

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,

Petitioner,

v.

MIRACOR MEDICAL SA,

Patent Owner.

IPR2025-00096 (Patent 11,351,356)

IPR2025-00112 (Patent 11,351,357)

IPR2025-00113 (Patent 11,376,415)

IPR2025-00114 (Patent 11,572,879)

IPR2025-00115 (Patent 11,674,517)

IPR2025-00116 (Patent 11,754,077)

**DECLARATION OF DR. ROBERT GALLEGOS 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., <i>End-Stage Congestive Heart Failure in the Adult Population: Ventricular Assist Devices</i> , Handbook of Cardiac Anatomy, Physiology, and Devices 725–732 (2015)
2004	Howard M. Loree II et al., <i>The HeartMate III: Design and In Vivo Studies of a Maglev Centrifugal Left Ventricular Assist Device</i> , 25 Artificial Organs 386–391 (2001)
2005	Greg W. Burgreen et al., <i>Computational Fluid Dynamics Analysis of a Maglev Centrifugal Left Ventricular Assist Device</i> , 28 Artificial Organs 874–880 (2004)
2006	David J. Farrar et al., <i>Design Features, Developmental Status, and Experimental Results With the Heartmate III Centrifugal Left Ventricular Assist System With a Magnetically Levitated Rotor</i> , American Society of Artificial Internal Organs (ASAIO) Journal 310–315 (2007)
2007	Abbott, <i>A Father of HeartMate 3 Wants A Bigger Family</i> , 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., <i>Design Rationale and Preclinical Evaluation of the HeartMate 3 Left Ventricular Assist System</i>

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	<i>for Hemocompatibility</i> , 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)
2010	American Heart Association News, <i>The past, present and future of the device keeping alive Carew, thousands of HF patients</i> , 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 in IPR2025-00096, -00112, -00113, and -00114; Chart of Petitioner’s Correlation of Claim Elements in IPR2025-00115 and -00116
2013	Donald Esmore et al., <i>VentrAssist Left Ventricular Assist Device: Clinical Trial Results and Clinical Development Plan Update</i> , 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

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Exhibit No.	Description
2019	Richard Wampler et al., <i>A Sealless Centrifugal Blood Pump with Passive Magnetic and Hydrodynamic Bearings</i> , 23 Artificial Organs 780–784 (1999)
2020	Trevor Symalla et al., <i>Choosing the Appropriate Left Ventricular Assist Device for Your Patient</i> , 36 (Suppl 2) Indian Journal of Thoracic and Cardiovascular Surgery S256–S264 (2020)
2021	Milad Hosseinipour et al., <i>Rotary Mechanical Circulatory Support Systems</i> , 4 Journal of Rehabilitation and Assistive Technologies Engineering, 1–24 (2017)
2022	Martin Stoiber et al., <i>A Passive Magnetically and Hydrodynamically Suspended Rotary Blood Pump</i> , 33 Artificial Organs 250–257 (2009)

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I, Dr. Robert Gallegos, 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 Nos. 11,351,356; 11,351,357; 11,376,415; 11,572,879; 11,674,517; and 11,754,077, all to Mohl et al. (referred to collectively herein as “the challenged patents”).

2. I am being compensated for my work in this case at a rate consistent with my clinical compensation. 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 a surgeon trained in the practice of general surgery and cardiothoracic surgery, board-certified by both the American Board of Surgery and

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the American Board of Thoracic Surgery. I am a Fellow of the American College of Surgeons and the American College of Cardiology. I have been practicing full-time in the field of cardiac surgery since completing my fellowship training in 2008. My clinical focus is on the treatment of adult cardiac disease, including cardiogenic shock, complex valve disease, aortic disease, and coronary disease.

5. I received my bachelor's degree in Biological Engineering from the University of California, San Diego (Revelle College) and my Doctor of Medicine from the UC San Diego School of Medicine. I completed my residency training in general surgery at the University of Minnesota, where I also earned my doctoral degree (PhD) in Experimental Surgery with a focus on cardiovascular disease. I subsequently earned my Master of Business Administration (MBA) with a certificate in Leadership from the University of Iowa.

6. During my doctoral studies, I published extensively in the field of animal models used for cardiovascular device evaluation. This work included the development of preclinical models specifically utilized for FDA approval processes within a GLP (Good Laboratory Practice) facility.

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7. Following residency, I matriculated to Brigham and Women's Hospital, a Harvard Medical School-affiliated institution, where I completed an advanced fellowship in cardiac surgery. My training and early career experience included transplantation, ventricular assist devices, and mechanical circulatory support strategies for patients with advanced heart failure.

8. At The Christ Hospital in Cincinnati, I served as Director of Mechanical Circulatory Support (MCS) and established one of the first non-transplant LVAD programs in the United States. Under my leadership, the program became one of the few non-transplant centers to participate in a major clinical trial focused on optimizing placement of the HeartMate II device to reduce the risk of device thrombosis. This work not only advanced surgical strategies for durable LVAD implantation but also helped expand access to advanced heart failure therapies for patients who were not transplant candidates.

9. I currently serve as Chief of the Division of Cardiac Surgery and Medical Director of the Cardiovascular and Thoracic Intensive Care Unit, where my clinical work emphasizes the management of adult cardiac disease, including acute cardiogenic shock. This involves rapid deployment of temporary and durable

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mechanical circulatory support, integration with advanced critical care strategies, and the development of institutional shock team protocols to improve outcomes in this critically ill population.

10. A true and correct copy of my curriculum vitae is included as Ex. 2018.

III. BASIS OF OPINIONS

11. 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 evaluate whether a person of ordinary skill in the relevant art (“POSA”) at the time of the invention of the challenged patents would have combined the teachings of references relied-upon to allegedly invalidate the challenged claims of the challenged patents in the following *Inter Partes* Reviews (referred to collectively herein as “the IPR proceedings”):

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12. All of the opinions I express in this Declaration have been made from the standpoint of a POSA at the time of the invention of the challenged patents, which I am informed is the claimed priority date of February 27, 2007.

13. 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

14. 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

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

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16. 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 challenged patents.

17. 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

18. I understand that patent claims are to be interpreted in light of a patent’s specification and prosecution history. I am informed that claim

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construction starts with the plain language of the claims as understood by a POSA at the time the patent application was filed.

C. Anticipation

19. 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.

20. 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.

21. 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

22. 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.

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23. 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.

24. 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.

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25. 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.

26. 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.

27. 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.

28. 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.

29. 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

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

30. 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. LEVEL OF SKILL IN THE ART

31. 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 at 6 (citing Ex. 1003 ¶ 18).¹ I also understand that the Patent Trial and Appeal Board

¹ All citations in this declaration are made to paper numbers and exhibits in IPR2025-00096, unless otherwise specified. The same or similar materials are filed in each of the other IPR proceedings identified in Section III of this declaration.

