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PATENT: 9,327,068, CLAIMS 10, 13-15, and 20

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TITLE: GUIDABLE INTRAVASCULAR BLOOD PUMP
AND RELATED METHODS

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**DECLARATION OF JOHN COLLINS REGARDING CLAIMS 10, 13-15,
AND 20 OF U.S. PATENT NO. 9,327,068**

I, John M. Collins, declare as follows:

1. My name is John M. Collins. My findings, as set forth herein, are based on my education and background in the fields discussed below. I am over 18 years of age. I have personal knowledge of the facts stated in this Declaration and could testify competently to them if asked to do so.

2. I am currently the Chief Operating Officer (“COO”) for the Consortia for Improving Medicine with Innovation and Technology (“CIMIT”). Founded by Massachusetts General Hospital, Brigham and Women’s Hospital, Charles Stark Draper Laboratory and Massachusetts Institute of Technology, CIMIT is a consortium of thirteen (13) of the greater Boston area’s premier clinical, research and academic institutions, including the Harvard Medical School and its teaching hospitals, along with a growing list of national and international affiliates. Its mission is to improve patient care by facilitating collaboration among clinicians, academics, engineers and entrepreneurs to catalyze the discovery, development and implementation of innovative technologies and procedures/systems that improve patient care. As COO, I am generally responsible for ensuring CIMIT’s “Finding, Funding and Facilitation” functions are effective and for facilitating teams of clinicians and engineers in the commercialization of technologies in the lab. I have worked at CIMIT since 2008.

3. Also since 2008, I have been the Chief Technology and Innovation Officer of Reed Collins LLC. In this role, I regularly provide technology, intellectual property, commercialization and business development consulting services for research teams, start-ups, and risk capital groups, as well as support some non-profits.

4. I received a B.S. (1980) in mechanical engineering from Rensselaer Polytechnic Institute in 1980, and an M.S. (1982) and Ph.D. (1988) in mechanical engineering from Massachusetts Institute of Technology (“MIT”). At MIT, I worked in the Fluids Lab under the direction of Professors Asher Shapiro and Roger Kamm. My academic work focused on mechanical engineering with a concentration on biomedical applications of fluid dynamics, including heat/mass transfer, with my Ph.D. and M.S. theses applying these principles to pulmonary dynamics. My M.S. thesis was on high frequency ventilation: at the time a novel way to ventilate babies without over-pressurization of the lung, avoiding damage to the lung during ventilator assist. My Ph.D. thesis was on experimental, analytical and numerical modeling of forced exhalation from the lung. The results were a computational model of the lung that allowed for more sophisticated diagnostics based on the results of the simple Forced Expiration Pulmonary Function (FEPF) test.

5. I have over 34 years of product design, development and consulting expertise covering a wide range of industry and products. Over that time, I have had a consistent focus on medical devices and technologies related to my particular expertise in design, fluid mechanics and heat/mass transfer. In addition to doing engineering work, including design and testing, my responsibilities have included assembling and managing teams to develop new consumer, industrial and medical products.

6. Prior to 2008, I held various positions at technology and product development companies. From 1982 to 1986, after receiving my M.S. degree at MIT, I worked at Booz, Allen & Hamilton, where I developed automotive, consumer, and industrial products. Examples include hydraulic systems for automotive anti-lock brakes and the Regina Rug Scrubber, which utilized a venturi sprayer to dispense a soap and water solution evenly over floor surfaces.

7. After taking time to return to MIT and complete my Ph.D. from 1986 to 1988, I was then employed by Arthur D. Little, Inc. (“ADL”) until 2002. I joined ADL as a design engineer and helped to form its medical products business. I progressed to being responsible for the Technology and Innovation (“T&I”) Directorate, with more than 250 staff. During my time at ADL, I worked on a number of medical products relating to the vascular system, including:

- cardiovascular stents and systems,

- scroll blood pumps,
- blood fluid warmers,
- ambulatory infusion pumps,
- neurological and vascular surgical navigation systems,
- end-end anastomosis devices,
- minimally invasive surgical vascular clip appliers, and
- vascular ligate and divide clip appliers.

8. From 2002 to 2008, I worked in close collaboration with CEO and owner, Dr. Kenan Sahin, to form TIAX LLC (“TIAX”) from the resources of ADL’s T&I Directorate. TIAX is a privately held technology transformation company focused on advancing and developing technologies for commercialization in several core technology areas, including clean energy and material, health and wellness (the health and wellness projects include vascular related devices such as neurovascular embolization coils, intraosseous infusion devices, and tourniquets, as well as other general medical devices such as ovulation diagnostics and breast cancer surgical margination diagnostics), appliances and HVAC systems, and enhanced security. During my tenure at TIAX, part of which I served as President, the World Economic Forum recognized TIAX as a Technology Pioneer in 2002 and as a New Champion in 2007.

9. I have experience as an innovator and inventor. I am a named inventor on more than 20 United States patents, in addition to foreign counterparts, on new products and manufacturing processes. Many of these patents are directed to technologies relating to medical devices including blood/fluid warmers. A copy of my latest *curriculum vitae* (CV) with additional details of my education, employment, patents and recent publications is attached as Appendix A.

10. I have previously served as a technical expert witness in numerous cases involving medical device technologies, including minimally invasive surgical instruments, trocars and seal mechanisms, surgical staplers laparoscopic insufflators, coronary and vascular stents, and temporal scanning thermometers. Below are representative cases I have submitted expert reports and/or testified either at trial or by deposition¹:

- **Johnson & Johnson Interventional Systems v. Cook, Inc.**, Docket No. IP95-1262-C-T/G (D. Ind. 1995)
- **Cordis Corporation.** v. Advanced Cardiovascular Systems (ACS), et al., Docket No. 97-550-SLR (D. Del. 1999)
- Medtronic AVE v. **Cordis Corporation**, Docket No. 99-833-SLR (D. Del. 2000)

¹ I submitted expert reports and/or testified on behalf of the parties in bold.

- **Cordis Corporation** v. Boston Scientific Corp., Docket No. 98-197-SLR (D. Del. 2000)
- Scimed v. **Johnson & Johnson**, Docket No. 99-904-SLR (D. Del. 2001)
- **Cordis Corp.** v. Boston Scientific Corp., Docket No. 03-27-SLR (D. Del. 2003)
- **Tyco Healthcare Group LP et al.** v. Applied Medical Resources Corp, Docket No. 9:09-cv-00176 (E.D. Tex. Oct 29, 2009)
- Applied Medical Resources Corporation v. **Tyco Healthcare Group LP**, Docket No. 2:11-cv-04203 (C.D. Cal. May 17, 2011)
- Stat Medical Devices Inc. v. **Canam Care LLC** et al., Docket No. 1:11-cv-00741 (D. Del. Aug 19, 2011)
- Applied Medical Resources Corporation v. **Tyco Healthcare Group LP**, Docket No. 8:11-cv-01406 (C.D. Cal. Sept 13, 2011)
- **Exergen Corporation** v. Brooklands Inc., Docket No. 1:12-cv-12243 (D. Mass. Dec 04, 2012)
- **Cooper Surgical, Inc.** v. Teleflex Medical Inc. et. al., Civil Action. No.13-CV-0240 (S.D.N.Y. Jan. 10, 2013)
- **Exergen Corporation** v. KAZ USA, Inc., Docket No. 1:13-cv-10628 (D. Mass. Mar 18, 2013)

- **Exergen Corporation** v. Thermomedics, Inc. et al., Docket No. 1:13-cv-11243 (D. Mass. May 21, 2013)
- **Fontem Ventures B.V.** et al. v. NJOY, Inc., Docket No. 2:14-cv-01645 (C.D. Cal. Mar 05, 2014)
- **NJOY, Inc.** vs. Fontem Holdings 1 B.V., Docket No. IPR2014-01289 (P.T.A.B. Aug. 14, 2014)
- **NJOY, Inc.** vs. Fontem Holdings 1 B.V., Docket No. IPR2014-01300 (P.T.A.B. Aug. 15, 2014)
- **DNA Genotek Inc.** v. Spectrum DNA et al., Docket No. 1:15-cv-00661 (D. Del. Jul 31, 2015)
- Ancestry.com DNA, LLC. v. **DNA Genotek, Inc.**, Inter Partes Review No. IPR2016-00060, Patent No. 8,221,381 B2 (PTAB Oct. 20, 2015)
- **Surgiquest, Inc.**, v. Lexicon Medical, LLC., No. 14-cv-0382–GMS (D. Del. Mar. 26, 2014)
- **Nu Mark LLC** v. Fontem Holdings 1, B.V., Inter Partes Review, PTAB-IPR2016-01773, Patent Nos. 9,320,300; 9,326,548; 9,326,549; 9,326,550; 9,326,551; 9,339,062; 9,364,027; 9,370,205 (PTAB Sept. 9, 2016)

