

Device to Assist the Performance of a Heart

IPR2025-00096	IPR2025-00112	IPR2025-00113	IPR2025-00114	IPR2025-00115	IPR2025-00116
US 11,351,356	US 11,351,357	US 11,376,415	US 11,572,879	US 11,674,517	US 11,754,077

Abbott Laboratories,
Petitioner

v.

Miracor Medical SA,
Patent Owner

PATENT OWNER MIRACOR MEDICAL SA'S ORAL ARGUMENT DEMONSTRATIVES

Topics

- Introduction
- Person of Ordinary Skill in the Art
- Claim Construction
- Instituted Grounds (all obviousness)
 - Ground 1: Wampler
 - Ground 2: Bourque-2001 & Wampler
 - Ground 3: Akamatsu
 - Ground 4: Schima & Akamatsu

IPR2025-00096 Paper 15 at 7, 43

Introduction

- Petitioner has not carried its burden to show unpatentability of any of the challenged claims
- Petitioner's failures extend from inappropriate and contradictory claim construction to unmakeable combinations that cannot work
- Each of the four grounds of alleged unpatentability fails

IPR2025-00096 Paper 33 at 1

Claim Construction – Axially Adjacent and Axially Closer

- Neither Wampler nor Akamatsu has a first magnetic device positioned *axially adjacent* to the magnetically driven rotor, or a second magnetic device positioned *axially closer* to the first magnetic device than to the magnetically driven rotor
- To diffuse this problem, Petitioner spins a false story from exhibits in the co-pending litigation

IPR2025-00096 Paper 33 at 4

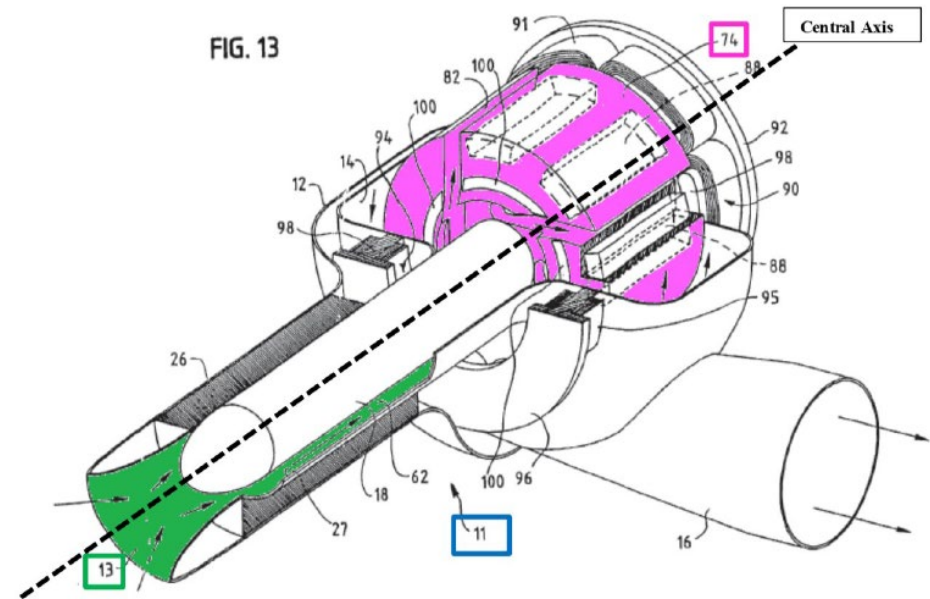
IPR2025-00112 Paper 31 at 4

Patent Owner Demonstrative Exhibit—Not Evidence

Wampler Does Not Teach or Suggest Axially Adjacent Magnetic Device and Rotor

There is no doubt that the magnet segments 88 (the “first magnetic device”) are *not adjacent* to the impeller 74 (the “magnetically driven rotor”). POR 11–15; Ex. 2015, ¶¶ 78–82.

82. In my opinion a POSA would have appreciated the plain and ordinary meaning of “adjacent” as including positioning of two components next to one another, including perhaps touching or sharing a common side. I believe a POSA would have interpreted adjacency along an axis to mean that two components are positioned next to one another when measured along the axis. In my opinion, adjacent positioning is distinct from positioning that involves components overlapping or occupying the same portion of an axis upon which they are positioned.



IPR2025-00096 Paper 33 at 8
IPR2025-00096 Ex. 2015 ¶ 82
IPR2025-00096 Paper 1 at 19

Axially Adjacent – The Board’s Construction

Accordingly, we find, for purposes of this Decision and based on the current record, that the plain and ordinary meaning of “at a position axially adjacent,” as shown by Patent Owner, is at a position “adjacent to one another as measured along a central axis,” and apply this definition to our analysis of Petitioner’s contentions below.

IPR2025-00096 Paper 15 at 25-26

Axially Adjacent – The Board’s Construction

U.S. Patent

Jun. 7, 2022

Sheet 2 of 3

US 11,351,356 B2

We find no sufficient support for Petitioner’s assertion that “a magnetic element sealed within a rotor is ‘at a position axially adjacent to the magnetically driven rotor.’” Pet. 26. Moreover, we find Patent Owner’s definition of the claim language reflects its plain and ordinary meaning and is consistent with the disclosure of the ’356 patent (which illustrates only a “magnetically driven rotor” positioned adjacent to a “first magnetic device” as measured along a central axis). *See* Ex. 1001 Fig. 2. It is also consistent with the construction Petitioner appears to contend is the correct construction, as applied by Petitioner in, for example, its contentions based on the asserted combination of Bourque and Wampler. *See* Pet. 61–62

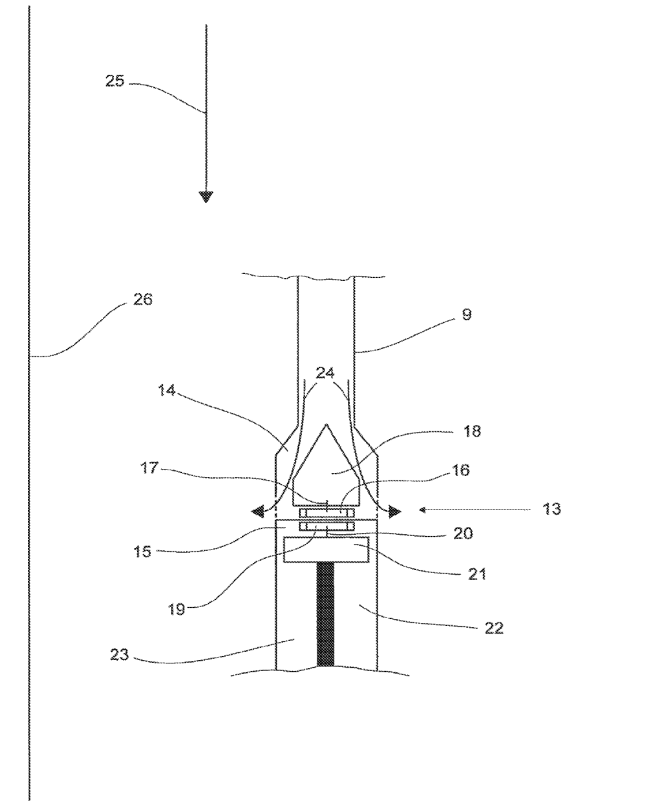


Fig. 2

IPR2025-00096 Paper 15 at 25

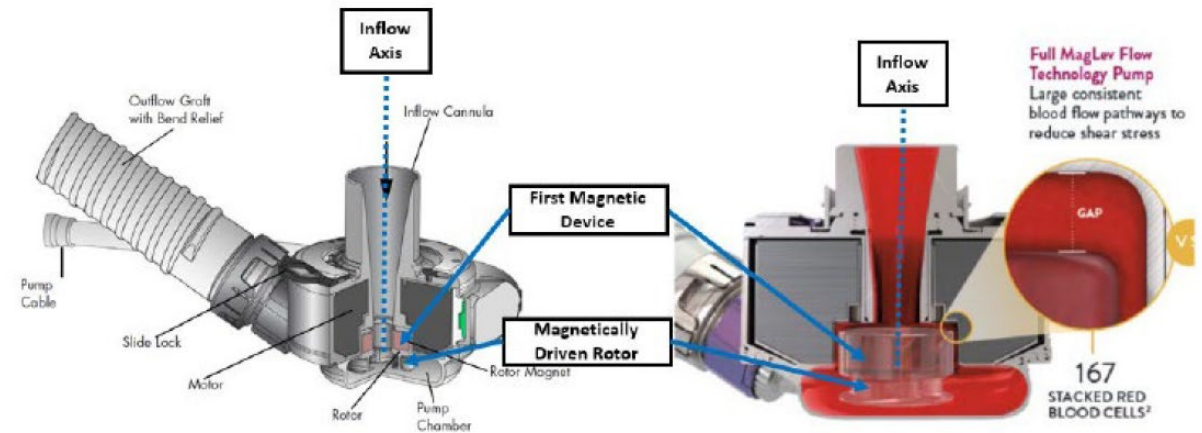
Axially Closer – The Board’s Construction

“for the second magnetic device to be ‘axially closer’ to the first magnetic device than the magnetically drive rotor, each of the components are configured such that they are colinear, or in the same line (or ‘axis’) in space, and the second magnetic device is closer to the first magnetic device along that axis than it is to the magnetically driven rotor.” Pet. 31 (emphases omitted); Ex. 1003 ¶ 220.

IPR2025-00112 Paper 13 at 23-24

Petitioner's Inappropriate Reliance on Litigation Charts – Axially Adjacent

New Exhibit 1036 is an infringement claim chart showing how Abbott's current product infringes claim 1. Addressing the specific claim language at issue here ("a magnetically driven rotor . . . axially adjacent to a first magnetic device"), the exhibit clearly points out a "magnetically driven rotor" and a "first magnetic device" that are "axially adjacent:"



IPR2025-00096 Paper 33 at 5-6
IPR2025-00096 Ex. 1036 at 5

Patent Owner Demonstrative Exhibit—Not Evidence

Petitioner's Inappropriate Reliance on Litigation Charts – Axially Adjacent

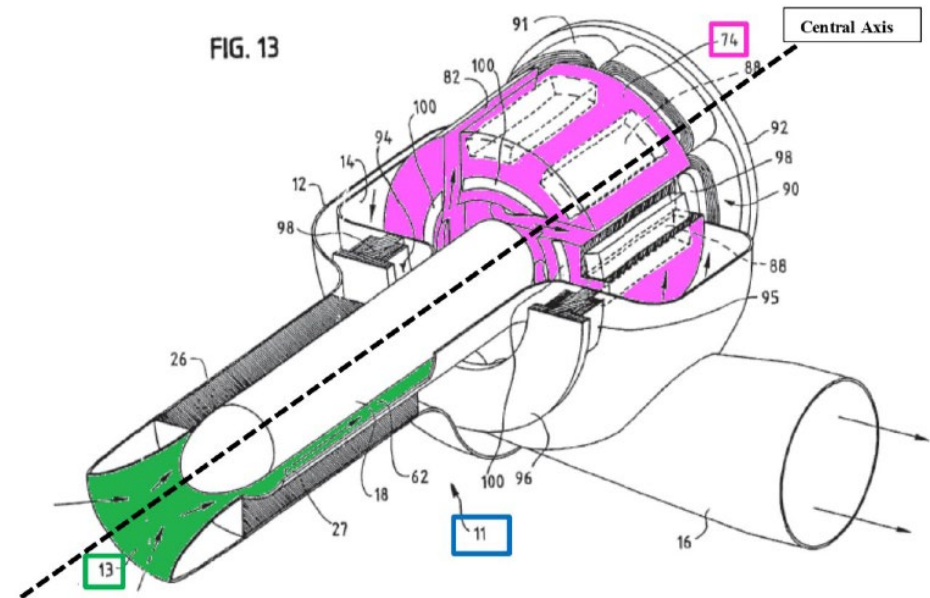
Petitioner, however, points to one erroneously placed arrow on one half of the figure on page 20 of the Exhibit (while not recognizing the 16 correct figures in that document alone) and announces that Patent Owner has taken a position on axially adjacent in the co-pending litigation that is different than the position it takes here. Rep. 3–9. That announcement is false. The figure from page 5, reproduced above, specifically addressing the claim language at issue here, is perfectly consistent with Patent Owner's arguments and the Board's conclusions in the Institution Decision.

IPR2025-00096 Paper 33 at 6

Wampler Does Not Teach or Suggest Axially Adjacent Magnetic Device and Rotor

Petitioner and its expert have stated that they are relying exclusively on the “second” embodiment of Wampler and that Figure 13 of Wampler is representative of that embodiment. Rep. 10; Ex. 2027, 48:21–51:11; Ex. 1042, ¶ 56.

8 THE WITNESS: Well, yes. As I said
9 in my report, I relied on what the disclosure of a
10 complete device depicted in Figures 11 to 14, and
11 of course the text which describes it.

