ABBOTT LABORATORIES,

PETITIONER

v.

MIRACOR MEDICAL SA,

PATENT OWNER

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

PETITIONER'S HEARING DEMONSTRATIVES – MARCH 5, 2026

Overview of challenged claims and grounds

Patent	Claims	Basis	Grounds/Reference(s)
356 Patent[1]	1-7, 10, and 12-13	§ 103	1. Wampler 2. Bourque/Wampler 3. Akamatsu 4. Schima/Akamatsu
357 Patent	1-3, 10-11, 14, and 17		
415 Patent	1-5, 10-11, 14, and 16-17		
879 Patent	1-2, 4-5, 7-8, 11-12, 14-16, and 18-20		
517 Patent	1-4, 10-11, 14-15, 17, 21-22, 24, 26, 28-30, 32-33, and 35		
077 Patent	1-5, 7, 10, 16-24, 26, and 28		

[1]All citations made to IPR2025-00096 (356 Patent) unless otherwise specified

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

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Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
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	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

E.g., Paper No. 1 (Pet.),

Ground 2 (Bourque/Wampler)

- ***Axially aligned***
  - **Bourque alone teaches "*axially aligned*"**
  - Bourque in view of Wampler teaches "*axially aligned*"
    - Multiple independent motivations to combine
    - Expectation of success

Challenged claims require "*rotor*" be "*axially aligned*" with "*inflow tube*"

Ex.1001 (356 Patent), claim 1

1. A method for assisting the blood circulation of a heart in a body, comprising:

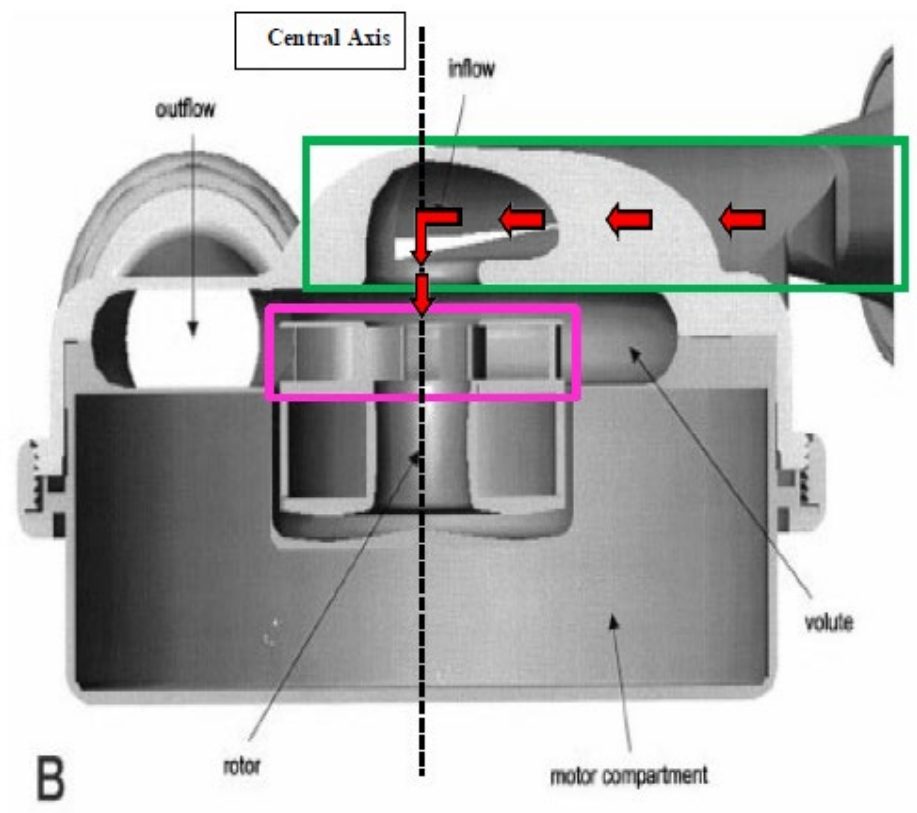
delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart, wherein the magnetically driven rotor is axially aligned with the inflow tube and 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, the magnetically driven rotor

Patent	Claim Limitation
356 Patent	1C
357 Patent	1B
415 Patent	1B
879 Patent	1A-B, 11A-D
517 Patent	1B, 21A, 21C
077 Patent	1B, 16A-C

E.g., Paper No. 1 (Pet.), 55-57.

Board found portion before 90 degree bend fails to teach *"axially aligned"*

ID at 31



ID, 32

subassembly is not axially aligned with the rotor. To show the required axial alignment, Petitioner appears to rely on an unidentified portion of Bourque's inflow subassembly, after the 90 degree bend, where Petitioner alleges "flow 'leav[es] the inflow conduit to enter the impeller.'" *Id.* We find on the current record Petitioner's arguments unconvincing.

ID, 32

878, Fig. 6). 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. Petitioner, however, alternatively relies on Wampler as teaching a rotor "axially aligned" with the inflow tube, which we turn to next.

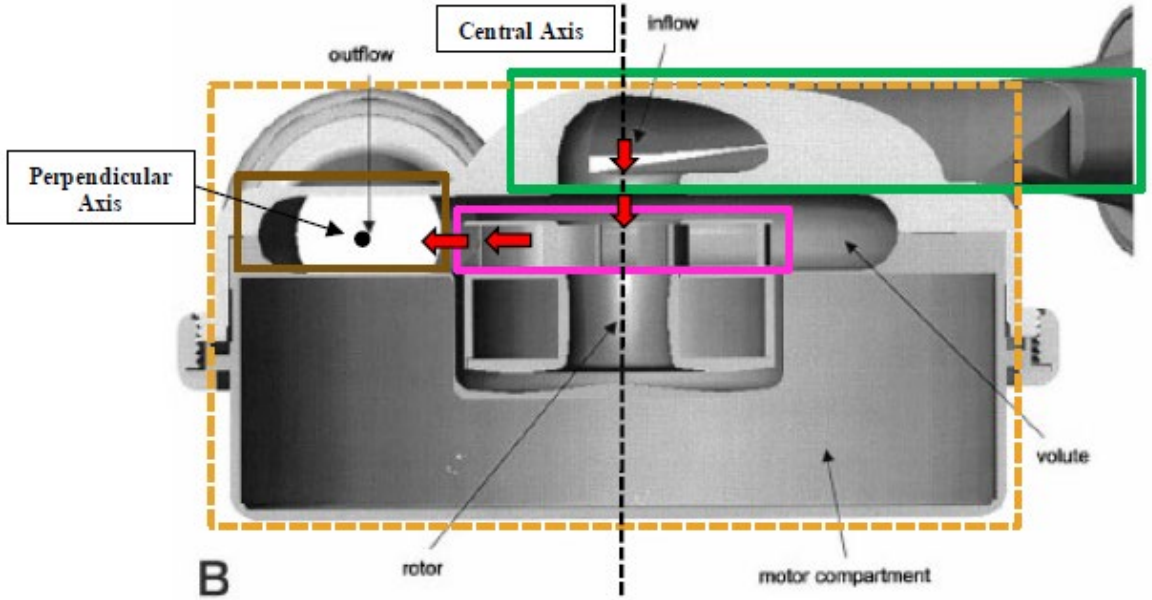
Like all centrifugal pumps, Bourque's rotor is "*axially aligned*" with its inflow

Ex. 1007 (Bourque)

HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor

KEVIN BOURQUE,* DAVID B. GERNES,* HOWARD M. LOREE II,* J. SCOTT RICHARDSON,* VICTOR L. POIRIER,* NATALE BARLETTA,† ANDREAS FLEISCHLI,† GIAMPIERO FOIERA,† THOMAS M. GEMPP,† RETO SCHOEB, ,† KENNETH N. LITWAK, ,‡ TAKEHIDE AKIMOTO,‡ MARY J. WATACH,‡ AND PHILIP LITWAK‡

Pet. at 68



E.g., Paper No. 26 (Pet. Reply), 15-17; Paper No. 1 (Pet.), 68.

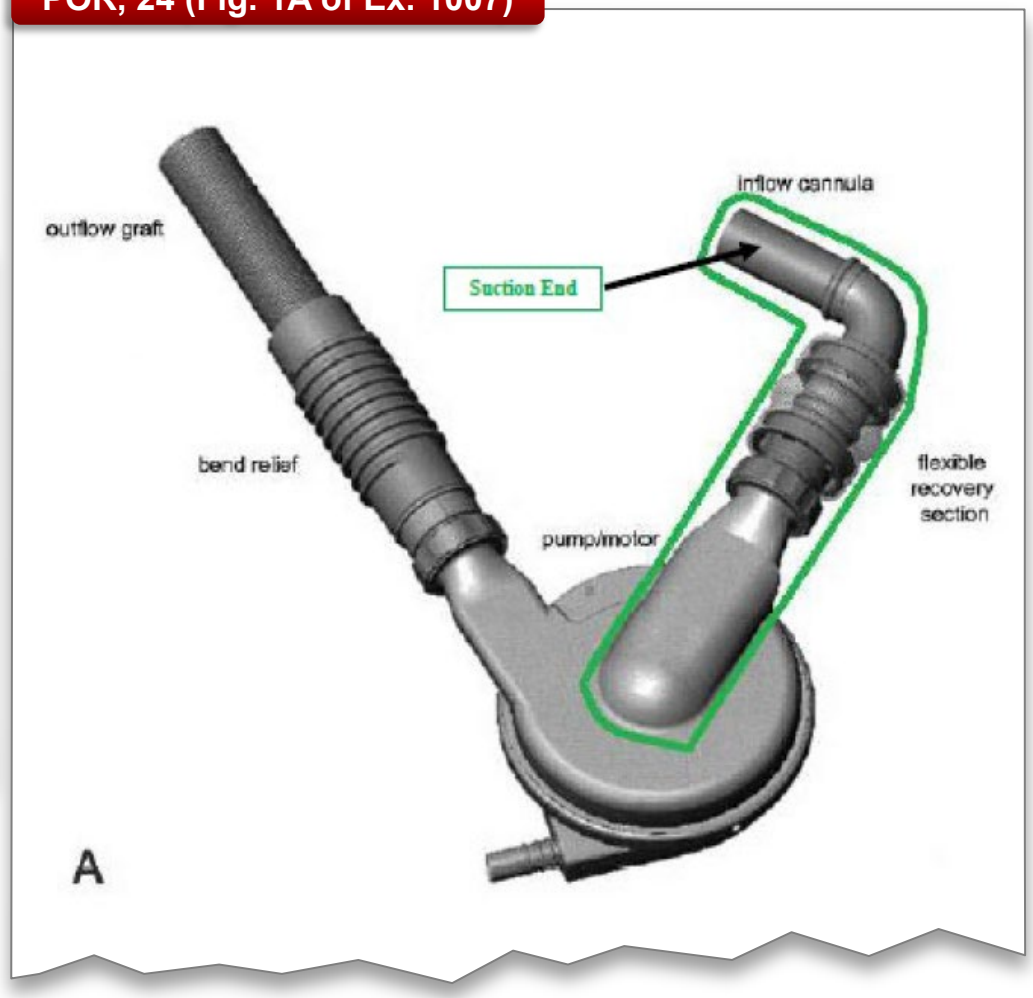
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

PO incorrectly asserts that "entirety" of inflow including "suction end" must be "*axially aligned*"

POR, 24

Petitioner, as it must, argues that the end of the "flexible recovery section" or "inflow cannula" is the "suction end" of an "inflow tube" that is "inserted into a ventricle of the heart." Pet. at 50–52; Crosby, ¶¶ 163–166. Accordingly, the entirety of the structure that connects the flow of blood from the heart to the pump in Bourque-2001 must correspond to the "inflow tube" of the claims. In addition to

POR, 24 (Fig. 1A of Ex. 1007)



Paper No. 22 (POR), 24.

Claim terms cannot be interpreted to exclude the only disclosed embodiment of inflow tube (9) in the Challenged Patents

***GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1311 (Fed. Cir. 2014)**

In this case, were we to adopt AgiLight's proposed construction, that the ***entire* inner profile** must be substantially ellipsoidal, we would **exclude the specification's only disclosed embodiment**.

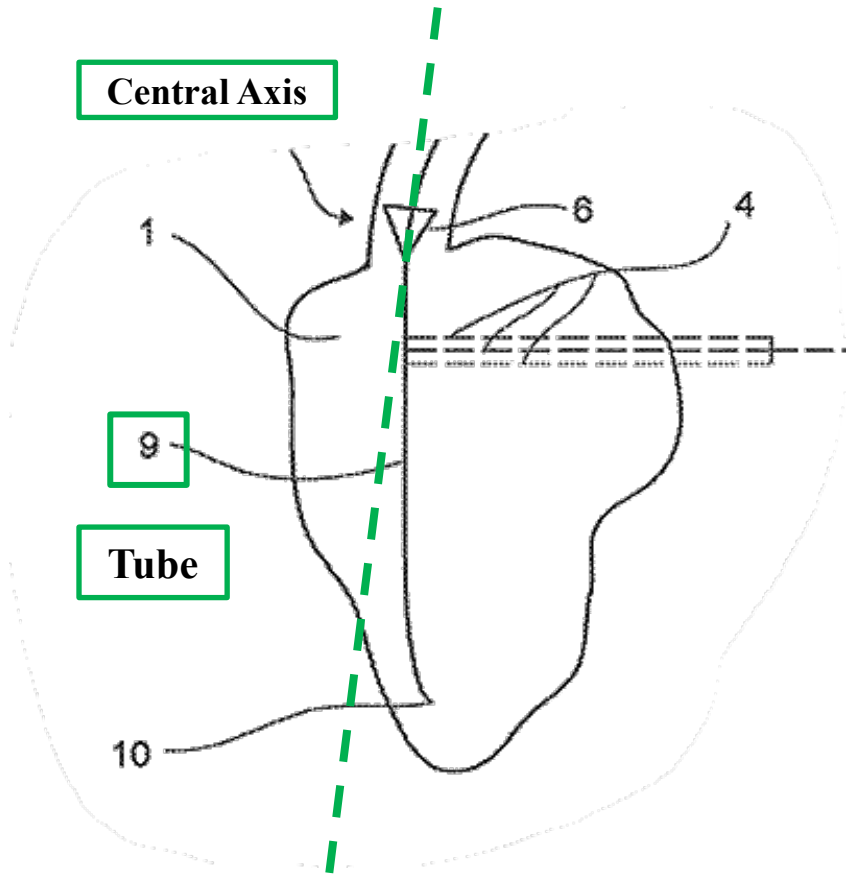
…

We normally do not construe claims in a manner that would exclude the preferred embodiment, especially where it is the only disclosed embodiment. *See MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed.Cir.2007). In particular, "where claims can reasonably [be] interpreted to include a specific embodiment, it is **incorrect** to construe the claims to exclude that embodiment, absent probative evidence on the contrary." *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed.Cir.2008). No such evidence exists in this case that would require us to construe "substantially ellipsoidal inner profile" in a manner that would exclude the [lone] embodiment."

E.g., Paper No. 26 (Pet. Reply), 15

PO's interpretation of "*axially aligned*" excludes the only disclosed embodiment of inflow tube (9)

Pet. Reply, 15-16



Ex.1040 (Leschinsky Tr.), 135:19-136:14

Q. And element 9, as shown here, has some flexibility or curvature, correct?
A. You're referring to position 10?
Q. Yes.
A. Well, **it's a little curved** from a straight line, yes.
Q. So if we start at the portion of 9 that's closer to Element 6 and we follow that line all the way down to where it's marked 10, you would agree that **the central axis follows Element 9**, correct?
A. I would agree.

Ex. 2015 (Leschinsky Dec.), ¶51

example, in Paper 1, 1–3 and Ex. 1003 ¶¶ 30–36 and 40. It is true that the '356 patent discloses one embodiment of its "device to assist the performance of a heart" that is built around a catheter, but this is an example embodiment and would not have been understood by a POSA as limiting the scope of the disclosure or its claims. Ex. 1001, Title.

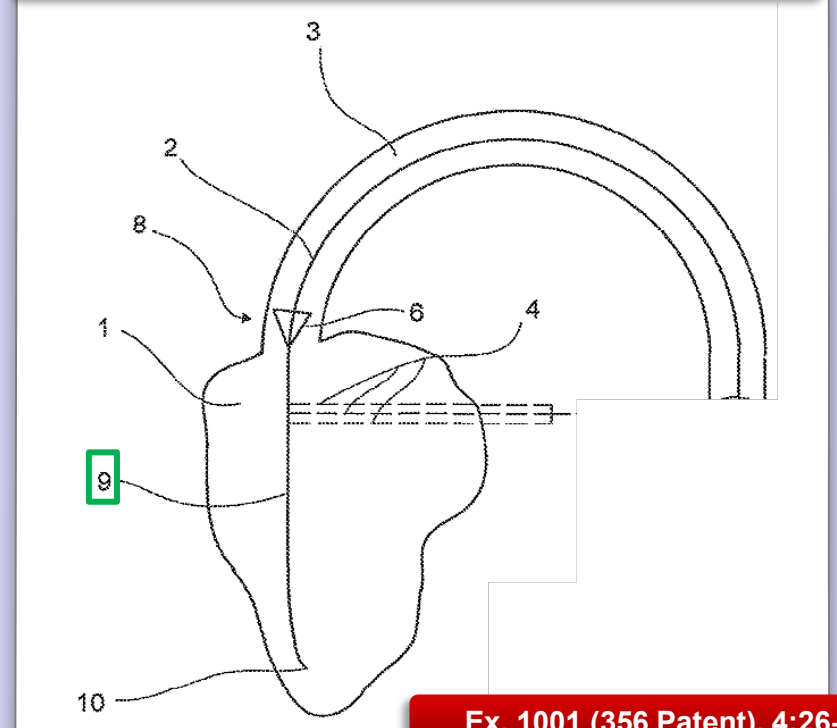
E.g., Paper No. 26 (Pet. Reply), 15-17

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Figure 2 of the Challenged Patents depicts a portion of the same embodiment of inflow tube (9)

Curved inflow tube (9)

Pet. Reply, 15-16; Ex. 1001 (356 Patent), Fig. 1

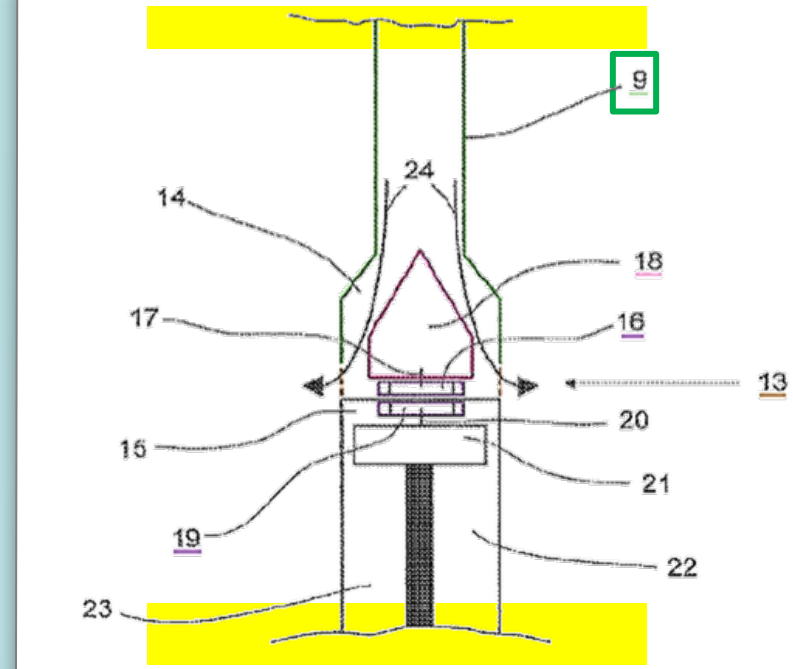


Ex. 1001 (356 Patent), 4:26-27

the catheter **2** having at its distal end tube **9** leading to the suction end **10**

A portion of curved inflow tube (9)

PO Sur-Reply, 13; Ex. 1001 (356 Patent), Fig. 2



Ex. 1001 (356 Patent), 4:47-65

In FIG. 2, the distal end of a modified catheter **2** is now illustrated … whereby a flow is formed in the region of the tube **9**