- Samofi Aventis US LLC, et. al v. **Merck Sharp & Dohme Corp.**, No. 1:16-cv-812-RGA (D. Del. Sept. 16, 2016)
- **Abiomed, Inc., et. al.** v. Maquet Cardiovascular, LLC, Inter Partes Review, Patent Nos: 8,888,728; 9,327,068; 7,022,100 (March 11, 2017)
- **Abiomed, Inc., et. al.** v. Maquet Cardiovascular, LLC, Inter Partes Review, Patent Nos: 9,545,468; 9,561,314; 9,597,437 (March 11, 2017)

11. I have reviewed the specification, claims, and file history of U.S. Patent No. 9,327,068 (the “’068 Patent”). I understand that the ’068 Patent was filed on November 17, 2014, and the ’068 Patent claims priority to PCT Application No. PCT/US00/24515, filed on September 1, 2000, and U.S. Provisional Application No. 60/152,249 (the “’249 provisional application”), filed on September 3, 1999. For the reasons explained below, it is my opinion that the claims of the ’068 Patent are not supported by the ’249 provisional application. Accordingly, for the purposes of determining whether a patent or publication will qualify as prior art, based on my understanding of entitlement – or not – to a priority date based on the adequacy of disclosure of the alleged priority support, the earliest date that the ’068 Patent could be entitled to is September 1, 2000.

12. I have reviewed the following prior art publications:

- E.P. 0157859 (“Moise”)
- E.P. 0916359 (“Siess ’359”)
- D.E. 19821307 (“Sammler”)²
- PCT Pub. No. WO 99/02204 (“Aboul-Hosn”)
- PCT Pub. No. WO 97/037696 (“Rau”)³
- U.S. Patent 4,479,497 (“Fogarty”)
- U.S. Patent 4,625,712 (“Wampler ’712”)
- U.S. Patent 4,846,152 (“Wampler ’152”)
- U.S. Patent 5,061,273 (“Yock”)
- U.S. Patent 5,921,913 (“Siess”)
- U.S. Patent 6,544,216 (“Sammler ’216”)
- U.S. Patent 6,248,091 (“Voelker”)
- U.S. Patent 6,176,822 (“Nix”)
- U.S. Patent 6,849,068 (“Bagaoisan”)
- Spryidon D. Mouloupoulos, Stephen Topax & Willem J. Kloff,

Diastolic Balloon Pumping (with Carbon Dioxide) in the Aorta—A

² Sammler was originally published in German. Arguments below regarding Sammler are based on a certified translation of this document.

³ Rau was originally published in German. Arguments below regarding Rau are based on a certified translation of this document.

Mechanical Assistance to the Failing Circulation, 65 Am. Heart J. 669-75, Issue 5 (1962) (“Moulopoulos”)

- Pierce, W. S. et al., *Portable artificial heart systems*, ASAIO Journal 29.1: 757-59 (Apr. 1983) (“Pierce”)
- R. Wampler et al., *Clinical Experience with the Hemopump Left Ventricular Support Device*, published in *Supported Complex and High Risk Coronary Angioplasty*, 1st Ed, Ch. 14, 231-249. (Springer 1991) (“Wampler”)
- Practical Angioplasty (David P. Faxon, M.D. ed., Raven Press 1993) (“Faxon”)
- Abou-Awdi N.L., et al., *Hemopump Left Ventricular Support in the Peripartum Cardiomyopathy Patient*, 8 J. Cardiovascular Nursing, Issue 2 (Jan. 1994) (“Abou-Awdi”)
- Lynn R. Williams, *Reference Values for Total Blood Volume and Cardiac Output in Humans*, Oak Ridge Nat’l Lab. (Sept. 1994) (“Williams”)
- E.E. Kunst, J.A. van Alste, T. Arts, and H. B. K. Boom, *Integrated Unit for Programmable Control of the 21F Hemopump and Registration of Physiological Signals*, Med. & 32 Biol. Eng. & Comput. 694-95 (Nov. 1994) (“Kunst”)

- Konishi, H. et al., *Controller for an Axial Flow Blood Pump*, 20 Artificial Organs 20(6): 618–20 (Jun. 1996) (“Konishi”)
- Andre F. Cournand, Control of the pulmonary circulation in man with some remarks on methodology, Nobel Lecture (Dec. 11, 1956) (“Cournand”)
- Colombo, *Selection of Coronary Stents*, Journal of the American College of Cardiology (2002) (“Colombo”)
- *Biophysical Measurements*, Tektronix, Inc. (1970) (“Tektronix”)
- D. Loisançe et al., Prophylactic Intraventricular Pumping in High-Risk Coronary Angioplasty, The Lancet (Feb 24, 1990) (“Loisançe”);
- *Biophysical Measurements*, Tektronix, Inc. (1970) (“Tektronix”)
- *Textbook of Medical Physiology* by Arthur C. Guyton and John E. Hall, 9th Edition (1996) (“Guyton”)
- Lawrence K. Altman, A Tiny Heart Pump Saves Its First Life, Researchers Report, N.Y. Times, May 5, 1988.
- Frank M. White. *Fluid Mechanics*, 2nd edition, 1986. (“White”)
- O. Jegaden, “Clinical results of Hemopump support in surgical cases,” 1991. (“Jegaden”)
- Wu, Z. et al, Fluid Dynamic Characterization of Operating Conditions for Continuous Flow Blood Pumps. ASAIO Journal (1999) (“Wu”)

13. I have read and understood each of the above prior art references. The disclosure of each of these publications provides sufficient information for someone to make and use an intravascular cardiac assist device or pump in combination with catheterization techniques, as described in the above references.

14. I have considered certain issues from the perspective of a person of ordinary skill in the art at the time of the filing (September 1, 2000) of the parent application (issued as U.S. Patent No. 7,022,100) to which the '068 Patent application claims priority. In my opinion, a person of ordinary skill in the art for the '068 Patent would have found the disclosures in the '068 Patent described in the prior art and therefore would have found the claims invalid.

15. I have been retained by Abiomed as an expert in the field of medical device technologies, including intravascular cardiac assist devices. I am being compensated at my usual consulting rate of \$400/hour for my time. My compensation is not dependent on and in no way affects the substance of my statements in this Declaration.

16. I have no financial interest in Abiomed. I similarly have no financial interest in the '068 Patent or related patents, or the current assignee, Maquet Cardiovascular LLC, and have had no contact with the named inventors of the '068 Patent.

I. RELEVANT LAW

17. I am not an attorney. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to my opinions. My understanding of the law is as follows:

A. Claim Construction

18. I have been informed that claim construction is a matter of law and that the final claim construction will ultimately be determined by the Board. For the purposes of my invalidity analysis in this proceeding and with respect to the prior art, I have applied the broadest reasonable construction of the claim terms as they would be understood by one skilled in the relevant art.

19. I have been informed and understand that a claim in *inter partes* review is given the “broadest reasonable construction in light of the specification.” 37 C.F.R. § 42.100(b). I have also been informed and understand that any claim term that lacks a definition in the specification is therefore also given a broad interpretation, based on its terms.

20. Moreover, should the Patent Owner, in order to avoid the prior art, contend that the claim has a construction different from its broadest reasonable interpretation, I have been informed and understand that the appropriate course is for the Patent Owner to seek to amend the claim to expressly correspond to its contentions in this proceeding.

B. Priority

21. I have been informed and understand that in order for a patent to claim priority to a provisional application, the subject matter of the patent must be supported by the provisional application, and the provisional application must have sufficient description to enable a person having ordinary skill in the art (“POSITA”) to practice the invention claimed in the patent.

C. Anticipation and Obviousness

22. My opinions are informed by my understanding of the relevant law. I understand that the patentability analysis is conducted on a claim-by-claim basis.