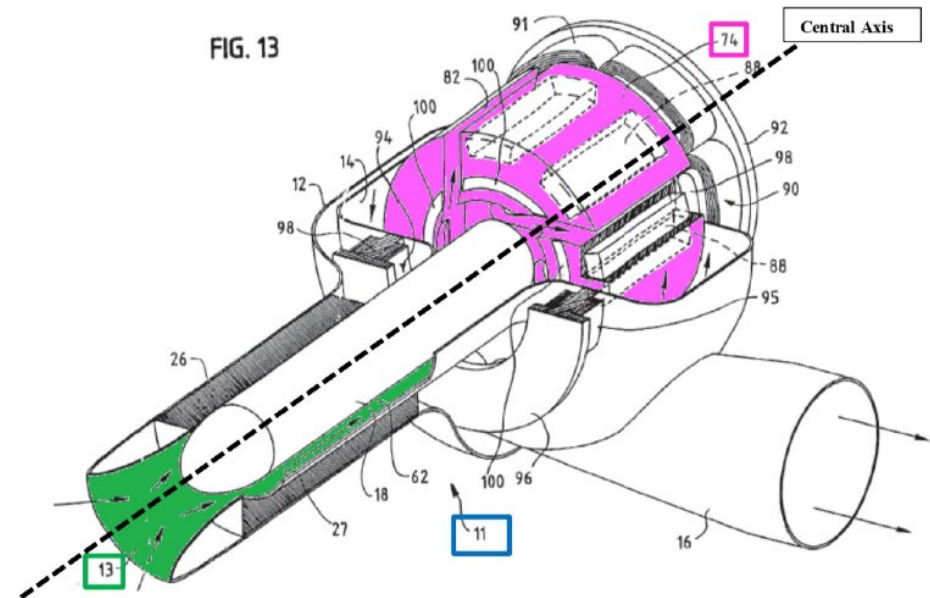


IPR2025-00096 Paper 33 at 8
IPR2025-00096 Ex. 2027, 51:8-11
IPR2025-00096 Paper 1 at 19

Wampler Does Not Teach or Suggest the Axially Closer Configuration

There is no doubt that the motor stators 90, 94 (the “second magnetic device”) are not axially closer to the magnet segments 88 (the “first magnetic device”) than to the impeller 74 (the “magnetically driven rotor”). POR 11–17.

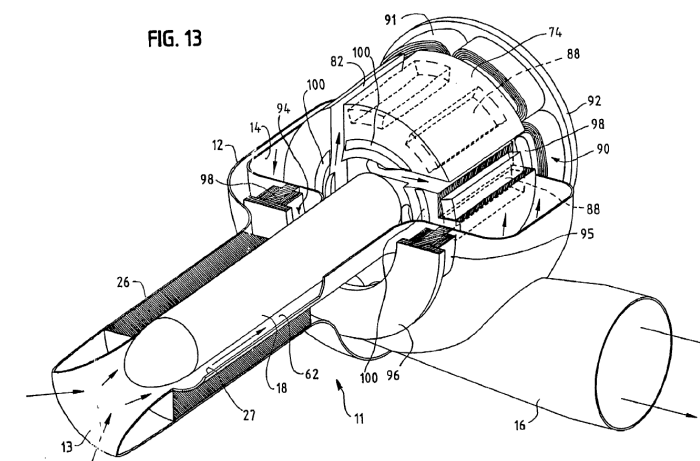
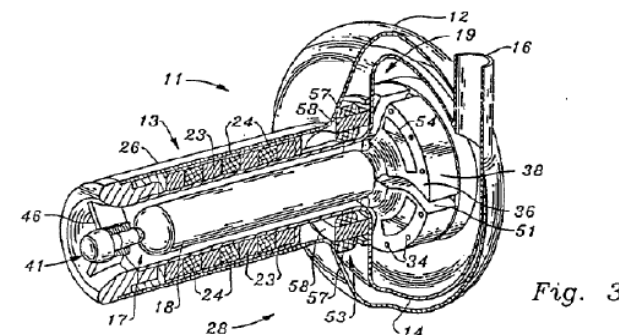
note that Wampler discloses its permanent magnet segments are “imbedded within each impeller blade sector,” suggesting that the impeller surrounds the magnets 88. Ex. 1008 at [0018]. Accordingly, it appears that the second magnetic device cannot be positioned axially closer to the first magnetic device at least because the magnetically driven rotor (impeller 74) surrounds the first magnetic device (magnets 88).



IPR2025-00112 Paper 31 at 8
IPR2025-00112 Ex. 2015 ¶ 98
IPR2025-00112 Paper 1 at 18

Wampler Teaches Away from Implanting its Second Embodiment in the Manner of its First Embodiment

Not only does Wampler not explicitly contemplate this combination, it actually teaches away from it. Wampler says of Figure 5 that “[g]ood anatomic compatibility is possible since the pump casing is *compact and disc-shaped*, fitting well between the apex of the heart and the adjacent diaphragm.” Ex. 1008, ¶ [0076] (emphasis added); *see also* Ex. 2015, ¶ 145. But the second embodiment has a very different size and shape of the portion of the device that would have to fit between the apex and diaphragm. Ex. 2015, ¶¶ 100–101.

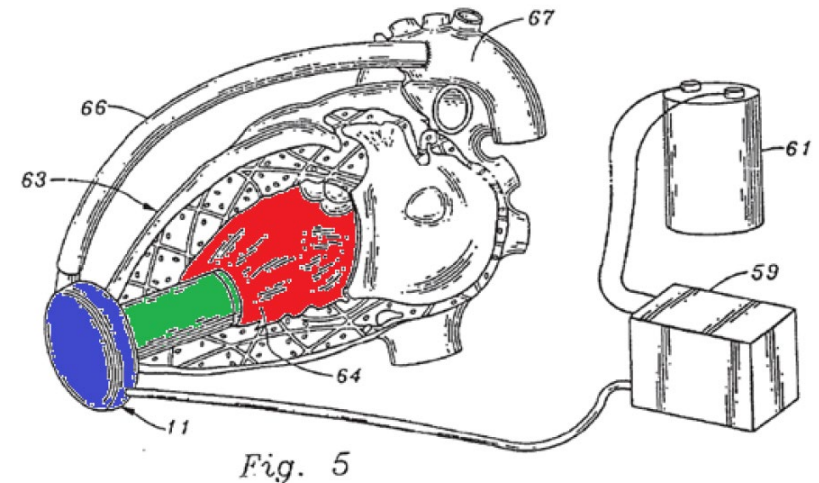


IPR2025-00096 Paper 33 at 17
IPR2025-00096 Ex. 1008, Figures 3, 13

Wampler's First and Second Embodiments Are Different In Critical Ways

The Petition in this matter depends on Figure 5 of Wampler. Element 1A requires a heart assist pump device to be implanted so that its inflow tube is placed into the apex of the left ventricle. The Petition only cites to Figure 5 of Wampler for this element.

The Petition cites again to Figure 5, and Wampler's description of it, for the purpose of combining Wampler with Bourque-2001 to allegedly teach that the inflow tube that is inserted into the apex of the left ventricle is axially aligned with the rotor. Pet. 55–57.



IPR2025-00096 Paper 33 at 15-16

IPR2025-00096 Paper 1 at 16-17

Patent Owner Demonstrative Exhibit—Not Evidence

Bourque-2001 Does Not Teach or Suggest a Rotor and Inflow Tube that are Axially Aligned

As to Petitioner's argument based on Bourque, alone, on the current record we agree with Patent Owner that Petitioner does not sufficiently show in the Petition that Bourque teaches a rotor "axially aligned" with the inflow tube. Petitioner contends that Figure 3 of Bourque teaches "delivering a

In Figure 1A, the "inflow cannula" and "flexible recovery section" form a right angle prior to the connection with the "pump/motor."

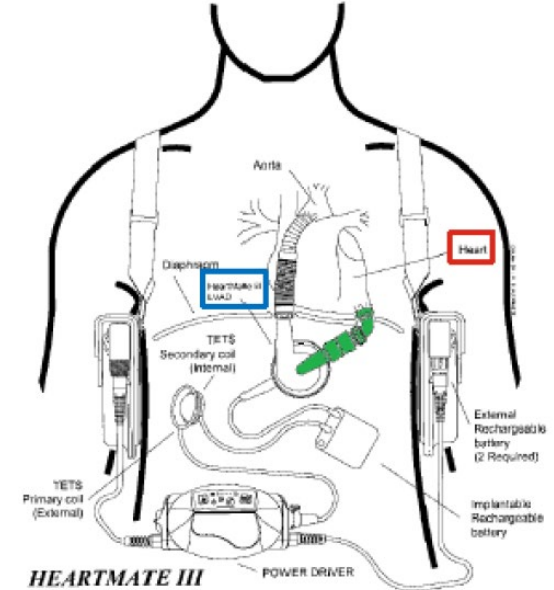
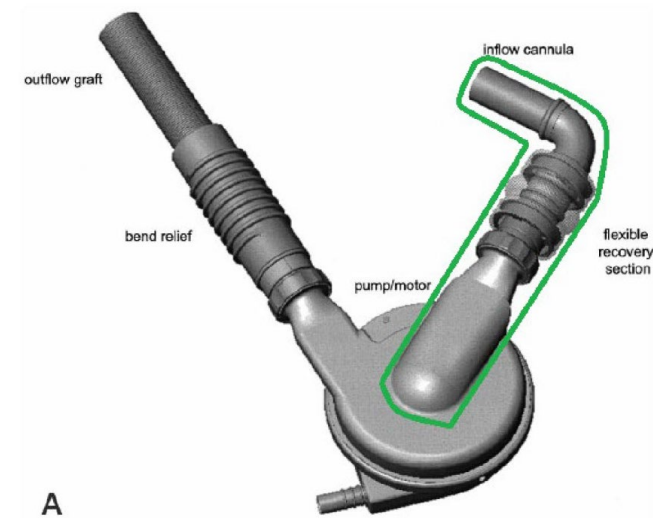


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

IPR2025-00096 Paper 15 at 28, 30

IPR2025-00096 Paper 1 at 52

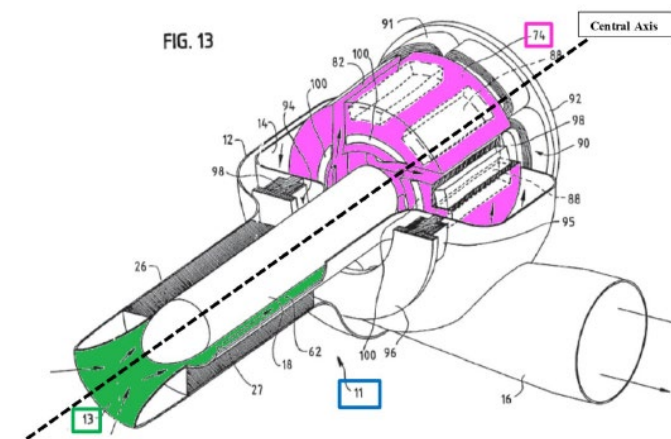
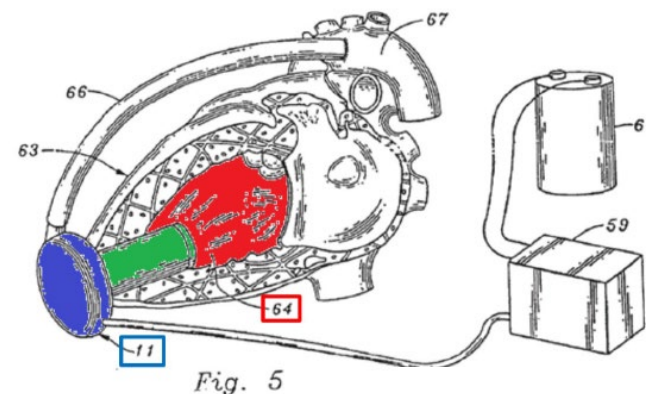
IPR2025-00096 Ex. 1003 ¶ 166

Patent Owner Demonstrative Exhibit—Not Evidence

Wampler Teaches Away from Implanting its Second Embodiment in the Manner of its First Embodiment

the impeller 74 of Figure 13 is much thicker than the impeller 19 of Figure 3, resulting in a thicker cylindrical shape for the second embodiment—not the compact, disc-shaped first embodiment that is critical for Petitioner’s case. And this is no accident. Discussing impeller 74, Wampler explains that this thickness of the impeller allows for fewer blades and results in less damage to the blood being pumped while still maintaining pumping efficiency. Ex. 1008, ¶ [0078].

Petitioner does not describe a motivation for changing the device of Figure 13 to provide the compact, disc-shaped effect of Figure 3—or even whether such a change is possible. Instead, Petitioner says that it is not combining elements from different embodiments—when Petitioner plainly does.



IPR2025-00096 Paper 33 at 18

Wampler's Second Embodiment was Not Implanted at the Apex of the Heart

Petitioner's expert Wieselthaler asserts that the HeartWare

HVAD "progressed from the design disclosed in Wampler's Patent" but provides no documentation to suggest that the devices were similar. Ex. 1041, ¶ 53. Again, on cross-examination, Dr. Wieselthaler, faced with the images below, had to admit that the second embodiment of Wampler and the HeartWare HVAD were different pumps:

21 Q. And is that the HeartWare HVAD that you
22 implanted that you describe in your declaration as
23 implanting beginning in March of 2006?
24 MS. RAGHAVAN: Objection. Form.

Page 57

1 A. It is the HeartWare HVAD.

2 BY MR. VARE:

3 Q. Okay. And the Figure 13 in your
4 declaration at Paragraph 53 is not the same device as
5 that shown in your presentation, Exhibit 2024, is it?

6 A. It's not the same, but once again, I
7 mentioned in 53, "The development of the HeartWare HVAD
8 progressed from the design disclosed in Wampler's
9 patent." And this is --

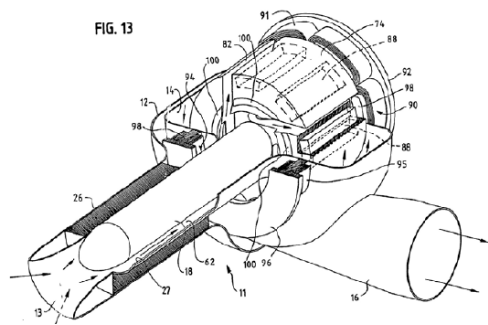
10 Q. It's not -- but it's not the same device?