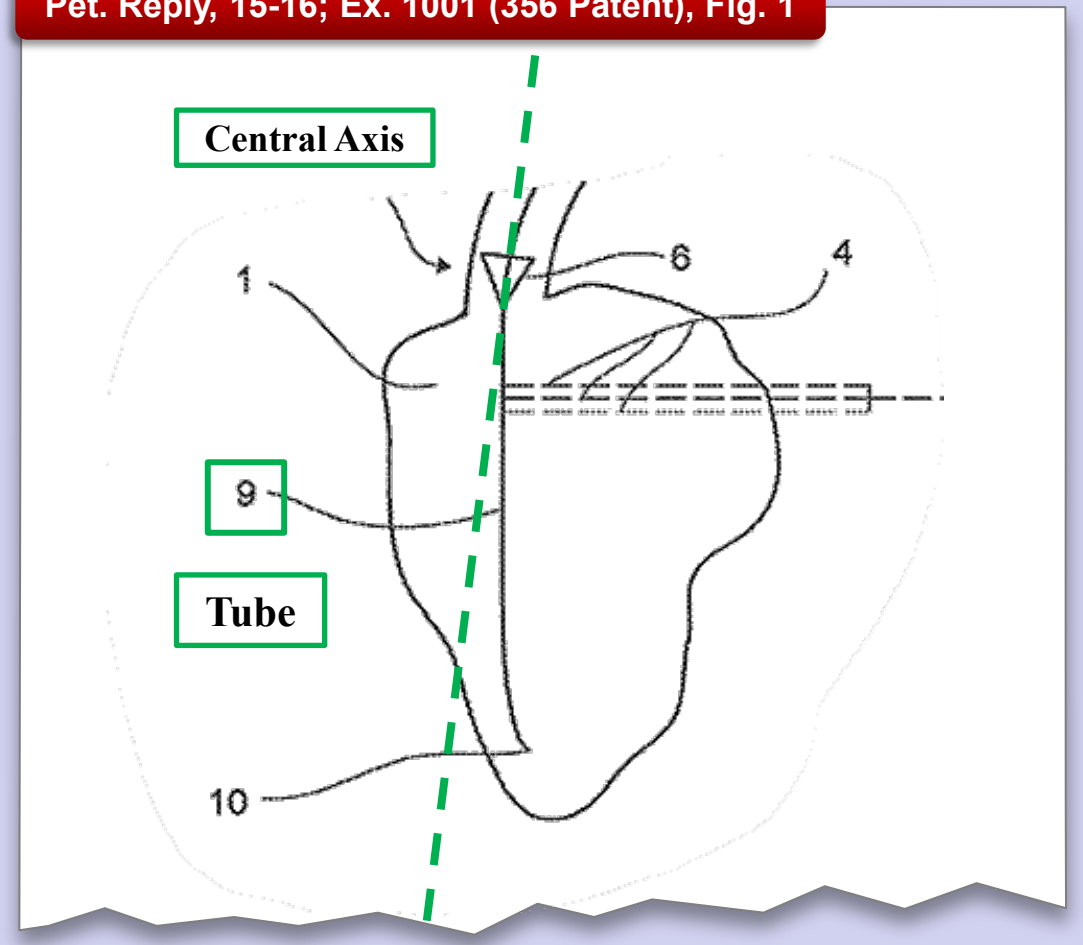
E.g., Paper No. 26 (Pet. Reply), 15-16; Paper No. 33 (PO Sur-Reply), 13

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Bourque's inflow is "*axially aligned*"

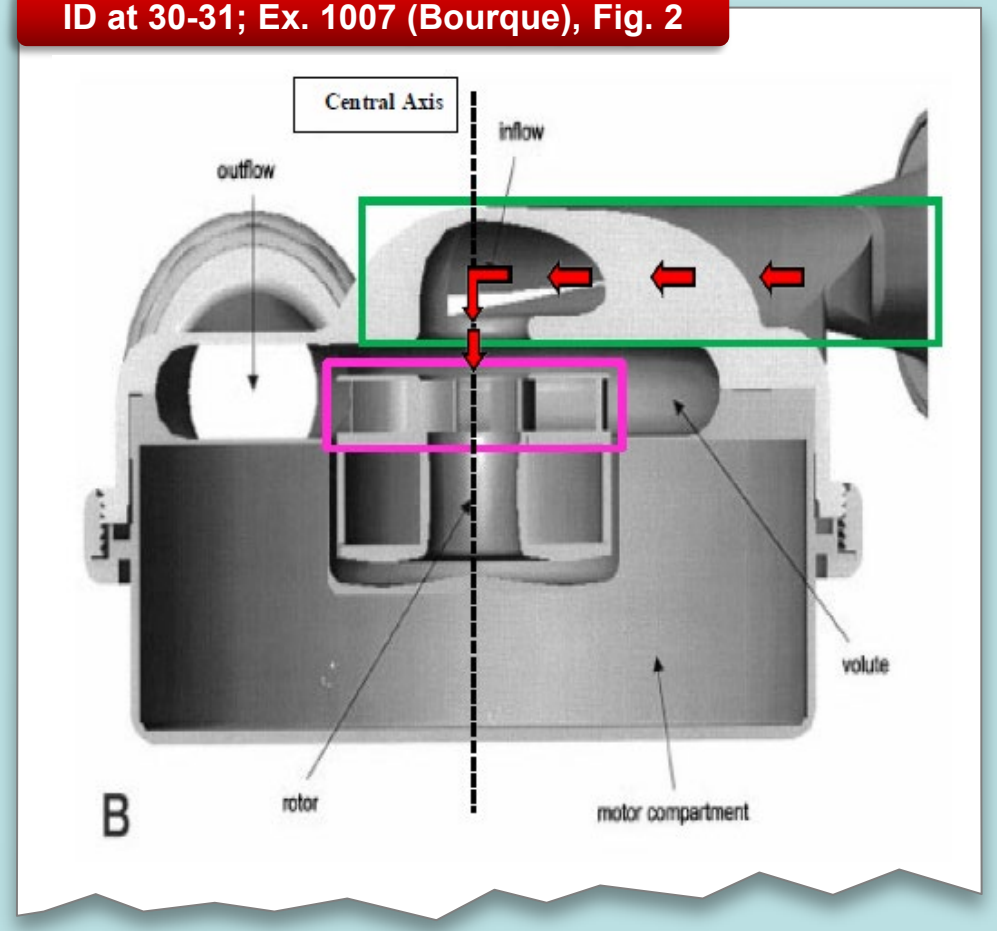
Curved inflow tube (9) is "*axially aligned*"

Pet. Reply, 15-16; Ex. 1001 (356 Patent), Fig. 1



Bourque's inflow is "*axially aligned*"

ID at 30-31; Ex. 1007 (Bourque), Fig. 2



E.g., Paper No. 26 (Reply), 15-16; Paper No. 15 (ID), 30-31

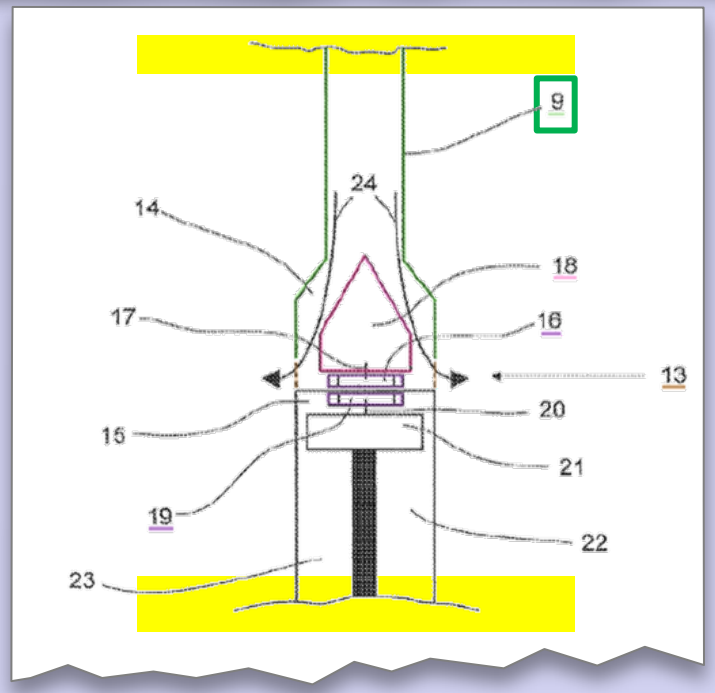
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Bourque's inflow is "*axially aligned*"

A portion of curved inflow tube (9) is "*axially aligned*"

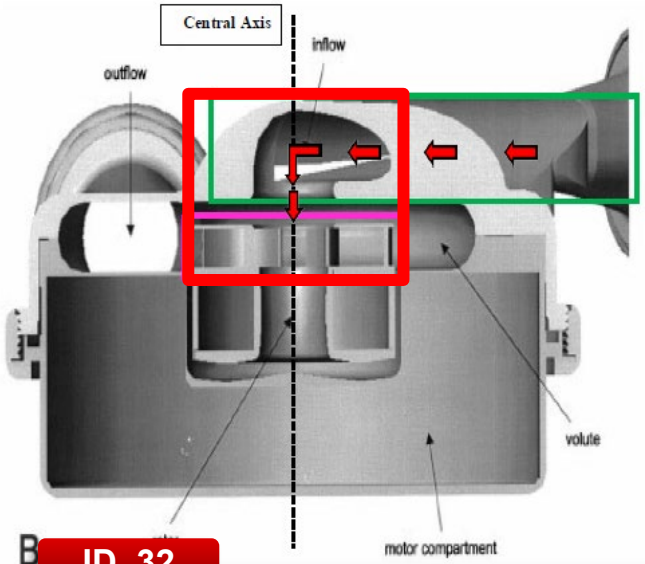
PO Sur-Reply, 13

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



A portion of Bourque's inflow is "*axially aligned*"

ID at 30-31; Ex. 1007 (Bourque), Fig. 2



ID, 32

subassembly is not axially aligned with the rotor. To show the required axial alignment, Petitioner appears to rely on an unidentified portion of Bourque's inflow subassembly, after the 90 degree bend, where Petitioner alleges "flow 'leav[es] the inflow conduit to enter the impeller.'" *Id.* We find on the current record Petitioner's arguments unconvincing.

E.g., Paper No. 26 (Reply), 15-16; Paper No. 15 (ID), 30-31

Roadmap

- ***Axially aligned***
  - Bourque alone teaches "*axially aligned*"
  - **Bourque in view of Wampler teaches "*axially aligned*"**
    - **Multiple independent motivations to combine**
    - Expectation of success

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

PO does not dispute Wampler teaches the "*axially aligned*" limitation

ID, 28

Owner argues that Bourque, alone, does not teach this limitation. Patent Owner does not dispute that the limitation is taught by Wampler, and instead argues Wampler cannot be combined with Bourque. Prelim. Resp. 30–44.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

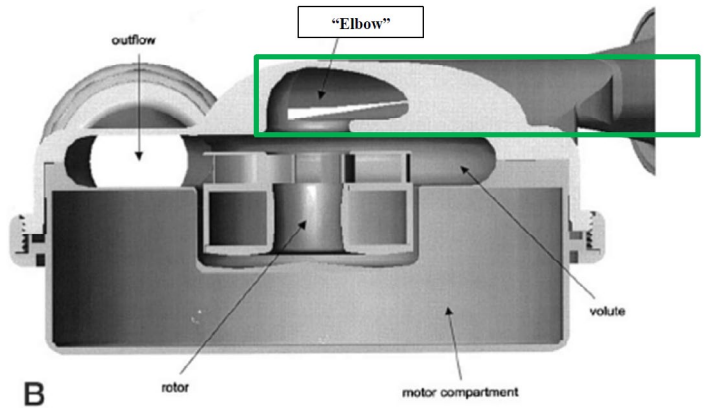
Wampler teaches eliminating Bourque's flow-restrictive elbow

Bourque

Ex.1007 (Bourque), 5

Designing with access to the resources and infrastructure of established, FDA approved LVADs (*i.e.*, HeartMate) has afforded the wherewithal to develop the HeartMate III pump (*i.e.*, hydrodynamic elements) and peripheral hardware (*i.e.*, inflow and outflow components) concurrently, borrowing from the enormous clinical experience gained with presently available HeartMate systems. Although generally regarded as secondary in im-

Ex.1003 (Crosby I), ¶460 (annotating Ex.1007, Fig. 1B)



Wampler

Ex. 1008 (Wampler), [0076]

[0076] The centrifugal design of the pump allows a considerable amount of flexibility during implantation. Owing to the axial inflow and radial outflow of the pump, a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting. Moreover, the pump can be rotated on its longitudinal axis to adjust the orientation of the discharge tube and minimize kinking and hydraulic losses in the vascular graft. Good 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 (Wampler), Fig. 5

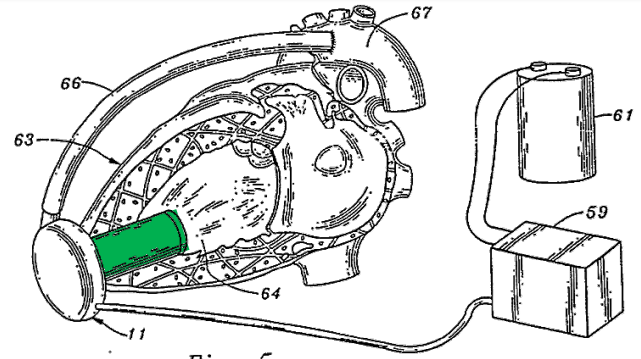


Fig. 5

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitioner offers several reasons to combine Bourque with Wampler

Pet., 80-82

A POSITA would have been motivated to apply the teachings of Wampler-169 to Bourque-2001 to eliminate its elbow so that its inflow tube would also serve as the inflow cannula placed into the apex of the left ventricle as expressly taught by Wampler-169 for several reasons. Ex.1003, ¶470.

ID, 34

3. Rationale in Support of Asserted Combination

Petitioner offers several reasons a person of ordinary skill in the art would have found it obvious to include Wampler's "techniques related to its axially aligned inflow tube" in the HeartMateIII device taught by Bourque.

Pet. Reply, 18-19

i. PO fails to rebut multiple, independent motivations to combine Bourque and Wampler.

A POSA would have been motivated "to eliminate [Bourque]'s elbow so that its inflow tube would also serve as the inflow cannula" "**for several reasons**" (Pet., 82):

1. Wampler teaches that Bourque's "flow restrictive" "elbow was unnecessary." Pet., 83;
2. The combination would "eliminate" "peripheral hardware" that caused "clinical troubles." Pet., 83-84;
3. The references "are analogous" and the "combination would have been the arrangement of old elements." Pet., 82-83; and
4. Instead of "in a preperitoneal pocket," the combination could be implanted above the diaphragm at "the apex of the heart," which would "reduce rates of infection." Pet., 84-86.

Eliminating Bourque's elbow outweighs benefits of eliminating flexible recovery section

PO argues for keeping the flexible recovery section

POR, 28

Another 2001 publication by Petitioner (which includes Mr. Bourque as an author) asserts that HeartMate III includes a "flexible cannula [that] is fitted upstream of the pump inflow to improve anatomical fit, to decouple the pump from cardiac motion, and to provide a point for clamping and ligation for pump explant." Ex. 2004 at 387. Again, Petitioner ignores its own strong statements as to why its proposed combination should not be made.

But a POSA may secure some benefits at the expense of others

***Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023)**

[A] skilled artisan may be motivated to combine particular features of different references, *e.g.*, **to secure some benefits at the expense of others**, even when bodily incorporation would be impossible or inadvisable.

ID, 36

provided certain benefits. It does not, however, address, for example, whether those benefits would have been lost in the asserted combination or whether a person of ordinary skill in the art would have understood the benefits of the asserted combination outweighed any detriments. Patent Owner's attorney arguments are not convincing on the current record.

Eliminating Bourque's elbow outweighs benefits of eliminating flexible recovery section

The elbow is flow restrictive

Ex.1007 (Bourque), 2

perpendicular to the body's long axis. That resulted in a sharp bend in the flow before it enters the impeller. To minimize the losses in this transition, the flow is slightly accelerated through this elbow. The flow exits the backswept blades of the impeller

Ex.2015 (Leschinsky Dec.), ¶¶133–134

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

134. Further, the computational fluid dynamics analysis also "reveals a slight degree of swirling flow in the elbow," including "a small pocket of preswirl [that] is induced from the impeller and migrates upward into the elbow." Ex. 2005

Shear forces impact blood integrity

Ex.1041 (Wieselthaler Dec.), ¶49

49. A POSITA would have recognized that the Bourque pump's elbow was flow restrictive and causes shear forces. The computational fluid dynamics analysis "reveals a slight degree of swirling flow in the elbow," including "a small pocket of pre-swirl [that] is induced from the impeller and migrates upward into the elbow." Ex. 2005, 5. A POSITA would have been motivated to eliminate the elbow to reduce shear forces, because excessive shear stress can damage blood cells, particularly causing hemolysis and platelet activation, as well as cause von Willebrand's-factor degradation. Eliminating the elbow would reduce shear, which would help maintain blood integrity and minimize thrombotic and hemorrhagic events, ensuring safer long-term circulatory support.

Paper No. 1 (Pet.), 80; Paper No. 26 (Pet. Reply), 19

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Roadmap

- ***Axially aligned***
  - Bourque alone teaches "*axially aligned*"
  - **Bourque in view of Wampler teaches "*axially aligned*"**
    - Multiple independent motivations to combine
    - **Expectation of success**
      - **PO is legally incorrect**
      - PO is factually Incorrect

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

PO argues no expectation of success for an LVAD implanted at the apex

POR, 32-33

As of the priority date, none of the experts in this proceeding were aware of an LVAD being implanted at the apex of the heart. Leschinsky, ¶ 150; Gallegos, ¶¶ 51–52; Ex. 2014 at 44, 52. Wampler proposed an LVAD that could be small enough to fit to the apex of the heart—but it was 10 years after Wampler's publication and 5 years after the priority date of the challenged patent that an LVAD was made small enough to fit there. Leschinsky, ¶ 150; Gallegos, ¶ 52; Ex. 2014 at 52.

POR, 32-33

Device	Weight	Volume	Location	Implanted in Humans?	Year of Publication or Approval
HeartMate II	281	63	Pocket	Yes	2000
Wampler	195	28	Apex	No	1998
Bourque-2001 (HeartMate III prototype)	474	168	Pocket	No	2001
HeartMate 3 (clinical)	200	80	Apex	Yes	2015
VentrAssist	298		Pocket	Yes	2003
HeartWare HVAD	145	50	Apex	Yes	2012

PO incorrectly asserts that Petitioner's motivation requires pump to be implanted at the apex

POR, 33

A POSA at the priority date would not have believed that the prototype HeartMate III pump of Bourque-2001 could have been successfully placed at the apex of the heart, as required by the stated motivation to combine, and would not have been so motivated. Leschinsky, ¶ 153; Gallegos, ¶ 53.

PO Sur-Reply, 23

3. Petitioner's Proposed Motivation to Combine Undoubtedly Requires 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

Paper 26 (Pet. Reply), 20; Paper 22 (POR), 33; Paper 33 (PO Sur-Reply), 23

Neither the claims nor Petitioner's combination require pump to be implanted at the apex

Claim 1

Ex.1001 (356 Patent), claim 1

1. A method for assisting the blood circulation of a heart in a body, comprising:

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 while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart,

Petition

Pet., 80-82

A POSITA would have been motivated to apply the teachings of Wampler-169 to Bourque-2001 to eliminate its elbow so that its inflow tube would also serve as the inflow cannula placed into the apex of the left ventricle as expressly taught by Wampler-169 for several reasons. Ex.1003, ¶470.

Wampler-169 expressly teaches that "[t]he centrifugal design of the pump allows a considerable amount of flexibility during implantation" because "a 90-degree redirection of the blood is effected **without the necessity of a flow-restrictive elbow fitting**." Ex.1008, [0076]. As demonstrated in Ground 1,

Legally incorrect to require apex placement when it is not part of the claims

***Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957-958 (Fed. Cir. 2023)**

The Board adopted a legally incorrect framing of the motivation-to-combine question when it confined the inquiry to whether a motivation would exist to make the Gerber-Young combination for use in the Young-specific trigeminal-nerve context. **That context is not part of the Medtronic patents' claims. The proper inquiry is whether the relevant artisan would be motivated to make the combination to arrive at the claims' actual limitations, which are not limited to the trigeminal-nerve context.** And the Board made no finding, and the parties have not pointed to evidence, that the space constraints of that context, on which the Board relied for finding no motivation to make the combination for trigeminal-nerve stimulation, are applicable to other nerve-stimulation contexts covered by the claims at issue, which include sacral-nerve stimulation.

PO incorrectly asserts that Bourque and Wampler "would be practically impossible to combine"

PO Sur-Reply, 20, 23

B. A Person of Ordinary Skill Would Not Combine Bourque-2001 and Wampler

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–

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. POR 30–37 ("A

Ex.2015 (Leschinsky Dec.), ¶¶ 168, 170

168. The above-described structure also provides important functionality to the Wampler pump that would preclude merging it with Bourque-2001. For

include magnets in the impeller that Bourque does not include. All of this functionality and structure would need to be redesigned to make the contended combination between Bourque-2001 and Wampler.

Paper 33 (PO Sur-Reply), 20, 22-23; Paper 26 (Pet. Reply), 19-21

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

PO's improper bodily incorporation argument should be rejected again

ID, 36

For similar reasons, Patent Owner's bodily incorporation argument that Bourque's pump would not fit in the location of Wampler is not convincing on the current record. Patent Owner argues that Wampler's

***Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023)**

The inquiry is not whether a relevant artisan would combine a first reference's feature with a second reference's feature … the claim defines the invention whose obviousness is being assessed and that a skilled artisan may be motivated to combine particular features of different references, *e.g.*, to secure some benefits at the expense of others, **even when bodily incorporation would be impossible** or inadvisable.