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(“PTAB”) found, for purposes of deciding to institute these proceedings, that “the [challenged patents] 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 [the challenged patents] is consistent with the definition of a person of ordinary skill in the art proposed by Petitioner.” Paper 15, 18–19.

32. 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 challenged patents. 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.

33. Patent Owner’s expert, Boris Leschinsky, has argued that a POSA would have a more specifically-focused level of skill than has been articulated by Petitioner. Ex. 2015 at 59. In particular, Mr. Leschinsky has expressed an opinion that a POSA would be better characterized as having at least a bachelor’s degree in

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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. Ex. 2015 at 59.

34. I agree with Mr. Leschinsky's proposed level of skill for a POSA for the reasons he has identified. Ex. 2015 at 59. Most particularly, I agree that the level of complication involved in developing cardiac assist devices and the critical, life-supporting nature of the heart and associated circulatory system warrants a more tailored level of experience, as opposed to experience designing and developing any implantable medical device.

35. I believe I satisfy both Petitioner's definition of a POSA and the modified definition proposed by Mr. Leschinsky. In particular, I am a medical doctor with significant knowledge of the human circulatory system anatomy and physiology, as well as long work experience exceeding the thresholds noted above specifically with regard to the use and implantation of implantable cardiac assist devices.

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VI. SUMMARY OF OPINIONS

36. I offer an expert opinion regarding whether a POSA at the time of the invention of the challenged patents in February 2007 would have been motivated to combine the teachings of Bourque-2001 (Ex. 1007) with Wampler (Ex. 1008) or to combine the teachings of Schima (Ex. 1005) with Akamatsu (Ex. 1006), specifically to use the blood pumps disclosed in each former reference in a manner disclosed in each latter reference. My opinion is that a POSA would not have been motivated to combine these references and, indeed, would have known that doing so would have been a practical impossibility at the time of the invention.

37. To begin, it is my opinion that the references allegedly disclosing delivery of a blood pump to the apex of a heart, Wampler (Ex. 1008) and Akamatsu (Ex. 1006), would not have been sufficient to instruct a POSA about how to achieve such positioning. This is because these references provide only a paucity of information about placing a blood pump at the apex of the heart. As a result, a POSA would have had to look to other disclosures at the time of the invention to enable practicing the alleged combination and, in combination with their other knowledge of the art at the time of the invention, would have

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immediately realized that the blood pump placements disclosed in Wampler and Akamatsu were merely aspirational intentions that were not practically achievable at the time of the invention.

38. Indeed, as of the priority date, I was not aware of any implantable left ventricular assist device (LVAD) blood pump being placed at the apex of the heart. Instead, all such devices were placed below the diaphragm, e.g., in a preperitoneal or abdominal pocket. The first LVAD to be placed at the apex of the heart was not used clinically until several years after the 2007 priority date.

39. Further, even if a POSA were to have understood how to achieve delivery of a pump to the heart from the teachings of Wampler or Akamatsu, they would have immediately appreciated that this would be impossible due to the size and weight of the pump being used. For example, the prototype HeartMate III device disclosed in Bourque-2001—which was very different from the clinical HeartMate 3 device brought to market years after 2007—was massive (as in, 3+ times the weight) compared to the size of the first LVAD positioned at the apex of the heart, the HeartWare HVAD, which also came years after the 2007 priority date and prior to the clinical HeartMate 3 device.

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40. Still further, in the case of Schima in particular, a POSA would have appreciated that the disclosed blood pump was wholly unsuitable for use in the body anywhere, much less delivery to the heart as Petitioner contends. A POSA would have instead appreciated that the pump of Schima was intended for extracorporeal use, as evidenced by a number of its features (e.g., barbed fittings for coupling with tubing, sharp edges, etc.).

41. In sum, it is my opinion that a POSA at the time of the invention of the challenged patents would not have been motivated—and indeed not able—to combine the Bourque-2001 and Wampler references, or the Schima and Akamatsu references, in the manner contended by Petitioner.

VII. A POSA WOULD NOT HAVE COMBINED BOURQUE-2001 WITH WAMPLER AS PETITIONER CONTENDS

42. Petitioner contends that it would have been obvious to combine Bourque-2001 with Wampler to fit the pump of Bourque-2001 “between the apex of the heart and the adjacent diaphragm,” such that an axially aligned inflow tube is or can be placed into the apex of the left ventricle. Paper 1 at 82; Ex. 1003 at ¶ 472. It is my opinion that a POSA would not have found it obvious to combine

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these references in this manner or been motivated to make such a combination because they would have appreciated the practical impossibility of delivering the pump of Bourque-2001 to the position shown in Wampler.

43. Turning first to Wampler, it is my opinion that the reference does not provide a disclosure sufficient to enable a POSA to deliver its blood pump to the heart in a patient. The reference includes one image, FIG. 5, showing the heart in isolation with the first embodiment of its pump 11 “placed into the apex of the left ventricle,” along with one additional paragraph describing the “good anatomical compatibility” of the pump 11. Ex. 1008 at [0075]–[0076]. I do not believe this is sufficient disclosure to enable a POSA to deliver the pump of Wampler to the heart of a patient. As a result, it is my opinion that a POSA at the time of the invention would have looked to other information in the art for additional information, including to additional information from the inventors of Wampler.

44. In seeking additional information, a POSA would have found, among other things, an article from 1999 by Richard Wampler and others describing further details of their “sealless centrifugal blood pump with passive magnetic and hydrodynamic bearings.” Ex. 2019 at 780. Based on this paper, a POSA would

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have learned that the Wampler pump had not been implanted in a patient and that any theoretical ability to do so, phrased as “good anatomical compatibility,” was due to the “disc shaped” pump housing that “displaces only 28 cc and should fit well within the pericardial space between the apex of the heart and the diaphragm.” Ex. 2019 at 781. The pump in total is noted as displacing 43 cc and weighing approximately 195 grams. Ex. 2019 at 781. A POSA would have further appreciated that this “small extracardiac volume will permit placement within a single body cavity (the pericardium), thus avoiding diaphragmatic penetrations and the displacement of lung tissue.” Ex. 2019 at 783.

45. It is therefore my opinion that a POSA would have appreciated that the ability to use the pump of Wampler in the aspirational manner disclosed would have depended on its small size and extracardiac volume, especially with regard to the “compact” and “disc-shaped” pump casing that would extend outside the heart. Ex. 2019 at 783; Ex. 1008 at [0076]. In contrast, the prototype HeartMate III pump of Bourque-2001 was over twice the weight and over four times the displaced volume of the Wampler pump that was contended to fit at the apex of the heart. Ex. 2019 at 781; Ex. 2004 at 389. The much larger prototype HeartMate III pump of

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Bourque-2001 could therefore not have been delivered to the heart in the manner suggested by Wampler without dire consequences for the patient, as explained in more detail below.