23. I have been informed and understand that a single piece of prior art “anticipates” a claim if each and every element of the claim is disclosed in that prior art. I further understand that, where a claim element is not explicitly disclosed in a prior art reference, the reference may nonetheless anticipate a claim if the missing claim element is necessarily present in the apparatus or is a natural result of the method disclosed—i.e., if the missing element is “inherent.”

24. I have been informed and understand that the prior art may render a patent claim “obvious.” I have been informed and understand that a patent claim can be considered to have been obvious to a person of ordinary skill in the art at the time the application was filed. This means that, even if all of the requirements of a claim are not found in a single prior art reference, the claim is not patentable if

the differences between the subject matter in the prior art and the subject matter in the claim would have been obvious to a person of ordinary skill in the art at the time the application was filed.

25. I have been informed and understand that two or more pieces of prior art that each disclose fewer than all elements of a patent claim may be combined to render a patent claim obvious if the combination of the prior art collectively discloses all elements of the claim and a POSITA at the time would have had reason to combine the prior art. I understand that this reason to combine need not be explicit in any of the prior art, but may be inferred from the knowledge of a POSITA at the time the patent application was filed.

26. I have been informed and understand that a determination of whether a claim would have been obvious should be based upon several factors, including, among others:

- the level of ordinary skill in the art at the time the application was filed;
- the scope and content of the prior art;
- what differences, if any, existed between the claimed invention and the prior art.

27. I have been informed and understand that the teachings of two or more references may be combined in the same way as disclosed in the claims, if

such a combination would have been obvious to one having ordinary skill in the art. In determining whether a combination based on either a single reference or multiple references would have been obvious, it is appropriate to consider, among other factors:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, and when combined, would yield predictable results;
- whether a person of ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person of ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the innovation applies a known technique that had been used to improve a similar device or method in a similar way.

28. I understand that one of ordinary skill in the art has ordinary creativity, and is not an automaton.

29. I understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

30. I appreciate that secondary considerations may be considered, if present, as part of the overall obviousness analysis. Such considerations do not appear to be present here. For example:

- I have never heard anyone offer praise for the '068 Patent, nor am I aware of any commercial success attributable to the '068 Patent.
- I am unaware of any copying of the alleged invention of the '068 Patent.
- I am unaware of any use to which the owner of the '068 Patent, Maquet Cardiovascular LLC, has put the patent except to assert it in litigation.

II. LEVEL OF ORDINARY SKILL

31. I have approached my analysis of the '068 Patent from the perspective of a POSITA at the time of the purported invention of the '068 Patent, which as discussed below is September 1, 2000, the earliest possible priority date.

32. I have been informed by counsel that a POSITA is a hypothetical person who is presumed to have known all of the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (1) type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology; and (5) educational level of active workers in the field. I have been informed by counsel that it is from the viewpoint of a POSITA that determines patentability.

33. Based on these factors, in my opinion, a POSITA would have had (i) a Bachelor's degree in mechanical or biomedical engineering, or a similar field, and two to three years of work experience in intravascular cardiac assist devices, (ii) a Master's degree in mechanical or biomedical engineering, or a similar field and two to three years of work experience in biomedical or related fields, or (iii) a PhD in mechanical or biomedical engineering, or a similar field.

34. I have been informed that Patent Owner takes a position that in order to be a POSITA, one would have to have either (i) an undergraduate degree in mechanical engineering or bioengineering or similar subject matter and at least 10 years of experience designing intravascular heart assist devices; or (ii) have an advanced degree in mechanical engineering or bioengineering (either a masters,

Ph.D., or equivalent course work) and at least five years of experience designing intravascular heart assist devices.

35. In my opinion, Patent Owner grossly overstates the requirement to qualify as a POSITA for the purposes of the '068 Patent. To obtain the level of ordinary skill in the art – intravascular heart assist devices – does not require at least a decade's worth of work experience combined with a bachelor's degree, nor does it require at least a half-decade's worth of work experience combined with a doctorate, and Patent Owner has provided absolutely no justification for such extensive experience and educational requirements. The complexities associated with intravascular heart assist devices cited by the Patent Owner are not unique and apply to many related devices. For example:

- Handling blood: All blood pumps must deal with the fact that blood is a difficult fluid to pump. Its character and the conditions which must be maintained to preserve its biologic function are well understood. The issues and challenges are the same in intravascular devices and extracorporeal devices. I have experience intravascularly with devices such as stents and neurovascular embolization coils and extracorporeally with devices such as blood warmers and scroll blood pumps.
- Miniaturization: All intravascular devices must be small enough to fit within the vasculature – in fact some intravascular devices such as

cardiac stents are much smaller than intravascular assist devices, but they are far from being “miniature” in the context of medical devices and instruments. For example, Voelker teaches that pumps inserted into the cardiac arteries during angioplasty must be smaller than 1.4mm (*see* Voelker at 2:60-61), which is consistent with my experience in cardiac stents that have “crossing profiles” (diameters) of just over 1mm when inserted (*See Colombo at Table 2*) and neurological embolization coils with which I also have experience are approximately 1mm in diameter as well. In contrast, intravascular heart pumps can be between 7 to 9 mm. *See* Wampler ’712 at 3:52-54.

- **Dynamic Environment:** The human body inherently operates as a dynamic environment. Blood, air, and other bodily fluids are constantly adjusting to a range of conditions to maintain physiologic function. The intravascular systems I have experience with all cope with this fact. For example, an advantage of scroll pumps is the ability to design a volumetric displacement that matches that of a healthy heart and its operation must be synchronized to match the ever changing cardiac rhythm.
- **Safety:** Safety of operation is critical in all medical devices and there is a large body of knowledge, as well as Federal regulations, that helps

developers create devices that meet high safety standards. Many of the medical devices I have experience with are like intravascular pumps, with an FDA Class 3 designation, which have well established criteria and rigorous review standards.

36. It appears Patent Owner is unjustifiably limiting the universe of individuals who qualify as a POSITA to the named inventors of the '068 Patent and only a handful of others.

37. While I disagree with Patent Owners position – I note that even under the Patent Owner's definition, I believe that I am, and was on or before September 1, 2000 at least a POSITA for purposes of the '068 Patent. *See* my CV attached at Appendix A. As set forth in my CV, and as I detailed above in this Declaration, I received my Ph.D. in mechanical engineering from MIT in 1988 with a focus on biomedical applications. From 1998 until 2002, which falls squarely within the relevant time period for the purposes of the '068 Patent, I worked at ADL (Arthur D. Little, Inc.) starting as a design engineer helping to form ADL's medical products business, eventually working my way up to being responsible for the T&I (Technology and Innovation) Directorate, with more than 250 staff members. During this time, I worked on the design of numerous medical products related to vascular and intravascular medical devices, including vascular stenting systems, neurological and vascular surgical navigation systems, minimally invasive surgical

vascular clip appliers, vascular ligate and divide clip appliers, scroll blood pumps, disposable aspirator pumps used in ophthalmic microsurgery, ambulatory infusion pumps, minimally invasive surgical access devices (Trocars), blood fluid warmers, and chest drainage devices. As such, my education and relevant work experience prior to September 1, 2000 satisfies Patent Owner's proposed definition of a POSITA for the '068 Patent.

38. Unless otherwise stated, my statements below refer to knowledge, beliefs, and abilities of a POSITA of the '068 Patent at the time of the purported invention of the '068 Patent. For example, when I state that something would have been understood, I am referring to that it would have been understood by a POSITA at the time of the '068 Patent's priority date.

III. BRIEF DESCRIPTION OF TECHNOLOGY

39. The '068 Patent relates to medical devices that fall under the broad umbrella of intravascular cardiac assist devices or "intravascular blood pumps." I use this general term to refer to minimally-invasive mechanical devices that are inserted and delivered to the human heart through the vasculature to assist in driving circulation of blood.

40. By September 2000, a great deal was known about intravascular blood pumps and how they could be designed. This was demonstrated by, for example, Wampler, Sammler, Siess, Aboul-Hosn, and Voelker, all of which I will discuss in

more detail below in relation to prior art authored by them. Moreover, as I also discuss below, it was well-known before September 2000 that intravascular blood pumps could be delivered into the vasculature by conventional cardiac catheterization techniques using a guide wire for cannula and catheter placement (*see* Faxon at 56-61 and Yock at 3:56-4:50), as disclosed for example in Aboul-Hosn, Sammler, Voelker, Jegaden, Bagaoisan and Siess. In my opinion, claims 10, 13-15, and 20 of the '068 Patent (the "Challenged Claims") recite nothing more than the same well-known intravascular blood pump technology systems, delivered to the vasculature using the same conventional guide-wire delivery mechanisms taught in the prior art.