11 A. It's not the same device.

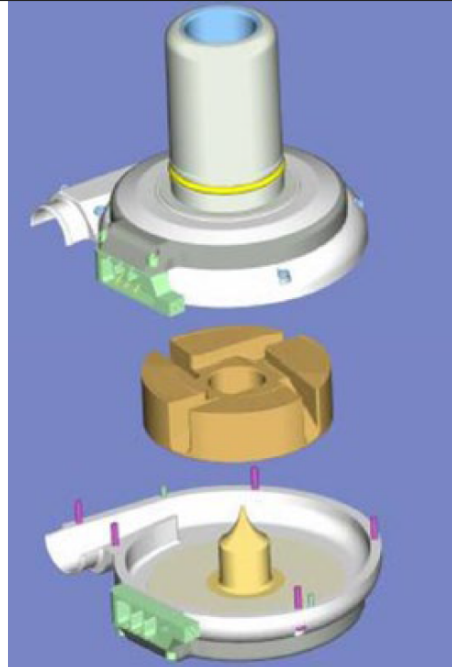
IPR2025-00096 Paper 33 at 19-20
IPR2025-00096 Ex. 2028, 56:21-57:11

Patent Owner Demonstrative Exhibit—Not Evidence

Wampler's Second Embodiment was Not Implanted at the Apex of the Heart



Ex. 1041, ¶ 53 (Wampler Fig. 13)



Ex. 2024, 51 (HeartWare HVAD)

3 Q. So just to be clear, you have never
4 implanted in a human being an LVAD configured or
5 structured as shown in Figure 13 of your declaration?

MS. RAGHAVAN: Objection. Form.

7 A. I never implanted an LVAD, you know, that
8 never came into existence, you know, and therefore I
9 couldn't implant it either in animal nor in a human
10 being.

Bourque-2001 Does Not Teach or Suggest a Rotor and Inflow Tube that are Axially Aligned

As to Petitioner's argument based on Bourque, alone, on the current record we agree with Patent Owner that Petitioner does not sufficiently show in the Petition that Bourque teaches a rotor "axially aligned" with the inflow tube. Petitioner contends that Figure 3 of Bourque teaches "delivering a

In Figure 1A, the "inflow cannula" and "flexible recovery section" form a right angle prior to the connection with the "pump/motor."

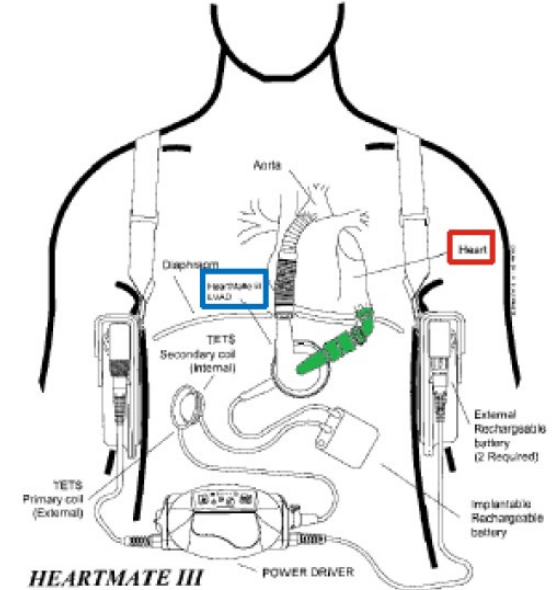
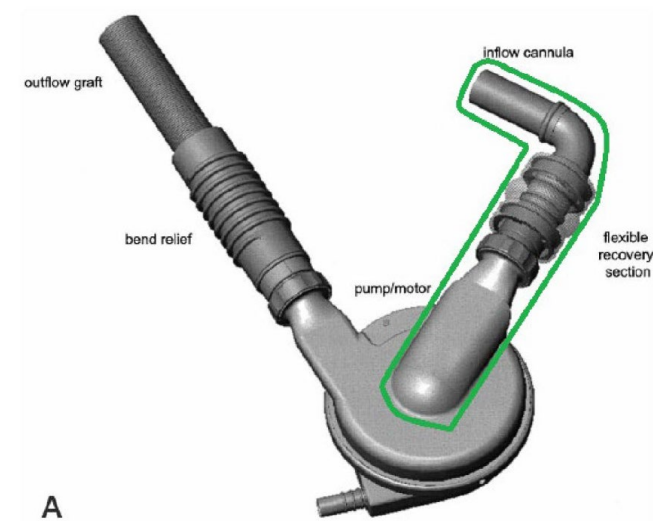


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

IPR2025-00096 Paper 15 at 28, 30

IPR2025-00096 Paper 1 at 52

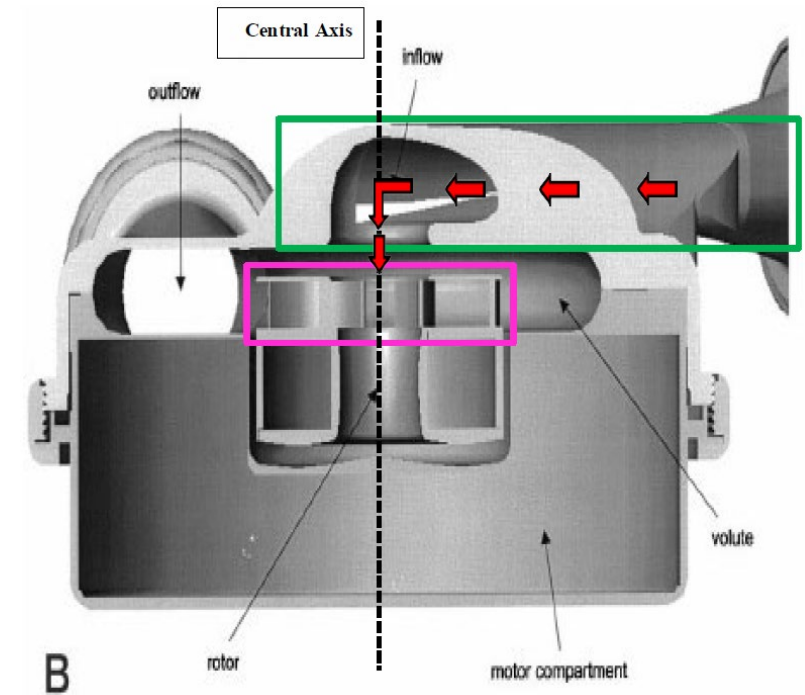
IPR2025-00096 Ex. 1003 ¶ 166

Patent Owner Demonstrative Exhibit—Not Evidence

Bourque-2001 Does Not Teach or Suggest a Rotor and Inflow Tube that are Axially Aligned

Petitioner's annotated version of Figure 1B, above, shows Bourque's inflow assembly (in a green outline) perpendicular to Bourque's impeller (in a pink outline). Petitioner annotated red arrows allegedly it is plainly clear from Figures 1A and 1B of Bourque that Bourque's inflow subassembly is not axially aligned with the rotor.

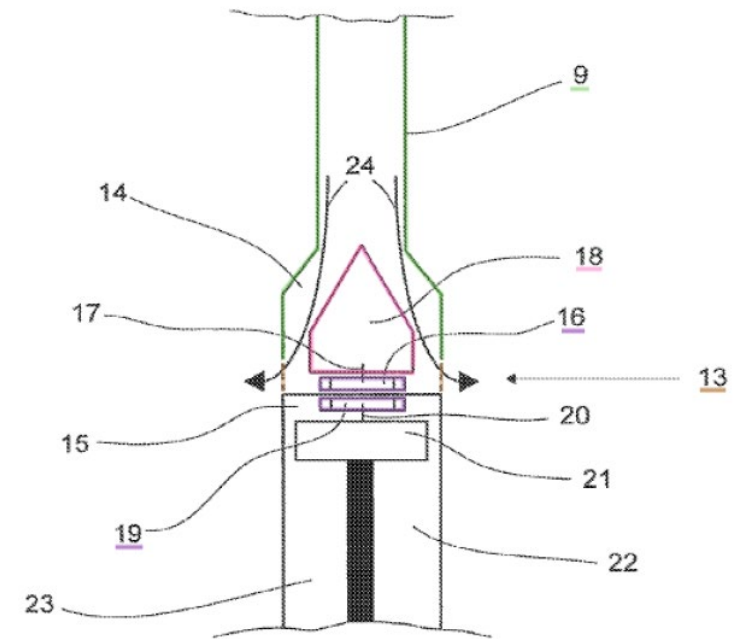
In sum, on the current record we agree with Patent Owner that Petitioner fails to sufficiently show that Bourque, alone, teaches a rotor “axially aligned” with the inflow tube, as required by claim 1.



IPR2025-00096 Paper 15 at 31-32

Bourque-2001 Does Not Teach or Suggest a Rotor and Inflow Tube that are Axially Aligned

Petitioner fails to recognize that Fig. 2 shows axial alignment between the rotor and the inflow tube. Ex. 2015, ¶ 131. Indeed, Petitioners expert Mr. Crosby agreed that Figure 2 illustrates an embodiment of the invention, agreed that the rotational axis of the rotor 18 (colored pink below using Petitioner's color convention) is straight up and down in the page, and agreed that the inflow tube 9 (colored green below) also extends straight up and down in the page. Ex. 2027, 28:10–32:5.



IPR2025-00096 Paper 33 at 13
IPR2025-00096 Ex. 1001, Figure 2

Patent Owner Demonstrative Exhibit—Not Evidence

Bourque-2001 Does Not Teach or Suggest a Rotor and Inflow Tube that are Axially Aligned

When asked whether the inflow tube and rotor illustrated in Figure 2 were axially aligned, Mr. Crosby asserted that he could not answer because he has never formed an opinion about what “axially aligned” means. Ex. 2027, 32:6–33:17. This position would seem to make it difficult for Petitioner to prove its case.

4 Q. Okay. So as you sit here today, you
5 have no opinion on what "axially aligned" means in
6 the context of the '356 patent; is that right?

7 MS. RAGHAVAN: Objection; form.

8 THE WITNESS: That wasn't part of my
9 assignment to come up with definitions of what the
10 terms mean. My assignment was to apply the
11 definitions of the board {ph} used in their
12 institutional decision and then consider the
13 opinions that Mr. Leschinsky provided on those
14 terms and discuss it in that context.

15 I haven't given any thought into what
16 that term might mean. I guess I could come back in
17 a week.

IPR2025-00096 Paper 33 at 13
IPR2025-00096 Ex. 2027, 33:4-17

Patent Owner Demonstrative Exhibit—Not Evidence

A POSITA Would Not Have Combined Bourque-2001 and Wampler

A Sealless Centrifugal Blood Pump with Passive Magnetic and Hydrodynamic Bearings

Richard Wampler, David Lancisi, Virote Indravudh, Raymond Gauthier, and Robert Fine

Petitioner's proposed motivation to combine fails because the Bourque-2001 pump is simply too big to meet the goals set by Petitioner's motivation. POR 26–42. Indeed, Richard Wampler himself criticizes magnetic suspension pumps like Bourque-2001 as being too big and heavy. POR 27; Ex. 2015, ¶ 138; Ex. 2019, 780.

Complete suspension with active magnetic bearings can be truly mechanically frictionless; however, the power requirements, 5–16 W, (9–13) for active magnetic suspension are much greater than any frictional losses observed in conventional bearings. The electromagnets used for active magnetic bearings add significant volume and weight, making these pumps large and heavy when compared to other rotary pump concepts. In addition, active suspension requires proximity sensors and servo circuits, which increase the complexity and number of conductors and may compromise reliability.

IPR2025-00096 Paper 33 at 20

IPR2025-00096 Ex. 2019 at 780

Petitioner's Motivations to Combine Require a Pump that Can Be Placed Between the Apex of the Heart and the Diaphragm

Petitioner relies on Wampler's statement that its "pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm." Ex. 1008, ¶ [0076]. The Petition and associated declaration refer to positioning the combination at this location at least 20 times. Ex. 2029. The Petition describes the motivation to combine this way:

Instead of borrowing parts from predecessor systems, a POSITA would have adhered to the express teachings of Wampler-169, which focused on "[g]ood anatomic compatibility" so that the device "fit[s] well between the apex of the heart and the adjacent diaphragm," eliminating the need for a peritoneal pocket dissection associated with increased rates of infection.

IPR2025-00096 Paper 33 at 23-24

IPR2025-00096 Paper 1 at 86-87

Patent Owner Demonstrative Exhibit—Not Evidence

Petitioner's Evidence for Motivation Fails Because a POSA Would Know the Bourque-2001 Pump Is Too Large

Petitioner even turns to a further pump (VentrAssist) that is not part of any ground asserted in the Petition and says that this pump, even though it is not implanted at the apex of the heart, is evidence of something. Rep. 21–22. Even if the VentrAssist pump were relevant to the asserted grounds, that pump is smaller than Bourque-2001, and Petitioner provides no evidence that a POSA would use Bourque-2001 in the same way.

IPR2025-00096 Paper 33 at 25
IPR2025-00096 Ex. 2015 ¶ 152

Device	Weight	Volume	Location
HeartMate II	281	63	Pocket
Wampler	195	28	Apex
Bourque-2001 (HeartMate III prototype)	474	168	Pocket
HeartMate 3 (clinical)	200	80	Apex
VentrAssist	298		Pocket
HeartWare HVAD	145	50	Apex

Petitioner's Evidence for Motivation Fails Because a POSA Would Know the Bourque-2001 Pump Is Too Large

Petitioner never disputes that the Bourque-2001 pump is too big for the combination's intended purpose. Instead, Petitioner argues incorrectly that it doesn't matter whether the Bourque-2001 pump is fit for the stated motivation. Rep. 17–18. Petitioner argues that a different pump that is not part of any asserted ground—the HeartWare HVAD—was being used in clinical trials (even if the structure of the pump was undisclosed). Rep. 18, 23–26.

IPR2025-00096 Paper 33 at 24

Petitioner's Evidence for Motivation Fails Because a POSA Would Know the Bourque-2001 Pump Is Too Large

Petitioner also argues that

Mr. Bourque himself recognized in 2006 that the Bourque-2001 pump was too big (though this admission came in a 2021 interview and the redesign that followed this recognition was first disclosed in a 2016 ASAIO article). Rep. 26–27; *contra* POR 35–37, Ex. 2015, ¶¶ 158–162.

IPR2025-00096 Paper 33 at 24

Failure of Evidence for the Motivation to Combine Dooms the Combination

Critically, Patent Owner’s Response cited case law, and in particular the *Intelligent Bio-Systems* case, to make the point that, if a skilled person would know that the combination would not work for the stated motivation, then motivation to combine fails even if the reason why it fails falls outside the claims. POR 37–40. In essence, even though the claims do not have a space constraint requirement, the undisputed fact that Bourque-2001 will not fit at the location necessary for the motivation is “central to a finding of no motivation to combine.” *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016).