46. Petitioner also contends that placement of the prototype HeartMate III pump in Bourque-2001 in a preperitoneal pocket below the diaphragm was merely a “design decision” stemming from a desire to utilize “peripheral hardware (i.e., inflow and outflow components) of its predecessor Heart-mate systems.” Paper 1 at 84–85; Ex. 1003 at ¶ 472. In my opinion, this statement ignores the reality that the large prototype HeartMate III pump of Bourque-2001 could not have been positioned at the apex of the heart, even if there were a desire to do so. That is, given the size of the pump in Bourque-2001, there was not a valid alternative “design decision” to place the pump at the apex of the heart, as Petitioner and its expert suggest. Instead, it is my opinion that the only other valid “design decision” for placement of the pump in Bourque-2001 would have been at another location remote from the heart, such as deeper in the abdomen. It is also my opinion that a POSA at the time of the invention would have appreciated that the size of the

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pump of Bourque-2001 would make it impossible to position as shown in Wampler.

47. Petitioner contends that a POSA would have recognized a disadvantage of a preperitoneal pocket due to “increased risk of infection,” and diverged from the teachings of Bourque-2001 by following Wampler’s focus on “good anatomical compatibility so that the device fits well between the apex of the heart and the adjacent diaphragm.” Paper 1 at 86–87; Ex. 1003 at ¶ 471. In my opinion, these statements simply ignore the fact that the pump of Bourque-2001 was too large to be placed between the apex of the heart and the diaphragm, and rely on references that compared rates of infection between pump placement intraabdominally and in a preperitoneal pocket. Ex. 1013 at 25–26; Ex. 1014 at 842. These references were not contemplating potential positioning at the apex of the heart because, like the pump in Bourque-2001, the subject pumps of these references were far too large for placement in the manner shown in Wampler. Accordingly, it is my opinion that a POSA would have understood the practical impossibility of the proposed combination, regardless of whether a preperitoneal pocket may have been associated with certain disadvantages. For a pump the size

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of that disclosed in Bourque-2001, I believe a POSA would have appreciated that the preperitoneal or intrabdominal pockets were the only practical options for placement, and the relative advantages or disadvantages cited would be with regard to these options, not with regard to potential placement at the apex of the heart.

48. Petitioner goes on to state that a POSA would have a reasonable expectation of success in combining Bourque-2001 and Wampler because the authors of Bourque-2001 taught that modifying the HeartMate III with an inflow cannula apical tube 45, which is inserted into the apex of the left ventricle, was not complex and well known in the art. Paper 1 at 87; Ex. 1018 at 6:62–7:5. This contention again strikes me as missing the key point. In my opinion, disclosure by the authors of Bourque-2001 that its prototype HeartMate III pump can connect to the same inflow tube as the predecessor HeartMate II device says nothing about an ability to change the position of the pump according to the teachings of Wampler. Indeed, both the HeartMate II pump and prototype HeartMate III pump of Bourque-2001 were positioned in a preperitoneal pocket. In my opinion, the fact that these two pumps could connect to the same inflow tube would not have suggested to a POSA that moving the pump of Bourque-2001 from a preperitoneal

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pocket to the apex of the heart would have been possible, much less “not complex” or “well known in the art.” To the contrary, it is my opinion that moving the pump of Bourque-2001 to the apex of the heart would not have been possible without making significant, complex changes to reduce the pump’s size and was not at all known in the art at the time of the invention.

49. On the latter point above, Petitioner further contends that a POSA would have had a reasonable chance of success that the Bourque-2001 and Wampler combination would fit well at the apex of the heart “due to the pump’s development as a compact device and the existence of several similar LVADs that fit well at that position.” Paper 1 at 87; Ex. 1003 at ¶¶ 473–476. I disagree with this statement and note that, as of the time of the invention, I was not aware of any LVADs approved for use at the apex of the heart as shown in Wampler. To support their statement, Petitioner points to Akamatsu and the HVAD, another LVAD developed by HeartWare that was, in fact, the first LVAD to be approved for use (years after the priority date for the challenged patents) with positioning at the apex of the heart. Ex. 1003 at ¶ 476. Petitioner also contends that these references show implanting a device at the apex of the heart was common at the time of the

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invention and a POSA would have reasonable expectation of success in view thereof. Paper 1 at 87–88; Ex. 1003 at ¶ 477. In my opinion, however, these other references would not have suggested to a POSA at the time of the invention that positioning a device like the pump of Bourque-2001 at the apex of the heart was well known and/or common. As detailed below, I do not think Akamatsu provides the contended disclosure of pump placement at the apex of the heart and is instead an aspirational intention, much like the limited disclosure in Wampler. Further, at the time of the invention, the HeartWare HVAD pump was not yet approved for use; it would not achieve this until years after 2007. The HVAD was also a significantly smaller device than the pump of Bourque-2001—over three times smaller in both weight and displaced volume. Ex. 1007 at 401; Ex. 2020 at S258. In my opinion, a POSA would have appreciated at the time of the invention that the ability of the HVAD to be positioned at the apex of the heart would not equate to the ability to similarly position a device the size of the pump in Bourque-2001.

50. Petitioner also contends that the combination of Bourque-2001 and Wampler would have been obvious to try because a POSA would have known that there were only “a finite (i.e., two) options for LVAD implantation: the device

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would be implanted at a preperitoneal pocket, or at the cardiac apex.” Paper 1 at 87; Ex. 1003 at ¶ 477. I disagree with this statement and it is my opinion that the cardiac apex would not have been an option to a POSA at the time of the invention when dealing with a device the size of the pump in Bourque-2001. In fact, it is my opinion that the “two” relevant options for implanting a pump of the size of Bourque-2001 at the time of the invention were instead a preperitoneal pocket or an intrabdominal pocket. Petitioner glosses over the fact that its references describing the relative advantages or disadvantages of preperitoneal pockets are comparing these pockets to intrabdominal pockets because implantation at the apex of the heart was not realistic for a device the size of the subject pumps (e.g., the prototype HeartMate III device of Bourque-2001 and earlier devices like the HeartMate II and HeartMate XVE). E.g., Ex. 1013 at 25–26.

51. Contrary to Petitioner’s contentions, as of the priority date I was not aware of any LVADs that were positioned at the apex of the heart. For example, I had experience working with various heart assist systems around the time of the invention, including extracorporeal pumps from Thoratec, as well as the HeartMate XVE and HeartMate II devices. All of the implantable LVADs that I worked with

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around the time of the invention were positioned in intraabdominal or preperitoneal pockets. Implanting these devices at the apex of the heart was not approved by regulatory authorities and, more practically, was impossible to do because of their large size.