41. This declaration relies on Aboul-Hosn as the primary reference. As I explain below, the intravascular blood pump technology recited in the Challenged Claims (including its components and guide wire delivery technique) was entirely disclosed in Aboul-Hosn or supplemented by a few well-known and minor details about where to place a blood pressure sensor (as taught in Sammler).

42. Before explaining my opinion in detail in relation to the Challenged Claims, I believe it is helpful to first explain the physiological context in which the intravascular blood pumps operated and the evolution of those devices, as of

2000⁴. I then explain the basic components of such devices, and the conventional guide mechanisms for delivering such devices. I then show in detail how each and every element of the Challenged Claims is disclosed and obvious in view of the prior art, showing how the claims provide nothing more than a routine and predictable implementation of the well-known elements and combinations thereof.

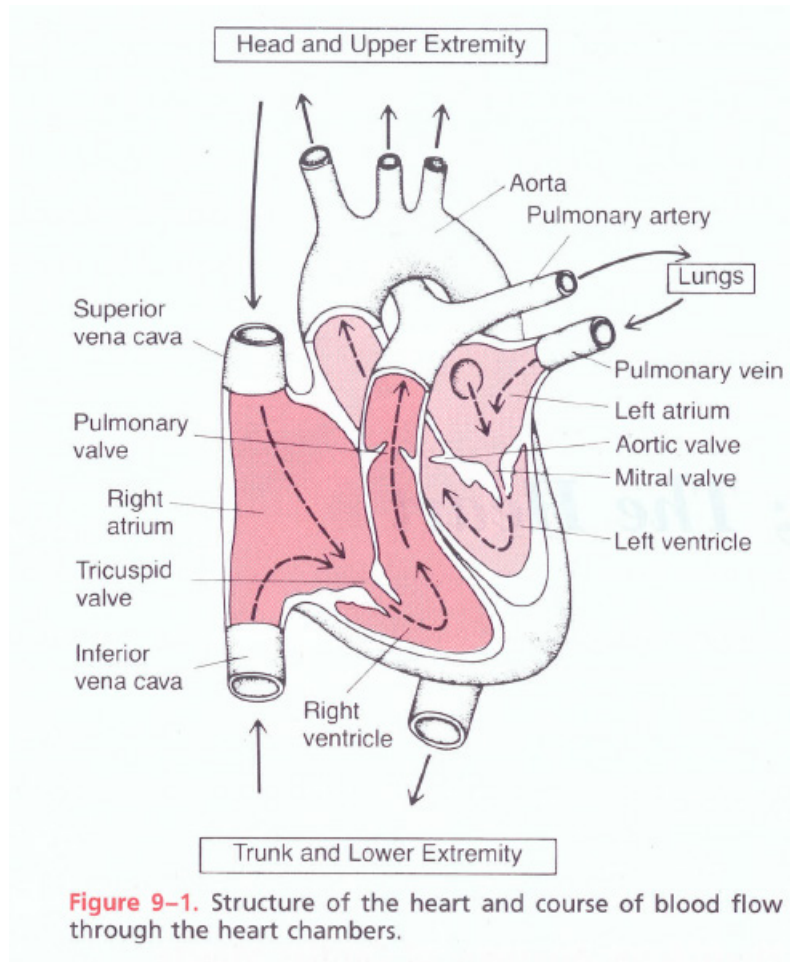
A. Circulatory Anatomy and Function

43. The human heart acts as a muscular pump with two key circulatory functions: (1) pump oxygenated blood from the lungs to the body and the brain, and (2) pump deoxygenated blood returning from the body and the brain to the lungs. While the blood does more than carry oxygen, with respect to circulation it is helpful to think in terms of oxygenated and deoxygenated blood.

44. The general anatomy of the human heart is illustrated below. The human heart consists primarily of a muscular tissue called myocardium, and four chambers—one atrium and one ventricle for each circulatory function. All deoxygenated blood (in the regions of the illustration below highlighted in the darker shade) enters the heart into the right atrium and passes to the right ventricle,

⁴ In my declaration, when I refer to a feature or principle as being “known,” “conventional,” or “obvious,” or indicate that it could be applied or performed or used, or any similar reference, I make that assessment as of the earliest possible priority date of the ’068 Patent (i.e., September 1, 2000), by which I mean to say that the feature or principle would have been “known,” “conventional” or “obvious,” or would have been applied, performed or used, prior to September, 2000.

which pumps the deoxygenated blood out of the heart and to the lungs via the pulmonary arteries. *See* Arthur C. Guyton, M.D., Textbook of Medical Physiology (9th ed. 1996), page 107. Once the blood has been oxygenated in the lungs, it returns to the heart via the pulmonary veins and enters the left atrium (in the regions of the illustration below highlighted in the lighter shade). *See* Arthur C. Guyton, M.D., Textbook of Medical Physiology (9th ed. 1996), Fig. 9-1. It passes to the left ventricle, which pumps the oxygenated heart through the aorta via the aortic valve. *Id.* The aorta is the main artery in the human body and distributes oxygenated blood to the body via a network of branching arteries and arterioles. *See* Arthur C. Guyton, M.D., Textbook of Medical Physiology (9th ed. 1996), pages 161-162.



B. Evolution of Intravascular Cardiac Assist Devices

45. Intravascular cardiac assist devices, such as blood pump systems, are minimally-invasive mechanical devices that provide cardiac assistance by increasing cardiac output and thereby improving tissue oxygenation. *See Wampler '712 at ABSTRACT.* Intravascular cardiac assist devices provide temporary support of diseased hearts, as well as rapid access during emergencies. *See Wampler '712 at 4:15-18.* Because it is an assist device, as opposed to a heart replacement, an intravascular cardiac assist device needs only to deliver a portion

of the total cardiac output (i.e. the amount of blood pumped by the heart per minute), which is about 5 to 7 liters per minute for an adult at rest. *See Williams at 9.*

46. These intravascular cardiac assist devices may be placed into the patient's heart either by conventional surgical implantation or, alternatively, using well-established, minimally invasive catheter-based techniques. Both the surgical implantation and catheter-based insertion techniques were known as of the September 1, 2000. For example, an intravascular cardiac assist pump could be inserted through a percutaneous incision into an artery and navigated through the vasculature (i.e. blood vessels within the circulatory system) with the help of a guide wire. *See Voelker at 1:32-33; 3:34-36.* Alternatively, the intravascular cardiac assist pump systems could also be inserted directly through a surgical incision into the aorta, the ventricles, or the atria of the heart and placed at the desired location within the heart.

47. To operate within the patient's vasculature and heart, the pumps must have a sufficiently small diameter (e.g., 7 to 9 mm or smaller), and any rigid portion must be short enough to be navigated through the curves of the vasculature and heart. *See Wampler '712 at 3:52-54; Voelker at 1:56-61; Aboul-Hosn at 6:24-7:5.* High speed axial flow pumps have been shown to be suitable for use in both

left heart and right heart circulatory assist applications. *See* Wampler '712 at 1:53-57; Sammler at 3:45-53; Aboul-Hosn at 26:8-16.

48. An older version of an intravascular cardiac assist device was an Intra-Aortic Balloon Pump (IABP). The first publication of IABP of which I am aware appeared in the American Heart Journal of May 1962 by S. Topaz Mouloupoulos and W. Kolff at the Cleveland Clinic. *See, e.g.,* Mouloupoulos.

49. An IABP is a counter-pulsation device consisting of a balloon mounted on a flexible catheter that is placed in the aorta. The balloon is inflated and deflated in synchrony with the cardiac cycle to augment cardiac output. *See, e.g.,* Mouloupoulos.

50. The axial flow pump was the next generation of intravascular pumps. *See* Wampler '712 at 1:20-28. Different from an IABP, an axial flow pump uses a rotating rotor in combination with a shroud around the rotor to effectively push blood axially along the pump. *See* Wampler '712 at Abstract. In other words, the blood flows in a direction parallel to the axis about which the rotor turns. *See* Wampler '712 at 1:53-55. The "Hemopump" catheter pump, invented by Richard Wampler in 1983, was a first-generation axial flow pump used in clinical practice. The first clinical trial for left ventricular assist for the Hemopump was completed in the United States from 1988 to 1991. *See* Abou-Awdi at Abstract.