As explained above, there is no doubt that the HeartMate III pump described in Bourque-2001 is too big to work and fit as described by Petitioner. In analogous situations, claims have been found not obvious. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016); *see also Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.* 141 F.4th 1367, 1381–82 (Fed. Cir. 2025). For example, in *Intelligent Bio-Systems*, petitioner’s motivation to combine depended upon the ability to meet a “quantitative deblocking requirement.” *Intelligent Bio-Systems*, 821 F.3d at 1868. The Board found that the Petition did not credibly explain how, under suitable conditions, the references would meet the quantitative deblocking requirement. *Id.* Even though the claims did not require quantitative deblocking, the shortcoming in the evidence was “central to a finding of no motivation to combine.” *Id.*

IPR2025-00096 Paper 33 at 21

IPR2025-00096 Paper 22 at 39

Wampler's Second Embodiment was Not Implanted at the Apex of the Heart

Petitioner tries to bolster its case by asserting that the HeartWare pump had been developed from Wampler's second embodiment and was implanted at the apex of the heart before the priority date of the '356 patent. Rep. 23–25. There are numerous problems with this assertion.

First, the HeartWare HVAD pump appears nowhere in the four grounds asserted in the Petition.

Further, there are no documents evidencing the structure of the HeartWare pump before the priority date. Petitioner and its experts refer to Exhibits 1015 and 1044—both of which are press releases with precious little information about the structure of the pump.

HEARTWARE - A NOVEL MINIATURIZED PASSIVE MAGLEV CENTRIFUGAL VAD

LaRose, J. A.¹; Gore, B. G.¹; Indravudh, V.¹; Frazier, O. H.²

[Author Information](#)
[ASAIO Journal 50\(2\):p 137, March 2004.](#)

A long term mechanical assist device must have the following attributes to be successful in a large patient population: capability of full ventricular support; small size and optimized fit; hemocompatibility; highly reliable, wearless design; high power efficiency. Heartware has developed a miniaturized passively magnetically suspended centrifugal VAD, which has a displaced volume of 50 cc and weighs 145 grams. The pump has a short integrated inflow cannula and an axial height less than one inch. The size of the device coupled with the perpendicular relationship of outflow to the inflow allows for intrapericardial pump placement and fast implantation. The short axial height is achieved through a proprietary design that integrates the motor into a wide-bladed impeller. Wearless pump design is achieved via a combination of passive ramp preload, and shrouded axial hydrodynamic seal. The simplicity of the design achieves a flow of 5.0 liters/min at 2500 rpm. The pump is highly power efficient and can maintain a pressure of 100 mmHg. The Heartware VAD is a novel, miniaturized, long term, mechanical ventricular assist device.

Copyright © 2004 by the American Society for Artificial Organs



ASX ANNOUNCEMENT
24 March 2006

First Human Implant of HeartWare's HVAD

On 22 March 2006, a 48 year old male patient suffering NYHA Class IV Heart Failure became the first recipient of HeartWare's HVAD mechanical circulatory assist device. The implant was conducted at the Vienna General Hospital and the surgical team was led by Dr Georg Wieselthaler, Clinical Director of Mechanical Circulatory Support at the University of Vienna.

The successful implant marks the start of HeartWare's CE mark clinical study. The trial protocol calls for the implantation of the device in twenty patients suffering advanced heart failure. The implants are to be conducted at the Vienna General Hospital (Austria), the Royal Perth Hospital (Australia), the Hannover Medical Centre (Germany) and Harefield Hospital (UK). HeartWare expects to complete patient enrolment in the trial by the end of 2006.

IPR2025-00096 Paper 33 at 18-19

Wampler's Second Embodiment was Not Implanted at the Apex of the Heart

Petitioner's expert Crosby states in his Reply Declaration that the HeartWare HVAD design is "largely identical to the Wampler second embodiment," but admitted on cross-examination that he had no idea what the structure of the HeartWare HVAD pump was. Ex. 1042, ¶ 65; Ex. 2027, 36:17–48:13.

19 Q. What does it look like?
20 MS. RAGHAVAN: Objection; form.
21 THE WITNESS: What does what look
22 like? The impeller; is that what you're asking?
23 MR. CAHILL: Yes.
24 MS. RAGHAVAN: Same objection.
25 THE WITNESS: I don't have one in

Page 39

1 front of me. It's a while since I've held one in
2 my hands. I wouldn't feel confident answering that
3 question without more data. And I'm not here as an
4 expert on the HVAD pump. You need to talk with
5 someone who has worked with that pump.
6 BY MR. CAHILL:
7 Q. You did express views about the HVAD
8 pump though, didn't you?
9 A. I did express views about the HVAD
10 pump, but I don't think I expressed a view which
11 would directly answer your question what does the
12 impeller look like unless you can point to it
13 somewhere in my report where I expressed that view.
14 I'd be happy to review it.
15 Q. When you prepared your reply
16 declaration, did you have an understanding of what
17 the rotor in the HeartWare HVAD pump looked like?
18 MS. RAGHAVAN: Objection; form.
19 THE WITNESS: I reviewed the
20 documents which are listed as exhibits in my reply
21 declaration, and I relied on those exhibits to form
22 my opinions. If you can point to one of those
23 exhibits which might answer your question, then I
24 can look at that exhibit.

IPR2025-00096 Paper 33 at 19
IPR2025-00096 Ex. 2027, 38:19-39:24

Patent Owner Demonstrative Exhibit—Not Evidence

Petitioner's Evidence for Motivation Fails Because a POSA Would Know the Bourque-2001 Pump Is Too Large

Petitioner even turns to a further pump (VentrAssist) that is not part of any ground asserted in the Petition and says that this pump, even though it is not implanted at the apex of the heart, is evidence of something. Rep. 21–22. Even if the VentrAssist pump were relevant to the asserted grounds, that pump is smaller than Bourque-2001, and Petitioner provides no evidence that a POSA would use Bourque-2001 in the same way.

IPR2025-00096 Paper 33 at 25
IPR2025-00096 Ex. 2015 ¶ 152

Device	Weight	Volume	Location
HeartMate II	281	63	Pocket
Wampler	195	28	Apex
Bourque-2001 (HeartMate III prototype)	474	168	Pocket
HeartMate 3 (clinical)	200	80	Apex
VentrAssist	298		Pocket
HeartWare HVAD	145	50	Apex

Patent Owner Has Rebutted All of Petitioner's Motivations to Combine

Petitioner claims that Patent Owner “fails to rebut multiple, independent motivations to combine Bourque and Wampler.” Rep. 18–19. Patent Owner addresses those reasons specifically at pages 40 to 42 of its POR. The reasons are not independent, and they further fail on their own.

Petitioner argues for the removal of the “flow restrictive elbow.” Rep. 18–19. But Mr. Bourque himself argued in favor of the elbow because it created a swirl that prevented stagnation of the flow and thus prevented thrombus formation. POR 41; Ex. 2015, ¶ 164; Ex. 2005, 878. Further, a skilled person would recognize that removing the elbow from this large and heavy pump would leave the pump with no practical way to be implanted in a human. Ex. 2015, ¶¶ 135–171; Ex. 2017, ¶¶ 42–69.

Computational Fluid Dynamics Analysis of a Maglev Centrifugal Left Ventricular Assist Device

*†Greg W. Burgreen, ‡Howard M. Loree II, ‡Kevin Bourque, ‡Charles Dague, ‡Victor L. Poirier, ‡David Farrar, *Edward Hampton, §Z. Jon Wu, ¶Thomas M. Gempp, and ¶¶Reto Schöb

clean. Careful examination reveals a slight degree of swirling flow in the elbow. CFD analysis indicates that a small pocket of preswirl is induced from the impeller and migrates upward into the elbow. The pocket is contained in size and extent by the main flow entering the rotor central core. No flow stasis is observed related to this swirling flow structure. In fact, vigorous surface washing is associated with the preswirl pocket.

IPR2025-00096 Paper 33 at 22

IPR2025-00096 Ex. 2005 at 878

Patent Owner Demonstrative Exhibit—Not Evidence

Patent Owner Has Rebutted All of Petitioner's Motivations to Combine

Petitioner argues that the combination would eliminate “peripheral hardware.” Rep. 18–19. Petitioner criticizes Patent Owner’s position on this point, but misses the critical first step in Patent Owner’s analysis—the peripheral hardware is only eliminated if the pump is placed at the apex of the heart. POR 41–42; Ex. 2015, ¶ 165. Otherwise, the pump would need to be connected to a cannula (“peripheral hardware”) for routing blood from the heart. *Id.*; see also Ex. 2027, 12:6–13:19 (describing for the VentrAssist pump that the inflow cannula attaches to the pump using a threaded element).

IPR2025-00096 Paper 33 at 22

Patent Owner Has Rebutted All of Petitioner's Motivations to Combine

Petitioner argues that the references “are analogous.” Rep. 19–20. Patent Owner very much disputes the argument that the proposed modification is a mere rearrangement of old elements—in particular, that there is any evidence for this proposition. POR 42. The more critical issue, even if the Bourque-2001 and Wampler references are in the same field, is that a skilled person would read those references and understand that it would be practically impossible to combine them because there would be no way to implant the resulting device.

IPR2025-00096 Paper 33 at 23
IPR2025-00096 Ex. 2015 ¶ 153
IPR2025-00096 Ex. 2017 ¶ 53

153. 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 placed at the apex of the heart, and therefore would not have been motivated to make the combination contended by Petitioner.

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.

Akamatsu Does Not Teach or Suggest Axially Adjacent Magnetic Device and Rotor

Petitioner essentially points to FIG. 2 of Akamatsu alone as support for teaching of claim element [1H], alleging with an annotated figure that the reference teaches a permanent magnet (purple) axially adjacent an impeller (pink) along a central axis (black). Pet. 99; Ex. 1003, ¶ 528.

Petitioner's marked up figure highlights that the permanent magnet is embedded within the impeller in an arrangement that is not axially adjacent. Indeed, Petitioner's expert Peter Crosby describes Akamatsu's teaching in exactly this way: "the permanent magnet embedded in the motor plate and the permanent magnet embedded in the impeller." Ex. 1003, ¶ 527 (citing Ex. 1006 at 4 and FIG. 2).

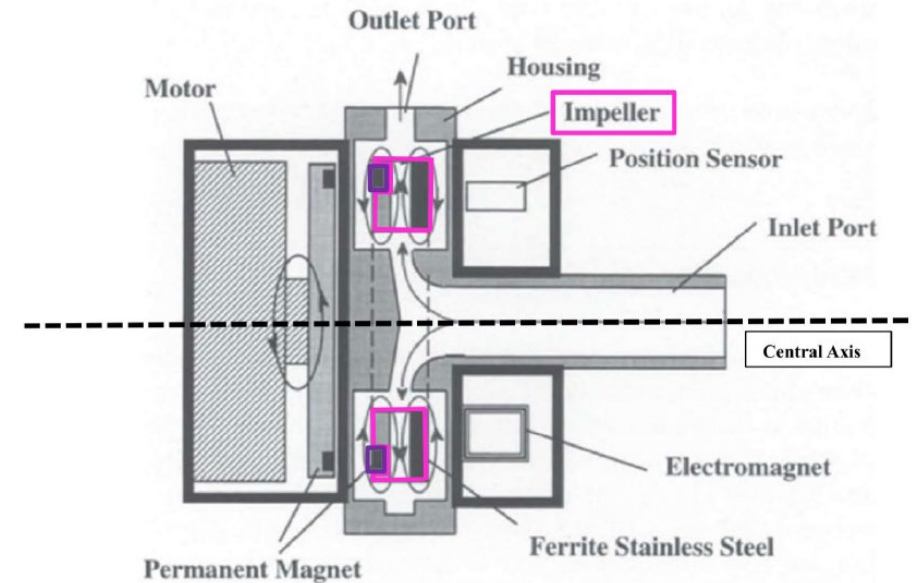


Fig. 2. Schematic cross section of the MSCP

IPR2025-00096 Paper 33 at 9-10
IPR2025-00096 Ex. 1003 ¶¶ 527-528
IPR2025-00096 Paper 1 at 99

Akamatsu Does Not Teach or Suggest the Axially Closer Configuration

Petitioner essentially points to FIG. 2 of Akamatsu alone as support for teaching of claim element [1J], alleging with an annotated figure that the reference teaches a first magnet (purple) axially closer to a second magnet (motor at left) than to an impeller (pink). Pet. 91; Ex. 1003, ¶ 494, 497.

Petitioner's marked up figure highlights that the permanent magnet is embedded within the impeller in an arrangement that does not place the purple bounded magnet axially closer to the motor magnet than the pink bounded impeller. Indeed, Petitioner's expert Peter Crosby describes Akamatsu's teaching in exactly this way: "the permanent magnet embedded in the motor plate and the permanent magnet embedded in the impeller." Ex. 1003, ¶ 442 (citing Ex. 1006, p. 4 and FIG. 2).