52. I have experience with implanting various LVADs in patients. For example, I have experience implanting both the HeartMate II device that is positioned in a preperitoneal pocket, as well as the HeartWare HVAD, the first available device that could be positioned at the apex of the heart. I implanted the HeartMate II device around the time of the invention, e.g., in 2008, and implanted the HVAD device starting around 2013 after it received FDA approval, several years after the priority date for the challenged patents. There are significant size differences between the HeartMate II device and the HVAD. The HeartMate II device weighed around 390 grams and a displacement volume of 63 ml. Ex. 2020 at S257. In comparison, the HVAD weighed around 140 grams (a reduction of around 64% from HeartMate II) and displaced around 50 ml (a reduction of around 20% from HeartMate II). Ex. 2020 at S258. This difference in size and weight

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enabled the placement of the HVAD at the apex of the heart while preventing the HeartMate II from being similarly disposed.

53. The prototype HeartMate III pump of Bourque-2001 was larger even than the HeartMate II device, weighing around 475 grams (an increase of around 21% from HeartMate II) and displacing around 175 ml (an increase of over 2.5x from HeartMate II). Ex. 1007 at 401. For this reason alone, I am confident that a POSA would not have viewed it as possible to position the pump of Bourque-2001 at the apex of the heart, even if they had wanted to do so.

54. In particular, in my opinion the “puck shaped portion” of the pump in Bourque-2001, including the motor, would be too large and heavy to be positioned at the apex of the heart. Bourque-2001 notes that the mass of this portion, including the motor, is 475 grams (this does not include the inflow cannula, recovery section, outflow graft, bend relief, or connecting hardware, which add another 60 grams) and its displaced volume is 175 ml. Ex. 1007 at 401. In addition, the diameter of the puck shaped portion is 69 mm and its height is 30 mm, with the inflow and outflow protruding several millimeters beyond this. Ex. 1007 at 401. This is significantly larger than, for example, the HeartWare HVAD, which was

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the first device to be approved for use with implantation at the apex of the heart.

By comparison, the HVAD had a weight of around only 145 grams (~30% of the pump in Bourque-2001), a diameter of 50 mm (~72% of the pump in Bourque-2001), a height of less than 25 mm (~83% of the pump in Bourque-2001), and a displaced volume of 50 ml (~28% of the pump in Bourque-2001). Ex. 1015; Ex. 2021 at 12.

55. It is my opinion that the authors of Bourque-2001 understood that their pump was too large to be positioned on the heart directly. They note, for example, 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. I understand this to convey an appreciation by the authors of Bourque-2001 that its pump was too large to be placed on the heart directly and that their positioning in a preperitoneal pocket, along with use of a “flexible recovery section” between the remotely-positioned pump and apical cannula that connects to the heart, alleviated problems that would have presented if the large pump were to be more directly attached to the heart.

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56. Other evidence supports that the authors of Bourque-2001 had not changed their opinion by the time of the invention in 2007. A paper by Mr. Bourque, among others, from around the time of the invention showed that, even years after Bourque-2001 was published, the blood pump was still being positioned remote from the heart and coupled to the heart using the same technique. Ex. 2006 at 311 and FIG. 1.

57. Petitioner's expert, Mr. Crosby, appears to have been aware of the limitations associated with implanting a large pump like the one disclosed in Bourque-2001 at the time of the invention. For example, at the time of the invention, Mr. Crosby worked for a company called Ventracor, which was making an LVAD called VentrAssist. That device weighed around 298 grams and was implanted in a pocket below the diaphragm; it was not placed at the apex of the heart. Ex. 2013 at 736. It is my opinion that, whether known personally to Mr. Crosby or not (he served in a management role at the company at the time of the invention), Ventracor's engineers actually designing the VentrAssist would have been aware that a device the size of the VentrAssist could not have been positioned at the apex of the heart and, for this reason, placement in a subdiaphragmatic

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pocket was utilized. The prototype HeartMate III pump of Bourque-2001 was a significant amount larger than the VentrAssist device at around 475 grams (59% heavier), and it is my opinion that no POSA at the time of the invention would have thought it possible to place the pump of Bourque-2001 at the apex of the heart. Ex. 1007 at 401.

58. Indeed, it appears that significant changes were made from the prototype HeartMate III device disclosed in Bourque-2001 to the clinical HeartMate 3 device that was ultimately positioned at the apex of the heart years after the priority date of the challenged patents. For example, the weight of the device dropped from around 475 grams to around 200 grams (~58% reduction) and the displacement dropped from around 175 ml to around 80 ml (~54% reduction). Ex. 1007 at 401; Ex. 2020 at S262.

59. In addition, Mr. Bourque himself has described that development of the HeartMate 3 clinical device involved creation of a “precursor device” around 2006 that was ultimately not adopted in favor of going “back to the drawing board, creating a smaller, simpler version.” Ex. 2010 at 5. The new design was further described in a 2016 paper. Ex. 2008 at 375 *et seq.* In a 2021 interview, Mr.

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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.

60. In order to make the clinical HeartMate 3 smaller, Bourque described doing a “couple key things. One, by flipping the rotor upside down, we’re able to gain a little bit of real estate. Second, the electronics themselves. Chips are smaller so we shrunk for that.” Ex. 2007 at 7. Bourque further noted: “But then, 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. And that took away this whole business about creating a pocket for the pump and then requiring a conduit between the heart and the pump. We just put this (the inflow cannula, if you’re scoring at home) right in the heart. So that made it smaller as well.” Ex. 2007 at 7. I read this to mean that the size reduction for the clinical HeartMate 3 device relative to the prototype HeartMate III pump disclosed in Bourque-2001 directly lead to a realization that implantation at the apex of the heart might be possible.

61. The changes that allowed a significant size reduction from the pump disclosed in Bourque-2001 to the clinical HeartMate 3 pump were ultimately

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patented by Bourque et al. U.S. Patent No. 10,500,321, which I understand has an earliest possible benefit date in August 2010, describes an “implantable blood pump” where the rotor is inverted relative to the arrangement shown in Bourque-2001 and the “flow of blood is passed through a motor stator to a rotor disposed within the blood flow channel.” Ex. 2009 at Title, Abstract, and Fig. 2. This patent also illustrates that this smaller pump design can be positioned at the apex of the heart. Ex. 2009 at Fig. 1. In my opinion, the innovations that resulted in the reduction in size and weight of the clinical HeartMate 3 device relative to the prototype device disclosed in Bourque-2001 were central to enabling its positioning at the apex of the heart. The award of a U.S. Patent to Bourque et al. for the new pump design with a reduced size and weight relative to the pump of Bourque-2001 suggests that more than merely “routine” changes to the pump disclosed in Bourque-2001 were required to enable delivery and positioning of the pump at the apex of the heart.

62. In my opinion, a POSA would have known at the time of the invention that there is very little space available between the apex of the heart and the diaphragm. In addition, a POSA would have known that any device implanted

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in the pericardial space should be of minimum possible size to avoid impinging on the heart or adjacent lungs. This is because doing so can have deleterious effects on the health of the patient, either due to complications with operation of the heart and/or the lungs.