Paper 15 (ID), 36; Paper 26 (Pet. Reply), 19-21

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Roadmap

- ***Axially aligned***
  - Bourque alone teaches "*axially aligned*"
  - **Bourque in view of Wampler teaches "*axially aligned*"**
    - Multiple independent motivations to combine
    - **Expectation of success**
      - PO is legally incorrect
      - **PO is factually Incorrect**

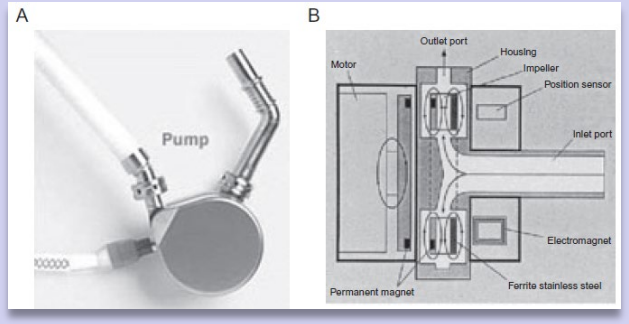
POSA would expect success given history of LVADs that fit well at these positions

In a preperitoneal pocket (below the diaphragm)

- VentrAssist



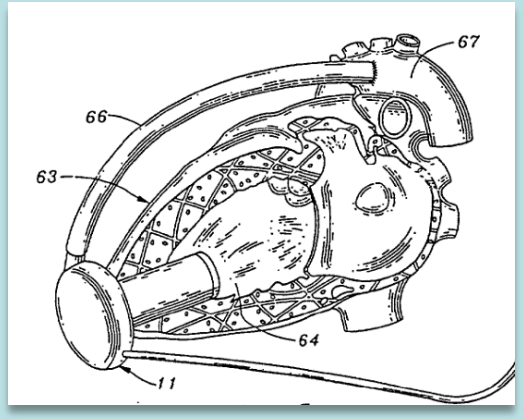
- DuraHeart



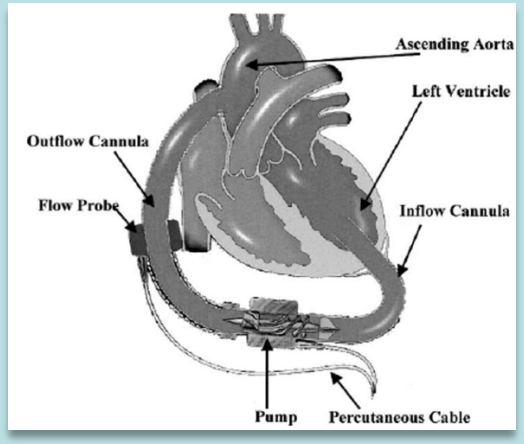
- 1st generation LVADs

At the apex of the heart (above the diaphragm)

- HeartWare HVAD



- MicroMed Debakey

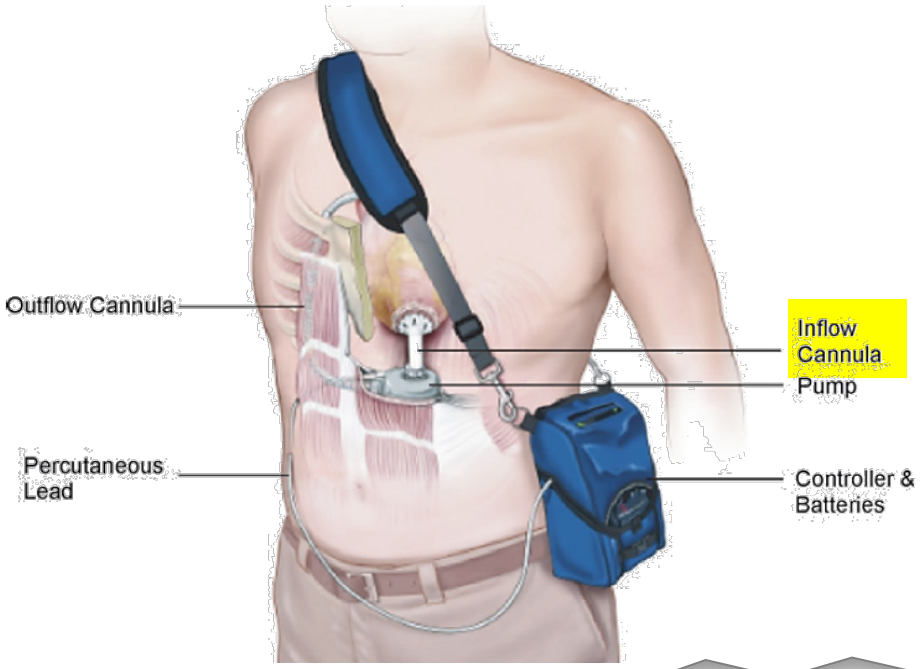


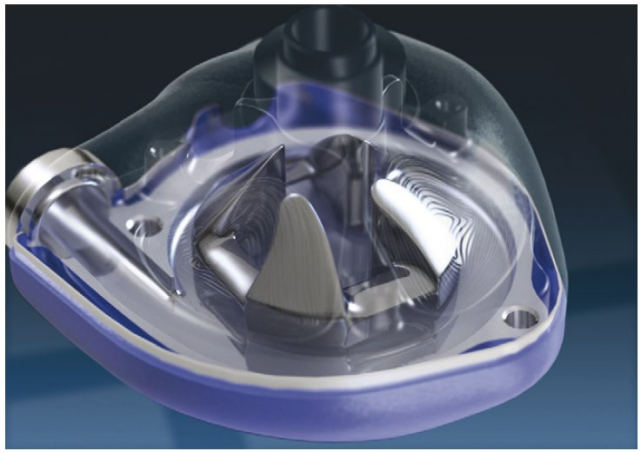
- Jarvik-2000

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Option 1: The VentrAssist fit in a peritoneal pocket, below the diaphragm

Ex.2013 (VentrAssist), 2





The VentrAssist™ is a third-generation centrifugal LVAD. The VentrAssist™ consists of a blood pump that is implanted in a small pocket created on the left side of the body, below the diaphragm and behind the posterior rectus sheath (Fig. 2). A cannula attached from the failing left ventricle delivers blood from the heart to the VentrAssist™ and a second cannula delivers the blood from the VentrAssist™ to the ascending aorta. A thin percutaneous lead from the pump exits the body

Option 2: Wampler HVAD fit at apex of the heart, above the diaphragm

Ex.1008 (Wampler), Fig. 5, [0075]

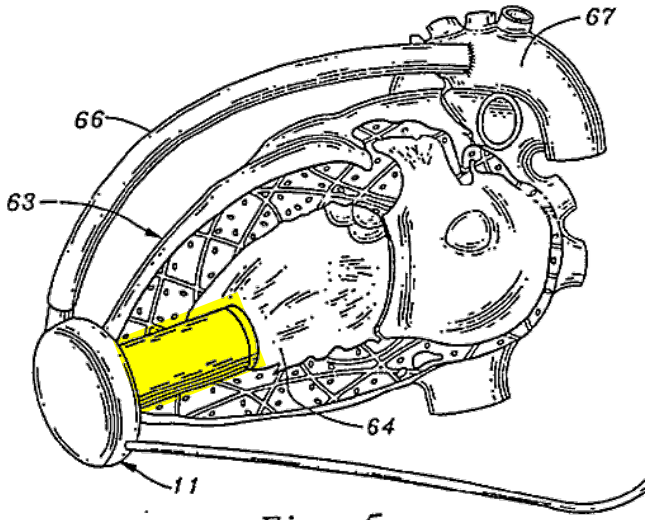


Fig. 5

[0075] Anatomical placement of the pump **11** is shown in **FIG. 5**. The simplified representation of a human heart **63**, includes a left ventricle **64** and an aorta **67**. The inlet tube **16** serves as the inflow cannula and is placed into the apex of the left ventricle **64**. An arterial vascular graft **66** is con-

Ex.1015 (HeartWare VAD)

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

PO is factually wrong that no LVADs were placed at the apex

POR, 31

i. The State Of The Art At The Priority Date Was That There Were No Clinical LVADS Placed At The Apex Of The Heart As Petitioner's Motivation Requires

Ex.2015 (Leschinsky Dec.), ¶150

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

placement, but it took over 10 years from the publication of Wampler (many more from its priority date) and 5 years after the priority date of the '356 patent before an LVAD was actually made small enough to be implanted at the apex of the heart.

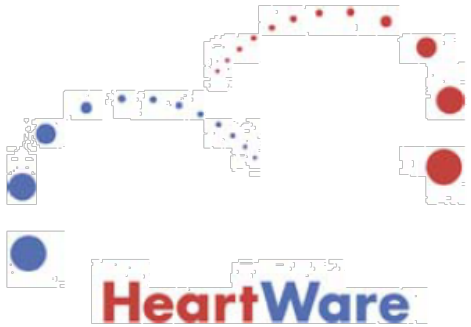
Ex.2017 (Gallegos Dec.), ¶51

51. Contrary to Petitioner's contentions, as of the priority date I was not aware of any LVADs that were positioned at the apex of the heart. For example, I

pockets. Implanting these devices at the apex of the heart was not approved by regulatory authorities and, more practically, was impossible to do because of their large size.

HVAD clinical trial had already begun before the priority date

Ex. 1044 (HVAD Implant)



ASX ANNOUNCEMENT

24 March 2006

First Human Implant of HeartWare's HVAD

Ex. 1044 (HVAD Implant)

Commenting on the first implant, Dr Wieselthaler said:

"*Our first clinical experience of the HVAD was extremely positive. The procedure was completed quickly and without incident, and our patient's early post-operative recovery has been excellent.*

The device's small size and configuration facilitated a relatively fast implant procedure. The surgery took only 85 minutes, significantly less than the time typically required to implant other devices. The patient was moved from the operating theatre into the post operative recovery area, conscious and off ventilation within seven hours. He continues to recover quickly and has met with his family. We are very pleased with these results."

PO incorrectly asserts that HVAD appears nowhere in the Petition

PO Sur-Reply at 19

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

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitioner relied on HVAD to support Ground 2 motivation to combine

Pet., 87

the art." Ex.1018, 6:62-7:5. A POSITA would also have had a reasonable expectation of success that the Bourque-2001/Wampler-169 combination would "fit[] well between the apex of the heart and the adjacent diaphragm" due to the pump's "development as a compact" device and the existence of several similar LVADs that fit well at that position. Ex.1007, 405; Ex.1003, ¶¶473-476 (analyzing LVADs that fit at the apex of the heart, including Wampler-169, Akamatsu-1999, and HVAD).

Ex.1003 (Crosby I), ¶476

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

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

PO incorrectly asserts that there are no documents evidencing the structure of HVAD before the priority date

PO Sur-Reply at 19

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

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Printed publications described the HVAD's structure, including its axial inflow and placement in pericardial space

Ex. 1015 (HeartWare VAD)

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 radial magnetic bearings, which also provide axial preload, and shrouded axial hydrodynamic thrust bearings. Enhanced reliability is achieved via the simplicity of the impeller suspension system, as well as by redundant stators and a fatigue resistant driveline. The pump can provide 2 to 12 litershin of flow at 2500 rpm. Through the novel motor and impeller integration, the pump is highly power efficient requiring only 4.5 Watts to deliver 5 I/min flow against 100 mmHg. The Heartware VAD promises to be an easily implantable, highly reliable,

Ex. 1044 (HVAD Implant)

The HVAD is the smallest 3rd generation circulatory assist device available. It is the only full-output pump implantable in the pericardial space and the only centrifugal pump implantable above the diaphragm. The pump's impeller design, together with its integrated inflow cannula, help to ensure optimal blood flow characteristics which should, over time, allow reduction of the anticoagulant levels typically required for LVAD recipients.

Deposition of Petitioner's Reply Expert Dr. Wieselthaler:

Ex. 2028 (Wieselthaler Tr.), 84:1-85:7

Q. Can you turn back to Exhibit 1015?
…
A: [Ex.1015] is not a journal article. **This is an abstract, you know, for a presentation** at the ASAIO meeting, you know, in 2004

Ex. 2028 (Wieselthaler Tr.), 84:1-85:7

Q: My question was, what is the basis of your statement that everybody knew how the HeartWare HVAD pump looked?

…

A: Okay. So since, actually, **in 2004 Jeff LaRose, you know, was presenting the shape and the size, you know, of the pump of the HeartWare HVAD pump**, you know, at that size -- at that time, it was more or less, you know, evident, you know, to the community, you know, that HeartWare is working on such a pump, you know, with a small size, you know. … But the pump -- the frozen design of the pump, you know, was around **beginning of 2004, and that's the reason why Jeff LaRose actually could present it at the ASAIO meeting**

The Board "must disregard" PO's experts' opinions regarding HVAD

***Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1378 (Fed. Cir. 2017)**

However, we **must disregard the testimony of an expert that is plainly inconsistent with the record** … That is the situation here, where Faerber makes several incorrect statements with respect to the record … .

Faerber first states that "Wulf gives no indication of whether any of these speeds … would cause items to settle around the cutter," and that Wulf "only discloses items settling when the motors stops." J.A. 430–31. **This is clearly contradicted by the record**, as Wulf teaches that "[p]ulsing the motor … at high and then low speeds permits the material being blended to fall back to the region of the cutting knives." Wulf, col. 1 ll. 36–38.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

By 2006, Kevin Bourque expected the combination would be successful

Ex.2007 (Bourque Interview), 5-8

"So in 2006, we said, 'Let's stop, let's do exactly this (the original [Bourque Ex.1007], larger HeartMate 3 design) but let's make it smaller. So we just did a smaller diameter version. This is the clinical HeartMate 3 now, a mini one of those. …

Chips are smaller so we shrunk for that," Bourque said. "But then, when we got this small, we said wait a minute, now we don't need to implant it down here (in the abdomen), we can go right in the chest. And that took away this whole business about creating a pocket for the pump and then requiring a conduit between the heart and the pump. We just put this (the inflow cannula, if you're scoring at home) right in the heart. So that made it smaller as well."

That refined design included removing redundancy, which was so complicated it compromised reliability.

Paper 26 (Pet. Reply), 26-27

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Claim 5 requires controlling the motor "*in response to measurement values indicative of cardiac output*"

Ex.1001 (356 Patent), claim 5

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.

Patent	Claim
356 Patent	**5**
357 Patent	n/a
415 Patent	n/a
879 Patent	**20**
517 Patent	**15**
077 Patent	n/a

E.g., Paper No. 1 (Pet.), 77

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Bourque teaches "*measurement values indicative of cardiac output*"

Bourque's external controller controls the pump based on the pump's speed

Ex.1007 (Bourque), 3

The electronics for power and control of the LVAD and for data acquisition resided on a shelf and alongside the cages containing the calves. The animals were continuously monitored for general welfare, and certain parameters such as

Ex.1007 (Bourque), 3

cular, Arvada, CO). Speed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III. All measurements were automatically processed and recorded using Labview (National Instruments, Austin, TX).

Bourque teaches "*measurement values indicative of cardiac output*"

The pump's speed is measured and is indicative of cardiac output

Ex.1007 (Bourque), 3

The pump was prescribed to run at 3,500 rpm perioperatively, then gradually adjusted to maintain volume flow rates at 5 ± 1 L/min throughout the study.

Pet. Reply, 27

3. [Claim 5]

Bourque discloses that "[s]peed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III." Ex.1007, 3. These parameters are "*measurement values indicative of cardiac output*," because the speed of the pump is a direct proxy indicative of cardiac output because it corresponds to blood outflow. Ex.1003, ¶¶429-430. Indeed, Bourque discloses that these parameters can be "adjusted to maintain volume flow rates." Ex.1007, 3.

Paper No. 1 (Pet.), 77; Paper No. 26 (Pet. Reply), 27

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Claim 7 requires "*providing feedback signals to the external control unit from one or more sensors*"

Ex.1001 (356 Patent), claim 7

7. The method of claim 1, further comprising providing feedback signals to the external control unit from one or more sensors.

Patent	Claim
356 Patent	7
357 Patent	11
415 Patent	11
879 Patent	n/a
517 Patent	11, 33
077 Patent	7, 26

Bourque teaches "*providing feedback signals … from one or more sensors*"

Bourque discloses measuring pump speed by providing feedback from a sensor

Ex.1007 (Bourque), 3

The electronics for power and control of the LVAD and for data acquisition resided on a shelf and alongside the cages containing the calves. The animals were continuously monitored for general welfare, and certain parameters such as

Ex.1007 (Bourque), 3

cular, Arvada, CO). Speed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III. All measurements were automatically processed and recorded using Labview (National Instruments, Austin, TX).

Ex.1003 (Crosby I), ¶439

439. For example, Bourque-2001 discloses that the "electronics for power and control of the LVAD and for data acquisition resided on a shelf." Ex.1007 at 403. Bourque-2001 further discloses that "[s]peed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III." A POSITA would have understood based on the disclosure of this setup that these speed and motor parameters were monitored by a sensor providing feedback to the controller.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Bourque teaches "*providing feedback signals … from one or more sensors*"

Bourque uses additional sensors to provide feedback signals

Ex.1007 (Bourque), 3

The electronics for power and control of the LVAD and for data acquisition resided on a shelf and alongside the cages containing the calves. The animals were continuously monitored for general welfare, and certain parameters such as

Ex.1007 (Bourque), 3

glycerin), and whole bovine blood. Flow measurements were made with an ultrasonic flow probe (Transonic Systems, Ithaca, NY), and pressure measurements were made with solid-state, catheter-type pressure transducers (Cobe Cardiovascular, Arvada, CO). Speed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III. All measurements were automatically processed and recorded using Labview (National Instruments, Austin, TX).

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	**Axially adjacent / axially closer (all claims)**		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Claim construction of "*axially adjacent*" and "*axially closer*"

'356 Patent, claim 1

magnetically driven rotor, the magnetically driven rotor being rotatable about a central axis and being rigidly coupled to a first magnetic device that is located within the surrounding rotor housing at a position axially adjacent to the magnetically driven rotor, wherein the

'357 Patent, claim 1

device, 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;

Patent	Claim term
356 Patent	"*axially adjacent*"
357 Patent	"*axially closer*"
415 Patent	"*axially adjacent*"
879 Patent	"*axially adjacent*" and "*axially closer*"
517 Patent	"*axially adjacent*" and "*axially closer*"
077 Patent	"*axially adjacent*" and "*axially closer*"

The Board's interpretations of "*axially adjacent*" and "*axially closer*"

'356 ID., 25-26

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.

'357 ID., 25-26

magnetic device than to the magnetically driven rotor." Resolution of the dispute over whether only a portion of the second magnetic device need be "positioned *axially closer* to the first magnetic device than to the magnetically driven rotor" to satisfy claim 1 would benefit from further development of the positions of the Parties at trial.

Paper No. 26 (Pet. Reply), 9, 29

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

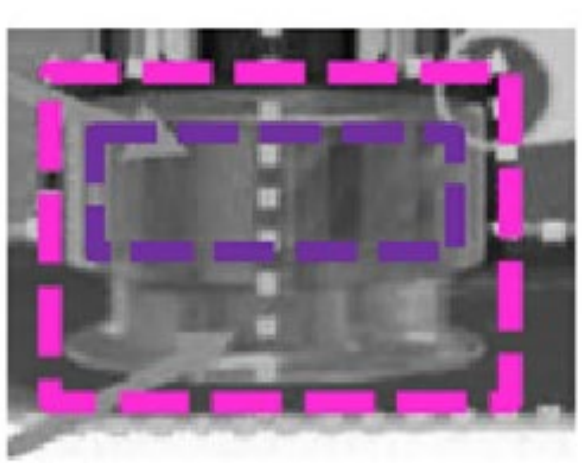
Roadmap

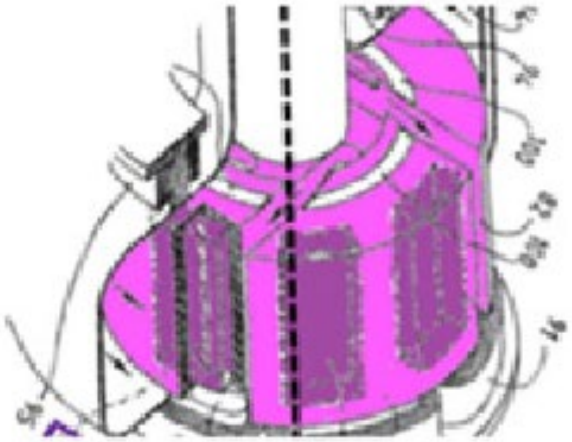
- ***Axially adjacent / axially closer***
  - **Wampler and Akamatsu disclose both terms under PO's district court interpretation**
  - Wampler and Akamatsu also disclose both terms under PO's IPR interpretation

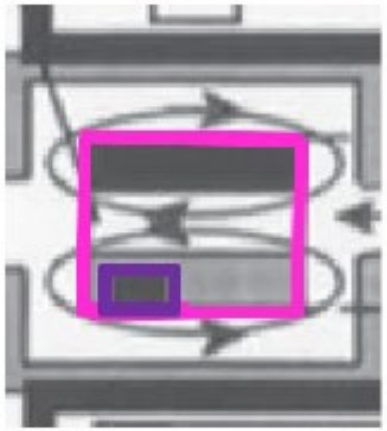
PO's efforts to twist the claims should be rejected

Pet. Reply, 7

HeartMate 3 | Wampler | Akamatsu







Ex.1042, ¶44. Thus, either *axially adjacent* includes parts that overlap (meaning Wampler and Akamatsu satisfy this limitation), or *axially adjacent* excludes such overlapping parts (meaning the accused product does not infringe). Leschinsky

PO's efforts to twist the claims should be rejected

***Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381 (Fed. Cir. 2021)**

We have repeatedly rejected efforts to twist claims, "like 'a nose of wax,' " in "one way to avoid [invalidity] and another to find infringement." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (citation omitted); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement.").