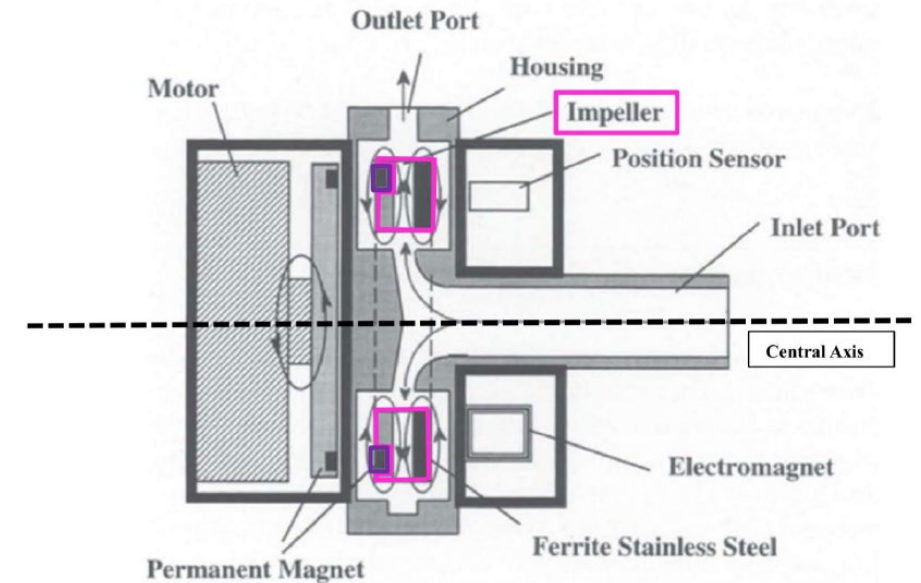


Fig. 2. Schematic cross section of the MSCP

IPR2025-00112 Paper 31 at 9-10
IPR2025-00112 Ex. 1003 ¶¶ 442, 497
IPR2025-00112 Paper 1 at 91

A POSA Would Not Combine Schima and Akamatsu

Akamatsu, like Bourque-2001, is simply too big to be implanted at the apex of the heart, and this undermines Petitioner's reasons for motivation.

Device	Weight (g)	Volume (ml)	Location
Bourque-2001 (HeartMate III prototype)	474	168	Pocket
Akamatsu	400	196	Pocket
HeartWare HVAD	145	50	Apex

188. It is my opinion that a POSA would have viewed the size of the pump disclosed in Akamatsu as prohibitive for implantation at the apex of the heart for the same reasons reviewed above with regard to the pump disclosed in Bourque-2001. A POSA would therefore not have understood FIG. 1 of Akamatsu to provide such a teaching due to the practical impossibility of implementation.

224. 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.

IPR2025-00096 Paper 33 at 25
IPR2025-00096 Ex. 2015 ¶ 187, 188, 224

Patent Owner Demonstrative Exhibit—Not Evidence

Comparisons of Akamatsu to DuraHeart Are Incorrect

Patent Owner's expert, Mr. Leschinsky, predicted exactly that: the Akamatsu pump would need to be implanted in a preperitoneal pocket like Bourque-2001 because it was too large. Ex. 2015, ¶ 222. Petitioner's expert, who implanted the DuraHeart, confirmed Mr. Leschinsky's intuition. Ex. 2028, 38:23–40:21.

222. 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.

IPR2025-00096 Paper 33 at 27
IPR2025-00096 Ex. 2015 ¶ 222

Comparisons of Akamatsu to DuraHeart Are Incorrect

Patent Owner's expert, Mr. Leschinsky, predicted exactly that: the Akamatsu pump would need to be implanted in a preperitoneal pocket like Bourque-2001 because it was too large. Ex. 2015, ¶ 222. Petitioner's expert, who implanted the DuraHeart, confirmed Mr. Leschinsky's intuition. Ex. 2028, 38:23–40:21.

2 Q. Where did you implant the DuraHeart pump
3 in a human? Like where in the body?

4 MS. RAGHAVAN: Objection. Form.

5 A. It was at that time, you know, implanted
6 in a preperitoneal pocket.

7 BY MR. VARE:

8 Q. Did you ever implant the DuraHeart pump at
9 the apex of the heart in the pericardial space?

10 A. Actually, in the pericardial space, it was
11 definitely too big, but once again, you know, on the
12 apical -- as in apical cannulation side, you actually
13 can place these pumps, you know, similar like the
14 VentrAssist pump, for example, in a subdiaphragmal
15 position, which is possible.

16 Q. Did you ever do that?

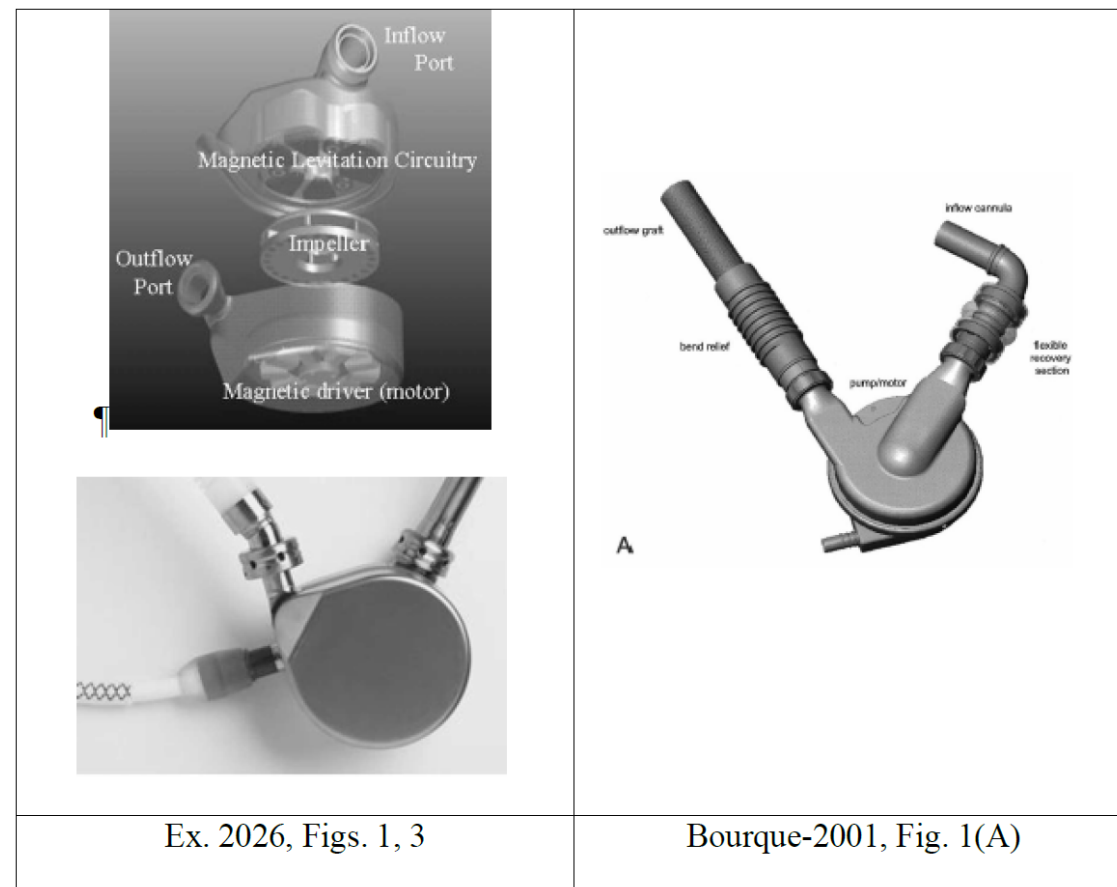
17 A. No, because I mean, we actually were in a
18 clinical trial, and you were not supposed to, you know,
19 change whatever you want to have. You were more or
20 less, you know, bound, you know, to what the company
21 and the PIs, you know, actually wanted.

IPR2025-00096 Paper 33 at 27
IPR2025-00096 Ex. 2028, 40:2-21

Comparisons of Akamatsu to DuraHeart Are Incorrect

Petitioner responds that Akamatsu not only would fit at the apex of the heart, but that its alleged commercial embodiment (“the DuraHeart”) was implanted in that way. Rep. 22–23. We discovered on cross-examination, however, that the DuraHeart pump was an altered version of the Akamatsu pump—set up for implantation in a preperitoneal pocket with a perpendicular inflow tube exactly like the similarly sized Bourque-2001 pump:

IPR2025-00096 Paper 33 at 26-27
IPR2025-00096 Ex. 2026, Figures 1, 3
IPR2025-00096 Ex. 1007, Figure 1(A)



Petitioner Fails to Show Unpatentability of External Controller

- For all combinations, Petitioner fails to show teaching of a controller that is external
- Petitioner quotes Patent Owner's expert for the idea that implanted pumps are controlled, but there is no disclosure that the controller is *external*, as required by the claims
- POR 21-22, 43-45, 52-56, 65-67

IPR2025-00096 Paper 33 at 28

Petitioner Fails to Show Unpatentability of Dependent Claims – Sensors Delivering Feedback to External Controller

- Certain dependent claims require one or more sensors that deliver feedback to an external controller that controls the pump
- No teaching of such feedback delivered to an external controller that is controlling the pump

IPR2025-00096 Paper 22 at 44-45, 66-67

Petitioner Fails to Show Unpatentability of Dependent Claims – Control Based on Parameter Indicative of Cardiac Output

- For both combinations, Petitioner fails to show teaching of control based on a parameter that is indicative of cardiac output
- Petitioner argues that the controller controls based on pump speed (Rep. 27, 32), but such disclosure does not meet the claim language

IPR2025-00096 Paper 33 at 28

Petitioner's "Public Use" Evidence Is Inadmissible

- Petitioner's "rebuttal" evidence all relates to alleged public uses of physical devices (HVAD, DuraHeart, VentrAssist, DeBakey, Jarvik-2000) and not to the printed publications upon which the Petition was based (Exs. 1005-1008)
- These physical devices cannot form the basis of IPR (§ 311(b))
- As demonstrated above, these physical devices were also not the same as the designs described in Exhibits 1005-1008
- This evidence is therefore irrelevant (FRE 401-403) and the testimony based upon it is unreliable (FRE 702)

IPR2025-00096 Papers 34, 40

Claim Construction – Magneto Coupling & By the Blood Flowing

- Petitioner proposes narrowing claim constructions for “Magneto Coupling” and “By the Blood Flowing” that are contradicted by its unpatentability positions
- Petitioner is playing games with claim construction by goading the Board into broad constructions to prove unpatentability and maintaining arguments for a narrower construction in district court to argue non-infringement

IPR2025-00096 Paper 33 at 2

Claim Construction – *Revvo Techs.* Decision

Recently, the Director vacated a Decision Granting Institution for just such game playing by a petitioner. *Revvo Techs. Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 (PTAB November 3, 2025). There, the petitioner adopted the patent owner’s broad proposed claim constructions from the co-pending district court litigation. *Id.*, 2. The petitioner’s claim construction positions were different than the narrow constructions that it proposed in the infringement case. *Id.* As happened here, the patent owner argued that these claim construction positions amounted to gamesmanship. *Id.* Also as happened here, the Board disagreed and adopted the broader claim constructions.

IPR2025-00096 Paper 33 at 2-3

Claim Construction – *Revvo Techs.* Decision

[T]he rules discourage petitioners from seeking broader constructions at the Board to support a patentability challenge while seeking narrower constructions in litigation to avoid infringement liability. As the Office explained when it changed the claim construction standard used in inter partes reviews and post-grant reviews to match the standard used in litigation, ‘[petitioners] will have less flexibility to advance inconsistent arguments about claim scope, and will instead be required to choose a single claim construction that best captures the true meaning of the patent claim.’

IPR2025-00096 Paper 33 at 3 (citing *Revvo Techs.*)

Petitioner's POSITA Definition

B. Person of Ordinary Skill in the Art

A Person of Ordinary Skill in The Art (“POSITA”) as of February 27, 2007, would have 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. Ex.1003, ¶18.

IPR2025-00096 Paper 1 at 6

Petitioner's POSITA Definition

18. A Person of Ordinary Skill in The Art (“POSITA”) as of the February 27, 2007 priority date of the 356 Patent would have: a) at least a bachelor’s degree in engineering; b) knowledge and experience in the anatomy and physiology of the human circulatory system; and c) at least five years of experience in design and development of implantable medical devices.

IPR2025-00096 Ex. 1003 ¶ 18

Institution POSITA Definition

We find, for purposes of this Decision, that the '356 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 '356 patent is consistent with the definition of a person of ordinary skill in the art proposed by Petitioner. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

IPR2025-00096 Paper 15 at 18-19

Patent Owner POSITA Definition

While Patent Owner did not take a position on the level of skill in the art prior to institution, Patent Owner contends that a POSA would have a level of skill more particularly tailored to the field of implantable cardiac assist devices. That is, a POSA would possess 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.

IPR2025-00096 Paper 22 at 3-4

Patent Owner POSITA Definition

Mr. Leschinsky testifies that this more specifically-directed level of skill in the art reflects the complicated and critical nature of cardiac assist devices. Leschinsky, ¶ 59. The field is high risk due to the level of complication involved in device development and the critical, life-supporting nature of the heart and associated circulatory system. *Id.* Dr. Gallegos, an experienced surgeon who implants cardiac assist devices, agrees with Mr. Leschinsky's assessment. Gallegos, ¶ 34.

IPR2025-00096 Paper 22 at 4

Patent Owner POSITA Definition

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 '356 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.

IPR2025-00096 Ex. 2015 ¶ 59

Patent Owner POSITA Definition

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.

IPR2025-00096 Ex. 2017 ¶ 34

Claim Construction – Magneto Coupling & By the Blood Flowing

For the purpose of Petitioner’s argument regarding its narrower construction, there are two types of magnetic couplings. The first type of magnetic coupling involves one permanent magnet driving movement of another permanent magnet. Pet. at 7–8. A second type of magnetic coupling involves an electromagnet (a stator) driving movement of a permanent magnet. Petitioner argues that “magneto coupling” as used in the ’356 patent should be limited to the first type (two permanent magnets) and that it must exclude the second type (electromagnetic driver), based on examples in the literature referring to a two-permanent-magnet system as magnetically coupled. *Id.*

But Petitioner does not believe its own proposed narrower construction. Both Wampler and Bourque-2001 use electromagnetic drivers—if the Board were to adopt Petitioner’s proposed claim construction, Grounds 1 and 2 would fail.

IPR2025-00096 Paper 22 at 5-6

Claim Construction – Magneto Coupling & By the Blood Flowing

66. For example, I note that the ‘356 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 ‘356 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 ‘356 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.