63. I also believe a POSA would have understood at the time of the invention that the weight of an implanted device at the apex of the heart is an important consideration, along with volume or size, and that this weight should also be minimized. The reason is that the heart moves when it beats. In a typical standing person, the apex of the heart will rise and fall, as well as twist, as the heart beats. A POSA would have understood that adding weight to the apex of the heart can impede its movement and impair its function when beating.

64. It is important to note that the heart still beats even after implanting an LVAD that reduces the required workload of the heart. In his deposition, Mr. Crosby suggested that, by the time of the invention, a patient with an LVAD had a heart that no longer moved or needed to move. Ex. 2014 at 61–65. I disagree with this statement. My experience is that the heart has continued to beat in my patients

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even after implantation of an LVAD, and that it is important to not impede this activity of the heart.

65. For example, in many cases a primary goal of an LVAD is to allow for heart recovery, meaning the goal is to allow the heart to beat and regain its strength over time (e.g., potentially to include reducing the function of the LVAD over time as the heart regains strength). This goal necessarily involves allowing the heart to continue beating after LVAD implantation.

66. In addition, an LVAD is, by definition, a device to assist the left side of the heart in operation. It does not support operation of the right side of the heart. It is therefore important to permit the right side of the heart to continue beating, even if the LVAD is being used to completely alleviate the workload of the left side of the heart such that the left side of the heart does not or need not beat.

67. It is my opinion that a POSA at the time of the invention would have known of the importance of permitting the heart to continue beating even after implantation of an LVAD and that this knowledge would have emphasized the importance of avoiding delivery of a large device, such as one the size of the pump in Bourque-2001, to the apex of the heart due to concerns about its size and/or

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weight impeding the ability of the heart to beat. A POSA would have at least known these concerns were relevant to the beating of the right side of the heart, even if the LVAD were discounting any desire for heart recovery and completely eliminating any need for the left side of the heart to beat.

68. If a pump is too big and attached to the heart in a manner that places the pump at the apex of the heart and hangs the weight of the pump from the heart, disastrous effects can result. For example, the size of the pump can impinge on the right side of the heart and/or the lungs, reducing their ability to function and sustain the patient's life. In addition, the weight of the pump can impede the ability of the heart to beat. While this may or may not be important to the operation of the left side of the heart, it will certainly be important to operation of the right side of the heart, which the LVAD does not support. Impairing operation of the right side of the heart can also threaten a patient's life and negate any potential benefit of an LVAD in supporting the left side of the heart.

69. In my opinion, a POSA at the time of the invention would not have positioned the pump of Bourque-2001 at the apex of the heart due to a belief that doing so would impair the functioning of the heart. This is because I believe a

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POSA at the time of the invention would have viewed the pump of the Bourque-2001 reference as clearly too large to be positioned at the apex of the heart, based both on its size and weight.

VIII. A POSA WOULD NOT HAVE COMBINED SCHIMA WITH AKAMATSU AS PETITIONER CONTENDS

70. Petitioner admits that Schima does not expressly disclose where its pump is placed, and instead relies on Mr. Crosby’s testimony that it would have been obvious to implant Schima’s device in the configuration described in Akamatsu. Paper 1 at 115–116; Ex. 1003 at ¶¶ 635, 641. In my opinion, a POSA at the time of the invention would never have contemplated implanting the pump disclosed in Schima in any manner because the pump plainly bears the hallmarks of an extracorporeal pump not intended for implantation in the body at any location. A POSA would therefore not have considered the pump of Schima deliverable to the heart in the claimed manner, including, for example by inserting the inlet of Schima’s pump into the ventricle of the heart.

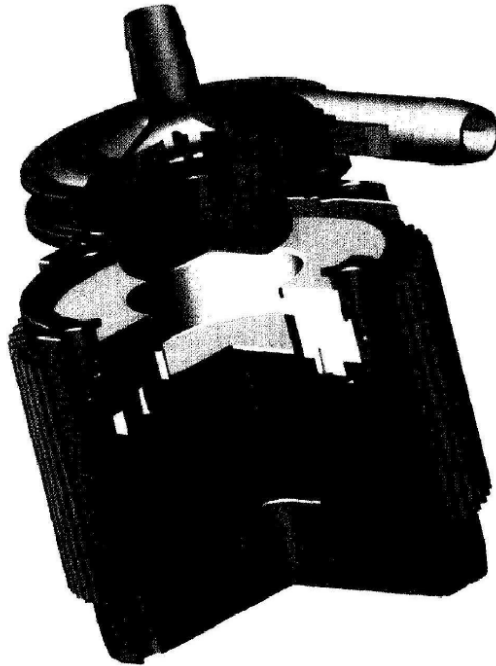
71. For example, Schima discloses that its invention relates to “a rotary pump for moving blood and other shear-sensitive liquids.” Ex. 1005 at [0001]. This

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mention of “other shear-sensitive liquids” is a prominent indication that the reference is not disclosing an implantable blood pump. Further, there are no other mentions in Schima of its pump being implanted, configured for implantation, etc.

72. The Schima pump instead appears more similar to the “centrifugal pump” disclosed in Ex. 1011 that is configured for use as an interchangeable pump head that can be coupled to a motor in an extracorporeal setting. Ex. 1011 at 1–2. That publication similarly discloses that its pump can be utilized for “pumping blood in extracorporeal circulatory support applications,” as well as for other industrial uses, such as “pumping CMP slurries and for gold plating during chip manufacturing.” Ex. 1011 at 3.

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Ex. 1011, Fig. 3

73. In my opinion, the Schima pump is also similar to other extracorporeal circulatory support pumps, such as pumps used on extracorporeal membrane oxygenation (ECMO) and heart-lung machines, as well as other extracorporeal LVADs. I believe that a POSA at the time of the invention would have understood Schima as directed to a similar extracorporeal pump. For example, the Thoratec PediMag and CentriMag devices are extracorporeal heart

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support pumps that utilize a similar pump housing disposed atop a motor, as shown in Fig. 15 below. Ex. 2021 at 13–15.



Ex. 2021, Fig. 15

74. Further, the Schima pump also appears similar to the BP-50 LVAD from Medtronic that is used extracorporeally with the Bio-Console 540, as shown in Fig. 19 below. Ex. 2021 at 15–16.

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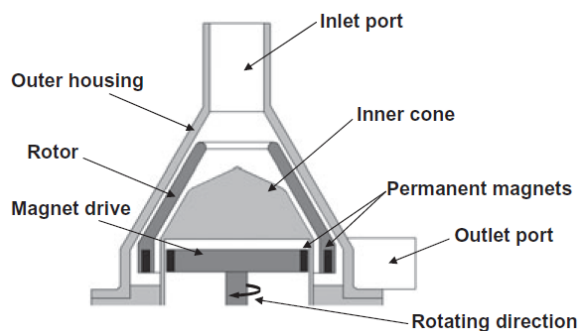
Figure 19. BP-50 LVAD (Courtesy of Medtronic). (a) BP-50 Bio-Pump and (b) Bio-Console 540.