51. The Hemopump used a fast-spinning rotor of a small diameter within a shroud, and by 1988, it had been demonstrated that such a design could provide the necessary flow without damaging the blood beyond physiologically reasonable limits.⁵ See Wampler '712 at 4:7-14.⁶

52. Distal to the pump is a short, flexible inlet cannula that creates a separation between the blood inflow and outflow and assists in the placement of the pump. See Wampler '712 at 2:59-63. Proximal to the pump is a sheath that connects the pump to components outside of the patient and is used to provide such things as a drive cable to drive the pump and purge fluid to lubricate the pump and drive cable and prevent thrombus formation. See Wampler '712 at 3:7-13.

53. A common application of the axial flow pump, such as the Hemopump, positions a cannula across the aortic valve, drawing blood from inside the left ventricle and depositing it in the aorta, thereby assisting the left ventricle with pumping oxygenated blood through the aorta to the rest of the body. For example, as shown in the annotated FIG. 1a of Wampler '712, below, the Hemopump positions the cannula 14 (blue) through the aortic valve 15 into the left ventricle 12, and positions the output of the pump 10 (green) in the aorta 16 to

⁵ Lawrence K. Altman, *A Tiny Heart Pump Saves Its First Life, Researchers Report*, N.Y. Times, May 5, 1988. <http://www.nytimes.com/1988/05/05/us/a-tiny-heart-pump-saves-its-first-life-researchers-report.html>

⁶ Dr. Wampler patented the Hemopump in Wampler '712, filed in September 1983. The Hemopump is described in Wampler '712 and an improved rotor for use in the Hemopump is described in Wampler '152.

provide left ventricular assist. The pump 10 is driven by a flexible shaft in the catheter (yellow) connected to a motor outside of the body. *See Wampler '712 at 2:57-60.*

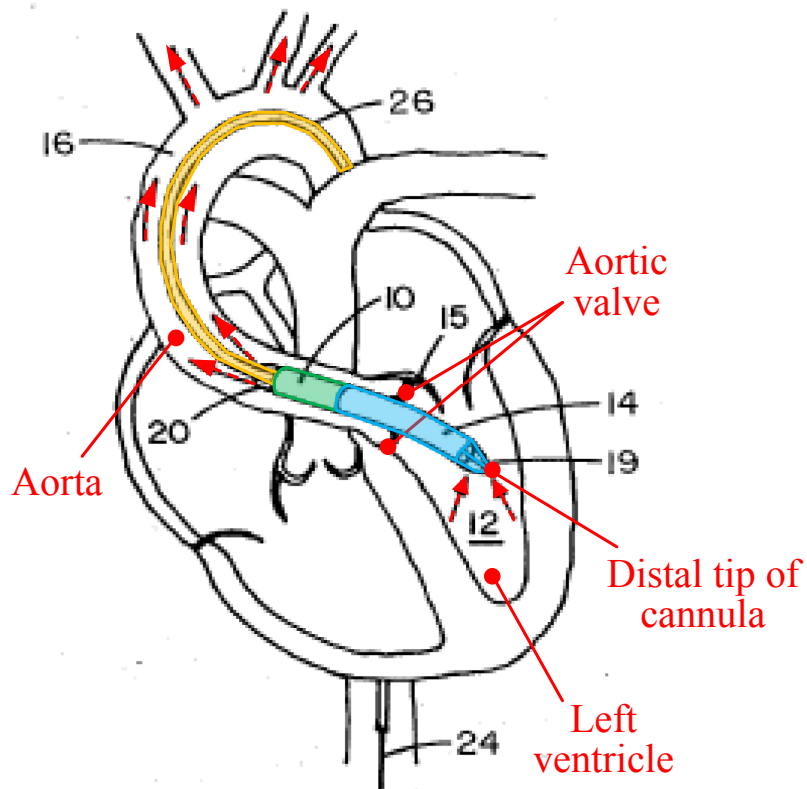


FIG. 1a

54. The arrows in annotated FIG. 1a above, highlighted in red, illustrate the movement of blood and how pump 10 (green) pumps blood from the left ventricle 12 into the aorta 16, providing left ventricular assist. *See Wampler '712 at 2:57-60.*⁷ Blood flows into the pump 10 (green) from the left ventricle 12 and

⁷ FIG. 1a of Wampler '712 shows one embodiment of a first version Hemopump. Wampler '152 and Wampler illustrate later version of the original Hemopump.

through the inlet element 19 of the tapered distal end of the cannula 14 (blue) and the interior of the cannula 14, and is then discharged at the outlet element 20 of the pump 10 (green) into the aorta 16. *See* Wampler '712 at 2:63-68.

55. Siess developed the next generation intravascular blood pump in the 1990s. The pump included an axial flow pump with a rotor and shroud connected to a drive unit with an onboard motor. *See* Siess at 6:26-47. The Siess system with the integrated motor relies on the same basic components of the Hemopump system, as explained below.

56. Also in the 1990s, Aboul-Hosn disclosed an intravascular blood pump system that, like Siess, relies on many of the same basic components of the prior art, as I will now explain.

C. Basic Components of an Intravascular Blood Pump

57. The basic components of intravascular blood pump systems were well known in the field by September 2000. They included at least the following components:

- (1) a cannula having a pump connected to its proximal end with a tapered distal end for effectuating placement in a heart chamber and separating the inlet and outlet of the pump (Wampler '712 at 2:57-67);
- (2) a rotating rotor (with rotor blades) within a shroud around the rotor, to push blood axially along the pump (Wampler '712 at 3:26-39);

- (3) a purge fluid system to prevent blood from entering certain mechanical parts of the pump motor and causing thrombus formation, as well as to provide lubrication to the mechanical parts (Wampler '712 at 3:40-51); and
- (4) a blood pressure monitoring system using fluid columns and other techniques to control the operation of the pump (Siess at 11:25-56).

58. These components are shown and discussed below.

59. Intravascular blood pump systems were delivered either percutaneously by catheter (*see generally* Wampler or Siess, or Aboul-Hosn at FIG. 23, 29:17-19, 32:9-13), or by a surgical approach that introduces the device directly into the vasculature near the heart (*see* Aboul-Hosn at 11:8-11, 21:19-22:30).

60. FIG. 1a illustrates an example of how to position the Hemopump in a human heart, by catheter, and FIG. 2 illustrates an axial cross section of the Hemopump's pump. *See* Wampler '712 at 2:40-48.

