wampler describes that its placement at the apex of the heart is possible because "the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm." Ex. 1008 at [0076]. Another paper by Wampler describing additional efforts to develop the pump shown implanted in Fig. 5 notes that the "disc shaped" housing "displaces only 28 cc" while the pump displaces 43 cc. Ex. 2019 at 781. That is, the "extracardiac volume will be only 28 cc." Ex. 2019 at 781. In addition, Wampler notes that the pump weighs 195 grams. Ex. 2019 at 781. Wampler surmises that this size and weight means the pump "should fit well within the pericardial space between the apex of the heart and the diaphragm." Ex. 2019 at 781.

131. It is also worth noting that Wampler can achieve the small size of its disc shaped housing because it places certain structures associated with radial support of the rotor within the inlet tube. Ex. 2019 at 781. And it uses lightly loaded and blood lubricated thrust bearings to constrain axial movement of the rotor. Ex. 2019 at 782.

132. The pump in Bourque-2001 does not have such a "compact" and "disc shaped" housing. Just the opposite, based on the above-noted 475 gram weight and 175 ml displacement of the pump in Bourque-2001, it is over twice the weight and several times the volume of the Wampler pump intended for implantation at the apex of the heart.

133. Further, the pump in Bourque-2001 includes the components necessary for "complete suspension" of its rotor utilizing active magnetic bearings, the same kind that Wampler warned "add significant volume and weight," along with compromising reliability, increasing complexity, drawing more power, etc. Ex. 2019 at 780; Ex. 1007 at 402–403. These components are all included in its motor compartment that would extend into the extracardiac space, even under Petitioner's flawed proposed combination.

134. All of this leads again to the conclusion that the pump of Bourque-2001, even if modified as Petitioner proposes, is far too large and heavy to be delivered to the heart in the manner Petitioner proposes.

135. In support of its position, Petitioner states that there were several LVADs available at the time of the invention that fit well at the apex of the heart. The first pump that I am aware of to be implanted at the apex of the heart in a human was the HeartWare HVAD, which weighed 140 grams and displaced 50 ml.

Ex. 2020 at S262. This pump received FDA approval for such implantation in 2012, years after the priority date of the '357 patent. Ex. 2003 at 729; Ex. 2020 at S258. I therefore do not agree with the contention that there were several LVADs available at the time of the invention that fit well at the apex of the heart. This means Wampler only proposed an unachievable concept of such a pump and placement, but it took over 10 years from the publication of Wampler (many more from its priority date) and 5 years after the priority date of the '357 patent before an LVAD was actually made small enough to be implanted at the apex of the heart.

136. Petitioner's expert, Mr. Crosby, was an executive at a company attempting to bring an LVAD to market around the priority date of the '357 patent. The device, VentrAssist by Ventracor, weighed 298 grams, so less than the pump of Bourque-2001. Ex. 2013 at 736. Despite this, VentrAssist was implanted in a preperitoneal pocket rather than at the apex of the heart, just like the pump in Bourque-2001, and just as a POSA would have expected was required at the time of the invention for a pump of its size and weight.

137. Below is a summary of information about various pumps described herein:

Device	Weight	Volume	Location	Implanted in Humans?	Year of Publication or Approval
HeartMate II	281	63	Pocket	Yes	2000

Wampler	195	28	Apex	No	1998
Bourque-2001 (HeartMate III prototype)	474	168	Pocket	No	2001
HeartMate 3 (clinical)	200	80	Apex	Yes	2015
VentrAssist	298		Pocket	Yes	2003
HeartWare HVAD	145	50	Apex	Yes	2012

138. In comparison to the HVAD and the pump developed (but not implanted) by Wampler, the pump of Bourque-2001 is massive. It would not have been possible to implant such a pump at the apex of the heart due to its size and weight, and would therefore not meet the requirements of Petitioner's contended motivation to combine Bourque-2001 with Wampler. In my opinion, a POSA would not have believed the pump of Bourque-2001 could have been successfully delivered to the heart in the manner Petitioner contends, and therefore would not have been motivated to make the combination contended by Petitioner.

139. One reason for the difficulty in implanting a large device at the apex of the heart is that there is limited space between the apex of the heart and the diaphragm. There is also limited space between the heart and the lungs on each side thereof. As a result, placing a large pump in this space can impinge on the heart and lungs with negative effect on the patient, i.e., impeding function of the heart and/or lungs.

140. In addition, the heart still beats even after an LVAD is implanted to assist it. Even if the LVAD is configured to completely relieve the load on the left side of the heart, the right side of the heart must still beat to continue operating (as its name suggests, an LVAD does not support the right side of the heart). When a heart beats, it moves, for example, lifting and turning in a standing patient. As a result, attaching a large and/or heavy pump directly to the heart such that the pump moves with the heart can disrupt the heart's movement and function. This can be especially detrimental to the beating and operation of the right side of the heart that is not being supported by the LVAD.

141. Petitioner's expert, Mr. Crosby, has admitted in his deposition that he did not consider the relative size and weight of the different pumps he was describing and proposing to combine at the apex of the heart. Ex. 2014 at 78, 92, 108. In my opinion, this is a key oversight that a POSA would have known to consider. Mr. Crosby explained that size and weight would not be important to a POSA at the time of the invention because the heart no longer beats with an LVAD supporting it. Ex. 2014 at 61–65. As noted above, I disagree with this contention.

142. There is a clinical HeartMate 3 device that is implanted at the apex of the heart. Ex. 2020 at S259. It was introduced years after the priority date of the '357 patent and the device is significantly smaller and lighter than the pump of

Bourque-2001, weighing 200 grams and displacing 80 ml. Ex. 2020 at S259, S262. In addition, Mr. Bourque has admitted that significant work was needed to change the early pump of Bourque-2001 into the clinical HeartMate 3 device.