Ex. 2021, Fig. 19

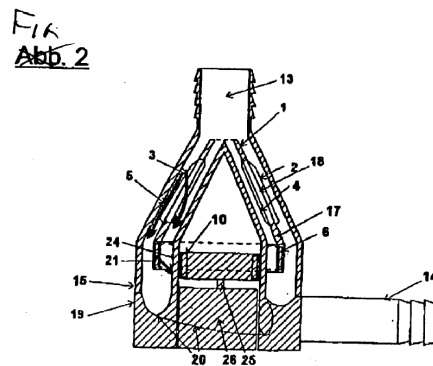
75. Still further, Heinrich Schima and other inventors of the cited Schima patent publication authored a later paper (Ex. 2022) that I believe describes a similar pump to what is disclosed in Schima and notes its use as an extracorporeal pump. For example, the paper describes the pump in a manner that appears to be

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similar to at least one embodiment of the Schima patent publication, e.g., as shown by Fig. 1 of Ex. 2022 and Fig. 2 of the cited Schima patent publication.



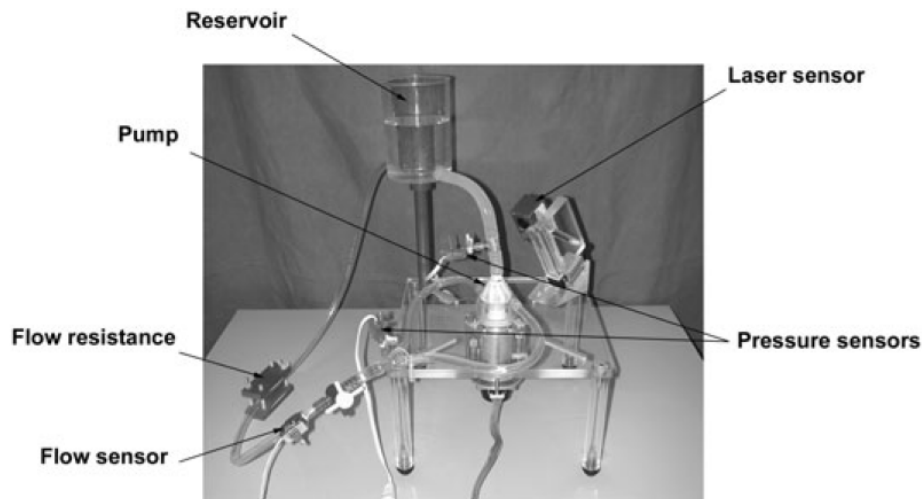
Ex. 2022, Fig. 1



Ex. 1005, Fig. 2

76. Ex. 2022 describes and depicts an extracorporeal pump and testing apparatus for in vitro testing on blood pumping, as shown by Fig. 3 below. The paper concludes that the pump performs “in the range of contemporary extracorporeal bearingless blood pumps, such as the Levitronix Centri[M]ag blood pump.” Ex. 2022 at 256. Note that the CentriMag pump is mentioned above (in ¶ 68) as another pump that appeared similar to Schima. Schima’s own later work therefore confirms my opinion on this similarity.

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Ex. 2022, Fig. 3

77. Ex. 2022 further concludes that the pump described therein is likely to have a “production cost low enough to allow its use in disposable pump heads.”

Ex. 2022 at 257. This configuration of an interchangeable pump head that couples with a motor is similar to another extracorporeal pump noted above in ¶ 67, i.e., the pump shown in Ex. 1011.

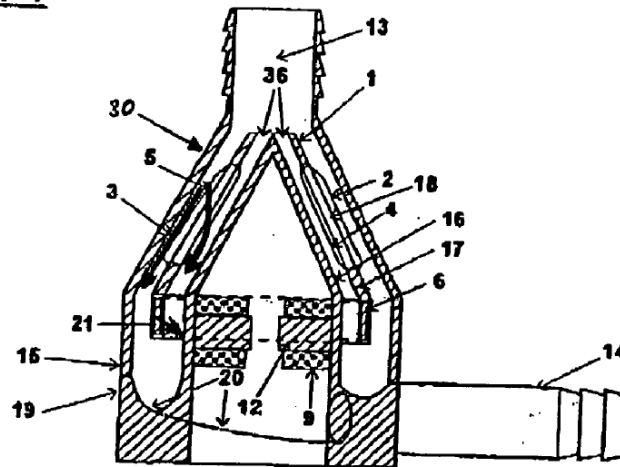
78. Beyond the language of the Schima publication and its similarity to other known extracorporeal pumps, the Schima pump includes features that a POSA at the time of the invention would have recognized were not suitable for implantation in the body, and especially delivery to the heart. For example, the

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inlet 13 and outlet 14 of the pumps disclosed in Schima have barbed ends configured to interface with tubing disposed over the ends. These barbed fittings are not utilized for interfacing with tissue walls in implanted devices, especially not with implanted blood pumps, and are instead common in extracorporeal applications, e.g., where access to the fitting is easy and frequent assembly/disassembly may be contemplated. In my opinion, a POSA at the time of the invention would have immediately appreciated that this feature of the pump in Schima made it inappropriate for use in the body. For example, I believe a POSA would have immediately understood that the inlet 13 of Schima would not have been insertable into a ventricle of the heart.

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Fig.
Abb. 1



Ex. 1005, Fig. 1

79. In addition, the pump in Schima has sharp, 90-degree edges at its bottom edge that would not be suitable for use in the body due to concerns about trauma to surrounding tissue. Ex. 1005, Fig. 1. These sharp edges, also shown at the bottom of Fig. 1 above, would have signaled to a POSA at the time of the invention that the Schima pump was not intended or suitable for use in the body, such that it would not have been deliverable to the heart in the manner claimed by the challenged patents.