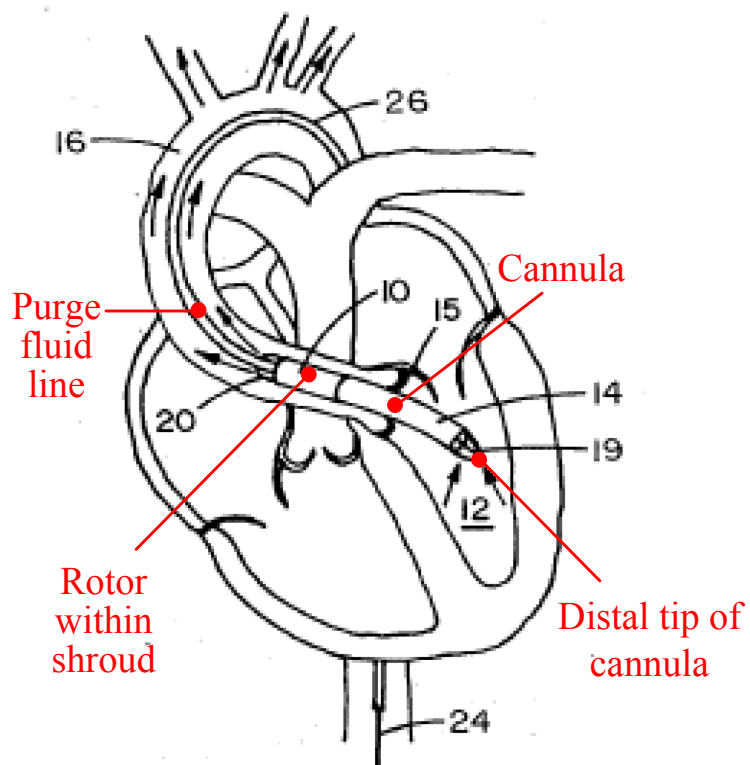


FIG. 1a

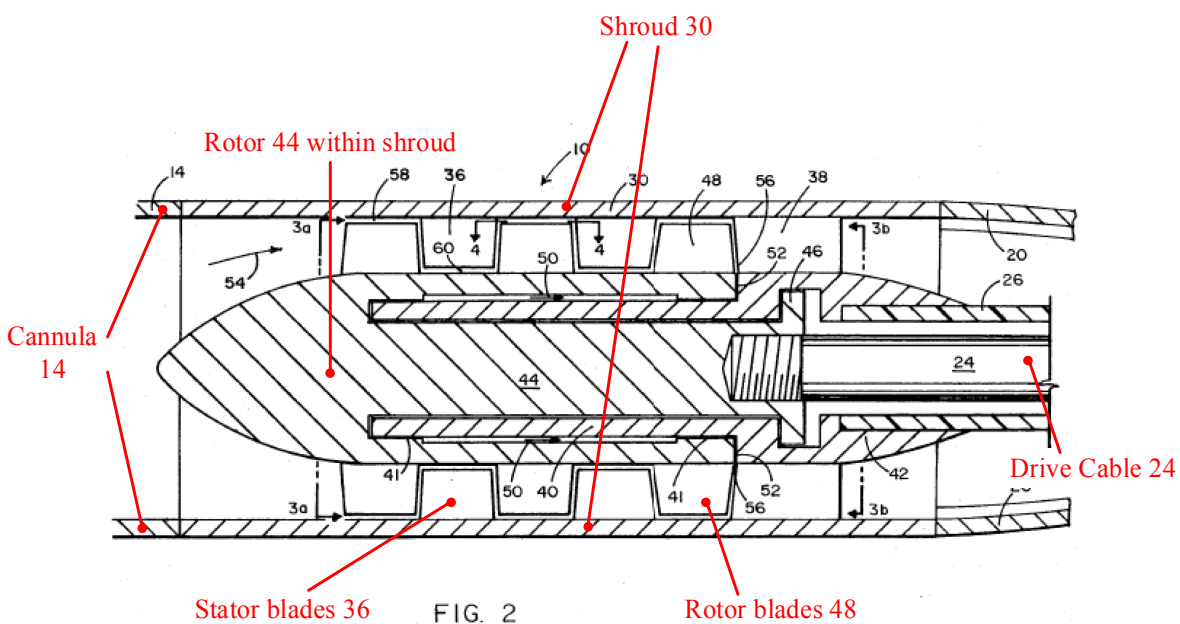
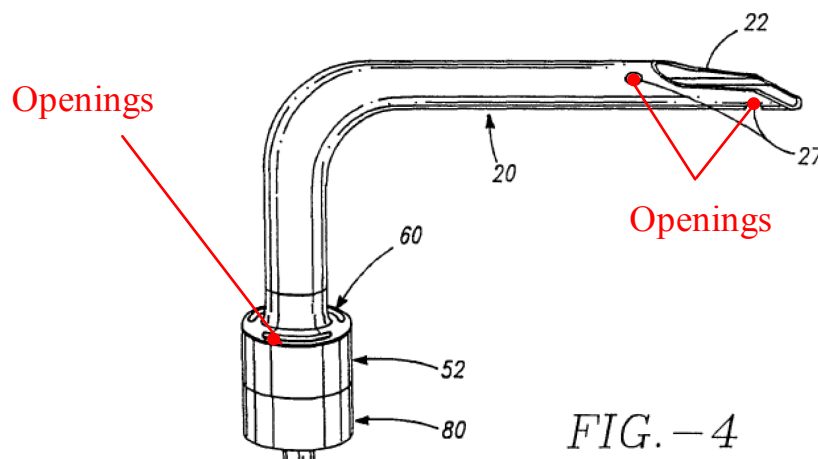
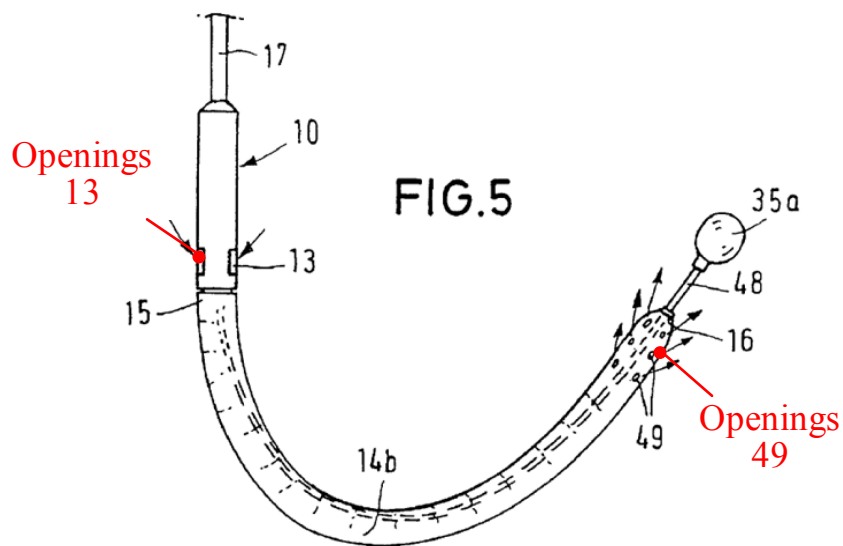


FIG. 2

a. Cannula

61. The cannula serves as a conduit for an axial flow intravascular blood pump system, providing a physical separation between the inlet to the pump system and its outlet. For example, to bridge across the aortic valve and pump blood from the left ventricle to the aorta during left ventricular cardiac assist. *See* Siess '359 at 6:4-12. The cannula serves as a conduit for an axial flow intravascular blood pump, providing a physical separation between the pump's inlet and outlet, and, for example, sits across the aortic valve during left ventricular cardiac assist. *See* Siess '359 at 2:25-30. Conventional cannulas in axial flow blood pumps commonly include multiple holes or openings that allow blood to flow into and out of the cannula when the pump is activated in vivo. Such openings are disclosed for example in Sammler FIG. 5 (openings 13 and openings 49) and Aboul-Hosn FIG. 4 (openings 27 and openings in housing cap 60), as shown below.



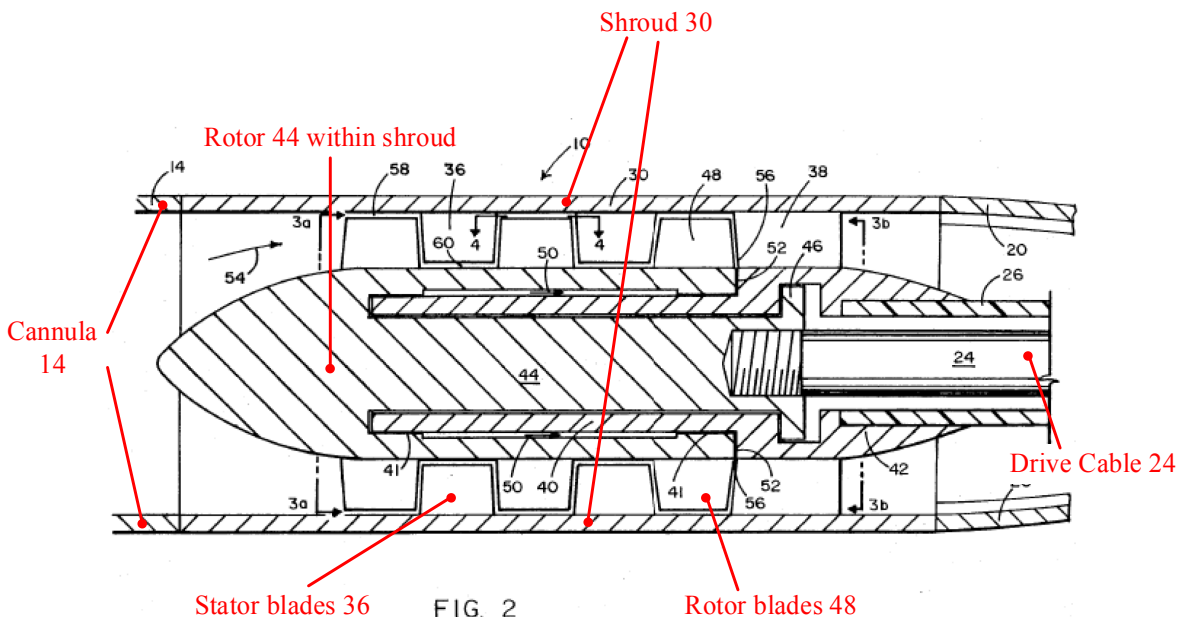
62. It was also a standard practice to reverse flow such that inlet openings would become outlet openings, and vice versa, so as to be able to use a pump for both left side and right side heart applications. *See, e.g., Aboul-Hosn at 26:8-10, FIG. 16.*

63. Conventional cannulas were stiff enough to allow the cannula's distal end to be routed through the vasculature by manipulation of the proximal end, but

also flexible enough to conform to the vasculature and not injure the tissue it contacts. *See* Siess '359 at 1:23-27.