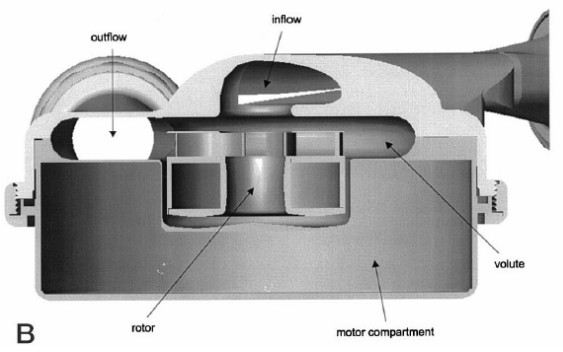
143. For example, Mr. Bourque noted the changes in an American Heart Association news article published in 2018: "Also potentially joining the field is HeartMate3. A precursor to that was almost ready in 2006 when the company went back to the drawing board, creating a smaller, simpler version, said Kevin Bourque, a vice president of research and design for engineering at St. Jude Medical who has been working on this concept since the start." Ex. 2007 at 5.

144. Mr. Bourque also described the new design in a 2016 ASAIO article. Ex. 2008 at 375. And, in a 2021 interview, Mr. Bourque noted that "in 2006, we said, 'Let's stop, let's do exactly this (the original, larger HeartMate 3 design) but let's make it the clinical HeartMate 3 now, a mini one of those." Ex. 2007 at 5–6.

145. Mr. Bourque also described key changes that enabled making a "mini" version of the pump of Bourque-2001. For example, he noted that "by flipping the rotor upside down," space was gained. Ex. 2007 at 7. Further, chip sizes reduced over time, so this allowed shrinking the device further. Ex. 2007 at 7. Mr. Bourque also pointed out that "when we got this small, we said wait a minute, now we don't need to implant it down here (in the abdomen), we can go right in

the chest." Ex. 2007 at 7. This "took away this whole business about creating a pocket for the pump and then requiring a conduit between the heart and the pump." Ex. 2007 at 7. Mr. Bourque is describing the essence of the points made above, i.e., that the pump of Bourque-2001 was simply too large and heavy to be implanted at the apex of the heart—and that doing so was only possible once the pump was redesigned in a manner that reduced its size significantly.

146. As might be expected, Mr. Bourque and Petitioner patented the new pump design that enabled placement at the apex of the heart. Ex. 2009. The patent illustrates Mr. Bourque's description of "flipping the rotor upside down" in FIG. 2 (below right), with the impeller blades 143 and permanent magnets 141 inverted from the configuration shown in Bourque-2001 (below left). In addition, blood flowed through the repositioned stator 120, which also helped reduce the size of the pump.



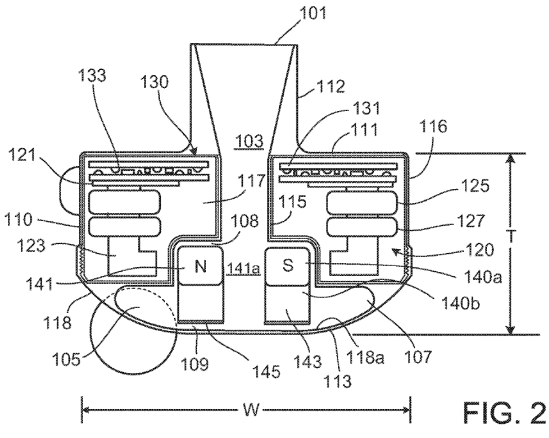


FIG. 2

147. Patents are granted to protect novel and non-obvious developments over the prior art, which would have included the pump of Bourque-2001 in the case of Ex. 2009. This evidences that the changes needed to implement the contended combination were not routine and were viewed by the US Patent and Trademark Office as sufficiently novel and nonobvious over the prior art to grant the patent. Further, it is my opinion that these changes would not have been routine or obvious to a POSA at the time of the invention.

148. Petitioner's various reasons for combining Bourque-2001 and Wampler all have failings. For example, Petitioner argues that a POSA would have been motivated expressly to move the pump of Bourque-2001 to the apex of the heart. Paper 1 at 74–78; Ex. 1003 ¶¶ 419–426. As explained above though, this would have been practically impossible to do and, if forced, would have had disastrous effects on the heart due to the size and weight of the Bourque pump and its impact on the heart function, including the unassisted right side that must continue beating even in the presence of an LVAD to assist the left side of the heart.

149. Petitioner further describes that the combination would remove a flow restrictive elbow. It is not clear that a POSA would have been motivated to remove this elbow. Paper 1 at 73; Ex. 1003 ¶¶ 411–414. Petitioner's own modeling of the

flow found benefits to the complicated flow pattern introduced by the elbow, however, including washing of an area that might otherwise be stagnant. Ex. 2005 at 878. In addition, this motivation is related to placement of the pump at the apex of the heart, which a POSA would not have done for all of the reasons reviewed above.

150. Petitioner also argues that the proposed combination will result in the pump inlet serving as the inflow cannula. Paper 1 at 73–74; Ex. 1003 ¶ 419. This supposedly provides a benefit of enabling removal of troublesome components. Paper 1 at 73–74; Ex. 1003 ¶ 419. But this also requires moving the pump to the apex of the heart, which is what allows removal of the inflow cannula. A POSA would not have been motivated to do this based on the size of the pump in Bourque-2001 that was clearly too large to be placed at the apex of the heart.

151. Petitioner further argues that modifying the pump of Bourque-2001 with "an inflow cannula apical tube, 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." Paper 1 at 77. For support, Petitioner cites to the Poirier patent (Ex. 1018) and the Crosby Declaration (Ex. 1003 ¶¶ 473–476). I disagree with this contention. The patent of Ex. 1018 discloses simply that inflow and outflow cannulas from the HeartMate II device (shown in Fig. 1) can be used with pumps like the one

disclosed in Bourque-2001 (shown in Fig. 4). Ex. 1018 at 6:62–7:5. That is not surprising given that both pumps (HeartMate II and the pump disclosed in Bourque-2001) were implanted in preperitoneal pockets remote from the heart due to their size and weight. In my opinion, this patent therefore suggests nothing about a change that would enable placing the pump at the apex of the heart.