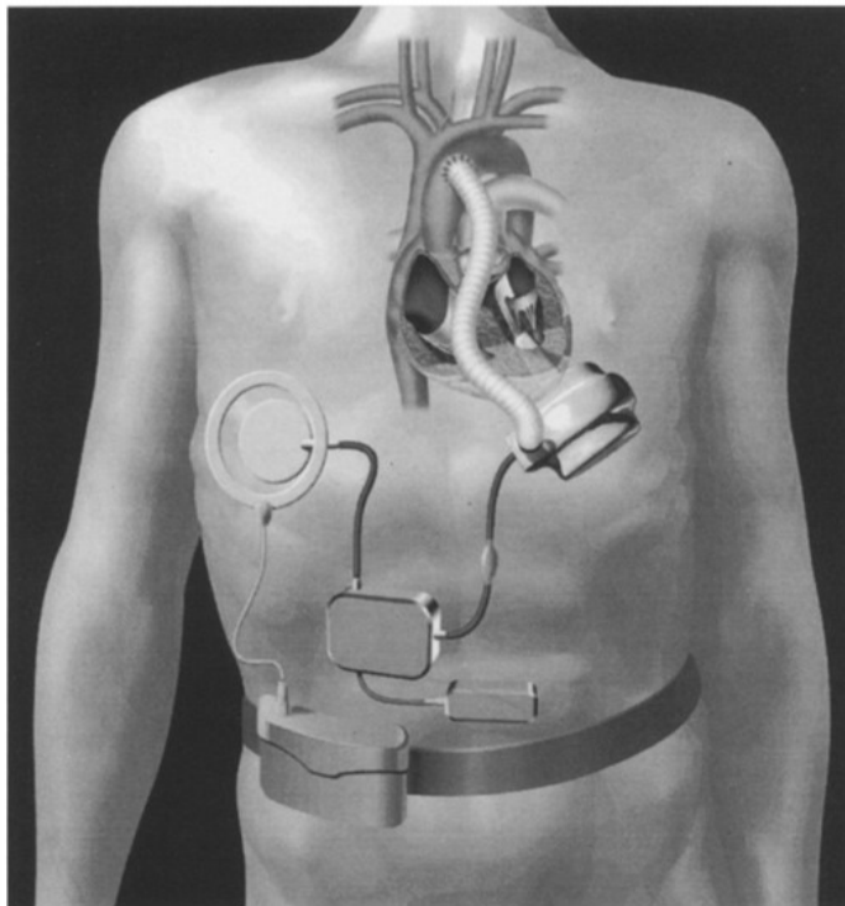
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80. Still further, the Schima patent is entirely silent on any of a variety of considerations for use of a blood pump in the body, including, for example, effects of long-term exposure to blood, implantation position or technique, control, power, etc. In my opinion, this further suggests that the Schima pump is intended for extracorporeal use where such considerations are not applicable or can be more easily addressed due to greater access, etc. I believe a POSA would have similarly appreciated that the pump of Schima was not intended for delivery to the heart, including insertion of its inlet into the heart, at the time of the invention based on the disclosure of the reference.

81. In my opinion, Petitioner's contention that Akamatsu discloses delivery to the heart such that an inlet tube is inserted into a ventricle of the heart is incorrect. In particular, Petitioner and Mr. Crosby essentially rely on Fig. 1 of Akamatsu to allegedly teach positioning a blood pump at the apex of the heart with an inlet tube inserted into a ventricle of the heart. Ex. 1003 at ¶¶ 637, 644. Akamatsu, however, does not describe the placement of the pump shown in FIG. 1 in any detail and it is not clear from the image exactly how or where the pump is positioned. As with the discussion of Bourque-2001 and Wampler above, in my

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opinion a POSA at the time of the invention would have had to consult other publications or other knowledge of the art to determine how to implant a pump according to the teachings of Akamatsu.



Ex. 1006, Fig. 1

82. In considering how to implant a blood pump according to the teachings of Akamatsu, a POSA would have appreciated that, to the extent Fig. 1

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of Akamatsu shows placement of a pump at the apex of the heart with an inflow tube inserted into a ventricle of the heart, this would have been an illustration of an aspirational intention for the future, not an implantation technique that was feasible at the time of the invention. As noted above in connection with the discussion of Bourque-2001 and Wampler, as of the priority date I was not aware of any other LVADs being implanted at the apex of the heart. Such devices would only be implemented years after the priority date of the challenged patents.

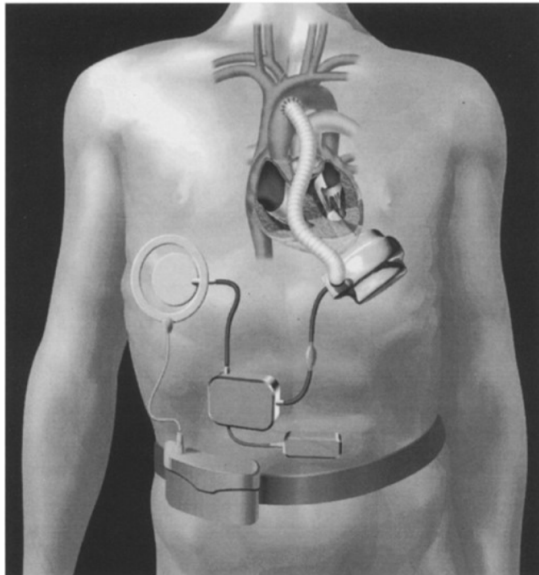
83. Further, a POSA would have appreciated at the time of the invention that it was not possible to position the blood pump of Akamatsu in the contended manner due to the size and weight of the pump itself. In particular, Akamatsu discloses that its pump was up to 83 mm in diameter, 50 mm in height, weighed 400 grams, and displaced 196 ml. Ex. 1006 at 4. As noted above, these dimensions place the device on par with the prototype HeartMate III device from Bourque-2001 that a POSA would have appreciated was not possible to implant at the apex of the heart. Indeed, the dimensions of the Akamatsu pump are, similar to the Bourque-2001 pump, several times the weight and displacement of the HeartWare HVAD, the first LVAD that was approved for implantation in the pericardial

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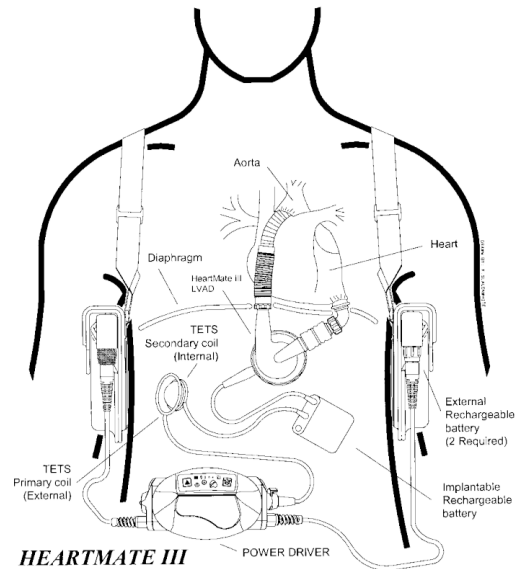
space, which was approved for use in this manner several years after the priority date of the challenged patents.