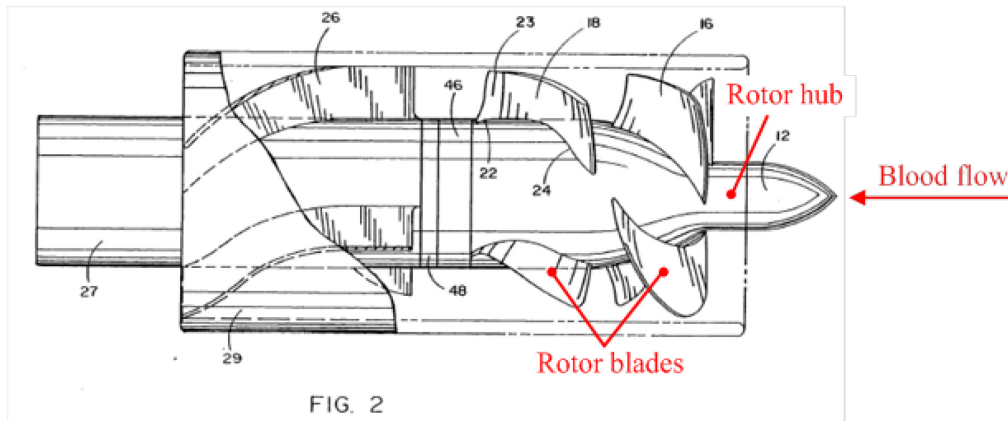
b. Pump

64. As mentioned previously, an axial flow intravascular blood pump connects to the cannula at the cannula's proximal end. The blood pump includes a rotatable rotor within a shroud to push blood axially along the pump. As annotated FIG. 2 of Wampler '712 shows, the Hemopump's cannula connected to a rotor within a generally cylindrical housing or shroud.

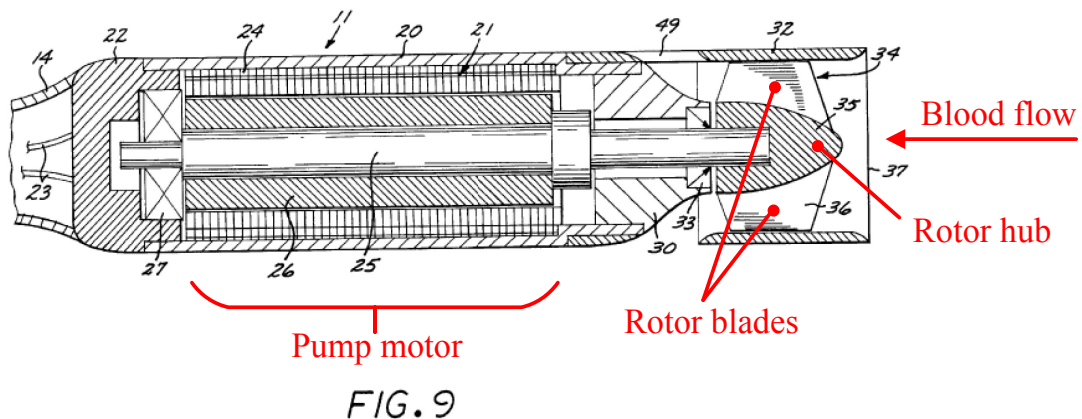


65. The purpose of the rotor is to push the blood axially along the pump—in a direction parallel to the axis of the rotor—while preventing hydrodynamic factors such as cavitation (i.e. small vapor cavities) and shear stress from damaging

blood beyond physiologically reasonable limits. *See, e.g.,* Wampler '712 at Abstract; 4:7-10. Conventional rotor designs for intravascular blood pumps typically included a tapered or conical hub where the blood enters to smooth the flow path and to manage the hydrodynamic factors, as well as one or more blades attached to the hub within a shroud to generate axial flow. For example, the Hemopump rotor as shown in FIG.2 of Wampler '152 had a tapering hub with one or more blades within a generically cylindrical housing to generate the axial flow. *See* Wampler '152 at 2:63-3:23; FIG. 2 (annotated below). The axial flow occurs because of the interplay between the blood and the rotor, along with the shroud that surrounds the rotor. The spinning rotor blades imparts axial and tangential forces on the blood, with the shroud counteracting the centrifugal forces caused by any tangential (spinning) motion, thereby “pushing” the blood axially along the tapered hub. Stationary blades attached to the shroud (“stators”) can be used to help reduce the tangential, rotational flow to improve the performance of the pump. *See, e.g.,* Siess at 6:54-59 (“Radial ribs 31, whose outer ends support the cylindrical tubular pump housing 32, extend radially outwardly from the end section 30c of the tube 30 and serve as fixed stator elements to direct the flow of fluid discharged from the adjacent impeller 34.”)



66. Other modern axial flow pump designs also include these conventional features. *See* Siess at 7:4-6; FIG. 9 (annotated below)



67. Additionally, the pump rotor can be driven (i.e. rotated) by a drive cable attached to a motor outside of the body, which is the case for the Hemopump (Wampler '712 at 3:7-16), or by a motor placed within the pump itself, such as disclosed by Siess (Siess at 6:26-30, FIG. 9 (annotated above)). For example, the pump design in Voelker recognizes both methods of driving the pump rotor. *See* Voelker at 2:26-28 ("Preferably, the pump is driven by a flexible shaft connected

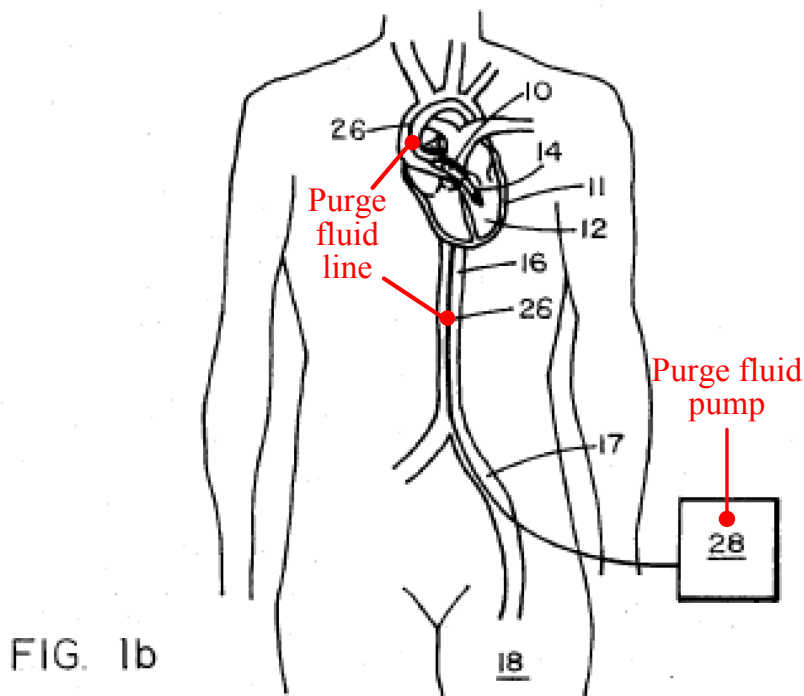
to a motor provided at the proximal end of the cathater [sic] hose....In general, the invention also provides for integrating a pump motor in the cathater [sic] in the immediate vicinity of the pump, the motor directly driving the impeller wheel, in this case.”).

c. Purge Fluid

68. Purge fluid systems were well known in the field to lubricate rotating components and prevent blood from forming thrombosis or entering the pump. The entry of blood into mechanical parts of the pump, such as the bearings, could cause rapid failure of the system because the blood would thicken and potentially coagulate (i.e. thrombosis) and greatly increase the friction between rotating parts, acting as a brake. Thus, conventionally, intravascular blood pumps use a continuous flow of purge fluid. Depending on the way the pump is driven (e.g. by a rotating mechanical drive cable such as used by the Hemopump or using a miniature electric motor as in Siess), some or all of the purge fluid exits the pump through a seal to prevent blood from entering the mechanical parts of the pump and fouling the pump, as well as to provide lubrication to the pump’s bearings and seals. In the case of a rotating mechanical drive cable, a fraction of the purge fluid can also be returned along the drive cable to provide lubrication before being captured outside of the patient. The other fraction exits the pump exits the pump into the blood stream preventing blood from entering the mechanical parts of the

pump and fouling the pump, as well as to provide lubrication to the pump's bearings and seals.