IPR2025-00096 Ex. 2015 ¶¶ 66-67

Claim Construction – Magneto Coupling & By the Blood Flowing

When advocating for their narrower construction, Petitioner takes the phrase “by the blood flowing” out of context from claim recitation [1M] and argues, because of an example in the specification and some examples in the art, that the term “by the blood flowing” requires the claimed medical device to have hydrodynamic bearings and that the term excludes devices having magnetic bearings. Pet. at 8–9. Again, this proposed claim construction would render Ground 2 null because the Bourque-2001 reference applies magnetic bearings.

IPR2025-00096 Paper 22 at 7

Claim Construction

74. Further, the ‘356 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 entirely 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.

76. It is therefore my opinion that the term “by the blood flowing,” taken in proper context of the disclosure of the ‘356 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.

IPR2025-00096 Ex. 2015 ¶¶ 74, 76

Claim Construction – *Revvo Techs.* Decision

- In *Revvo*, the Director found that the same claim construction tactics utilized by Petitioner here warranted vacating the institution
- Permitting Petitioner’s two claim constructions and adopting their narrower construction would exclude all of Bourque-2001, Wampler, and Akamatsu because Bourque-2001 lacks “by the blood flowing” and all three lack “magneto coupling”

IPR2025-00096 Paper 33 at 3-4

Axially Adjacent – The Intrinsic Record

79. I also do not believe that a POSA would have understood the term “at a position axially adjacent” to allow for adjacency along any axis, as also contended by Petitioner. Paper 1 at 27; Ex. 1003 at ¶¶ 198–199. This is because claim 1 of the ‘356 patent, for example, indicates which axis is implicated for the term “at a position axially adjacent” in a manner that a POSA would have appreciated at the time of the invention.

80. In particular, claim element [1E] recites that the magnetically driven rotor is rotatable about a central axis, while element [1F] recites that the magnetically driven rotor is rigidly coupled to a first magnetic device. In view of this, in my opinion a POSA would have understood that the recitation in claim element [1H] that the first magnetic device is at a position axially adjacent to the magnetically driven rotor would mean that the two components are positioned adjacent to one another as measured along the previously recited central axis about which the magnetically driven rotor spins.

IPR2025-00096 Ex. 2015 ¶¶ 79-80

Axially Adjacent – The Intrinsic Record

81. Moreover, the meaning of axial adjacency illustrated by claim elements [1E] and [1F] is further supported by the complementary reference to the concept of radial adjacency in claim element [1L]. Claim element [1L] recites “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 inflow tube and the central axis of the magnetically driven rotor.” In my opinion, this recitation conveys that radial adjacency relates to positioning along a radial direction extending out from a central axis of the rotor that is perpendicular to the central axis of the rotor. In my opinion, a POSA would have appreciated that this helps clarify the concept of axial adjacency as relating to positioning in a direction extending along (e.g., coextensive with or at least parallel to) the central axis of the rotor.

IPR2025-00096 Ex. 2015 ¶¶ 81

Axially Closer – The Board’s Construction

First, Petitioner relies on Figure 11A of Wampler, which Petitioner reproduces in the Petition with coloring to show impeller 74 (in pink), magnetic pieces 88 (in purple) and motor stators 94 in blue. Pet. 33. However, as Patent Owner shows in its opposition, Petitioner’s annotated Figure 11A shows “there can be no doubt” that the upper portion of rotor 74 and magnetic pieces 88 “are the exact same distance” from motor stator 94. Prelim. Resp. 21 (providing additional annotations to Petitioner’s annotated version of Figure 11a showing with an orange arrow where the elements are the same distance apart). Recognizing the readily apparent potential deficiency in Wampler, Petitioner argues that “the vast majority of the

impeller 74 is spaced significantly farther apart from the stators 90 and 94 than the magnetic pieces 88 are positioned from the stators 90 and 94.” Pet. 33–34 (emphases omitted). On the current record we find insufficient Petitioner’s implicit argument that only a *portion* of (or a “vast majority” of) the “second magnetic device” (rotor 74) need be closer to the “first magnetic device” (the rotor) to satisfy the “axially closer” limitation. Petitioner offers no explanation in the Petition to show that the requirement of claim 1 that “the second magnetic device” is “positioned *axially closer* to the first magnetic device than to the magnetically driven rotor,” does not require that *all* of “the second magnetic device” be “positioned *axially closer* to the first magnetic device than to the magnetically driven rotor.”

IPR2025-00112 Paper 13 at 24-25

Axially Closer – The Board’s Construction

In the alternative, Petitioner argues that “it would have been obvious to position the motor stators 90 and 94 ‘axially closer’ to the magnetic pieces 88 than to the impeller.” Pet. 34 (citing Ex. 1003 ¶ 223). According to Petitioner, a person of ordinary skill in the art “would have been motivated to do so because the motor stators act upon the magnetic pieces—positioning those elements closer to each other would facilitate that action.” *Id.* (citing Ex. 1003 ¶ 223).

Patent Owner disputes the logic of Petitioner’s asserted rationale and explains “the magnetic interaction between the stator 94 and the magnet 88 has nothing to do with the impeller 74,” and “[e]ven if Petitioner is right that the distance between the stator 94 and the magnet 88 matters—that still has no effect on the relative distance between the stator 94 and the magnet 88 as

opposed to the stator 94 and the impeller 74.” Prelim. Resp. 22 (further stating that “the distance between the stator and the magnet may matter, but this fact does not provide a motivation to change the relative distance between the stator and the magnet with respect to the stator and the impeller”) (citing Ex. 1003 ¶ 223). In other words, Petitioner appears to propose a modification to Wampler that does not promote the benefit Petitioner identifies as the reason for its proposed modification. Petitioner also argues it would have been an “obvious design choice,” because there is allegedly no suggestion that “such relative locations are critical to the claimed invention.” Pet. at 34–35 n.7. Petitioner’s argument appears at odds with its asserted rationale for modifying Wampler and is largely unsupported on the current record.

IPR2025-00112 Paper 13 at 25-26

Axially Closer – The Board’s Construction

Lastly, Petitioner argues that in the Parallel Proceeding Patent Owner “alleges that a ‘stator’ satisfies this limitation,” and that “[a]ssuming that interpretation,” Wampler discloses the limitation. Pet. 35 (citing Ex. 1008 ¶ 72; Ex. 1003 ¶¶ 226–227). Patent Owner argues that Petitioner’s reliance on alleged arguments in the Parallel Proceeding is misplaced because it “has nothing to do with the relative distance between the stator and the impeller.” Prelim. Resp. 22–23.

IPR2025-00112 Paper 13 at 26

Axially Closer – The Board’s Construction

Lastly, Petitioner argues that in the Parallel Proceeding Patent Owner “alleges that a ‘stator’ satisfies this limitation,” and that “[a]ssuming that interpretation,” Wampler discloses the limitation. Pet. 35 (citing Ex. 1008 ¶ 72; Ex. 1003 ¶¶ 226–227). Patent Owner argues that Petitioner’s reliance on alleged arguments in the Parallel Proceeding is misplaced because it “has nothing to do with the relative distance between the stator and the impeller.” Prelim. Resp. 22–23.

In sum, we find Patent Owner’s arguments refuting Petitioner’s contention that the Challenged Claims would have been obvious over Wampler, alone, have substantial merit.

IPR2025-00112 Paper 13 at 26

Axially Closer – The Board’s Construction

Patent Owner argues, and we agree, that Petitioner’s annotations to Figure 2 of Akamatsu are misleading and “makes it seem as though the purple boxes extend to the left more than the pink boxes—implying that the first magnetic device is axially closer to the second magnetic device than the magnetically driven rotor—but that isn’t the case.” Prelim. Resp. 50–51.

In sum, we find Patent Owner’s arguments refuting Petitioner’s contention that the Challenged Claims would have been obvious over Akamatsu, alone, have substantial merit.

IPR2025-00112 Paper 13 at 38-39

Patent Owner Demonstrative Exhibit—Not Evidence

Petitioner's Inappropriate Reliance on Litigation Charts

Petitioner never addresses the plain meaning of “axially adjacent.” Petitioner also never addresses the intrinsic evidence that shows the first magnetic device being disposed next to (adjacent to) a magnetically driven rotor. Institution 25; Ex. 1001, Fig. 2.

Petitioner never addresses the failings of their positions regarding “axially closer.” For example, they simply advise the Board that it can dispense with the issue by deciding the case on different grounds.

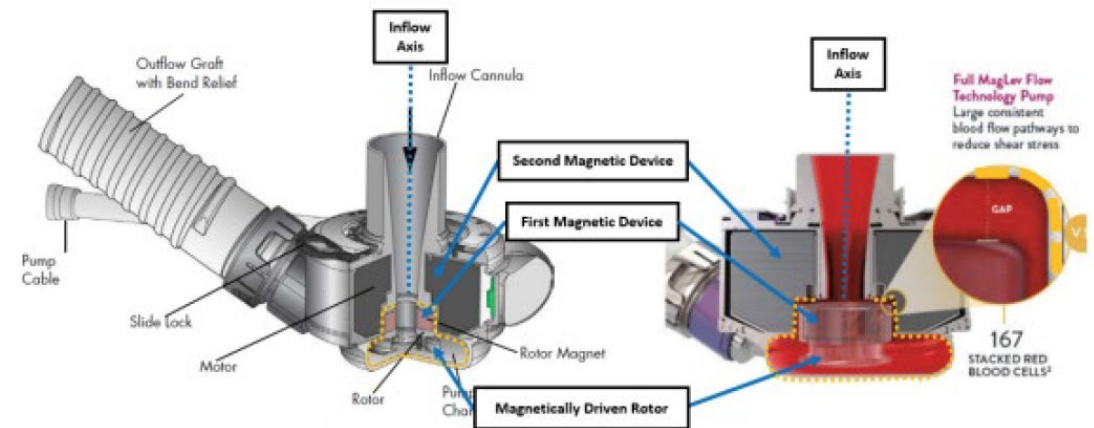
Instead, Petitioner introduces a new and different exhibit from the co-pending litigation that relates to a product accused of infringement. Rep. 3–9; Ex. 1036. Worse, Petitioner misrepresents what that exhibit shows.

IPR2025-00096 Paper 33 at 5
IPR2025-00112 Paper 31 at 5

Patent Owner Demonstrative Exhibit—Not Evidence

Petitioner's Inappropriate Reliance on Litigation Charts – Axially Closer

New Exhibit 1036 is an infringement claim chart showing how Abbott's current product infringes claim 1. Addressing the specific claim language at issue here ("the second magnetically device [be] positioned axially closer to the first magnetic device than to the magnetically driven rotor"), the exhibit notes that a "second magnetic device" is positioned axially closer to the "first magnetic device" than to the "rotor" with reference to the following figure:



IPR2025-00112 Paper 31 at 5-6

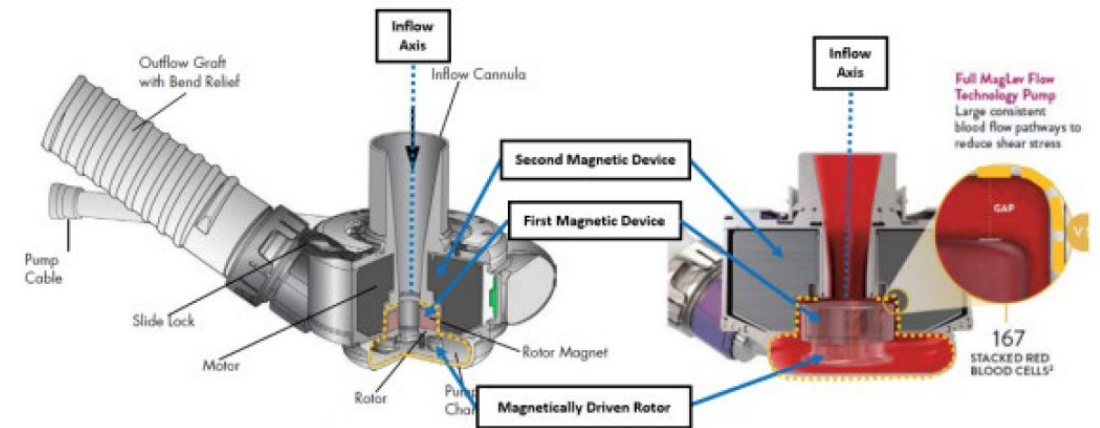
IPR2025-00112 Ex. 1036 at 8

Patent Owner Demonstrative Exhibit—Not Evidence

Petitioner's Inappropriate Reliance on Litigation Charts – Axially Closer

None of the various colored boxes added by Petitioner in their Reply are included in the exhibit, and Patent Owner does not agree with Petitioner's delineations here.

Just as they did in the Petition—and the Board discounted—Petitioner announces that Patent Owner has taken a position on axially closer in the co-pending litigation that is different than the position it takes here. Rep. 3–9. That announcement is false. The figure from page 8, reproduced above, specifically addressing the claim language at issue here, is perfectly consistent with Patent Owner's arguments and the Board's conclusions in the Institution Decision.



IPR2025-00112 Paper 31 at 6

Petitioner's Contradictions Regarding Litigation Charts

Earlier in this proceeding Petitioner and its expert took the exact opposite position to the one they take now. In his opening Declaration, Mr. Crosby stated:

I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that maps the impeller portion of the “rotor” of the “HeartMate 3” to the “magnetically driven rotor” element recited in Claim 1. Ex.1019, at pp. 4 (Complaint, Ex. 7).

Ex. 1003, ¶ 160. That is, when they thought that it helped them, Petitioner and its expert believed that the infringement charts in the co-pending litigation identified the impeller portion of the rotor as the magnetically driven rotor. Now, when they have a different objective, they believe that the infringement charts in the co-pending litigation identify the entire rotating mass as the magnetically driven rotor.