84. As a result, in my opinion a POSA at the time of the invention would not have understood from Akamatsu that a blood pump can be positioned at the apex of the heart with an inlet tube disposed into a ventricle of the heart. In my opinion, a POSA would have taken from Akamatsu and its Fig. 1 at best only an aspirational intention to eventually achieve such placement if the size and weight of the pump would permit it. Given the size and weight of the pump disclosed in Akamatsu, I believe a POSA at the time of the invention would have instead understood the positioning shown in Fig. 1 of Akamatsu to be a preperitoneal or intraabdominal pocket, similar to the positioning shown in Fig. 3 of Bourque-2001. This would be a reasonable conclusion to a POSA at the time of the invention given the disclosed sizes of the pumps in both Akamatsu and Bourque-2001, as well as the lack of detail in Fig. 1 of Akamatsu, e.g., not showing the diaphragm.

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Ex. 1006, Fig. 1



Ex. 1007, Fig. 3

85. Further, in my opinion Schima would not have suggested to a POSA any ability to achieve a pump of reduced size relative to the pump disclosed in Akamatsu. Schima is silent regarding the size or weight of its pump, so does not provide any point of comparison to suggest it is smaller than the pump disclosed in Akamatsu. In addition, the pump in Schima utilizes a conical rotor and pump housing that tends to have a larger axial height than the flatter disc-like rotor and pump housing of Akamatsu. In view of this, it is my opinion that a POSA would understand the pump design of Schima to likely be less suitable for positioning in

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the pericardial space in view of the increased height of the device due to the use of a conical rotor.

86. Petitioner and Mr. Crosby state that a POSA would have been motivated to deliver Schima's pump to the heart according to Akamatsu's teachings because the teachings of the references are complementary or directed to similar problems. Paper 1 at 117; Ex. 1003 at ¶ 644, 781–782. In my opinion, Petitioner and Mr. Crosby are utilizing too high a level of abstraction to facilitate combining the references. At a certain level of abstraction, any reference directed to a blood pump can be considered complementary. But abstracting away the particular teachings of the references allows ignoring important considerations that would have caused a POSA at the time of the invention to avoid combining them. One prominent example here is the fact that a POSA would have appreciated at the time of the invention that Schima's pump is not suitable for use in the body at all, much less at the apex of a heart. Nor are particular features of Schima's pump, such as the inlet 13, suitable for insertion into the heart. In my opinion, this important realization would have prevented a POSA at the time of the invention

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from considering combining Schima with Akamatsu as Petitioner and Mr. Crosby contend to use the pump of Schima according to the teachings of Akamatsu.

87. The same issues of improper abstraction to enable equivalence is present in Petitioner and Mr. Crosby's contentions regarding use of the pump in Schima with the controller of Akamatsu as well. It is my opinion that a POSA at the time of the invention would not have replaced the pump of Akamatsu with the pump of Schima and used the Akamatsu controller to run the pump of Schima. This is because LVAD blood pumps at the time of the invention had specialized controllers designed to operate only the specific pump for which they were developed, and the idea of swapping one controller between different types of pumps would have been unheard of and not approved by regulatory authorities.

88. For example, it is not clear from the disclosure of Akamatsu or Schima that the controller of Akamatsu would be sufficient to run the pump of Schima. In fact, it is my opinion that a POSA at the time of the invention would have presumed the opposite, i.e., that a controller configured to operate one LVAD pump would not be suitable for use with a different type of LVAD pump that might require different operating parameters, startup procedures, safety checks, etc.

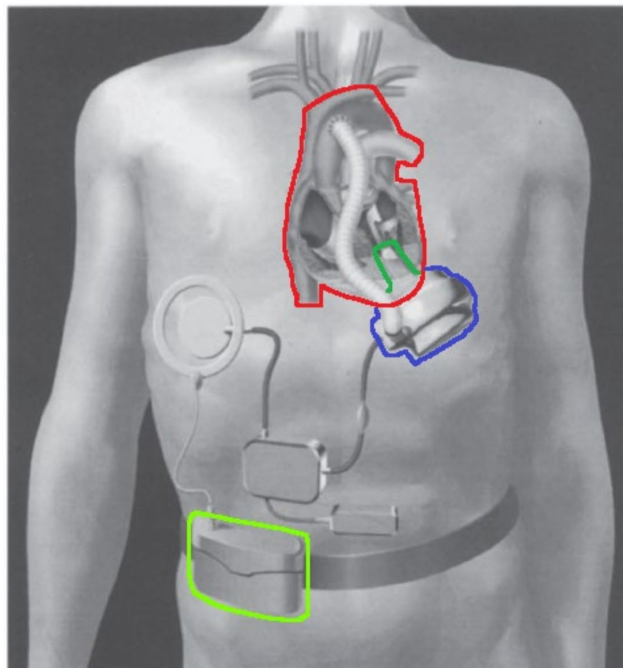
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89. In addition, in my opinion Akamatsu’s disclosure regarding an external controller suffers from the same problems described above with regard to delivery of its pump to the heart. That is, there is very little clear disclosure in Akamatsu regarding whether an external controller was utilized and Petitioner and Mr. Crosby instead make assumptions based on the schematic system illustrated in Fig. 1. Paper 1 at 136–137; Ex. 1003 at ¶ 790.

90. For example, Petitioner annotates Fig. 1 of Akamatsu as shown below and contends that the component circled in lime green is an external controller. Ex. 1003 at ¶ 790. There is no such explicit disclosure in Akamatsu, however, and it is at least equally possible that the aspirational illustration of Fig. 1 includes an implantable controller (e.g., one of the components not highlighted in the annotated figure) as part of the discussed “next phase” “totally implantable LVAS.” Ex. 1006 at 7. In fact, in my opinion an implanted controller would have been required in the configuration shown in Fig. 1 because Akamatsu describes it as showing a “totally implantable left ventricular assist system.” Ex. 1006 at 3. In such a system, the belt-mounted component outlined in lime green would need to be removable, e.g., for a patient to shower, etc., and therefore an implanted

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controller would be needed to operate the pump. In my opinion, a POSA at the time of the invention would not have reached Petitioner's conclusions regarding the obviousness of using an external controller based on teachings in Akamatsu.



Petitioner's Annotated Fig. 1 of Ex. 1006

91. Regardless of whether use of external controllers was shown in Akamatsu or otherwise common at the time of the invention, however, it is my opinion that it was not common to change a controller and pump pairing to use the controller with a different type of pump. In my opinion, therefore, a POSA at the

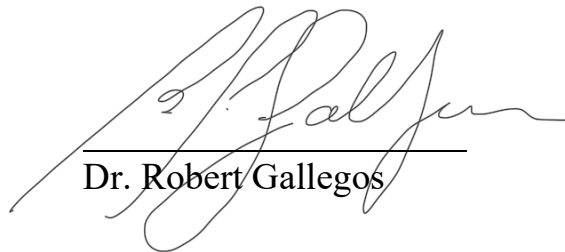
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time of the invention would not have thought it obvious to combine the controller of Akamatsu with the pump of Schima with any reasonable expectation of success.

IX. CONCLUSION

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1101 of Title 18 of the United States Code.

Date: **9/30/25**



Dr. Robert Gallegos