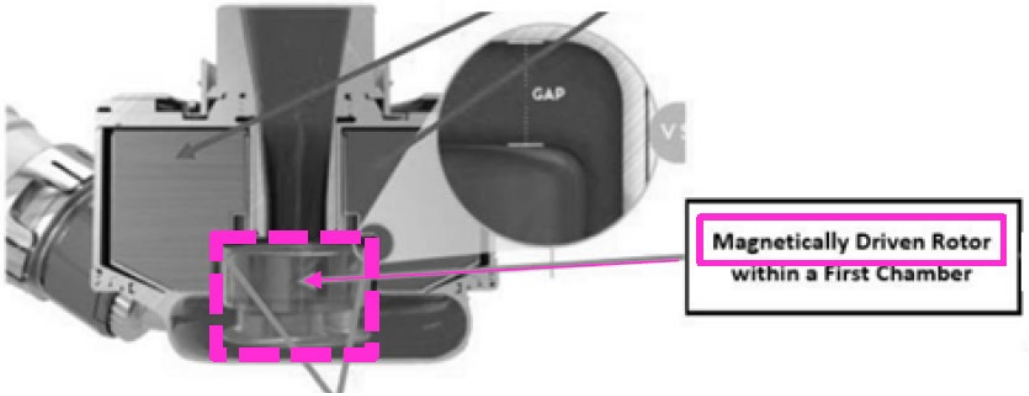
***Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20, 4 (Squires Nov. 3, 2025) (precedential)**

The Board's claim construction rules are designed to ensure that the Board correctly construes claim terms and to minimize inconsistency in claim construction between forums.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

To allege infringement, PO asserts that "*axially adjacent*" includes components that overlap or occupy the same portion of an axis

Pet. Reply, 5-6 (citing Ex.1036 (Miracor ICs), 20 (annotated))



Ex.1040 (Leschinsky Tr.) 69:11-70:9

Q. Which element would you consider to be the rotor impeller?

…

A. Well, the rotational part, the part that rotates is the rotor.

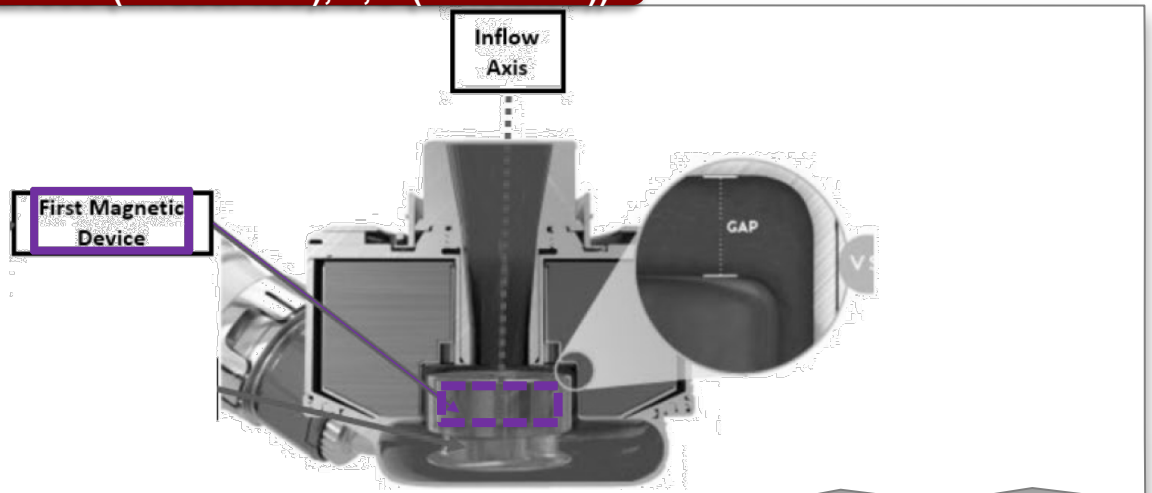
Q. And which part would that be?

…

A. -- you have a part that rotates, and the part that is the housing is stationary. So **everything that rotates is a rotor**.

To allege infringement, PO asserts that "*axially adjacent*" includes components that overlap or occupy the same portion of an axis

Pet. Reply, 4-5
(citing Ex.1036 (Miracor ICs), 5, 9 (annotated))



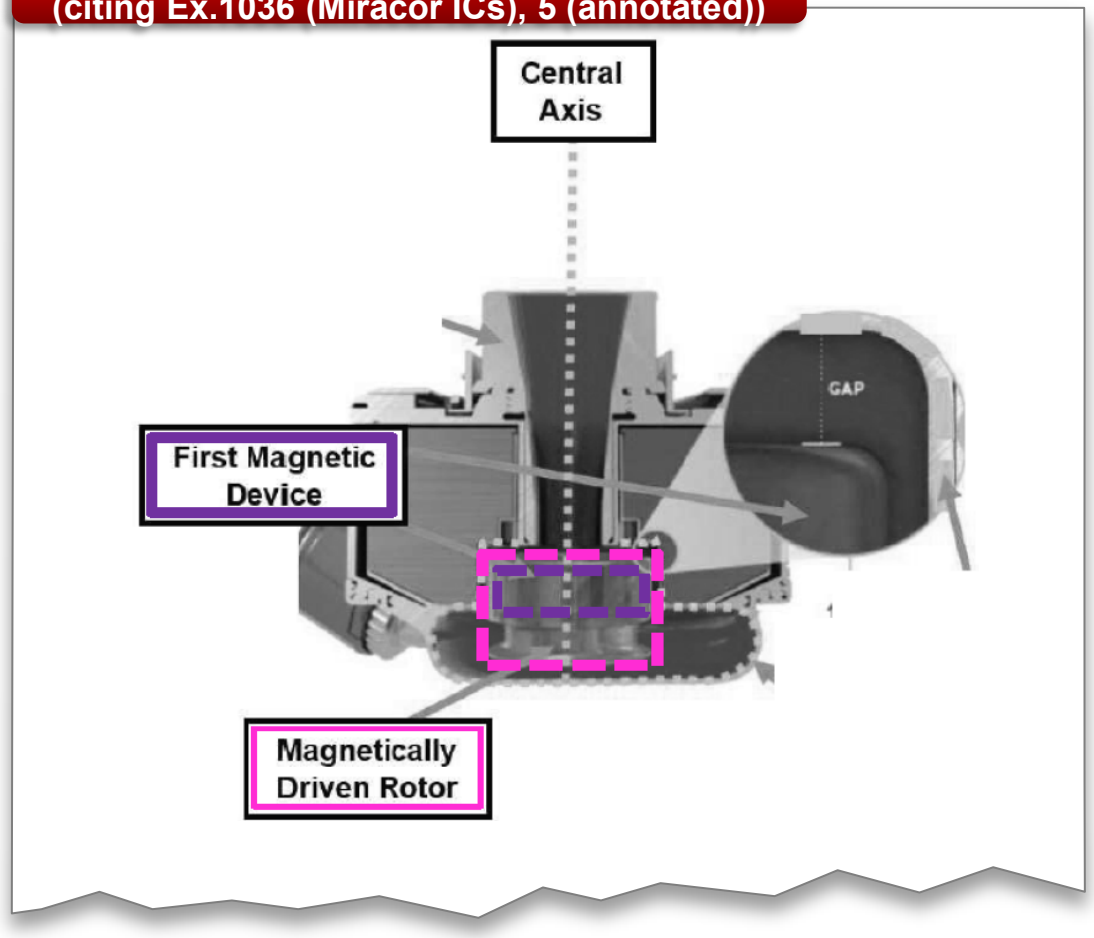
The Rotor is fully supported by magnetic levitation, obviating mechanical or fluid bearings and essentially eliminating Rotor mechanical wear as a reliability factor. Both drive (i.e. rotation) and levitation of the Rotor is accomplished using a single Stator comprising iron pole pieces, a back-iron, copper coils, and position sensors. By measuring the position of a permanent magnet in the Rotor and appropriately controlling the current in the drive and levitation coils, the radial position and rotational speed of the Rotor is actively controlled. Because of the permanent magnet's attraction to the iron pole pieces, the rotor passively resists excursion in the axial direction, whether such excursion is translation or tilting.

Paper No. 26 (Pet. Reply), 4-5.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

To allege infringement, PO asserts that "*axially adjacent*" includes components that overlap or occupy the same portion of an axis

Pet. Reply, 5-6
(citing Ex.1036 (Miracor ICs), 5 (annotated))



Ex.1036 (Miracor ICs), 3



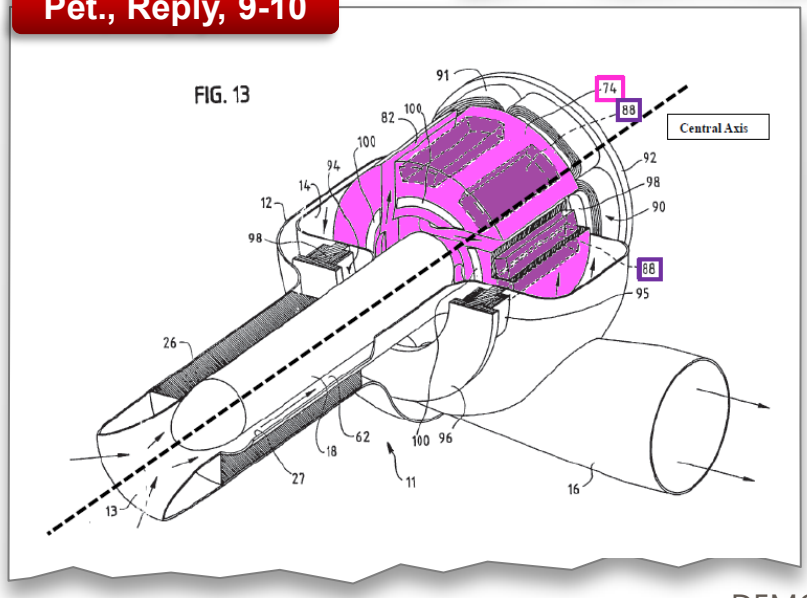
Paper No. 26 (Pet. Reply), 6.

To avoid invalidity, PO asserts that "*axially adjacent*" cannot include components that overlap or occupy the same portion of an axis

POR, 14-15, 52

The concept of "adjacent" components is clear from its plain and ordinary meaning. *Id.* at ¶ 82. Adjacent components along an axis have positioning next to one another, perhaps touching or sharing a common side, when measured along the axis. *Id.* This is distinct from components that are aligned with one another such that they overlap or occupy the same portion of an axis upon which they are positioned. *Id.*

Pet., Reply, 9-10



Ex.1006 (Akamatsu), Fig. 2

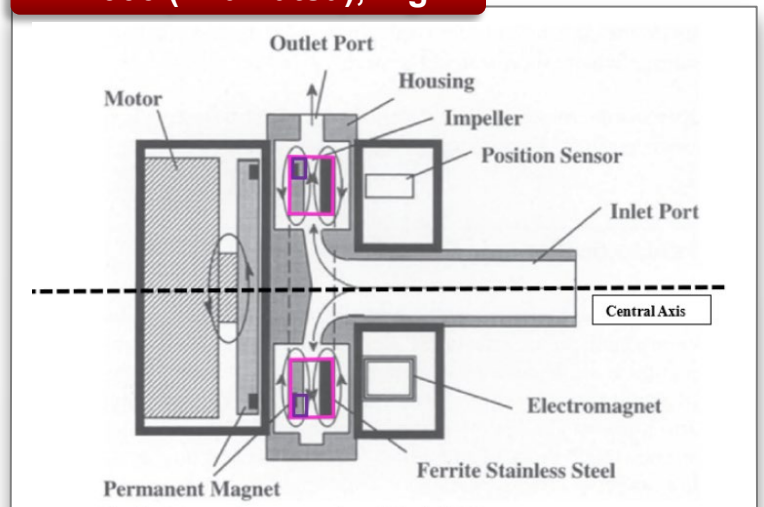
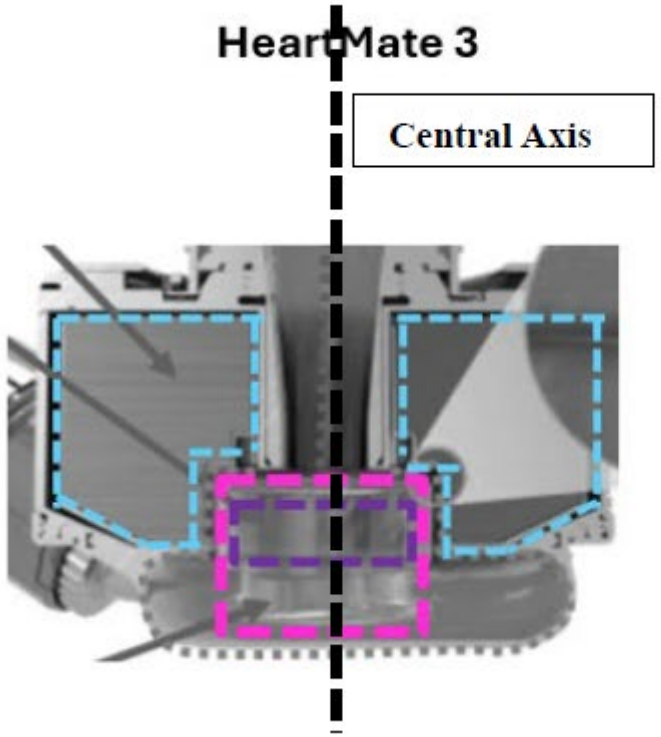
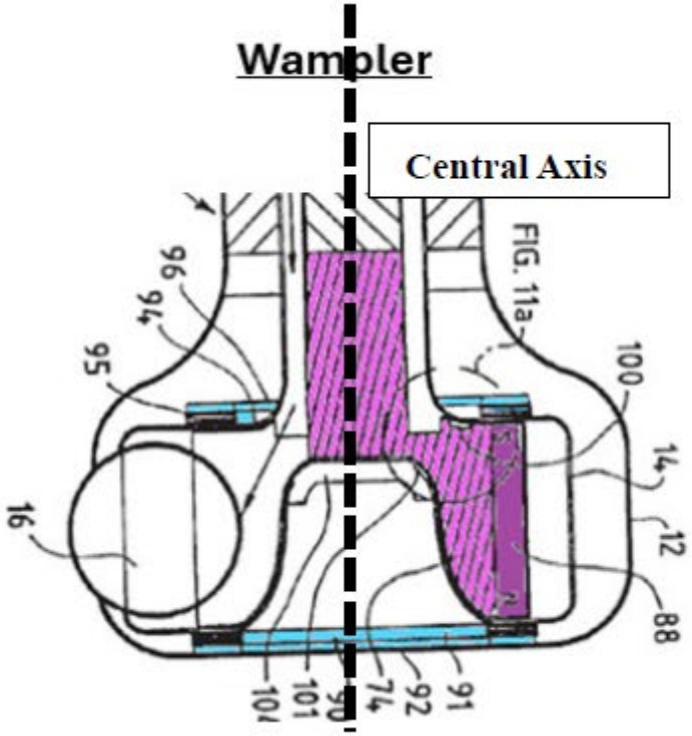


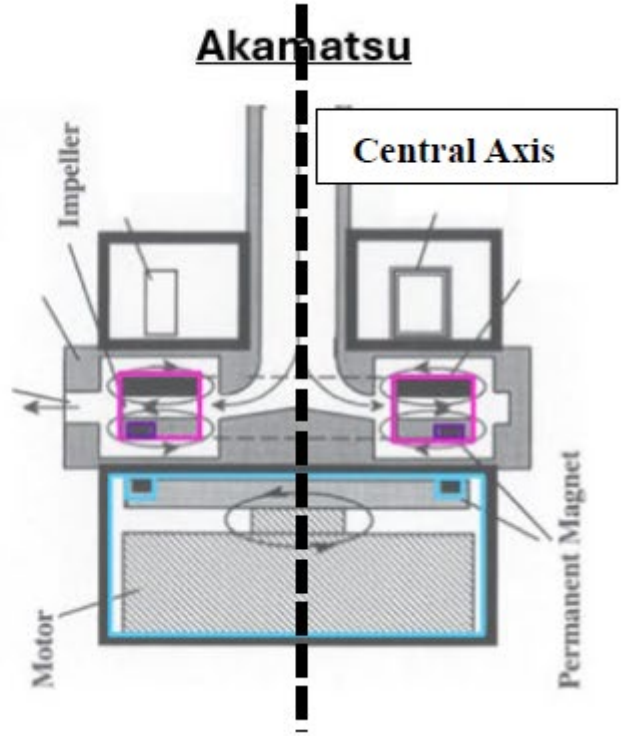
Fig. 2. Schematic cross section of the MSCP

"*Axially closer*" presents the same issue as "*axially adjacent*"

'879 Pet. Reply, 13







Roadmap

- ***Axially adjacent / axially closer***
  - Wampler and Akamatsu disclose both terms under PO's district court interpretation
  - **Wampler and Akamatsu also disclose both terms under PO's IPR interpretation**

Wampler teaches "*axially adjacent*" under any construction

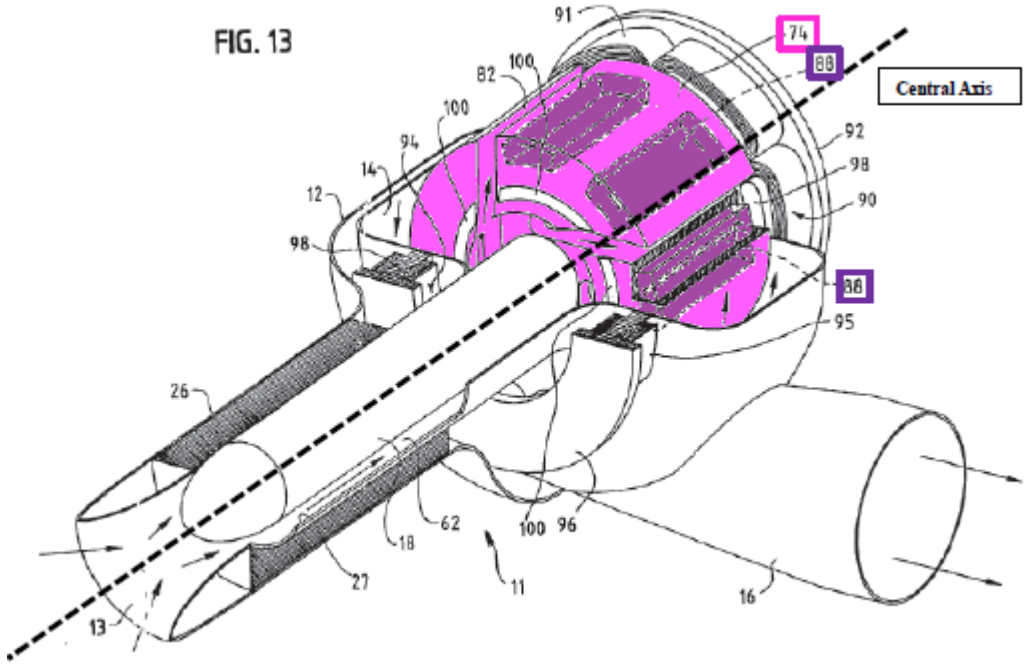
Under PO's IPR interpretation, Wampler's magnetic pieces touch and share side with impeller

POR, 14

The concept of "adjacent" components is clear from its plain and ordinary meaning. *Id.* at ¶ 82. Adjacent components along an axis have positioning next to one another, perhaps touching or sharing a common side, when measured along the axis. *Id.* This is distinct from components that are aligned with one another such

Ex.1040 (Leschinsky Tr.), 75:3-19

Q. Are [the magnetic pieces and rotor] in contact at at least one side?
A. Well, they are embedded, so **they clearly are in contact with the rotor** because they're inside it. ... **all sides of the -- of the magnetic pieces are in contact** with the internal volume of the rotor, I suppose.



Paper No. 22 (POR), 14; Paper No. 26 (Pet. Reply), 9-10.

Wampler teaches "*axially closer*" under any construction

Under PO's IPR interpretation, Wampler's second magnetic device is axially closer to the first magnetic device than to the impeller

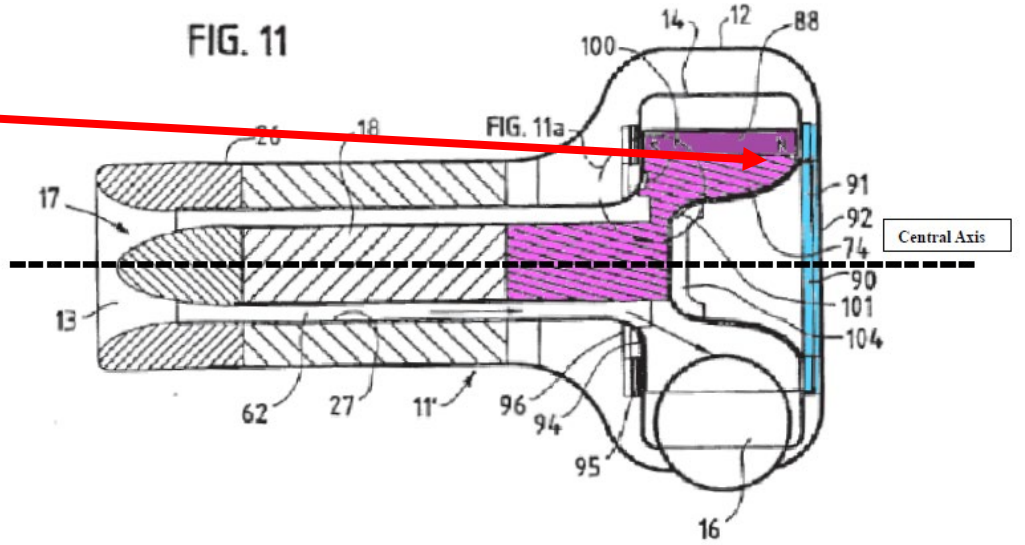
'357 POR, 9

Patent Owner contends that it is possible to rely on a distance defined by only a portion of a component but, if there are different portions of a first

'357 Pet. Reply, 10

Wampler also teaches or suggests this limitation under PO's construction from the POR. The "minimum distance" (POR, 9) between "motor stator 90" and "magnetic pieces 88" is "*axially closer*" than the minimum distance to the "impeller 74," which curves away from "motor stator 90":

'357 Pet. Reply, 11



Akamatsu teaches "*axially adjacent*" under any construction

Under PO's IPR interpretation, Akamatsu's permanent magnet touches and shares side with impeller

POR, 14

The concept of "adjacent" components is clear from its plain and ordinary meaning. *Id.* at ¶ 82. Adjacent components along an axis have positioning next to one another, perhaps touching or sharing a common side, when measured along the axis. *Id.* This is distinct from components that are aligned with one another such

Ex.1040 (Leschinsky Tr.), 78:6-11

Q. So is the permanent magnet touching the impeller?

A. Well, it's the same answer as with the previous one where the permanent magnet is embedded in the impeller, so to that extent, **they're touching**.