IPR2025-00096 Paper 33 at 7
IPR2025-00096 Ex. 1003 ¶ 160

Patent Owner Demonstrative Exhibit—Not Evidence

Petitioner's Contradictions Regarding Litigation Charts

In fact, Patent Owner identifies the impeller portion as the magnetically driven rotor in its infringement charts, and Petitioner identifies the impeller portion as the magnetically driven rotor in Wampler. *See* Ex. 2014, 40:19–41:1

19 So the idea that a rotor is everything that
20 rotates is not supported by the 356 patent itself. So
21 I've tried to map the way the 356 patent uses the term
22 to the way Wampler uses the term. And it appears that
23 the 356 patent, the term rotor is really used to
24 describe the element that rotates that pumps the blood,
25 and I've tried to use the same approach in the Wampler

Page 40

1 description. So to make them consistent here.

IPR2025-00096 Paper 33 at 7
IPR2025-00096 Ex. 2014, 40:19-41:1

Patent Owner Demonstrative Exhibit—Not Evidence

Bourque-2001 Does Not Teach or Suggest a Rotor and Inflow Tube that are Axially Aligned

Petitioner accuses Patent Owner of taking the position that “axially aligned” requires the entirety of the inflow tube to be aligned in a straight, unbent line along the rotor’s axis. Rep. 15. This is untrue and unnecessary—Patent Owner’s position is that an inflow tube that is perpendicular to the rotor’s axis is not axially aligned with the rotor’s axis. POR 23–25.

Nevertheless, Petitioner turns to the intrinsic evidence, namely Fig. 1, to argue that the “sole” embodiment of the ’356 patent does not have a perfectly straight inflow tube—and so Bourque-2001’s perpendicular inflow tube can be axially aligned. Rep. 15–16.

U.S. Patent Jun. 7, 2022 Sheet 1 of 3 US 11,351,357 B2

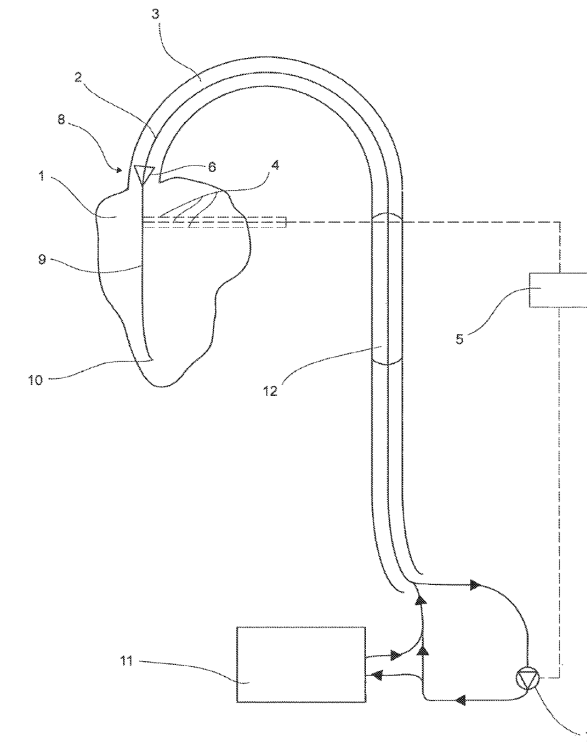


Fig. 1

IPR2025-00096 Paper 33 at 12
IPR2025-00096 Ex. 1001, Figure 1

Patent Owner Demonstrative Exhibit—Not Evidence

Petitioner's Combinations Fail

Petitioner argued strenuously in its Petition and opening expert declaration that the reason why a person of ordinary skill in the art would combine Bourque-2001 and Wampler was so that the Bourque-2001 pump could be placed at the apex of the heart in the same manner as Wampler. *See* Ex. 2029 (listing 20 times that Petitioner and its expert make this claim). Patent Owner persuasively explained that a skilled person would not see it that way—that the Bourque-2001 pump was simply too large and heavy to fit at the apex of the heart and that a POSA would find the combination unusable. Petitioner never disputes this evidence or explanation. Instead, Petitioner points to other pumps that are not part of its grounds and incorrectly argues that it does not matter whether the pump would work for the motivated purpose.

IPR2025-00096 Paper 33 at 14

Petitioner's Combinations Fail

Petitioner also has a problem with its presentation of Wampler. It admits that it relies only on the second embodiment of Wampler—but when it does so, it loses its teaching of placing the pump at the apex of the heart. In an attempt to cure this, Petitioner argues that the second embodiment of Wampler became the HeartWare HVAD product that was ultimately implanted at the apex—but cross-examination showed that HeartWare HVAD was a different pump whose structure was not disclosed before the priority date.

IPR2025-00096 Paper 33 at 14

Petitioner's Combinations Fail

Turning to Akamatsu and Schima, a POSA looking at Akamatsu, like Bourque-2001, would find it to be too big and heavy to mount at the apex of the heart pursuant to Petitioner's motivation. Not being able to argue that a POSA would see it differently, Petitioner argues that the Akamatsu became the DuraHeart pump, which was implanted more than 20 times. We learned on cross-examination, however, that the DuraHeart pump was implanted in a preperitoneal pocket with a perpendicular inflow tube just like Bourque-2001 because "it was definitely too big" to fit anywhere else.

IPR2025-00096 Paper 33 at 15

Combination of Bourque-2001 and Wampler Fails

Petitioner insists that it does not rely on the first embodiment of Wampler—
which is the embodiment that is mounted at the apex of the heart—but instead
relies on the second embodiment with no motivation, teaching, or reasons as to
why the second embodiment would be mounted in the same manner as the first.

8 THE WITNESS: Well, yes. As I said
9 in my report, I relied on what the disclosure of a
10 complete device depicted in Figures 11 to 14, and
11 of course the text which describes it.

IPR2025-00096 Paper 33 at 15
IPR2025-00096 Ex. 2027, 51:8-11

Patent Owner Demonstrative Exhibit—Not Evidence

Wampler’s First and Second Embodiments Are Different In Critical Ways

Now, Petitioner asserts strenuously that it does not rely on the first embodiment of Wampler (including Figure 5), but only on the second embodiment. Rep. 10–13. In doing so, Petitioner argues that it need not find a motivation to combine features between the first and second embodiments, citing case law for the proposition that no such motivation is needed when the prior art explicitly contemplates the combination of the disclosed functionalities. *Id.*, 11.

A. Ground 1: Wampler 9

1. [1H]: “axially adjacent” 9

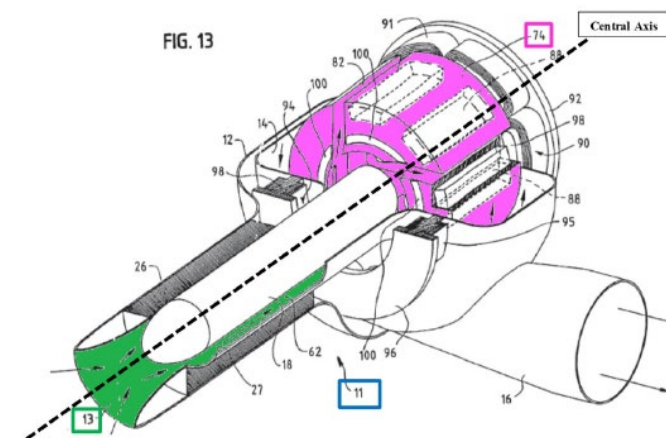
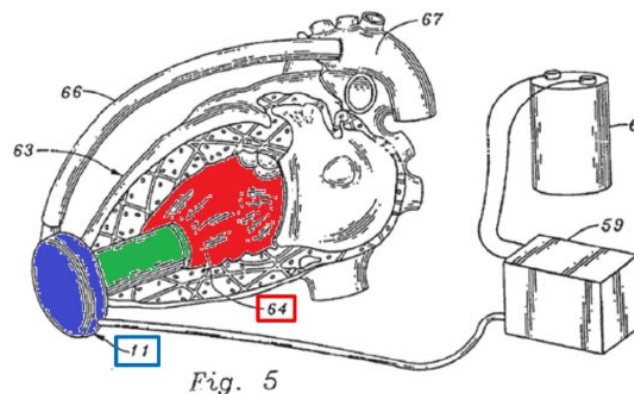
2. Petitioner relies on a single embodiment. 10

8 THE WITNESS: Well, yes. As I said
9 in my report, I relied on what the disclosure of a
10 complete device depicted in Figures 11 to 14, and
11 of course the text which describes it.

IPR2025-00096 Paper 33 at 16
IPR2025-00096 Paper 26 at I
IPR2025-00096 Ex. 2027, 51:8-11

Wampler Teaches Away from Implanting its Second Embodiment in the Manner of its First Embodiment

101. Petitioner's expert, Mr. Crosby, has stated he is relying only on a different embodiment of a pump disclosed in Wampler, namely, the embodiment shown in FIG. 11 *et seq.* Ex. 2014 at 34–35. There is no disclosure in Wampler, however, of this different embodiment implanted in the manner of the first embodiment. For example, there is no counterpart to Fig. 5 showing the pump of FIG. 11 implanted in a heart, nor is there any description to this effect in the specification. Further, this second embodiment of a pump is different from the first embodiment pump, especially with regard to the portion that would extend outside the heart if implanted in the manner of Fig. 5. For example, Petitioner's annotated version of Fig. 5 is shown below next to their annotated version of Fig. 13, which shows the different pump of the second embodiment. Of note is the difference between the smaller blue disc shaped portion in Fig. 5 that extends outside the heart versus the larger pink portion (and surrounding housing) in Fig. 13.



IPR2025-00096 Ex. 2015 ¶ 101

Petitioner's Evidence for Motivation Fails Because a POSA Would Know the Bourque-2001 Pump Is Too Large

Petitioner argues that Bourque-2001 describes the specific placement of its pump in a peritoneal pocket as the best option—but the law doesn't require Petitioner's alternative placement (at the apex of the heart) to be the best option—only a suitable option. Rep. 20–21. But the whole point of Patent Owner's extensive analysis of the size of the Bourque-2001 pump is to show that it was practically impossible to place the pump at the apex of the heart because it will not fit. POR 30–36. The apex of the heart is not a suitable option for implantation of the Bourque-2001 pump.

153. 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 placed at the apex of the heart, and therefore would not have been motivated to make the combination contended by Petitioner.

IPR2025-00096 Paper 33 at 25

IPR2025-00096 Ex. 2015 ¶ 153

Patent Owner Demonstrative Exhibit—Not Evidence

Appendix – ‘356 Patent Challenged Claims

Claim No.	Claim Language
[1PRE]	A method for assisting the blood circulation of a heart in a body, comprising:
[1A]	delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart
[1B]	while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart,
[1C]	wherein the magnetically driven rotor is axially aligned with the inflow tube
[1D]	and [the magnetically driven rotor] is rotatable within a surrounding rotor housing of the heart assist pump device to act upon blood flowing from the inflow tube toward the magnetically driven rotor,
[1E]	the magnetically driven rotor being rotatable about a central axis
[1F]	and [the magnetically driven rotor] being rigidly coupled to a first magnetic device
[1G]	that [first magnetic device] is located within the surrounding rotor housing
[1H]	[the first magnetic device is] at a position axially adjacent to the magnetically driven rotor,
[1I]	wherein the heart assist pump device further includes: a second magnetic device axially aligned with the inflow tube
[1J]	and [the second magnetic device is] positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device

Claim No.	Claim Language
[1K]	while [the second magnetic device is] being spaced apart and sealed from both the magnetically driven rotor and the first magnetic device,
[1L]	and 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 inflow tube and the central axis of the magnetically driven rotor,
[1M]	wherein the magneto coupling orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and
[1N]	connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device,
[1O]	the external control unit being positioned exterior to the body while the inflow tube of the heart assist pump device is in the heart.
[2]	The method of claim 1, wherein in response to the rotation of the magnetically driven rotor via the magneto coupling, guide surfaces of the magnetically driven rotor produce centrifugal flow components.
[3A]	The method of claim 2, wherein the surrounding rotor housing comprises at least one sealing wall between the first magnetic device and the second magnetic device,
[3B]	and the first magnetic device is positioned between the second magnetic device and the magnetically driven rotor.

IPR2025-00096 Exhibit 1001

Appendix – ‘356 Patent Challenged Claims

Claim No.	Claim Language
[4]	The method of claim 3, wherein the first magnetic device rotates together with the magnetically driven rotor relative to the surrounding rotor housing.
[5]	The method of claim 1, wherein the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart.
[6]	The method of claim 1, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor.
[7]	The method of claim 1, further comprising providing feedback signals to the external control unit from one or more sensors.
[10]	The method of claim 1, wherein the external control unit is configured to regulate operation of the second magnetic device based on a fixed control value.
[12]	The method of claim 1, wherein the second magnetic device is positioned closer to the blood outflow port than the second magnetic device is positioned relative to the suction end of the inflow tube.
[13]	The method of claim 1, wherein the heart assist pump device is a catheter device.

IPR2025-00096 Exhibit 1001

Appendix – ‘357 Patent 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.

IPR2025-00112 Exhibit 1001

Appendix – ‘357 Patent Challenged Claims

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

IPR2025-00112 Exhibit 1001

Appendix – ‘415 Patent Challenged Claims

Claim No.	Claim Language
[1PRE]	A system for assisting the blood circulation of a heart in a body, comprising:
[1A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart;
[1B]	a magnetically driven rotor axially aligned with the inflow tube and being spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle,
[1C]	the magnetically driven rotor being rotatable within a surrounding rotor housing to act upon blood flowing from the inflow tube toward the 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]	and [the magnetically driven rotor being] axially adjacent to a first magnetic device
[1G]	that [the first magnetic device] is located within the surrounding rotor housing;
[1H]	a second magnetic device axially aligned with the inflow tube
[1I]	and [the second magnetic device is] positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device
[1J]	while [the second magnetic device] being spaced apart and sealed from both the magnetically driven rotor and the first magnetic device by at least one sealing wall, the second magnetic device being positioned axially spaced apart from 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 remains adjacent to and spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and
[1M]	an external control unit configured to regulate operation of the second magnetic device,
[1N]	the external control unit being positionable exterior to the body while the inflow tube of the heart assist pump device is in the heart,
[1O]	wherein the external control unit is 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.
[3A]	The system of claim 2, wherein the surrounding rotor housing comprises the at least one sealing wall
[3B]	and the first magnetic device is positioned between the second magnetic device and the magnetically driven rotor.
[4]	The system of claim 3, wherein the first magnetic device rotates together with the magnetically driven rotor relative to the surrounding rotor housing.