152. Contrary to Petitioner contentions, there is no evidence that substituting Wampler's inlet into the pump of Bourque-2001 would be not complex, and it was not known. Wampler has a unique inlet with rotor and spindle that extend into the outlet to provide radial magnetic bearings and a forward thrust bearing. Ex. 1008 at Figs. 1–4. Wampler therefore not only includes an axially aligned inlet tube, but the inlet tube has magnets that cooperate with the magnetic spindle of its rotor to form a necessary part of the entire pump design. Ex. 1008 at Figs. 1–4. The pump in Bourque-2001 does not include a spindle like Wampler, and its pump housing is much larger because it has to provide rotor stability using larger magnets disposed in the housing. Ex. 1007 at 402–403. The pump of Bourque-2001 therefore cannot fit into the position of Wampler's Fig. 5 because of its much larger size. For example, the pump in Bourque-2001 is disclosed as being 69 mm in diameter and 30 mm high, with a weight over 400 grams. Ex. 1007 at 401. The pump in Wampler is much smaller, weighing only 195 grams. Ex. 2019

at 781. Further, Wampler describes the pump as having an impeller diameter of 1.0 inch to 1.5 inch (38 mm), and an impeller height 0.2 to 0.5 inch (12 mm). Ex. 1008 at [0077]. While these dimensions may not be directly comparable (e.g., pump overall diameter vs. impeller diameter), they convey the large relative difference in size between the pump of Bourque-2001 and the pump shown implanted in the heart in Wampler. Moreover, the structure detailed above is part of what makes Wampler's extracardiac disc smaller and enables the placement of the first embodiment Wampler pump at the apex of the heart, as shown in Fig. 5.

153. The above-described structure also provides important functionality to the Wampler pump that would preclude merging it with Bourque-2001. For example, the Wampler pump utilized thrust bearings to provide bi-stable operation. That is, due to a variability of inlet pressure throughout the cardiac cycle, the rotor of Wampler moves axially back and forth with every heartbeat to reduce the risk of thrombosis. Wampler has both the magnetic suspension and lightly loaded thrust bearings to provide for this motion, while the pump of Bourque-2001 does not. Without thrust bearings, the function of impeller stability would need to be accomplished using additional magnets, which would make the pump bigger and heavier (indeed, this is the case with Bourque-2001).

154. Further, the spindle in front of the impeller is critical to radial stability and therefore a critical part of the pump beyond just the inlet tube. For example, without the spindle, the housing would have to include more magnets and thereby become larger/heavier, precluding the same implantation position shown in Fig. 5.

155. Still further, the inlet flow proceeds in the annular space outside the spindle in Wampler, not as a central flow as in Bourque-2001, which changes the flow dynamics and the shape of impeller. Finally, the thick blades of Wampler include magnets in the impeller that Bourque does not include. All of this functionality and structure would need to be redesigned to make the contended combination between Bourque-2001 and Wampler.

156. I therefore believe that the proposed modification of Bourque-2001 and Wampler would not be "not complex" and was certainly not "well known in the art" to a POSA at the time of the invention. Just the opposite, a POSA at the time of the invention would not have been motivated to make the combination in view of the large size of the pump in Bourque-2001. Even if they did make such a combination, it would involve significant work and innovation to achieve. I therefore do not think a POSA would have any reasonable expectation of success in making the contended combination of these two dramatically different designs. I also therefore believe it would not have been obvious to try such a combination, as

there are myriad factors at play that involve fundamental design choices being changed to facilitate the contended combination.

C. Bourque-2001 and Wampler Do Not Teach or Suggest Dependent Claims

1. Claim 11 *further comprising one or more sensors that deliver feedback signals to the external control unit*

157. Petitioner contends that Bourque-2001 discloses use of an "ultrasonic flow probe" and "solid-state catheter-type pressure transducer" to provide feedback signals to an external control unit. Paper 1 at 69; Ex. 1003 ¶¶ 391–396. Bourque-2001 does not disclose that such measurements are provided to the external control unit that controls operation of the pump though. Instead, the reference separately discloses use of "electronics" for "power and control of the LVAD" and "for data acquisition" that are on a shelf during its experiments. Ex. 1007 at 403. When describing pump control, it states that "speed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III." And separately notes that all measurements from the above-noted sensors "were automatically processed and recorded using Labview." Ex. 1007 at 403. There is no indication that a feedback signal from a sensor was provided to an external control unit that was responsible for controlling the pump, rather than to a separate experimental data logging instrument.

158. Wampler is also deficient with regard to claim 7. As noted above, Wampler states that its controller 59 can be "interconnected" with "sensors on various organs," but nothing more. There is no disclosure of an example sensor, its feedback, how the latter might be used with the former, or a rationale that might motivate a POSA to implement the method recited in claim 5.

XII. GROUND 3—ALLEGED OBVIOUSNESS OF CLAIMS 1–3, 10, 11, 14, AND 17 OVER AKAMATSU

A. Claim 1

1. [1J] *The second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor*

159. As noted above in Section VIII.C regarding claim construction of "axially closer," the Board has adopted a construction requiring the second magnetic device, magnetically driven rotor, and first magnetic device to be "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." Paper 13 at 23–24.

160. Petitioner relies on FIG. 2 of Akamatsu as support for teaching of claim element [1J], alleging with an annotated figure that the reference teaches a motor (blue) positioned axially closer to a permanent magnet (purple) than to an impeller (pink). Paper 1 at 91; Ex. 1003 ¶ 494, 497. This description and figure

represent the extent of Petitioner's analysis of this claim element. Moreover, Akamatsu provides no useful disclosure regarding how its impeller and permanent magnets are assembled or coupled to one another.