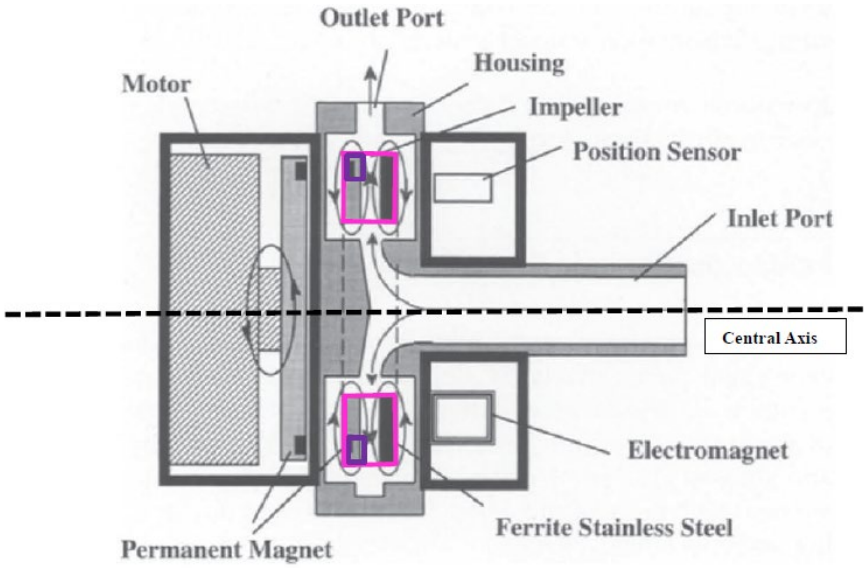


Fig. 2. Schematic cross section of the MSCP

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Paper No. 22 (POR), 14; Paper No. 26 (Pet. Reply), 29-30.

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	**Rotor positioned outside a ventricle of a heart (all claims)**	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	**Rotor remains entirely spaced apart (all claims)**	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Claims require a "*rotor … positioned outside the ventricle of the heart*"

Ex.1001 (356 Patent), claim 1

1. A method for assisting the blood circulation of a heart in a body, comprising:
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 while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart,

Patent	Claim Limitation
356 Patent	1B
357 Patent	n/a
415 Patent	1B
879 Patent	n/a
517 Patent	1B
077 Patent	1B

E.g., Paper No. 1 (Pet.), 17.

PO argues that Petitioner mixes Wampler's first and second embodiments

POR, 15

2. **Ground 1 Impermissibly Mixes Teachings From Distinct Embodiments Without A Supporting Rationale**

Petitioner impermissibly selects features from distinct embodiments in Wampler without providing any analysis regarding *why* they would have been combined in the contended manner. In *Abiomed, Inc. v. Maquet Cardiovascular,*

POR, 16

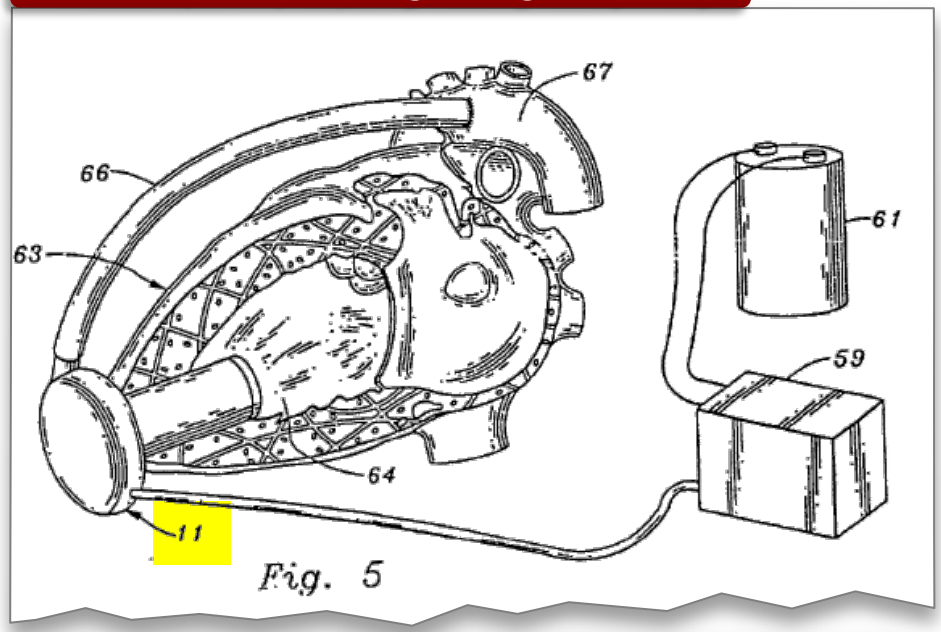
Further, Petitioner's expert has admitted that Wampler discloses multiple distinct embodiments of a pump. Ex. 2014 at 34–35. ***Petitioner's expert also contends that he relies only on one of these embodiments, i.e., the embodiment shown in FIGS. 11 et seq.*** *Id.* But this is clearly not the case because Petitioner and its expert rely on teachings from other figures (e.g., FIG. 5) showing a different embodiment (i.e., the embodiment of FIGS. 1–8), though there is no discussion of why such teachings can be combined.

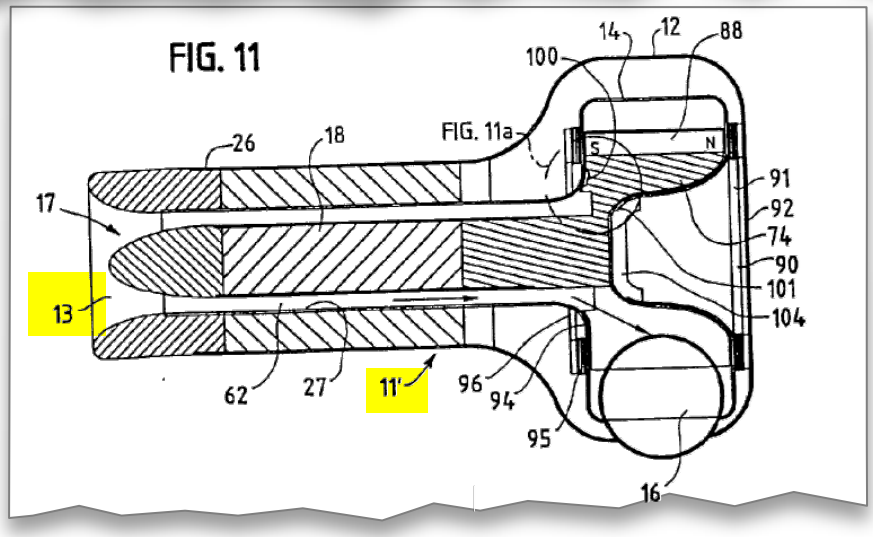
Paper No. 22 (POR), 15-16.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitioner relies only on Wampler's second embodiment

Ex.1008 (Wampler), Fig. 5; Fig. 11, [0080]





Ex.1008 (Wampler), [0080]

Referring to **FIGS. 11, 11*a*, 12, 13** and **14**, the blood pump **11'** shown therein is similar in many respects to blood pump **11** illustrated in FIGS. **1-8**, and includes housing **12** having an elongated inlet tube **13** and a scroll-shaped impeller casing or volute **14**. A discharge tube **16** extends through the housing to communicate with the interior periphery of casing **14**. Tube **16** has a tangential orientation with respect to a radius of the casing, for effectively channeling the blood output from the pump.

Ex.1040 (Leschinsky Tr.), 132:8-133:8

"And the shape of the pump, broadly speaking, at least in the portion that goes into the ventricle is similar [between pump 11 and pump 11']."

No proof of motivation is required because Petitioner is not combining embodiments

***Philip Morris Prods., S.A. v. RAI Strategic Holdings, Inc.*, IPR2020-00921, Paper 32 at 27, 34, n.14 (PTAB June 30, 2022)**

Although Patent Owner is correct that proof of motivation is required when **combining multiple embodiments from a single reference** (PO Resp. 31, 42 (citing *Stepan*, 868 F.3d at 1345–46 n.1)), that **is not what Petitioner is doing here**. As discussed above, Morgan teaches alternative heating element arrangements for a smoking article. Ex. 1005, 3:28–37, 5:6–25, 6:23–62, Figs. 2–8. **No proof of motivation is required** for combining any of Morgan's heating element arrangements with the rest of the smoking article **because Morgan expressly teaches those combinations**.

...

Our finding is based on Morgan's description of Figures 7 and 8 and the figures themselves, including Morgan's **use of the same names and reference numerals to identify features that are common** to embodiment 10 in Figures 1–4 and embodiment 70 in Figures 7 and 8. For example, in both cases, Morgan refers to cavity 30 and disposable portion 21.

Paper No. 26 (Pet. Reply), 10-11, 13

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Wampler's second embodiment also teaches disputed elements [1M], [1N], and [1O]

Ex.1001 (356 Patent), claim 1

cally driven rotor, 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

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, the external control unit being positioned exterior to the body while the inflow tube of the heart assist pump device is in the heart.

Patent	Claim Limitation
356 Patent	[1M], [1N], and [1O]
357 Patent	[1L] and [1M]
415 Patent	[1L], [1M], [1N], and [1O]
879 Patent	[1I], [1J], [11J], and [11K]
517 Patent	[1L], [1M], [21J], [21K], and [21L]
077 Patent	[1K], [1L], [1M], [16L], [16M], [16N]

E.g., Paper No. 1 (Pet.), 37-41.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	**a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)**	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Claims require a "*suction end of an inflow tube … inserted into a ventricle of the heart*"

Ex.1001 (356 Patent), claim 1

1. A method for assisting the blood circulation of a heart in a body, comprising:

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 while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart,

Patent	Claim Limitation
356 Patent	**[1A]**
357 Patent	n/a
415 Patent	**[1A]**
879 Patent	n/a
517 Patent	n/a
077 Patent	n/a

E.g., Paper No. 1 (Pet.), 16-17.

Akamatsu teaches [1A]—*"a suction end of an inflow tube … is inserted into a ventricle of the heart"*

Pet. Reply, 28
(citing Ex.1006 (Akamatsu), Fig. 1 (annotated))

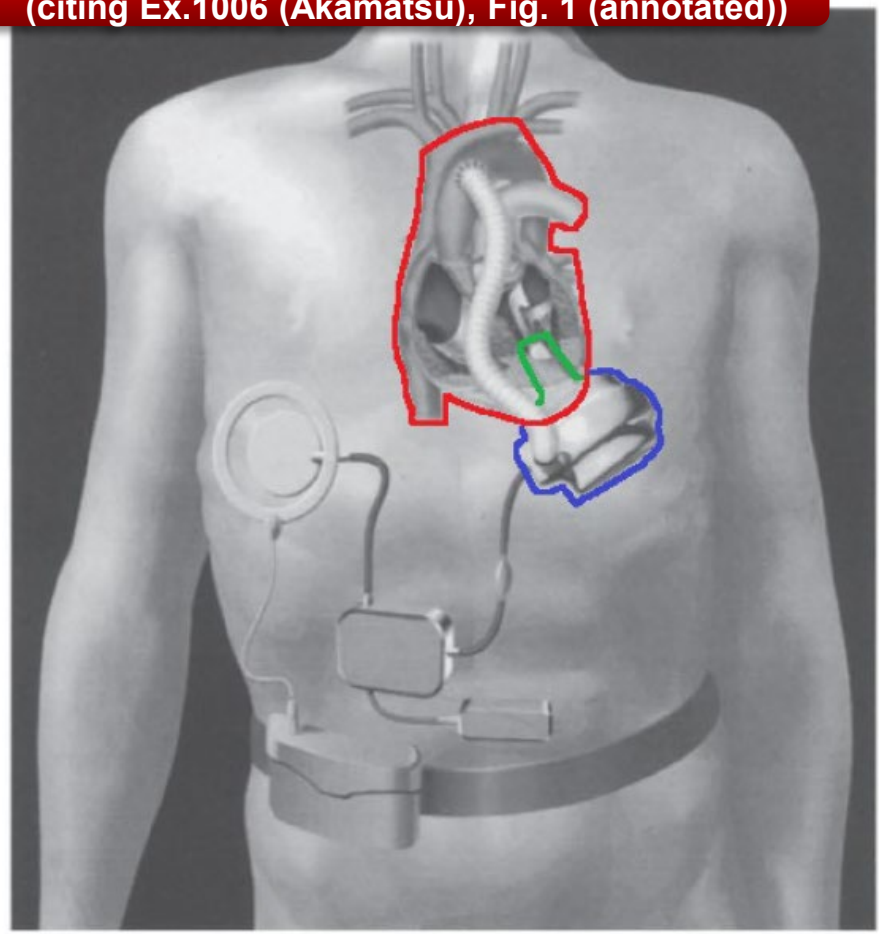


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006 (Akamatsu), 3-4

Intrathoracic implantation of the MSCP

The Model II and modified Model II pumps were intrathoracically implanted in sheep 4 (45 kg) and sheep 5 (80 kg). The pump was percutaneously driven. The surgical proce-

operate for more than 2 years in ex vivo animal model. In vivo evaluation using intrathoracic implantation of Model II demonstrated excellent anatomical fit in a small animal weighing 45 kg. All experiments in animals with the Model

Paper No. 1 (Pet.), 89-91; Paper No. 26 (Pet. Reply), 28.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	**an external control unit (all claims)**	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	**An external control unit … while an inflow tube is in a heart (all claims)**	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Claims require "*an external control unit*" and an "*inflow tube … in the heart*"

Ex.1001 (356 Patent), claim 1

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, the external control unit being positioned exterior to the body while the inflow tube of the heart assist pump device is in the heart.

Patent	Claim Limitation
356 Patent	[1N], [1O]
357 Patent	[1M]
415 Patent	[1M], [1N], [1O]
879 Patent	[1J], [11K]
517 Patent	[1M], [21L]
077 Patent	[1M], [16N]

E.g., Paper No. 1 (Pet.), 106-109.

Akamatsu teaches "*connecting an external control unit*"

Model II (external controller)

Ex.1006 (Akamatsu), Fig. 3

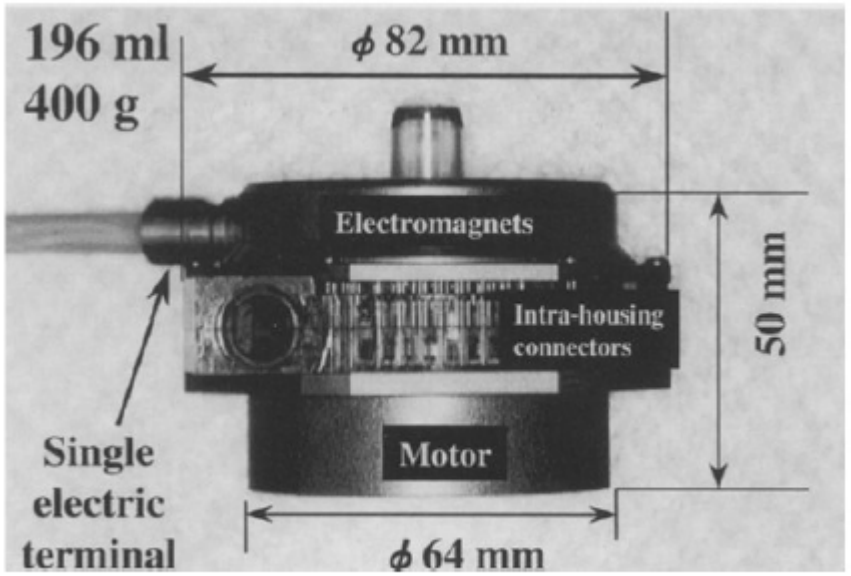


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Pet. Reply, 30

2007." Ex.1040, 130:9-12. And the fact "[t]he pump was percutaneously driven," demonstrates to a POSA that the that the controller was external. Ex.1003, ¶568.

Model III (implantable controller)

Pet., 107

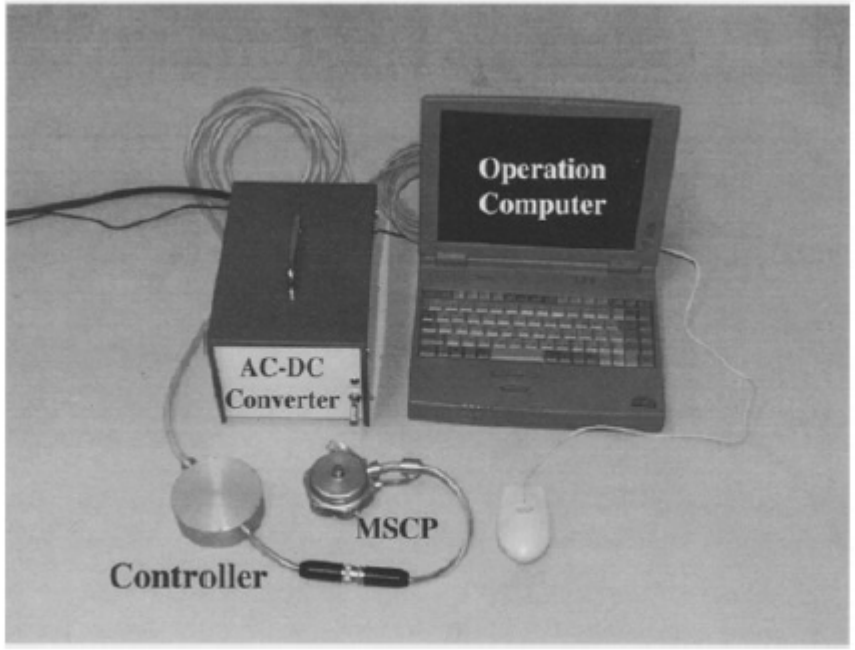


Fig. 7. Model III system with an implantable controller

For the next phase, we have developed the Model III system, consisting of a prototype MSCP with a sensorless motor and dual electric wires and an implantable controller 10mm in diameter and 39mm thick (Fig. 7). The input

Paper No. 1 (Pet.), 106-108; Paper No. 26 (Pet. Reply), 30.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		**a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)**
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Claims require a "*suction end of an inflow tube … inserted into a ventricle of the heart*"

Ex.1001 (356 Patent), claim 1

1. A method for assisting the blood circulation of a heart in a body, comprising:

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 while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart,

Patent	Claim Limitation
356 Patent	**[1A]**
357 Patent	n/a
415 Patent	**[1A]**
879 Patent	n/a
517 Patent	n/a
077 Patent	n/a

E.g., Paper No. 1 (Pet.), 115-18.

Schima/Akamatsu teaches "*delivering a heart assist pump device to the heart*"

Schima teaches an implantable LVAD

Ex.1005 (Schima), [004]-[008]

[0004] Therefore solutions have been suggested to provide pumps without axles or mechanical bearings. Thus Akamatsu et al (see e.g. *Artificial Organs* 1997, Vol. 21, No. 7, pp. 645-638) proposes a pump where the rotor of a centrifu-

[0005] Kung and Hart (*Artificial Organs* 1997, Vol. 21. No. 7, pp. 645-650) suggest a pump where the journaling is done purely hydraulically by a geometric distribution of

[0006] Furthermore, Allaire et al (see e.g. *Artificial Organs* 1996, Vol. 20, No. 7, pp. 582-690) suggest a centrifugal pump where the rotor is journaled by a relatively

[0007] Golding (U.S. Pat. Nos. 5,324,177 and 5,370,509) has in addition suggested floating a conical rotor with helical

[0008] Finally Woodward et al (WO 00/12587) proposes a pump whose rotor is hydrodynamically journaled, the rota-

Ex.1003 (Crosby I), ¶636

636. For example, Schima describes "overcoming" a number of existing heart assist pumps that were in development at the time. *See* Ex.1005, [0004], [0005], [0006], [0007], [0008]. Each of the heart assist pumps described in those publications were *delivered 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.*

Ex.1040 (Leschinsky Tr.), 207:5-8

Schima discloses various uses, including that of pumping blood … it **may be used as an LVAD**

Paper No. 26 (Pet. Reply), 31.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Schima/Akamatsu teaches "*delivering a heart assist pump device to the heart*"

Schima overcomes disadvantages with Akamatsu, but it could be implanted in the same way

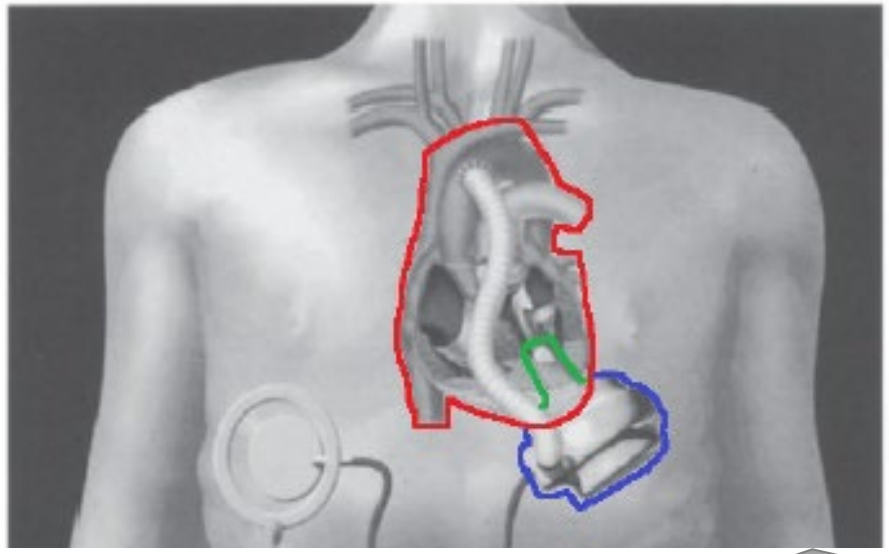
Ex.1005 (Schima), [004]

[0004] Therefore solutions have been suggested to provide pumps without axles or mechanical bearings. Thus Akamatsu et al (see e.g. *Artificial Organs* 1997, Vol. 21, No. 7, pp. 645-638) proposes a pump where the rotor of a centrifugal pump is driven from one side by a standard motor and is stabilized by a controlled electromagnet. This pump above all is of complex construction and there is a small gap between the rotor and the housing for proper electrical operation.