IPR2025-00113 Exhibit 1001

Appendix – ‘415 Patent Challenged Claims

Claim No.	Claim Language
[5]	The system of claim 1, wherein the magnetically driven rotor is sealed from the second magnetic device and a drive source that regulates the operation of the second magnetic device.
[10]	The system of claim 1, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor.
[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 10, wherein the external control unit is configured to regulate operation of the second magnetic device based on a fixed control value.
[16]	The system of claim 1, wherein the second magnetic device is positioned closer to the blood outflow port than to the suction end of the inflow tube.
[17]	The system of claim 1, wherein the heart assist pump device is a catheter device.

IPR2025-00113 Exhibit 1001

Appendix – ‘879 Patent Challenged Claims

Claim No.	Claim Language
[1PRE]	A system for assisting blood circulation of a heart, the system comprising:
[1A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path aligned with a central axis;
[1B]	a magnetically driven rotor aligned with the central axis and
[1C]	that is rotatable about the central axis within a surrounding rotor housing to drive blood flowing from the inflow tube toward the magnetically driven rotor,
[1D]	the magnetically driven rotor being rigidly coupled and axially adjacent to a first magnetic device within the surrounding rotor housing;
[1E]	a second magnetic device axially aligned with the central axis
[1F]	and positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device
[1G]	while both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap sized for passage of the blood during rotation of the magnetically driven rotor; and
[1H]	a blood outflow port positioned radially adjacent the magnetically driven rotor such that the blood driven by the magnetically driven rotor exits the surrounding rotor housing in a direction substantially perpendicular to the central axis,
[1I]	wherein the magneto coupling orients the magnetically driven rotor so that the magnetically driven rotor remains adjacent to and spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and

Claim No.	Claim Language
[1J]	an external control unit configured to regulate operation of the second magnetic device, the external control unit being positionable exterior to a body when the heart assist pump device is delivered to the heart, wherein the external control unit is connectable to the heart assist pump device for operating 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: a guide surface to produce centrifugal flow components.
[4]	The system of claim 1, wherein the heart assist pump device further comprises a sealing wall positioned between the second magnetic device and the magnetically driven rotor.
[5]	The system of claim 4, wherein the sealing wall at least partially defines the gap sized for passage of the blood.
[7]	The system of claim 1, wherein the first magnetic device is positioned within a first chamber, the second magnetic device is positioned within a second chamber, and the first chamber is sealed from the second chamber
[8]	The system of claim 7, wherein the heart assist pump device further comprises a wall separating the first chamber from the second chamber.
[11PRE]	A system for assisting blood circulation of a heart, the system comprising:
[11A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;
[11B]	one or more walls at least partially defining a chamber to receive blood from the inflow tube;

IPR2025-00114 Exhibit 1001

Appendix – ‘879 Patent Challenged Claims

Claim No.	Claim Language
[11C]	a magnetically driven rotor axially aligned with the inflow axis
[11D]	and [the magnetically driven rotor] being rigidly coupled and axially adjacent to a first magnetic device that is axially aligned with the inflow axis,
[11E]	the magnetically driven rotor and first magnetic device being rotatable about an axis of rotation aligned with the inflow axis to drive the blood flowing from the inflow tube;
[11F]	a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis
[11G]	and [the second magnetic device is] spaced apart from the magnetically driven rotor such that a wall of the one or more walls defining the chamber is positioned between the magnetically driven rotor and the second magnetic device,
[11H]	the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor so as to magnetically drive rotation of the magnetically driven rotor relative to the one or more walls via a magneto coupling with the first magnetic device; and
[11I]	a blood outflow port positioned such that the blood driven by the magnetically driven rotor exits the chamber in a direction substantially perpendicular to the inflow axis
[11J]	wherein the magneto coupling orients the magnetically driven rotor so that both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor; and
[11K]	an external control unit configured to control operation of the second magnetic device based on a fixed value to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device.

Claim No.	Claim Language
[12]	The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components.
[14]	The system of claim 11, wherein the one or more walls and the magnetically driven rotor define a gap separating the magnetically driven rotor from the one or more walls, the gap configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor.
[15]	The system of claim 14, wherein the gap surrounds the magnetically driven rotor.
[16]	The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis.
[18]	The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.
[19]	The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber.
[20]	The system of claim 11, wherein the external control unit is configured to regulate operation of the second magnetic device based on a defined cardiac output.

IPR2025-00114 Exhibit 1001

Appendix – ‘517 Patent 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 and having a suction end insertable into a ventricle of the heart;
[1B]	a magnetically driven rotor axially aligned with the inflow tube and being spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle
[1C]	the magnetically driven rotor being rotatable within a surrounding rotor housing to act upon blood flowing from the inflow tube toward the 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]	and [the magnetically driven rotor is] axially adjacent to a first magnetic device
[1G]	that [the first magnetic device] is located within the surrounding rotor housing
[1H]	a second magnetic device axially aligned with the inflow tube
[1I]	and [the second magnetic device is] positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device
[1J]	while [the second magnetic device is] being spaced apart and sealed from both the magnetically driven rotor and the first magnetic device by at least one sealing wall, the second magnetic device being positioned axially spaced apart from 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 transverse to the central axis of the magnetically driven rotor,
[1L]	wherein when the magnetically driven rotor is rotated, the magnetically driven rotor remains adjacent to and spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and
[1M]	an external control unit configured to regulate operation of the second magnetic device, wherein the external control unit is 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.
[3A]	The system of claim 2, wherein the surrounding rotor housing comprises the at least one sealing wall,
[3B]	and the first magnetic device is positioned between the second magnetic device and the magnetically driven rotor.
[4]	The system of claim 3, 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 both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor.
[11]	The system of claim 10, further comprising one or more sensors that deliver feedback signals to the external control unit.

IPR2025-00115 Exhibit 1001

Appendix – ‘517 Patent Challenged Claims

Claim No.	Claim Language
[14]	The system of claim 10, wherein the external control unit is configured to regulate operation of the second magnetic device based on a control value.
[15]	The system of claim 14, wherein the control value indicative of a defined cardiac output for control of the heart assist pump device.
[17]	The system of claim 1, wherein heart assist pump device is a catheter device.
[21PRE]	A system for assisting blood circulation of a heart, the system comprising:
[21A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;
[21B]	one or more walls at least partially defining a chamber to receive blood from the inflow tube;
[21C]	a magnetically driven rotor axially aligned with the inflow axis and being rigidly coupled [to a first magnetic device]
[21D]	and [a magnetically driven rotor is] axially adjacent to a first magnetic device that is axially aligned with the inflow axis,
[21E]	the magnetically driven rotor and first magnetic device being rotatable about an axis of rotation aligned with the inflow axis to drive the blood flowing from the inflow tube;
[21F]	a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis
[21G]	and [the second magnetic device is] spaced apart from the magnetically driven rotor such that a wall of the one or more walls defining the chamber is positioned between the magnetically driven rotor and the second magnetic device, the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor

Claim No.	Claim Language
[21H]	so as to [the second magnetic device] magnetically drive rotation of the magnetically driven rotor within the chamber via a magneto coupling with the first magnetic device; and
[21I]	a blood outflow port positioned radially outward of the magnetically driven rotor such that the blood driven by the magnetically driven rotor exits the chamber in a direction transverse to the inflow axis
[21J]	wherein the magneto coupling orients the magnetically driven rotor so that both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor; and
[21K]	an external control unit configured to control operation of the second magnetic device based on a control value indicative of a defined cardiac output,
[21L]	wherein the external control unit is 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.
[22]	The system of claim 21, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components.
[24]	The system of claim 21, wherein the one or more walls and the magnetically driven rotor define a gap separating the magnetically driven rotor from the one or more walls, the gap configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor.
[26]	The system of claim 24, wherein at least part of the gap extends along radially outward from the magnetically driven rotor.

IPR2025-00115 Exhibit 1001

Appendix – ‘517 Patent Challenged Claims

Claim No.	Claim Language
[28]	The system of claim 21, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.
[29]	The system of claim 28, wherein the wall of the one or more walls separates the first chamber from the second chamber.
[30]	The system of claim 21, wherein the first magnetic device comprises a permanent magnet.
[32]	The system of claim 21, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor.
[33]	The system of claim 21, further comprising one or more sensors that deliver feedback signals to the external control unit.
[35]	The system of claim 21, wherein heart assist pump device is a catheter device.

IPR2025-00115 Exhibit 1001

Appendix – ‘077 Patent 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 and having a suction end insertable into a ventricle of the heart;
[1B]	a magnetically driven rotor assembly configured to be axially aligned with the inflow tube and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle,
[1C]	the magnetically driven rotor assembly comprising a first magnetic device that is rigidly coupled to and axially adjacent to a rotor
[1D]	[the rotor] having guide surfaces to produce centrifugal flow components,
[1E]	the magnetically driven rotor assembly being rotatable about a central axis within a surrounding stationary housing to act upon blood flowing from the inflow tube to the rotor
[1F]	while the magnetically driven rotor assembly is entirely spaced apart from the stationary housing by a gap sized for passage of the blood;
[1G]	a second magnetic device axially aligned with the inflow tube and positioned to magnetically drive rotation of the magnetically driven rotor assembly via a magneto coupling with the first magnetic device
[1H]	while [the second magnetic device is] being spaced apart and sealed from both the rotor and the first magnetic device of the magnetically driven rotor assembly,
[1I]	the second magnetic device being positioned axially spaced apart from the guide surfaces of the rotor;

Claim No.	Claim Language
[1J] ¹	a blood outflow port positioned radially adjacent the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the surrounding stationary housing in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly,
[1K] ²	wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and
[1L] ³	an external control unit configured to regulate operation of the second magnetic device based upon a control value indicative of cardiac output,
[1M] ⁴	wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.
[2]	The system of claim 1, wherein the first magnetic device is configured to be positioned between the second magnetic device and the guide surfaces of the rotor of the magnetically driven rotor assembly.

¹ This element was labeled [1K] in the Petition’s Claim Index, as label [1J] was skipped.

² This element was labeled [1L] in the Petition’s Claim Index, as label [1J] was skipped.

³ This element was labeled [1M] in the Petition’s Claim Index, as label [1J] was skipped.

⁴ This element was omitted from the Petition’s Claim Index.

IPR2025-00116 Exhibit 1001

Appendix – ‘077 Patent Challenged Claims

Claim No.	Claim Language
[3]	The system of claim 2, wherein the first magnetic device is configured to rotate together with the rotor relative to the surrounding stationary housing.
[4]	The system of claim 3, wherein the second magnetic device is positioned closer to the blood outflow port than to the suction end of the inflow tube.
[5]	The system of claim 1, wherein the magnetically driven rotor assembly is sealed from the second magnetic device and a drive source configured to regulate the operation of the second magnetic device.
[7]	The system of claim 1, further comprising one or more sensors configured to deliver feedback signals to the external control unit.
[10]	The system of claim 1, wherein the heart assist pump device is a catheter device.
[16PRE]	A system for assisting blood circulation of a heart, the system comprising:
[16A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;
[16B]	chamber walls at least partially defining a chamber to receive blood from the inflow tube;
[16C]	a magnetically driven rotor assembly configured to be axially aligned with the inflow axis and comprising a first magnetic device
[16D]	that [the first magnetic device] is rigidly coupled to and axially adjacent to a rotor
[16E]	[the rotor] having guide surfaces to produce centrifugal flow components,

Claim No.	Claim Language
[16F]	the rotor and the first magnetic device of the magnetically driven rotor assembly being rotatable within the chamber about an axis of rotation
[16G]	[the axis of rotation is] aligned with the inflow axis to drive the blood flowing from the inflow tube;
[16H]	a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis
[16I]	and spaced apart from the magnetically driven rotor assembly such that a wall of the chamber walls defining the chamber is positioned between the magnetically driven rotor assembly and the second magnetic device,
[16J]	the second magnetic device positioned axially closer to the first magnetic device than to the rotor of the magnetically driven rotor assembly so as to magnetically drive rotation of the magnetically driven rotor assembly within the chamber via a magneto coupling with the first magnetic device; and
[16K]	a blood outflow port positioned radially outward of the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the chamber in a direction substantially perpendicular to the inflow axis,
[16L]	wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the chamber walls by a gap sized for passage of the blood; and
[16M]	an external control unit configured to control operation of the second magnetic device based on a control value indicative of cardiac output

IPR2025-00116 Exhibit 1001

Appendix – ‘077 Patent Challenged Claims

Claim No.	Claim Language
[16N]	wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.
[17]	The system of claim 16, wherein the first magnetic device is rigidly coupled to the rotor of the magnetically driven rotor assembly at a position between the second magnetic device and the rotor.
[18]	The system of claim 16, wherein said gap sized for passage of the blood is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly.
[19]	The system of claim 18, wherein the gap surrounds the magnetically driven rotor assembly.
[20]	The system of claim 18, wherein at least part of the gap extends radially outward from the magnetically driven rotor assembly.
[21]	The system of claim 20, wherein at least part of the gap extends along a face of the magnetically driven rotor assembly that is axially opposite from the inflow tube.
[22]	The system of claim 16, wherein the chamber is a first chamber within which the magnetically driven rotor assembly is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.
[23]	The system of claim 22, wherein said wall of the chamber walls separates the first chamber from the second chamber.
[24]	The system of claim 16, wherein the first magnetic device comprises a permanent magnet.
[26]	The system of claim 16, further comprising one or more sensors configured to deliver feedback signals to the external control unit.

Claim No.	Claim Language
[28]	The system of claim 16, wherein the heart assist pump device is a catheter device.

IPR2025-00116 Exhibit 1001