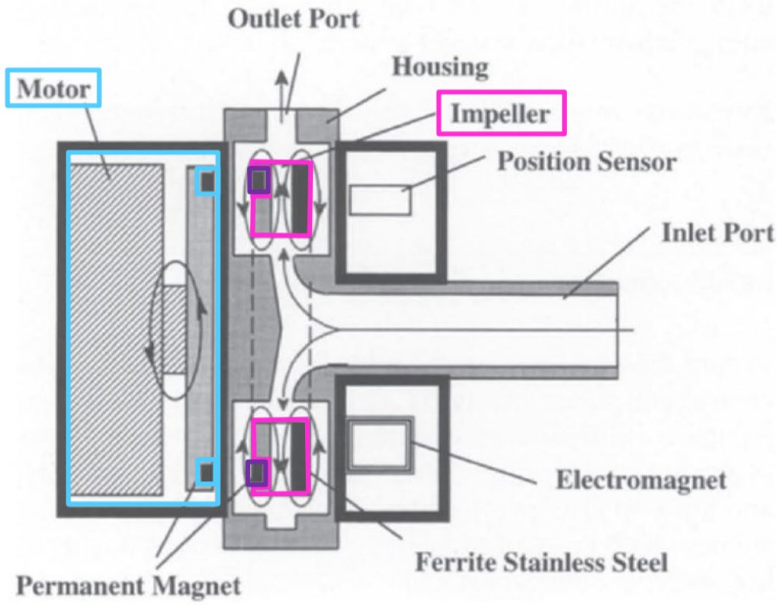


Fig. 2. Schematic cross section of the MSCP

161. Petitioner appears to have drawn their annotations in the figure above in a manner that shows the purple boxes surrounding the permanent magnets as extending farther toward the motor than the pink box highlighting the impeller. This gives the impression that the magnets (first magnetic device) of the impeller (magnetically driven rotor) are axially closer to the motor (second magnetic device) than the impeller itself. This is misleading, however.

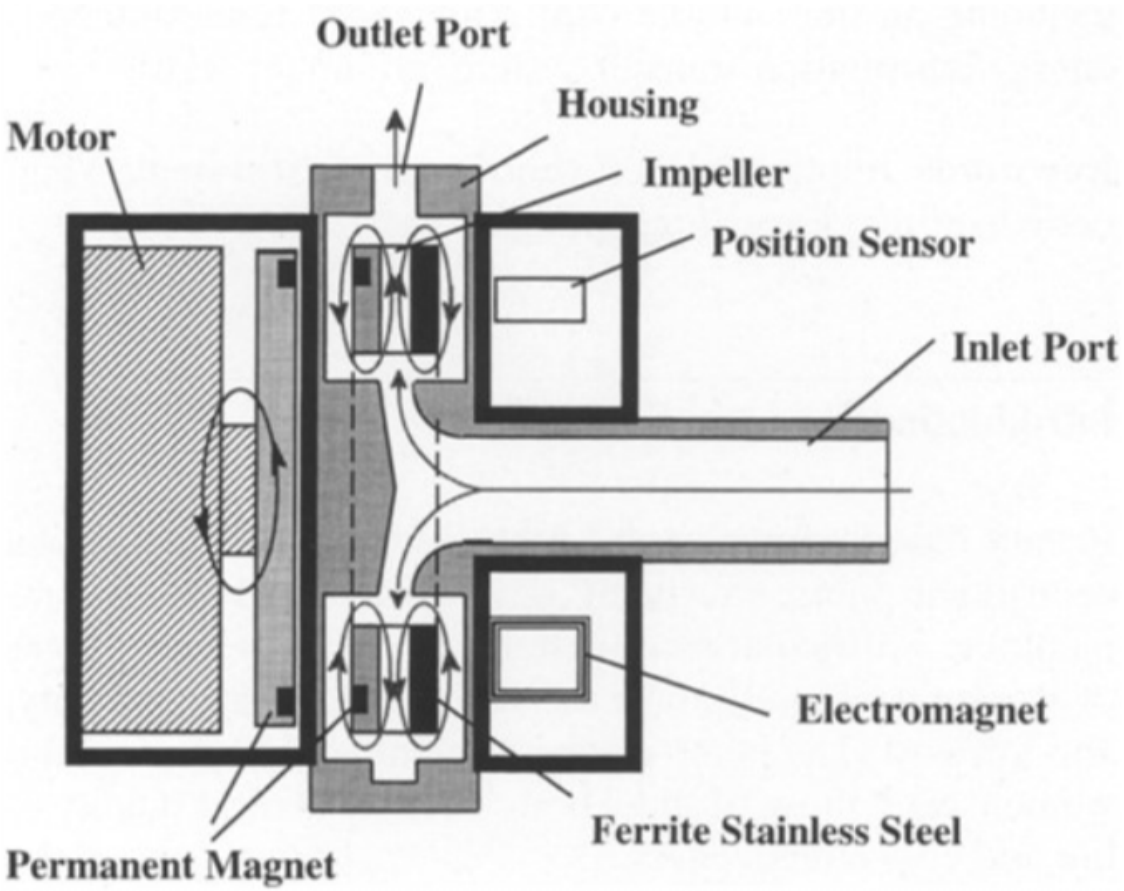


Fig. 2. Schematic cross section of the MSCP

162. The only disclosure Akamatsu includes is the schematic illustration of Fig. 2. Inspecting the original form of this figure without Petitioner's annotations (shown above), however, reveals that the permanent magnets of the impeller appear to be, at most, flat with the left side of the impeller. This would mean these components have the same axial distance to the motor, i.e., along the horizontal or X-axis in the figure. Further, close inspection suggests that the permanent magnet may be inside the impeller, similar to the above-described embedded magnet pieces 88 of Wampler embedded in its impeller 74.

163. In my opinion, Akamatsu therefore cannot teach or suggest a second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor, and a POSA would not have understood the reference to teach such a configuration.

2. [1M] ***An external control unit configured to regulate operation of the second magnetic device, the external control unit connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device***

164. Petitioner relies on Fig. 1 to provide disclosure regarding element [1M], even though the various components illustrated in the figure are not spelled out in Akamatsu.

165. For example, Petitioner contends that Akamatsu "teaches or suggests a controller (worn externally in Figure 1)" based on a marked-up version of FIG. 1 highlighting the alleged controller as a belt-mounted component circled in lime green. Paper 1 at 95; Ex. 1003 ¶¶ 517–521.