[0009] The present invention therefore has the object of overcoming these disadvantages. Mechanical depositions, dead-water zones or zones of reduced flow velocity and small gaps are to be avoided. The number of parts should be small and the construction simple.

Pet., 117

In the Schima/Akamatsu combination, Schima's pump is "*deliver[ed]…to the heart*" so that its inlet 13 is "inserted into the left ventricle," as taught by Akamatsu-1999 (Ex. 1006, 4) and illustrated:



Paper No. 1 (Pet.), 115-17.

Schima/Akamatsu teaches "*delivering a heart assist pump device to the heart*"

PO argues that Schima resembles an extracorporeal pump but ignores its similarities to VentrAssist

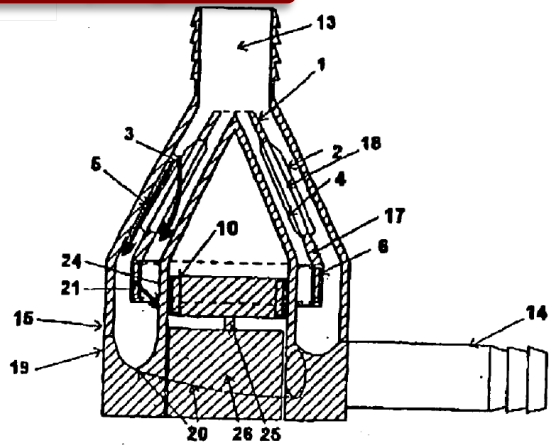
POR, 57-58

¶ 71. Even the illustrated connections of the inlet 13 and outlet 14 appear to be conventional barbed fittings configured for use with tubing and clamps to achieve a seal, rather than structures configured to interface with the heart or other anatomical structures. Leschinsky, ¶ 212; Gallegos, ¶ 78.

Ex.1042 (Crosby II), ¶98

as taught by Akamatsu, as I explained in my First Declaration. For example, both the VentrAssist and Schima have: fittings for connections to an inflow and outflow; a conical impeller and conical housing to facilitate hydrodynamic suspension of the impeller; an axial inflow and radial outflow of the pump, allowing for a 90 degree redirection of the blood without a flow-restrictive elbow fitting; magneto coupling drive (applying Mr. Leschinsky's definition); and other similarities. *Compare* Ex.2013, Figs 1-3 *with* Ex.1005, Fig. 2.

Ex.1005 (Schima), Fig 2



Ex.2013 (VentrAssist), Figs 1 & 3



DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Paper No. 26 (Pet. Reply), 31.

Schima/Akamatsu teaches these claim elements for the same reasons as Akamatsu

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	**an external control unit (all claims)**
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	**an external control unit (all claims)**	**An external control unit … while an inflow tube is in a heart (all claims)**
	An external control unit (all claims)	**An external control unit … while an inflow tube is in a heart (all claims)**	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	**Measurement values indicative of cardiac output (claim 5)**
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Claim 5 requires controlling the motor "*in response to measurement values indicative of cardiac output*"

Ex.1001 (356 Patent), claim 5

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.

Patent	Claim
356 Patent	**5**
357 Patent	n/a
415 Patent	n/a
879 Patent	**20**
517 Patent	**15**
077 Patent	n/a

Eg., Paper No. 1 (Pet.), 143.

Schima/Akamatsu teaches *"measurement values indicative of cardiac output"*

The pump's speed is measured and is indicative of cardiac output

Ex.1006 (Akamatsu), 2

animals were observed. The pump was operated at a fixed rotational speed. Model I was evaluated in one sheep and

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		**Feedback signals … from one or more sensors (claim 7)**

Claim 7 requires "*providing feedback signals to the external control unit from one or more sensors*"

Ex.1001 (356 Patent), claim 7

7. The method of claim 1, further comprising providing feedback signals to the external control unit from one or more sensors.

Patent	Claim
356 Patent	7
357 Patent	11
415 Patent	11
879 Patent	n/a
517 Patent	11, 33
077 Patent	7, 26

Eg., Paper No. 1 (Pet.), 144.

Schima/Akamatsu teaches "*providing feedback signals to … from one or more sensors*"

Schima/Akamatsu uses sensors to provide feedback signals

Ex.1006 (Akamatsu), 3

the three electromagnets. The electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing. Up to now, we have devised three prototype

Ex.1006 (Akamatsu), 2

Model II in two sheep. Aortic pressure and pump flow rate were continuously measured throughout the experiments.

Paper No. 1 (Pet.), 144; Paper No. 26 (Pet. Reply), 32.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

No significance to dispute over definition of a POSA

- Petitioner proposed and the Board adopted:
  - "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**"

- PO proposed tailoring that definition to include:
  - "at least five years' experience designing and developing **implantable cardiac assist devices** in particular"

- PO no longer disputes whether Mr. Crosby meets the definition (Sur-Reply at 1)

Paper No. 33 (PO Sur-reply), 1.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitioner presented four grounds to address disputed claim constructions

Ex.1003 (Crosby I), ¶ 147

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

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

Paper No. 1 (Pet.), 9-100.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

No inconsistency in Petitioner's claim construction arguments

"magneto coupling"

ID, 21-22

In sum, Petitioner maintains a narrower construction of "magneto coupling" is correct, and alleges grounds of unpatentability based on both its narrower proposed construction (a construction encompassed by the broader construction), as well as based on the broader construction that Patent Owner does not dispute. We, therefore, find no merit to Patent Owner's argument that Petitioner's contention "contradicts itself" or fails to present a "*prima facie* obviousness position." *See* Prelim. Resp. 3. Patent Owner does not dispute the broader construction applied by Petitioner, which encompasses the narrower construction Petitioner proposes. For purposes of this Decision, we apply the broader construction of "magneto coupling," which encompasses generating a rotating field either by rotating magnets or by an electromagnet / stator.

"by the blood flowing"

ID, 21-22

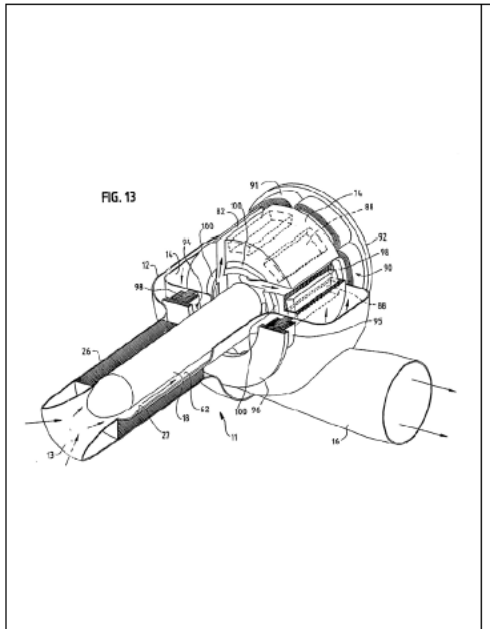
In sum, Petitioner maintains a narrower construction of the "by the blood flowing" claim language is correct, and alleges grounds of unpatentability based on both its narrower proposed construction (a construction encompassed by the broader construction), as well as based on the broader construction that Patent Owner does not dispute. We, therefore, find no merit to Patent Owner's argument that Petitioner's contention "contradicts itself" or fails to present a "*prima facie* obviousness position." *See* Prelim. Resp. 4–5. Patent Owner does not dispute the broader construction proposed by Petitioner, which encompasses the narrower construction. For purposes of this Decision, we apply the broader construction of the "by the blood flowing" claim language, which encompasses both a hydrodynamic bearing and a magnetic bearing.

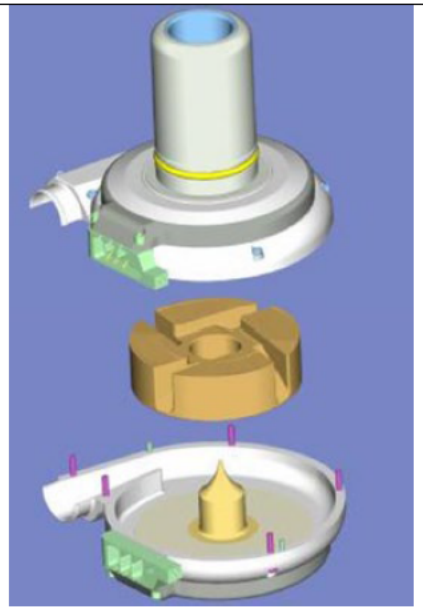
E.g., Paper No. 15 (ID), 21-22.

PO argues that the Wampler and HVAD pumps are different

PO Sur-Reply, 19-20

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:

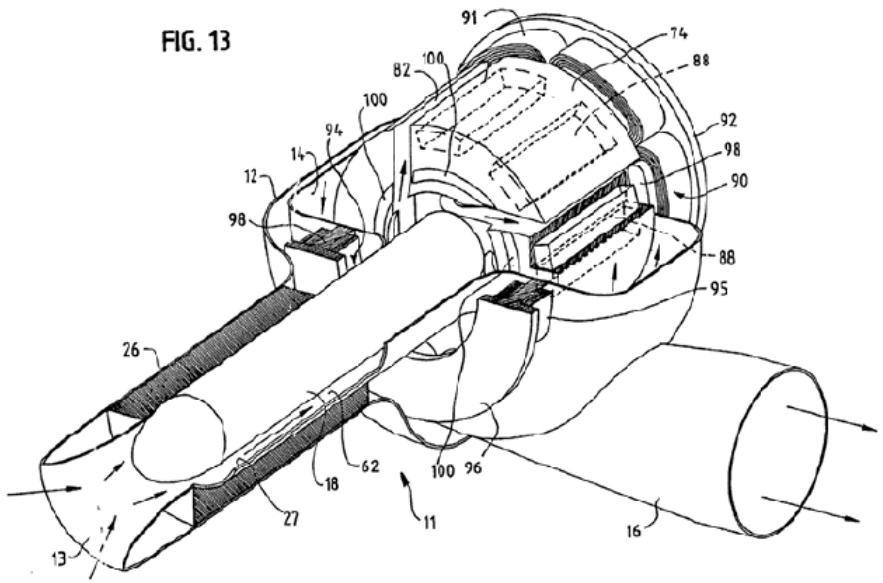




No dispute that the HVAD progressed from the Wampler design

Ex.1041 (Wieselthaler Dec.), ¶53

53. The development of the HeartWare HVAD progressed from the design disclosed in Wampler's Patent, shown below:



Ex.1045 (Gallegos Tr.), 103:25-104:6

Q. Yes. So to revisit that, do you agree that the HeartWare HVAD is a Wampler pump?
A: Yes, it's a pump that ultimately became known as HeartWare. ...

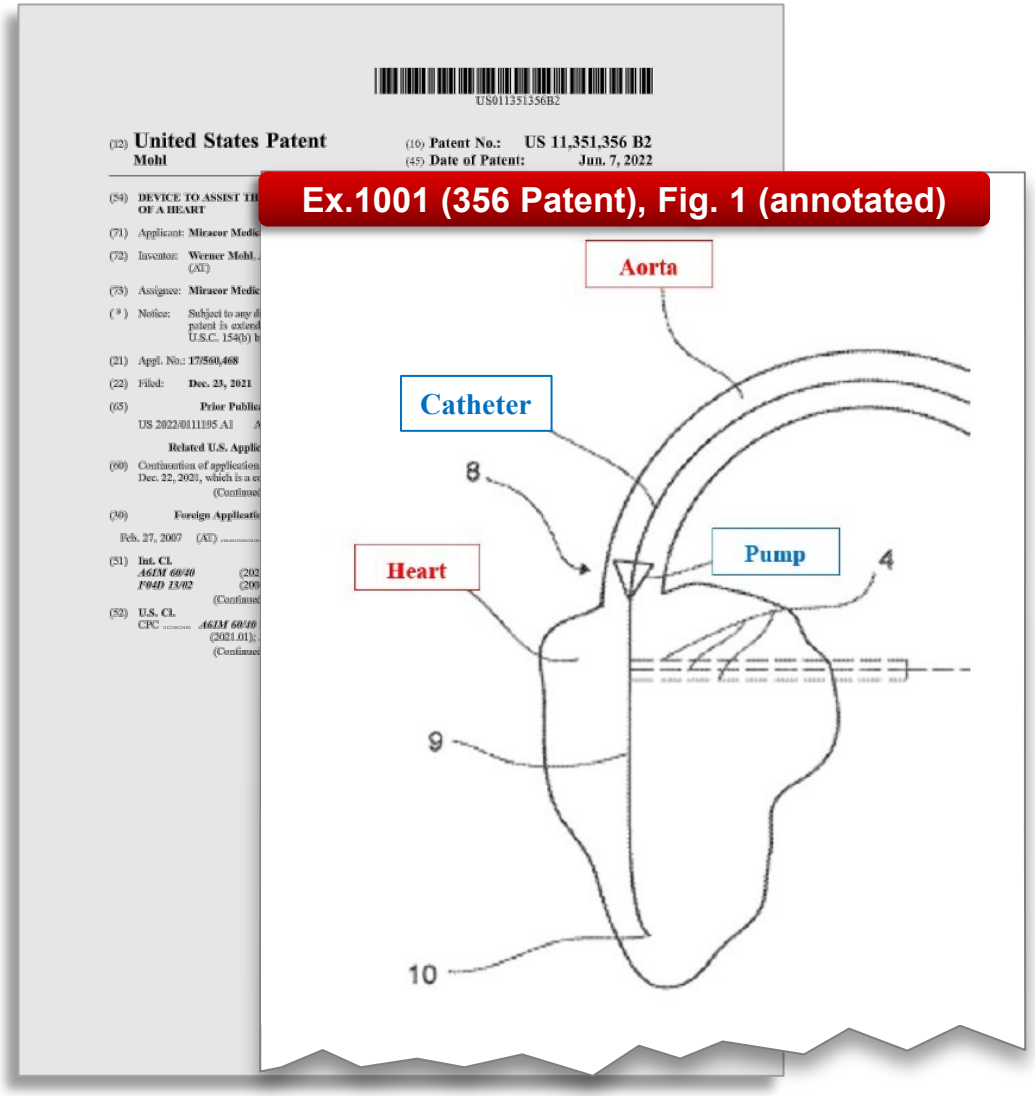
Ex.1042 (Crosby II), ¶61

Wampler's second embodiment (pump 11`) was developed into the HeartWare HVAD, which was clinically implanted in many patients before the priority date. Ex.1044.

Paper 26 (Pet. Reply), 13, 18-21

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

The shared specification is directed to a blood pump built around a "catheter"



ID, 3

was known. *Id.* at 1:65–2:4. The '356 patent describes a device that dispenses with the external blood pump and, instead, uses a heart ventricle catheter having, at its distal end, a fluid-driven rotary pump for improving blood circulation at a particular location. *Id.* at 2:23–42. The pump includes

Ex.2015 (Leschinsky Dec.), ¶51

example, in Paper 1, 1–3 and Ex. 1003 ¶¶ 30–36 and 40. It is true that the '356 patent discloses one embodiment of its "device to assist the performance of a heart" that is built around a catheter, but this is an example embodiment and would not have been understood by a POSA as limiting the scope of the disclosure or its claims. Ex. 1001, Title.

E.g., Paper No. 1 (Pet.), 1-2.

Not all Challenged Claims require a "*catheter;*" but they all allegedly cover LVADs

US011351356B2

(12) **United States Patent**
Mohl

(10) **Patent No.: US 11,351,356 B2**
(45) **Date of Patent: Jun. 7, 2022**

(54) **DEVICE TO ASSIST THE PERFORMANCE OF A HEART**

(58) **Field of Classification Search**
CPC .. A61M 60/40; A61M 60/405; A61M 60/148; A61M 60/135; A61M 60/422;
(Continued)

(71) Applicant: **Miracor Medical SA**, Awans (BE)

(72) Inventor: **Werner Mohl**, Altenmarkt-Thenneberg

(56) **References Cited**

Ex.1001 (356 Patent), claim 1 (no catheter required)

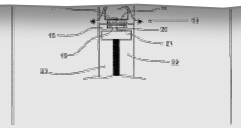
The invention claimed is:

1. A method for assisting the blood circulation of a heart in a body, comprising:

delivering a heart assist pump device to the heart so that

Ex.1001 (356 Patent), claim 13 (catheter required)

13. The method of claim **1**, wherein the heart assist pump device is a catheter device.

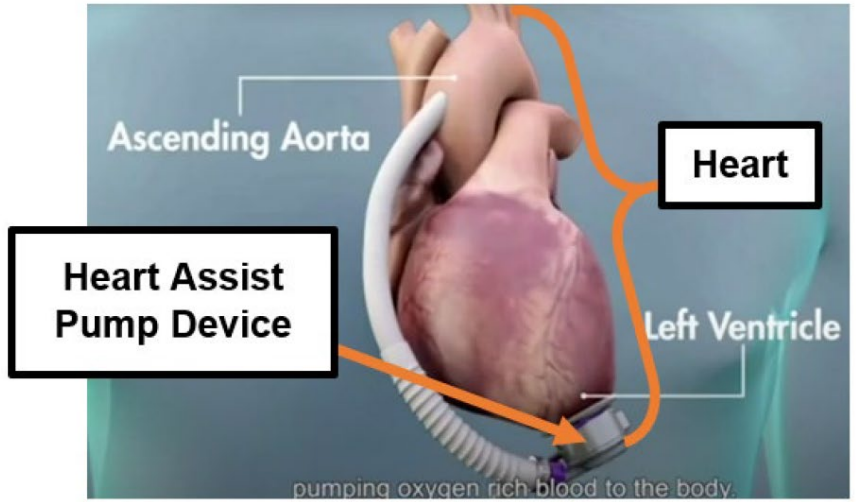


Abbott v. Miracor, IPR2025-00096
Abbott Ex. 1001, p. 1 of 9

PO Sur-reply, 5

New Exhibit 1036 is an infringement claim chart showing how Abbott's current product infringes claim 1. Addressing the specific claim language at issue

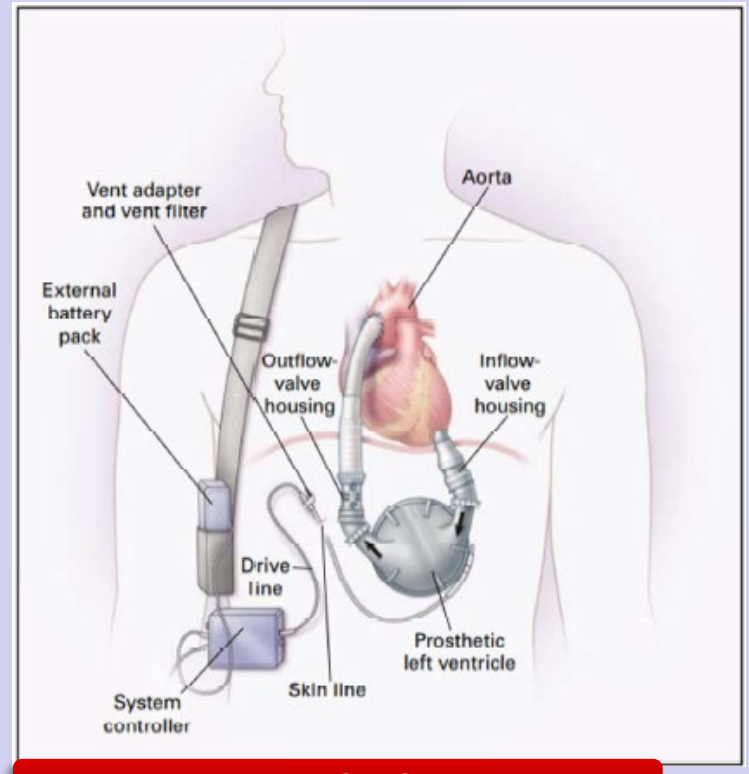
Ex. 1036 (Miracor ICs)



E.g., Paper No. 1 (Pet.), 1-2.