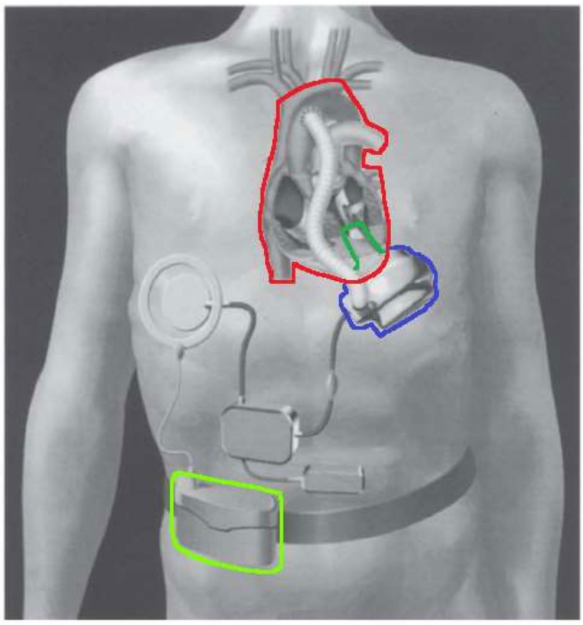


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

166. Akamatsu is silent regarding what this component is, or what any of the other components are in Fig. 1. As noted previously, Fig. 1 is clearly a conceptual and aspirational drawing of a system not actually implemented at the time of Akamatsu's publication. Further, the only direct description of the figure says that it is an illustration of a "totally implantable left ventricular assist system." Ex. 1006 at 3. Such a system would require that the controller operating the pump be an implanted controller, not an external controller. For example, in a "totally implantable" system, a patient would need to be able to remove the belt and the component outlined in lime green coupled thereto in order to, for example, shower. If the component outlined in lime green were the external controller as contended by Petitioner, the pump would no longer run if the belt were removed. I therefore

believe a POSA would instead understand the "totally implantable" system of Fig. 1 in Akamatsu to suggest use of an implanted controller to operate the implanted pump.

167. For example, it is also possible that the component highlighted in lime green is a power source, such as a battery. The lime green outlined component is coupled to a wire extending to a ring positioned over what appears to be an implanted disc. This may be a transcutaneous energy transfer (TET) system used to transfer electrical power from outside the body to inside the body. Further, the implanted disc is itself coupled to what may be an implanted controller disposed above the lime green outlined component in FIG. 1. In support of this is Akamatsu's disclosure of aspirations to use a "a prototype MSCP with…an implantable controller," as well as "a totally implantable LVAS" including "a transcutaneous energy and information transfer system and internal/external batteries." Ex. 1006 at 7.

168. Regardless, however, that Akamatsu is simply not clear on what it is disclosing and a POSA would not necessarily take from this figure the teachings that Petitioner contends.

169. Further, after identifying what may be an external power source coupled to an implanted controller as the claimed external controller, Petitioner

contends that disclosure of the "next phase" Model III pump with an implantable controller shows that earlier disclosure of a "percutaneously driven" Model II pump involves use of an external controller. Paper 1 at 96; Ex. 1003 ¶¶ 517–518. This is speculation by Petitioner without any backing from Akamatsu. For example, a percutaneously driven pump (i.e., with a power source outside the body and drive leads extending into the body) could still utilize an implanted controller coupled to the pump.

170. For these reasons, it is my opinion that Akamatsu lacks sufficient disclosure to teach or suggest the recitation of claim element [1M].

XIII. GROUND 4—ALLEGED OBVIOUSNESS OF CLAIMS 1–3, 10, 11, 14, AND 17 OVER SCHIMA IN VIEW OF AKAMATSU

A. Claim 1

1. [1A] A *heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path*

171. Petitioner admits that Schima is silent regarding whether its disclosed pump is deliverable to the heart. Paper 1 at 103; Ex. 1003 ¶¶ 561–568. Petitioner relies on Akamatsu to remedy this deficiency of Schima, contending that "it would have been obvious to implant Schima's device in the configuration described by Akamatsu." Paper 1 at 102. I disagree with this contention. At the outset, I refer to my point above about each LVAD representing a delicate balance of myriad

factors and goals that a POSA would not be motivated to alter in view of potentially unpredictable—and serious—follow-on effects. The contention to simply use a different device in such a context is, in my opinion, an oversimplification of the issues involved.

172. It is my opinion that a POSA would not have found Schima's device capable of delivery to the heart in the configuration described by Akamatsu. One reason for this is that I believe a POSA would have recognized Schima as a pump intended for extracorporeal use and therefore would not have found considered it capable of delivery to the heart, much less to be positioned at the apex of the heart as Petitioner contends.

173. It is my opinion that a suggestion to deliver a device to the heart that is not specifically designed for this purpose fails on its face as an oversimplification of the issues that surround development of an implantable medical device, especially a cardiac assist device.

174. Moreover, it appears to me that Schima's pump is not configured for delivery to the heart at all. Indeed, there is no teaching or suggestion in Schima to suggest that its pump is configured for use in the body.

175. Moreover, Petitioner is not suggesting some combination of features from Schima's pump with pump of Akamatsu, but instead contends that a POSA

would have simply delivered the Schima pump to the heart by implanting "the Schima device in the configuration described by Akamatsu." Paper 1 at 102.

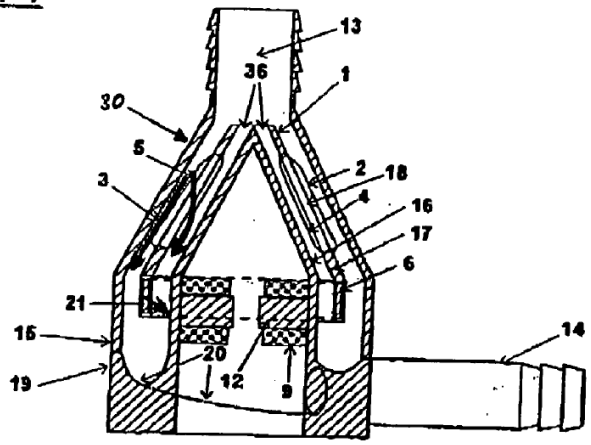
176. There are a number of reasons why I believe a POSA would not have understood Schima's pump as being deliverable to the heart and was, instead, intended for extracorporeal use outside the body. For example, Schima discloses that its pump is suitable for use in "moving blood and other shear-sensitive liquids," which suggests it is a device configured to use in multiple applications, not specifically configured for implantation in the body. Ex. 1005 at [0001]. In contrast, I believe every implantable device that I have worked with has been specifically engineered for its purpose of operating within the body.

177. Further, the pump disclosed in Schima bears several hallmarks or features that indicate it is not a device suitable for implantation in the body—features that I believe a POSA would have understood in view of Schima's disclosure and an ordinary level of skill in the art.

178. One example is the illustrated connections of the inlet 13 and outlet 14 on Shima that appear to be conventional barbed fittings configured for use with tubing and clamps to achieve a seal. These types of components are not used in devices being implanted within the body due to lack of access after implantation, etc. In contrast, these types of connections are utilized in extracorporeal pumps

where access to the pump is easier throughout its lifecycle, and in other industrial uses. For example, such fittings are often used for attachment of a Tygon 3/8 tube in an extracorporeal configuration for external bypass. I also think a POSA would have considered such fittings as not capable of delivery to the heart, e.g., insertion into the heart through a hole formed therein, because such a connection would be rudimentary, unreliable, potentially traumatic to the heart, and potentially life threatening to a patient. A POSA would instead have expected pump deliverable to the heart to include different connecting structures configured to interface with the heart or other anatomical structures.

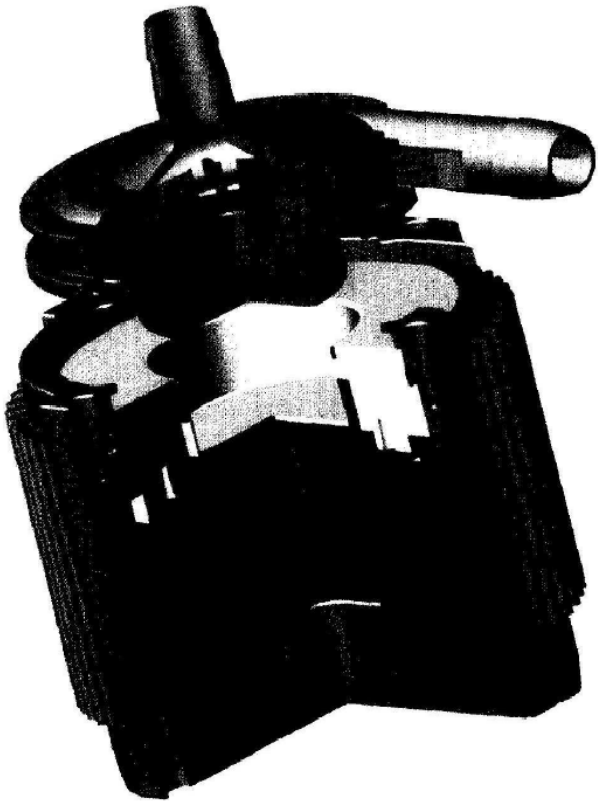
Fig.
Abb. 1



179. Another example is the relatively sharp, 90-degree edges found on external-facing surfaces of the Schima pump, such as its housing. Such edges are

not typical for an implanted device due to concerns about the edges causing trauma to surrounding tissue as the pump moves relative to the body.

180. In contrast, I believe the pump in Schima is similar to extracorporeal pumps known in the art. For example, Exhibit 1011 is another reference directed to a multi-fluid-application pump design like Schima, and it acknowledges contemplated use only extracorporeally or in industrial settings. Ex. 1011 at 3–4 and FIGS. 4–5. Delivering a device configured for use outside the body or in industrial settings to the heart in the contended manner is a complicated endeavor that was not within the scope of disclosure in either Schima or Ex. 1011, and in my opinion would not have been obvious to a POSA at the time of the invention.



Ex. 1011, Fig. 3

181. In my opinion, the Schima pump also appears similar to other known extracorporeal circulatory support pumps. These can include pumps used on extracorporeal membrane oxygenation (ECMO) and heart-lung machines, as well as other extracorporeal LVADs. The Thoratec PediMag and CentriMag devices are examples of extracorporeal heart support pumps that utilize a similar pump housing disposed atop a motor, as shown in Fig. 15 below. Ex. 2021 at 13–15. In my opinion, a POSA would have understood Schima as directed to a similar extracorporeal pump.



Ex. 2021, Fig. 15

182. The Schima pump also appears similar to Medtronic's BP-50 LVAD that is used extracorporeally, as shown in Fig. 19 below. Ex. 2021 at 15–16.

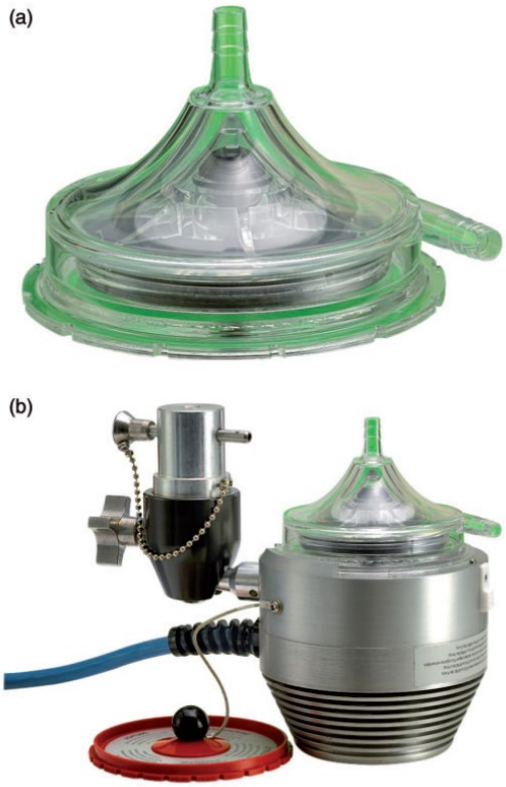
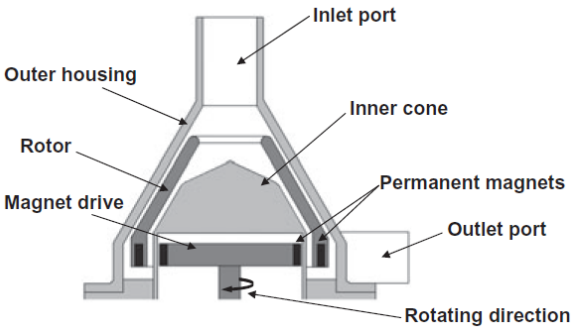


Figure 19. BP-50 LVAD (Courtesy of Medtronic). (a) BP-50 Bio-Pump and (b) Bio-Console 540.