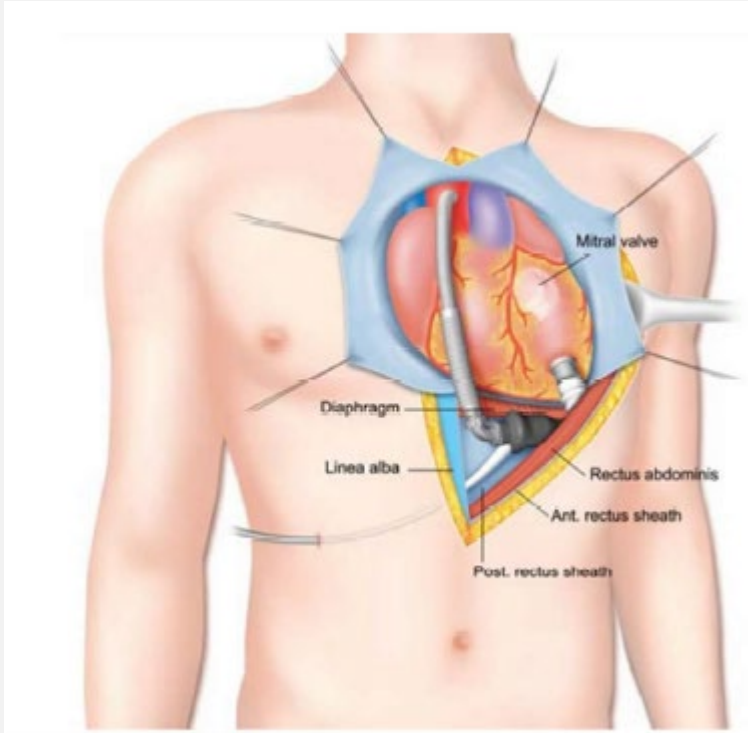
Prior art 3rd–generations LVADs used magnets to eliminate mechanical bearings

1st Gen (pulsatile)



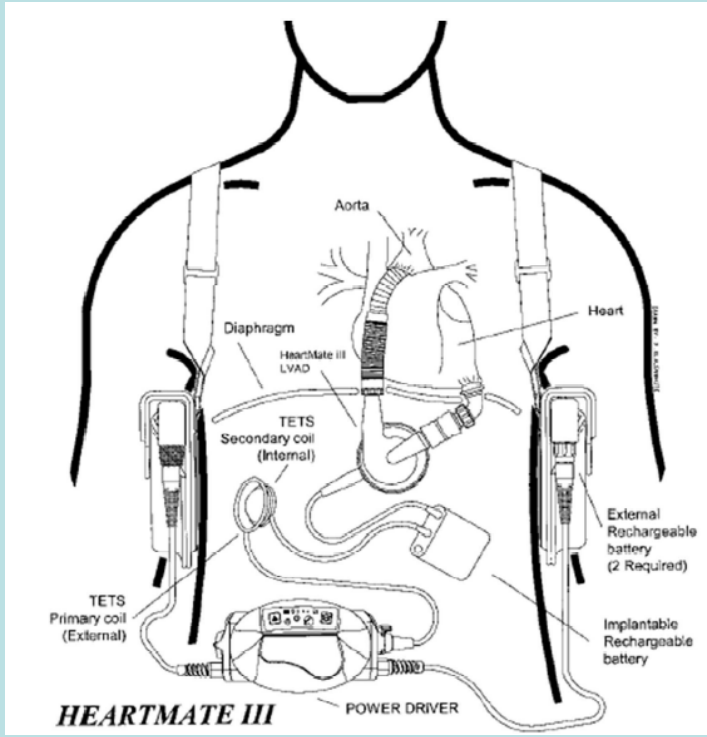
Ex.1012 (REMATCH Study), Fig. 1

2nd Gen (mechanical bearings)



Ex.1013 (HeartMate II), 25

3rd Gen (no mechanical bearings)

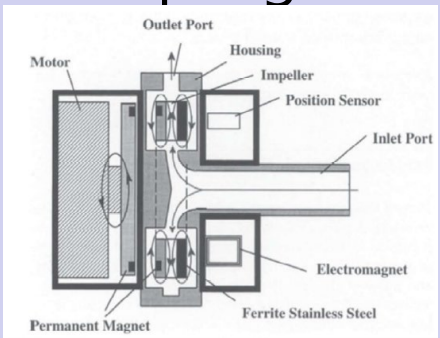


Ex.1007 (Bourque), Fig.3

LVADs used two different drive-types and two different bearing-types

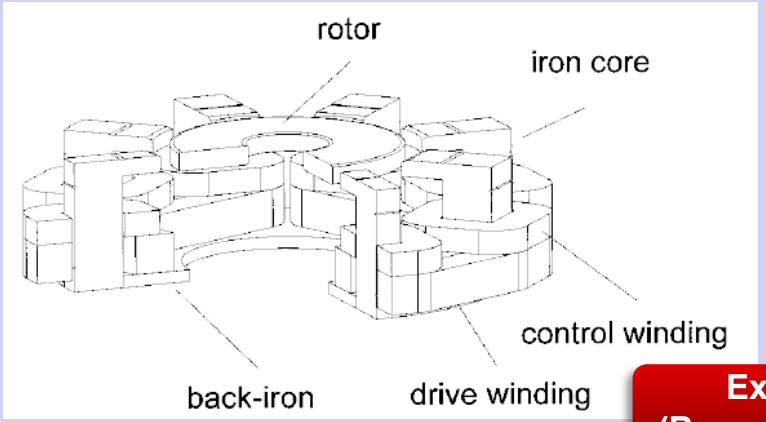
Drive-type

- Magnetic coupling:



Ex.1006 (Akamatsu), Fig.2

- Electromagnetic drive:



Ex.1007 (Bourque), Fig.4

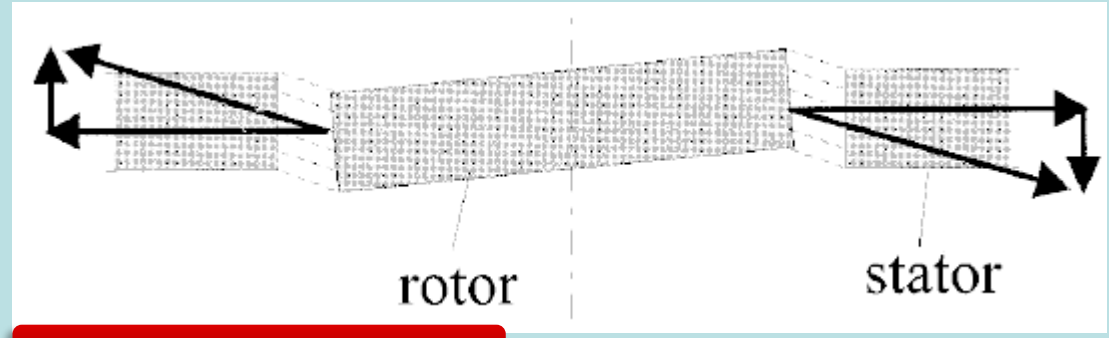
Bearing-type

- Hydrodynamic bearing:

> [0020] In certain embodiments, a plurality of hydrodynamic thrust bearings are located outside of the axis of rotation of the rotor. The hydrodynamic bearings are wedge-shaped and, during rotation of the rotor and impeller, the hydrodynamic bearings are separated from the casing by a fluid film and are not in direct mechanical contact with the casing.

Ex.1008 (Wampler), [0020]

- Magnetic bearing:



Ex.1007 (Bourque), Fig.5

E.g., Paper No. 1 (Pet.), 3; Ex.1003, ¶¶53-60

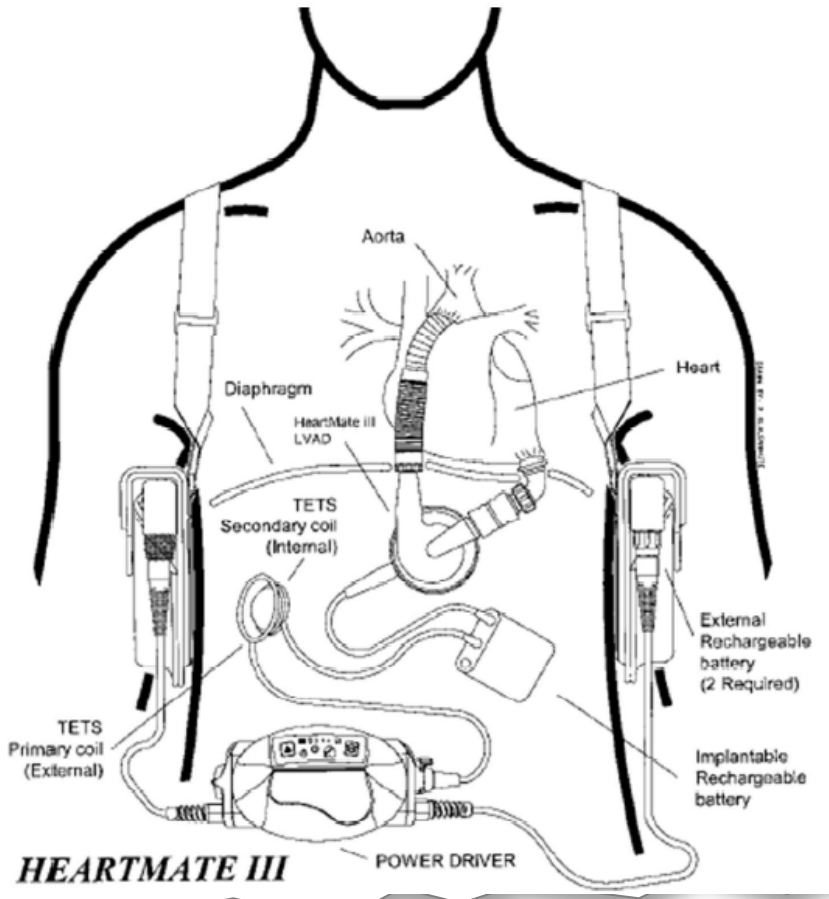
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Bourque uses the 1st and 2nd generation inflow/outflow components

Ex.1007 (Bourque), 5

Designing with access to the resources and infrastructure of established, FDA approved LVADs (*i.e.*, HeartMate) has afforded the wherewithal to develop the HeartMate III pump (*i.e.*, hydrodynamic elements) and peripheral hardware (*i.e.*, inflow and outflow components) concurrently, borrowing from the enormous clinical experience gained with presently available HeartMate systems. Although generally regarded as secondary in im-

Ex.1007 (Bourque), Fig. 3



E.g., Paper No. 1 (Pet.), 83-84.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Wampler uses the LVAD's centrifugal design to eliminate elbow components

Ex.1008 (Wampler), [0076]-[0076]

[0075] Anatomical placement of the pump **11** is shown in **FIG. 5**. The simplified representation of a human heart **63**, includes a left ventricle **64** and an aorta **67**. The inlet tube **16** serves as the inflow cannula and is placed into the apex of the left ventricle **64**. An arterial vascular graft **66** is connected on one end to tube **16** and on the other end to the aorta **67** through an end to side anastomosis.

[0076] The centrifugal design of the pump allows a considerable amount of flexibility during implantation. Owing to the axial inflow and radial outflow of the pump, a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting. Moreover, the pump can be rotated on its longitudinal axis to adjust the orientation of the discharge tube and minimize kinking and hydraulic losses in the vascular graft. Good 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 (Wampler), Fig. 5

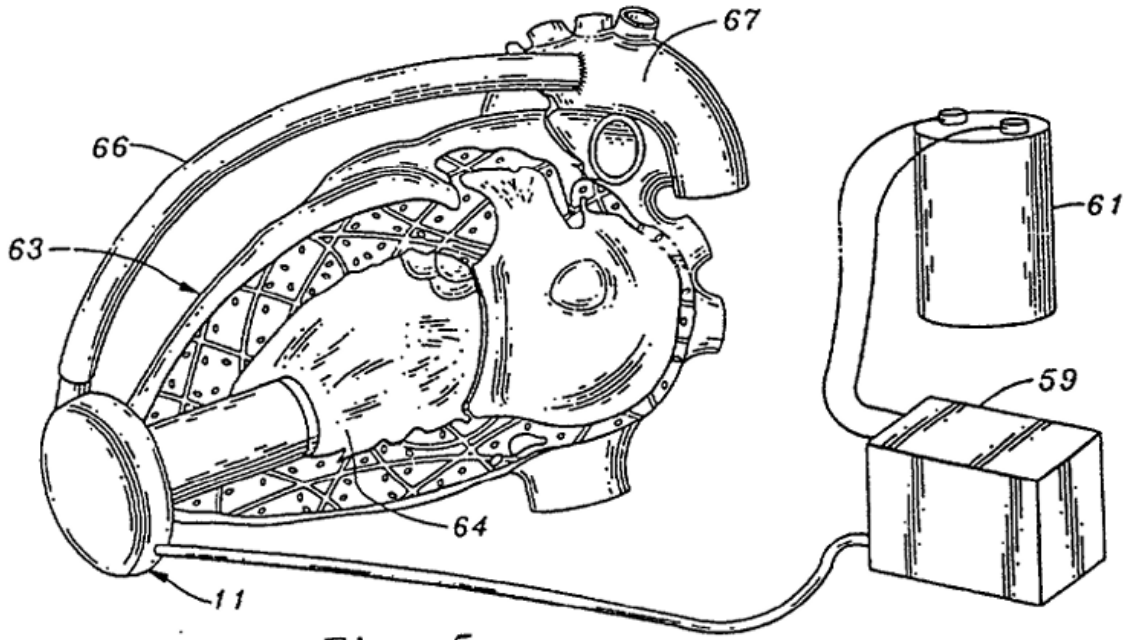


Fig. 5

E.g., Paper No. 1 (Pet.), 81-82.

Akamatsu similarly teaches implantation at the apex using an axial inflow

Ex.1006 (Akamatsu), 3

Intrathoracic implantation of the MSCP

The implantable Model II had a good anatomical fit in the chest cavity of a small sheep weighing 45 kg (sheep 4).

Ex.1006 (Akamatsu), 4

years. We have demonstrated that the Model I MSCP can operate for more than 2 years in ex vivo animal model. In vivo evaluation using intrathoracic implantation of Model II demonstrated excellent anatomical fit in a small animal weighing 45 kg. All experiments in animals with the Model

Ex.1006 (Akamatsu), Fig. 1

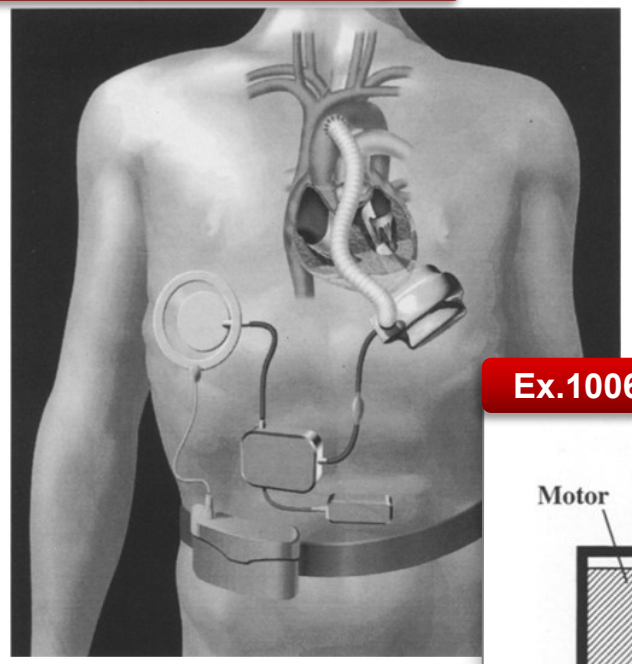


Fig. 1. Schematic illustration of the Terumo Implant
tricular Assist System (T-ILVAS)

Ex.1006 (Akamatsu), Fig. 2

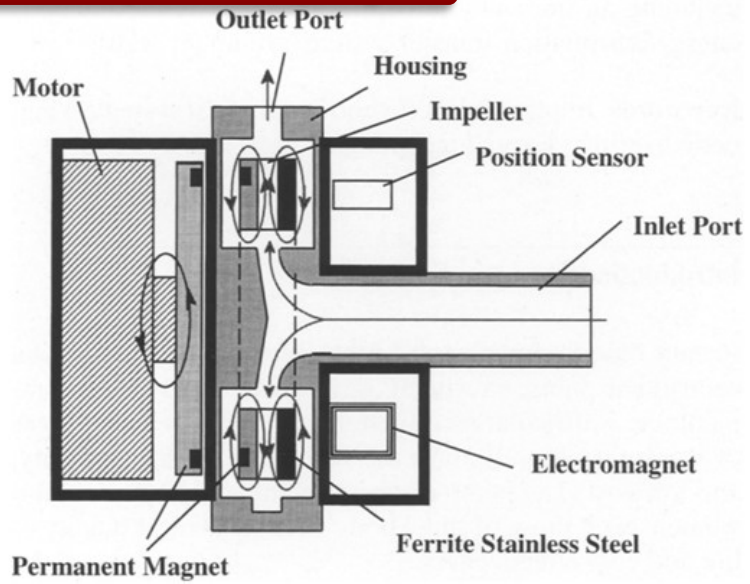


Fig. 2. Schematic cross section of the MSCP

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

E.g., Paper No. 26 (Pet. Reply), 25-26.

The Challenged Patents follow the design principles taught by Schima

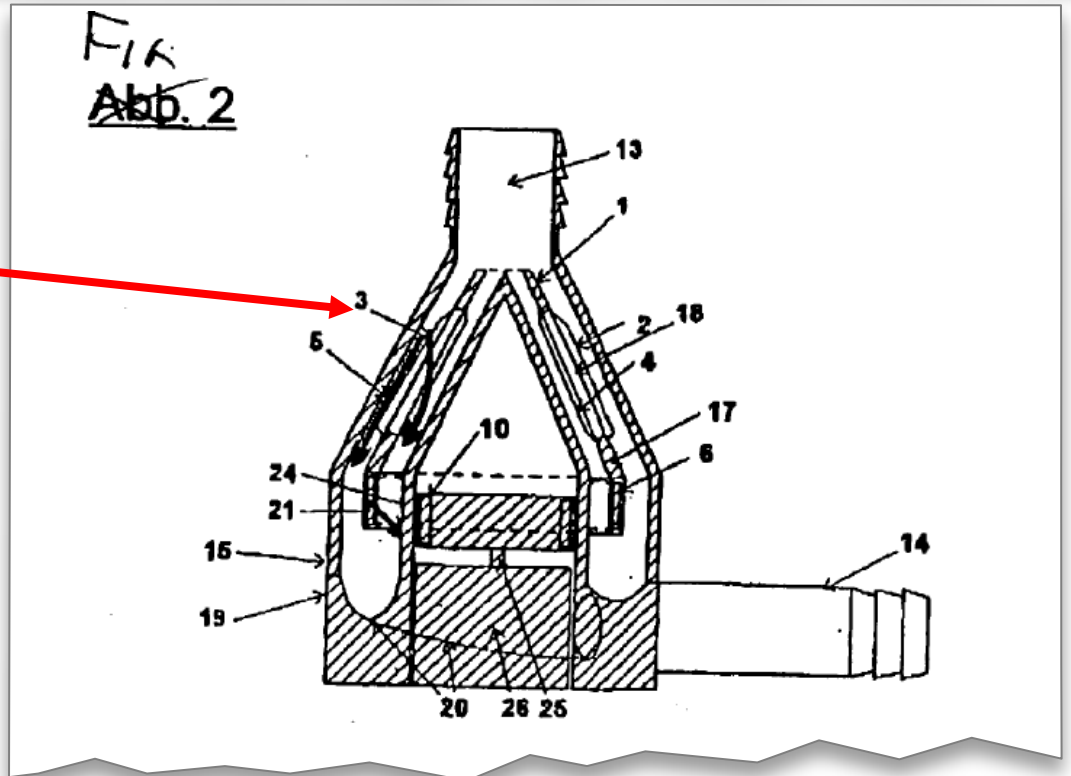
Ex.1001 (356 Patent), 3:17-36

The rotor itself can follow design principles such as described for example in WO 01/70300 A1. The rotary pump shown and described there for conveying blood and other highly sensitive fluids is formed as an external electromagnetically driven pump which is not directly suitable for incorporation into a catheter. The known design namely assumes that centrifugal flow components and flow components directed against a housing are present, in which the flow components directed against the housing serve primarily for the non-contact mounting and stabilizing of the rotor in the housing. However, with an arrangement of the rotor at the distal end of a catheter, a closed housing can not be readily realised with regard to flow technology, because such housing walls must in fact lie at a precisely defined distance from the rotor, which, however, is not readily guaranteed at the distal end of a catheter. However, for the desired conveying capacity with the axial pump according to the invention, provision is also made according to the invention that the rotor has guide surfaces to produce centrifugal flow components.