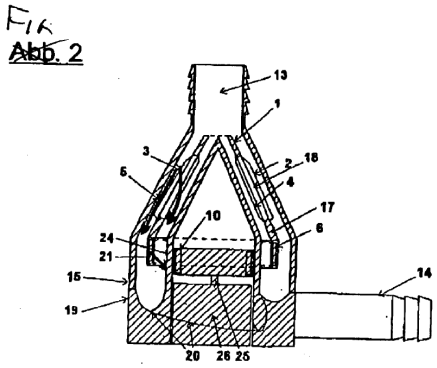
Ex. 2021, Fig. 19

183. Further confirmation of the idea that Schima discloses an extracorporeal pump not intended for implantation in the body can be found in later work (Ex. 2022) by Heinrich Schima and several of the other inventors further describing the pump disclosed in Schima. The pump is similar to the pump disclosed in Schima, as shown in Fig. 1 of Ex. 2022 and Fig. 2 of Schima below. The authors describe the pump and various performance tests, noting that it performs "in the range of contemporary extracorporeal bearingless blood pumps." Ex. 2022 at 256. They mention the CentriMag pump noted above as one of these

"contemporary extracorporeal blood pumps," which reinforces my view above regarding their similarity. Ex. 2022 at 256. They further describe that the Schima pump is likely to have "a production cost low enough to allow its use in disposable pump heads." Ex. 2022 at 257. This configuration of a disposable pump head that can be placed into a motor is similar to that disclosed in Ex. 1011.



Ex. 2022, Fig. 1



Ex. 1005, Fig. 2

184. It is my opinion that a POSA at the time of the invention would have understood from Schima's disclosure what was later made more explicit in Ex. 2022, namely that the pump in Schima is an extracorporeal blood pump that is not deliverable to the heart in the manner Petitioner contends. A POSA therefore would not have combined this pump with Akamatsu as Petitioner contends.

185. In addition, even if Schima were to be delivered to the heart in the manner Petitioner contends, I do not believe this would meet all elements of the claim because Akamatsu's pump was aspirational and too large to be implanted in

the contended manner. On this point, I refer to my comments above regarding Akamatsu in Section XII.

186. Regarding element [1A], for example, it is simply not clear from Akamatsu that the reference discloses delivering its pump so that a suction end of an inflow tube is inserted into a ventricle of the heart. Petitioner relies on the conceptual drawing of FIG. 1 of Akamatsu to suggest the claimed delivery of a heart assist pump recited in element [1A], but this configuration is not actually shown. Instead, Petitioner marks up FIG. 1 to show a feature that is not clear in the original.

187. Akamatsu also discloses a "paracorporeally" positioned pump, as well an "intrathoracically implanted" pump, in a way that suggests the use of "inflow and outflow conduit" extending between the "inlet port" and "outlet port" of the pump to the descending aorta and the ventricular apex, respectively. Ex. 1006 at 4. This suggests the inlet port of Akamatsu's pump is not itself inserted into a ventricle of the heart as Petitioner contends.

188. Still further, and as noted above, a POSA at the time of the invention would not have understood Akamatsu to provide a teaching of implanting its pump at the apex of the heart due to the size and weight of the disclosed pump in that reference. Instead, it is my opinion that Fig. 1 of Akamatsu would instead have

conveyed to a POSA that its large pump be implanted in the manner that all such pumps were implanted at the time of the invention, namely, in a preperitoneal or intraabdominal pocket. Fig. 1 of Akamatsu is not detailed enough to determine otherwise and, in my opinion, a POSA would clearly understand that pericardial implantation was not possible in view of the size of the pump in Akamatsu.

189. There is no disclosure in Schima about the size of its pump. There is, however, evidence to suggest Schima's pump would also be too large to fit at the apex of the heart. For example, Schima discloses a "diagonal pump" that utilizes a conical rotor. Ex. 1005 at [0012]; Ex. 2022 at 251. Such a device generally has a larger axial height than a device with a flatter disc-shaped rotor, such as the pump in Akamatsu.

190. I therefore think that, even if a POSA were to have combined Schima and Akamatsu, they would not have understood that implantation at the apex of the heart with an inlet tube disposed in the left ventricle of the heart was possible.

2. [1M] ***An external control unit configured to regulate operation of the second magnetic device, the external control unit connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device***

191. Petitioner admits that Schima does not disclose connecting an external control unit to its pump. Paper 1 at 121; Ex. 1003 ¶ 644. Schima, then, cannot be said to teach or suggest claim element [1M]. Petitioner attempts to fix this by relying on Akamatsu and incorporating by reference arguments regarding this claim element in connection with Ground 3. Paper 1 at 121–123; Ex. 1003 ¶ 645.

192. All of my comments above with regard to Ground 3 are applicable to show the deficiencies of Akamatsu with regard to this element.

193. For example, Petitioner's reliance on the unidentified component shown in Akamatsu's FIG. 1 and circled in lime green. Petitioner contends it is an external controller, but there is no disclosure to this effect. Akamatsu is silent regarding what this component is specifically, as it is for all of the components pictured in FIG. 1. The only disclosure the reference does include, describing the illustration is of a "totally implantable" LVAD, suggests there is an implanted controller instead. Ex. 1006 at 3.

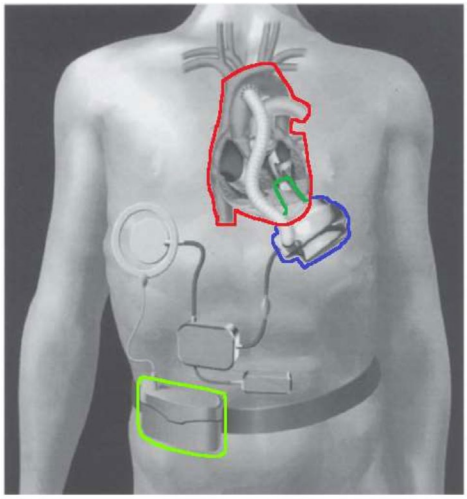


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

194. A combination of Schima and Akamatsu therefore fails to teach or suggest claim element [1M] for the same reasons identified with regard to Ground 3 over Akamatsu alone.

B. A POSA Would Not Have Been Motivated to Combine Schima and Akamatsu As Petitioner Contends

195. Petitioner identifies a number of reasons for combining Schima with Akamatsu. It is my opinion that all of these reasons are deficient and fail to appreciate what a POSA would have readily understood: the device of Schima is not intended for delivery to the heart, or use in the body at all, and therefore would not have been combined with Akamatsu in order to deliver the Schima pump to the heart.

196. Petitioner states that the proposed combination would result in use of a controller from Akamatsu with the pump of Schima, as well as implantation of

Schima with the inlet 13 inserted into the left ventricle as taught by Akamatsu. Paper 1 at 127. I disagree for the reasons noted above. For example, I disagree that Akamatsu would have taught a POSA about the use of an external controller or the delivery of a pump to the heart in the contended manner. This is at least because of the thin disclosure in Akamatsu and the disclosed large size of its pump that could not have been delivered to the heart in the contended manner, i.e., positioned in the pericardial space to achieve placement of its inlet in the ventricle.

197. Petitioner also contends that Schima and Akamatsu are analogous art to the '357 patent and reasonably pertinent to a problem the '357 patent seeks to solve. Paper 1 at 127–128. The identified field of endeavor, "to assist the performance of a heart with…a rotary pump and driven via magneto coupling," is taken at too high a level of abstraction because it allows false equivalence to be drawn between the implantable pump of Akamatsu and the extracorporeal pump of Schima. While both references may be directed to assisting performance of a heart, a POSA would have immediately appreciated that the pump of Schima cannot be delivered to the heart in the manner disclosed in Akamatsu.

198. The same is true of the identified "pertinent problem," which Petitioner identifies as "reducing mechanical stress on the blood during pumping." As with the identified field of endeavor, I think this is abstracted to a level that

fails to pick up on important distinctions between the two references that a POSA would have appreciated and that would have eliminated any motivation for the POSA to combine the references in the manner Petitioner contends.

199. Petitioner also suggests the combination of Schima and Akamatsu would have been an arrangement of old parts performing known functions, and that they would yield no more than expected results. Paper 1 at 128. I disagree and again highlight that a POSA would not have considered delivering the extracorporeal pump of Schima to the heart in the manner contended by Akamatsu. And, even if they had done so, Akamatsu fails to provide the teaching Petitioner contends based on the size of the disclosed pump in Akamatsu that could not be delivered to the apex of the heart as Petitioner contends. Petitioner's expert, Mr. Crosby, has admitted that he did not consider the sizes and weights of the pumps he has proposed to combine. Ex. 2014 at 78, 92, 108. This is a key failing that would have stopped a POSA from combining the references at the time of the invention.

200. Petitioner also contends that the teachings of the two references are complementary. Paper 1 at 128–129. This is true, however, only when viewed through the selectively blinded glasses that Petitioner and their expert wear. Including the context that a POSA would have understood, including the inability

of Akamatsu to teach or suggest delivering its pump to the apex of the heart and the unsuitable nature of Schima for delivery into the body anywhere, the teachings are far less complementary.

201. Finally, Petitioner contends that a POSA would have a reasonable expectation of success that Schima's pump could be controlled and implanted according to Akamatsu's teachings. Paper 1 at 129. I disagree with this contention. A POSA would not have had a reasonable expectation of success in delivering the extracorporeal pump of Schima to the heart. Furthermore, Akamatsu fails to teach or suggest delivering its pump to the apex of the heart as Petitioner contends. Akamatsu also has deficient teachings with regard to an external controller, and a POSA would certainly not have thought that a controller configured to use with Akamatsu's pump would be suitable for use with the Schima pump. Pump-controller pairings for LVADs are specifically tailored and a POSA would not swap out one side of the pairing with any reasonable expectation of success.

202. For example, the pumps of Schima and Akamatsu have different systems of rotor control and suspension, so it would not be possible to use Akamatsu's controller to drive the pump of Schima.

203. For these reasons, it is my opinion that a POSA would not have been motivated to combine Schima and Akamatsu as Petitioner contends.

C. Schima and Akamatsu Do Not Teach or Suggest Dependent Claims

1. Claim 11 *further comprising one or more sensors that deliver feedback signals to the external control unit*

204. Petitioner concedes that Schima does not disclose any external control unit and relies on Akamatsu for this teaching. Paper 1 at 126; Ex. 1003 ¶ 667–668. Petitioner contends that a POSA would understand Akamatsu's disclosure of "three position sensors to maintain the impeller free-floating at the center of the pump housing" as requiring providing feedback signals from the sensors to an external control unit. Ex. 1003 ¶ 667. Petitioner relies on an embodiment of a pump shown in Fig. 1 though, which is described as a "totally implantable" LVAD. Ex. 1006 at 3. As noted above, a totally implantable system would require basic pump control by an internal control unit to allow a user to remove, e.g., the belt and attached component that Petitioner contends to be the external control unit.

XIV. CONCLUSION

205. In this report, I have presented my opinions regarding the validity of the challenged claims of the '357 patent based on the information available to me. My opinions are subject to change in view of opinions provided by the Petitioner

or its expert, or any additional information that I may receive. I reserve the right to supplement my opinions accordingly.

206. 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. I further declare that all opinions expressed herein are my own. I recognize that this Declaration will be filed as evidence in contested cases before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. These statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: September 30, 2025

/ Boris Leschinsky /
Boris Leschinsky