Ex.1005 (Schima), cover, Fig. 2

(19) **United States**
(12) **Patent Application Publication** (10) **Pub. No.: US 2003/0124007 A1**
Schima et al. (43) **Pub. Date: Jul. 3, 2003**

(86) PCT No.: **PCT/AT01/00086**



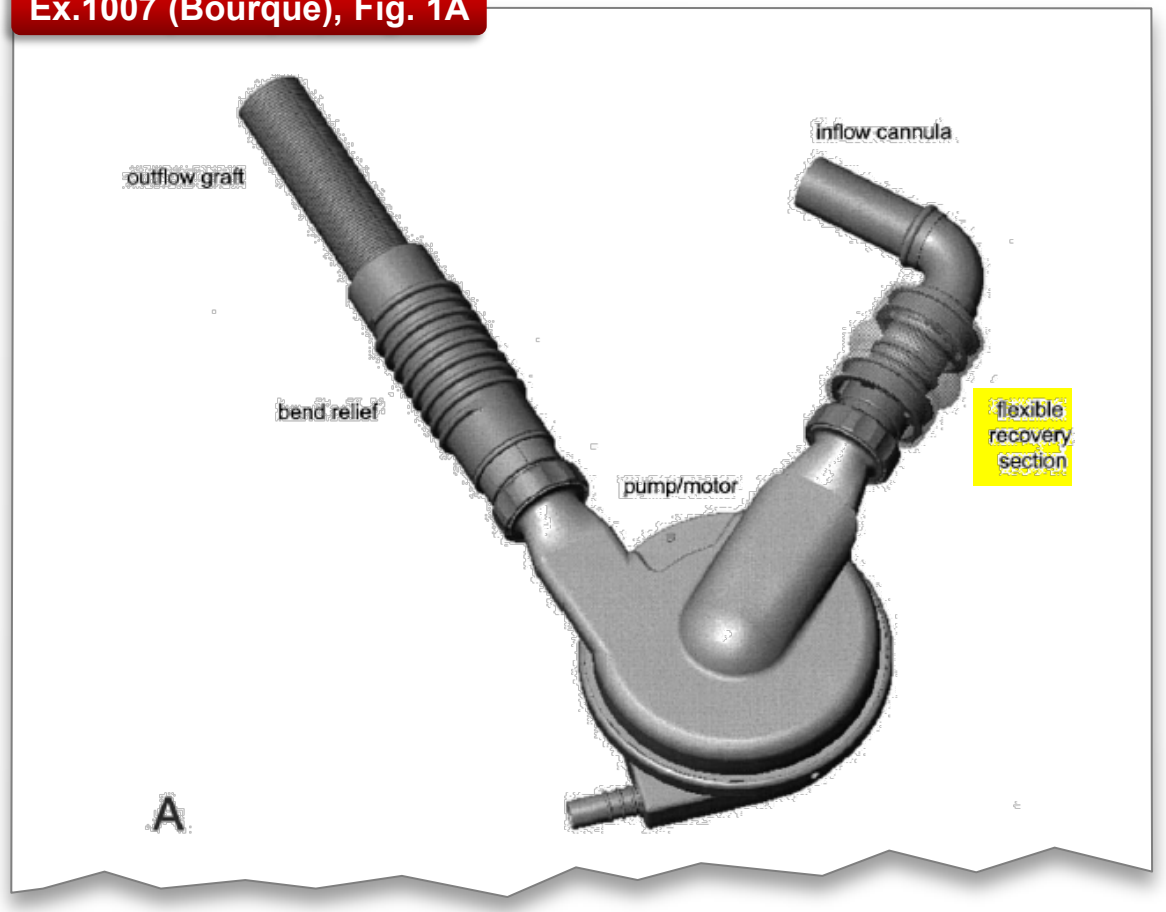
2. The combination would remove old hardware that caused "clinical troubles"

Ex.1007 (Bourque), 5

ligation available near the inflow cannula. In the HeartMate III, both of these requirements are met with a flexible "recovery section" between the pump and apical cannula (*i.e.*, in order that the pump can be removed, leaving behind the cannula).

Designing with access to the resources and infrastructure of established, FDA approved LVADs (*i.e.*, HeartMate) has afforded the wherewithal to develop the HeartMate III pump (*i.e.*, hydrodynamic elements) and peripheral hardware (*i.e.*, inflow and outflow components) concurrently, borrowing from the enormous clinical experience gained with presently available HeartMate systems. Although generally regarded as secondary in importance when setting out on a new pump design (compared to the primary purpose of "pumping"), items such as cannula, grafts, articulating mechanical joints, valves (if any), connectors, and cables can account for most of the propensity for clinical troubles when implanted. This is expected to be increasingly true as the

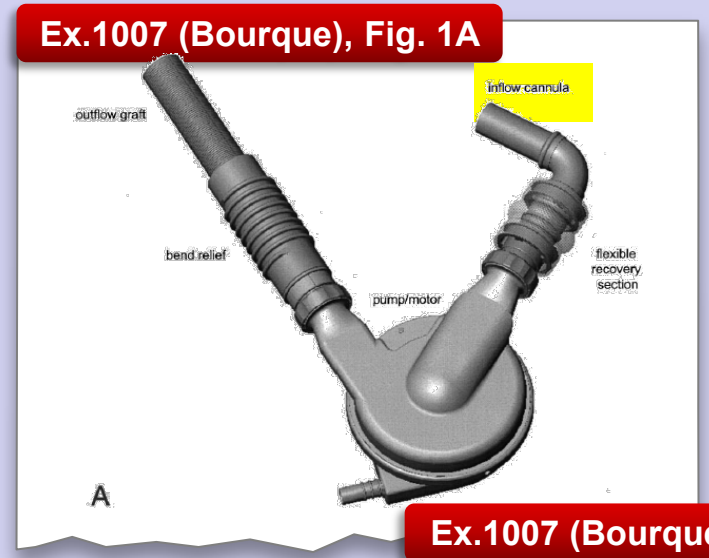
Ex.1007 (Bourque), Fig. 1A



3. Combining the analogous references would have been the arrangement of old elements

Bourque uses an "inflow cannula"

Ex.1007 (Bourque), Fig. 1A



Ex.1007 (Bourque), 5

Designing with access to the resources and infrastructure of established, FDA approved LVADs (*i.e.*, HeartMate) has afforded the wherewithal to develop the HeartMate III pump (*i.e.*, hydrodynamic elements) and peripheral hardware (*i.e.*, inflow and outflow components) concurrently, borrowing from the enormous clinical experience gained with presently available HeartMate systems. Although generally regarded as secondary in importance when setting out on a new pump design (compared to the primary purpose of "pumping"), items such as cannula, grafts, articulating mechanical joints, valves (if any), connectors, and cables can account for most of the propensity for clinical troubles when implanted. This is expected to be increasingly true as the

Wampler's "inflow cannula" functions as the "inlet tube"

Ex.1008 (Wampler), [0076]-[0076]

[0075] Anatomical placement of the pump **11** is shown in **FIG. 5**. The simplified representation of a human heart **63**, includes a left ventricle **64** and an aorta **67**. The inlet tube **16** serves as the inflow cannula and is placed into the apex of the left ventricle **64**. An arterial vascular graft **66** is connected on one end to tube **16** and on the other end to the aorta **67** through an end to side anastomosis.

Ex.1008 (Wampler), Fig. 5

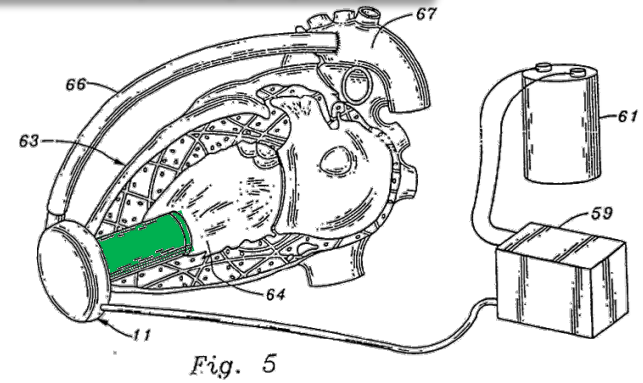


Fig. 5

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

4. Fitting the combination at the apex of the heart would reduce infection

Ex.1041 (Wieselthaler Dec.), ¶¶69-70

69. By 2007, instead of designing a pump to borrow parts from the predecessor HeartMate systems, a POSITA would have prioritized "[g]ood anatomic compatibility," as taught by Wampler, 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. Ex.1008, [0076].

therefore, they needed a large space for pre- or intraperitoneal implantation. The large wound created led to an increased risk of bleeding and infections with subsequently increased morbidity." Ex. 1050, 1 (cleaned up). With the transition to continuous-flow technology, LVADs featured significant miniaturization. These devices had "smaller artificial surface" and "smaller weight and size" compared to the earlier generation devices, and allowed for the first time implantation into the chest. Ex. 1050, 2 (cleaned up).

Paper No. 26 (Pet. Reply), 2, 20-21

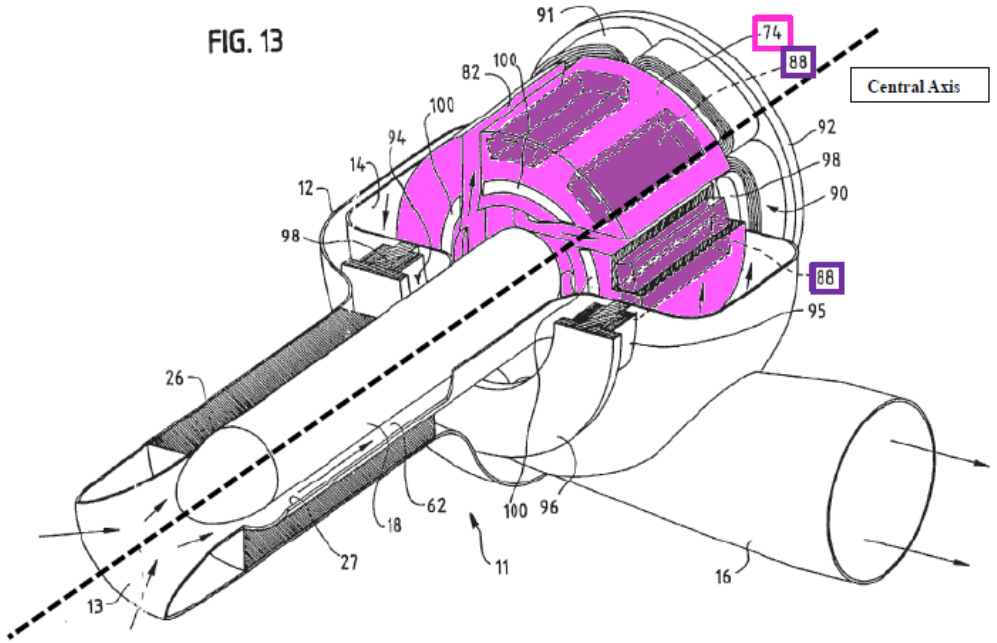
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

To avoid invalidity, PO asserts that "*axially adjacent*" cannot include components that overlap or occupy the same portion of an axis

POR, 14-15

Accordingly, Wampler cannot teach or suggest a first magnetic device that is at a position axially adjacent to a magnetically driven rotor based on the positioning of its magnet segments 88 and impeller 74 because these components are not adjacent to one another as measured along the central axis of the device. Instead, the magnet segments 88 and impeller 74 are aligned with, and overlap, one another as measured along the central axis based on the disclosed configuration where the magnet segments are housed within the impeller blades. *See* Ex. 1008,

Pet., Reply, 9-10



To avoid invalidity, PO asserts that "*axially adjacent*" cannot include components that overlap or occupy the same portion of an axis

POR, 52

Accordingly, Akamatsu cannot teach or suggest a first magnetic device that is at a position axially adjacent to a magnetically driven rotor based on the positioning of its permanent magnets and impeller because these components are not adjacent to one another as measured along the central axis of the device. Instead, the permanent magnets and impeller are aligned with, and overlap, one another as measured along the central axis based on the disclosed configuration.

Ex.1006 (Akamatsu), Fig. 2

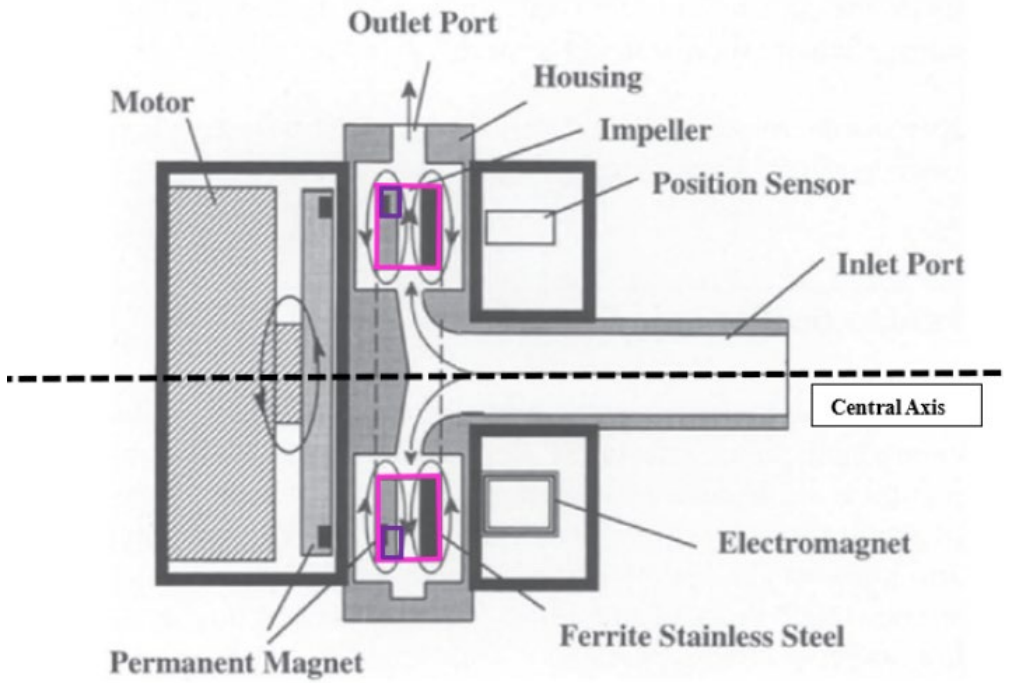


Fig. 2. Schematic cross section of the MSCP

Paper No. 22 (POR), 52; Paper No. 26 (Pet. Reply), 29-30.

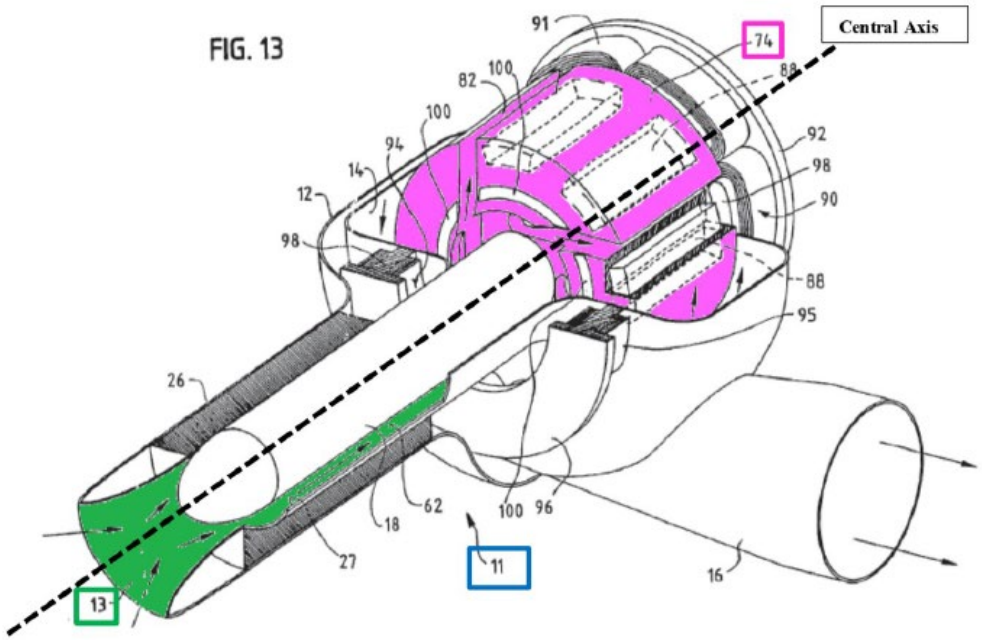
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	**Rotor positioned outside a ventricle of a heart (all claims)**	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	Rotor remains entirely spaced apart (all claims)	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

Wampler teaches a "*rotor … positioned outside the ventricle of the heart*"

Pet., 19



Pet., 18

Ex.1008, Fig. 13; Ex.1003, ¶163; *see also id.*, ¶¶159, 162. As demonstrated in [1A], inlet 13 "is placed into the apex" while the "disc-shaped" portion of the pump, including its **impeller**, fit between the heart and diaphragm ("*positioned outside the ventricle*"). *Supra* [1A].

Wampler teaches a "*rotor … positioned outside the ventricle of the heart*"

PO argues the rotor is not "*outside the heart*" because it includes both the impeller and the shaft

POR, 17-18

In addition, Petitioner selectively defines the rotor of Wampler in order to meet the [1B] recitation that the magnetically driven rotor is positioned outside the ventricle of the heart based on the illustrated positioning of the embodiment shown in FIG. 5. But Wampler defines its rotor 17 as including both the impeller 74 and a support shaft or spindle 18.

POR, 19-20

If the rotor 17 of Wampler includes the impeller 74 and shaft 18, the reference cannot teach or suggest a method that includes delivering a heart assist pump device to a heart so that a magnetically driven rotor of the device is positioned outside the ventricle of the heart. Comparing the FIG. 5 embodiment

Paper No. 22 (POR), 17-20.

Wampler teaches a "*rotor … positioned outside the ventricle of the heart*"

PO's argument ignores Wampler's description and contradicts its own patent specification

Pet. Reply, 13

PO also argues that "Petitioner selectively defines" Wampler's "impeller 74" as the claimed "*magnetically driven rotor*," and insists that it also "includes the [] shaft 18." POR, 17–19. But Wampler describes that its "impeller" is the "*magnetically driven*" element, not its rotor or shaft. Ex.1008, [0018] ("Torque drive is imparted to the impeller by magnetic interaction"); Ex.1042, ¶¶74-77. Leschinsky concedes that Wampler's impeller—not the shaft—is responsible for pumping the blood (Ex.1040, 119:20-120:10) and that it is *positioned outside the ventricle of the heart*.Ex.1040, 114:19-115:17. PO's argument that the rotor must include the shaft also contradicts its own patent specification, which contemplates that "a shaft" and "a rotor" are separate elements. Ex.1001, 4:50-53 ("a shaft 17 with a rotor 18").

Ex.1008 (Wampler), [0018]

[0018] The thick impeller blades are also used advantageously to house magnets used in the pump drive system. Torque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing. Back-EMF

Ex.1001 (356 Patent), 4:50-53

respectively arranged. The bar magnet **16** is connected here at the distal end outwards via a shaft **17** with a rotor **18**, whereas the bar magnet **19** lying on the inside is connected via a shaft **20** with a drive wheel **21**. The drive wheel **21** is

Paper No. 26 (Pet. Reply), 13.

Overview of disputed claim elements

Ground 2 (Bourque/Wampler)	Ground 1 (Wampler)	Ground 3 (Akamatsu)	Ground 4 (Schima/Akamatsu)
Axially aligned (all claims)	Axially adjacent / axially closer (all claims)		a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)
Measurement values indicative of cardiac output (claim 5)	Rotor positioned outside a ventricle of a heart (all claims)	a suction end of an inflow tube … is inserted into a ventricle of the heart (all claims)	an external control unit (all claims)
Feedback signals … from one or more sensors (claim 7)	**Rotor remains entirely spaced apart (all claims)**	an external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)
	An external control unit (all claims)	An external control unit … while an inflow tube is in a heart (all claims)	Measurement values indicative of cardiac output (claim 5)
	An external control unit … while an inflow tube is in a heart (all claims)		Feedback signals … from one or more sensors (claim 7)

For [1M], [1N], and [1O], PO again argues Petitioner has mixed Wampler's embodiments

POR, 20

But, Petitioner relies on the embodiment of FIGS. 1–8 in Wampler to disclose various features where convenient, such as the implantation of the pump in a heart shown in FIG. 5. The embodiment of the pump shown in FIG. 5, however, includes thrust bearings 39 and 41 to maintain positioning of the rotor 17 relative to the housing 12. Ex. 1008, ¶¶ [0058]–[0062]. Given that the thrust

POR, 22

35. For element [1O], however, Petitioner cites to controller 59 and the implanted pump shown in FIG. 5 of Wampler, which shows components from the embodiment of FIGS. 1–8. Pet. at 40–41; Ex. 1008, ¶¶ [0070]–[0072].

POR, 21

the embodiment shown in FIG. 11. Ex. 2014 at 34–35. For element [1N], however, Petitioner cites to controller 59 shown in FIG. 5 of Wampler, which shows the controller in use with the pump embodiment of FIGS. 1–8. Pet. at 39–40; Ex. 1008, ¶¶ [0070]–[0072].

Paper No. 22 (POR), 20-22.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

For the same reasons, Wampler's second embodiment teaches [1M], [1N], and [1O]

Pet. Reply, 14

ii. [1M]

PO does not dispute that the Second Embodiment includes "hydrodynamic bearings [that] maintain the impeller entirely spaced apart from the casing 14," which discloses this claim element. POR, 20-21. Instead, PO incorrectly argues that "Petitioner relies on the [First Embodiment]," which "includes thrust bearings" that "involve contact with the rotor," and that Petitioner fails to explain why a POSA would "have substituted the various disclosed embodiments." POR, 20–21. But as explained above, the bearings (hydrodynamic vs. thrust) are presented as alternatives. PO's "First Embodiment" argument should be disregarded. *Supra* §IV.A.2.

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iii. [1N] and [1O]

Again, PO is wrong that there is "no disclosure in Wampler of the [Second Embodiment] coupled to the controller 59 of FIG. 5" and that Petitioner had to explain "why a POSA would have combined [] two embodiments disclosed in Wampler." POR, 21-22. The Second Embodiment is configured in the same manner as FIG. 5, including its connection to controller 59. *Supra* §IV.A.2. Moreover, Leschinsky conceded "any pump of that type would have a . . . controller" (Ex.1040, 198:16-23), and Wampler describes a controller "worn externally." Ex. 1008, [0070]; Ex.1042, ¶¶79-82.

Paper No. 26 (Pet. Reply), 14.

PO argues that Akamatsu is too big to fit at the apex, but apex placement is not required

PO Sur-reply, 15

> 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

***Axonics, Inc.*, 73 F.4th at 957**

> That context is not part of the Medtronic patents' claims. The proper inquiry is whether the relevant artisan would be motivated to make the combination to arrive at the claims' actual limitations, which are not limited to the trigeminal-nerve context.

Paper No. 33 (PO Sur-reply), 15.