69. For example, in the Hemopump shown below in annotated FIGS. 1b and 2 of Wampler '712, "[t]he journal bearings 41 are lubricated by a continuous flow of purge fluid 50...introduced into the pump 10 under pressure through the catheter 26" using the purge fluid pump 28. *See* Wampler '712 at 3:14-18, 3:40-42; *see also* Kunst at 695 ("The axial pump is connected to a steel drive cable incorporated in a double lumen catheter, through which a lubrication fluid is purged."); Wampler at 234 ("Approximately 300 cc/day of D40W is pushed by a roller pump through purge tubing toward the pump via four outer lumens in the sheath. About 200 cc/day of the purge fluid flows across the seal into the patient and prevents blood elements from migrating into the pump. ... The remaining 100 cc/day of the purge fluid is drawn away from the pump around the drive cable and motor magnet to a return bag"). "The purge fluid 50 flows through the face seal 52 and is eventually discharged into the blood stream 54 at interface 56." *See* Wampler '712 at 3:42-45.



70. The Hemopump used a “blood-compatible fluid” such as ethanol or similar bacteriostatic agent for the purge fluid. *See* Wampler ’712 at Abstract and 2:27-30. A commonly used purge fluid was a 40% dextrose solution. *See, e.g.*, Wampler at 234.

71. As explained above, the purge fluid flowed through the purge seal (between the rotating and stationary parts of the pump), a majority of which is discharged into the blood stream and the remainder returning back out of the patient's body to a return bag. *See* Wampler at 234. Wampler '712 explains that by maintaining an outflow of purge fluid into the blood stream, blood did not come

into contact with the rotor and stator surfaces, which prevents thrombus formation in the blood pump. *See* Wampler '712 at 3:42-51; *see also* Moise at 2:47-56; Siess at 3:50-54 (“This provides the two fold advantage of positively preventing fluid incursion into the pump and continually lubricating the seal surfaces to extend service life and minimize risk of thrombi formation related to dissipation in the seal.”).

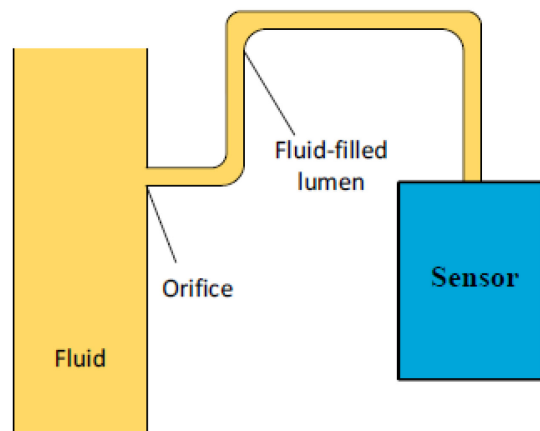
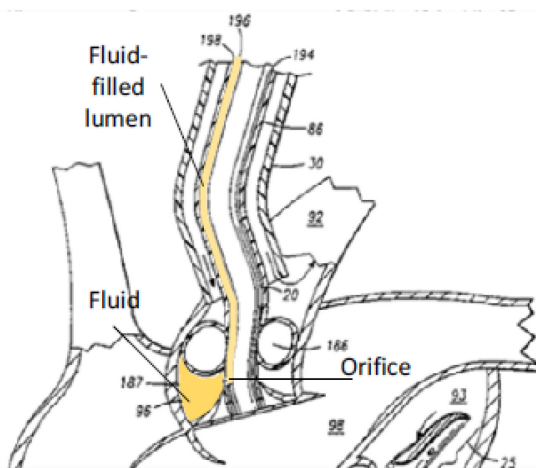
d. Pressure Control and Monitoring

72. It was well known that the blood pressure can be measured and used to control the operation of the pump. In fact, monitoring the pressure in the vicinity of the pump, such as the output pressure or differential pressure between the output and input, to control the speed of the pump was a conventional feature added shortly after the development of the Hemopump. *See, e.g.*, Siess at 4:29-41.

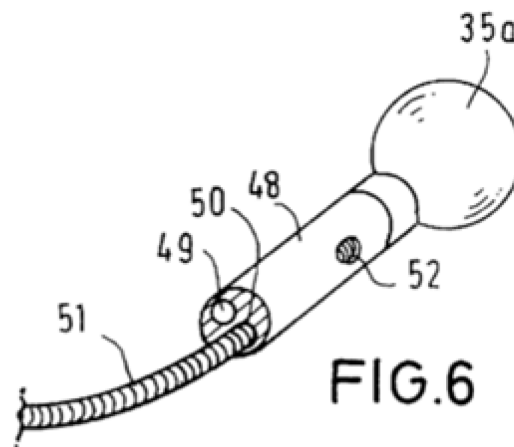
73. There were three primary ways of determining the pressure—measuring remotely through a fluid-filled lumen that communicates the hydrostatic pressure from one open end of the lumen to the other, measuring directly using miniature electronic sensors, or calculating the pressure based on the motor/pump characteristics and electrical power applied. Below I illustrate several examples of well-known techniques to determine blood pressure in an intravascular blood pump.

74. Measuring pressure remotely through a hydrostatic pressure tubes was well known in the art, with the pressure at one of the tube filled with static fluid being the same as at the other, adjusted for any differences in height. The application of this approach to measure pressure within the heart was well-known long before the priority date of this patent. The Nobel Prize in Physiology or Medicine was awarded in 1956 jointly to three men for “discoveries in heart catheterization and pathological changes in the circulatory system.” *See* Andre F. Cournand et al, Nobel Prize in Physiology or Medicine 1956, Nobel Prize, http://www.nobelprize.org/nobel_prizes/medicine/laureates/ (last visited Jan. 25, 2017). In his acceptance remarks, Andre F. Cournand describes that “in the early days, pressures in the right atrium and in the right ventricle were recorded through a single-lumen catheter, connected to a Hamilton manometer,” and that “although the Hamilton manometer was subsequently replaced by a strain gauge in association with electronic recorders, it is well to recall that most of our early knowledge of pressure pulses was obtained by using this device.” Cournand, *Control of the pulmonary circulation in man*, at 531, 533. In addition, by the 1970’s, cardiac catheters were used to take direct blood pressure measurements in the patient’s heart using either a fluid-filled lumen and a pressure transducer outside of the patient’s body, or a small pressure transducer attached directly to the distal tip of the catheter. *See* Tektronix, *Biophysical Measurements*, at 93-99.

75. Aboul-Hosn relies on a similar basic pressure measurement technique derived from fundamental hydrostatic fluid principles to determine pressure in the heart, e.g., in the aorta. Aboul-Hosn describes a hole in the wall of a duct and an associated static fluid column or fluid-filled lumen to communicate duct pressure to a sensor. *See* Aboul-Hosn at 28:14-17. Fluid in the lumen may in turn press up against a pressure sensor located outside the patient. In Aboul-Hosn, “orifice 187 may be positioned anywhere along the cannula 20 surfaces” and may be “used as ... a port for measuring pressure in areas proximal to the orifice.” Aboul-Hosn at 28:14-17. As illustrated in annotated FIG. 19 below, orifice 187 in Aboul-Hosn opens into lumens 196, 198, which are equivalent to fluid-filled tubes, and capture the pressure in the aorta 92. *See* Aboul-Hosn at 28:14-17; *see also* White at 64, 96. A POSITA would readily understand that fluid in the lumens 196, 198 may similarly press up against a pressure sensor located outside the patient.

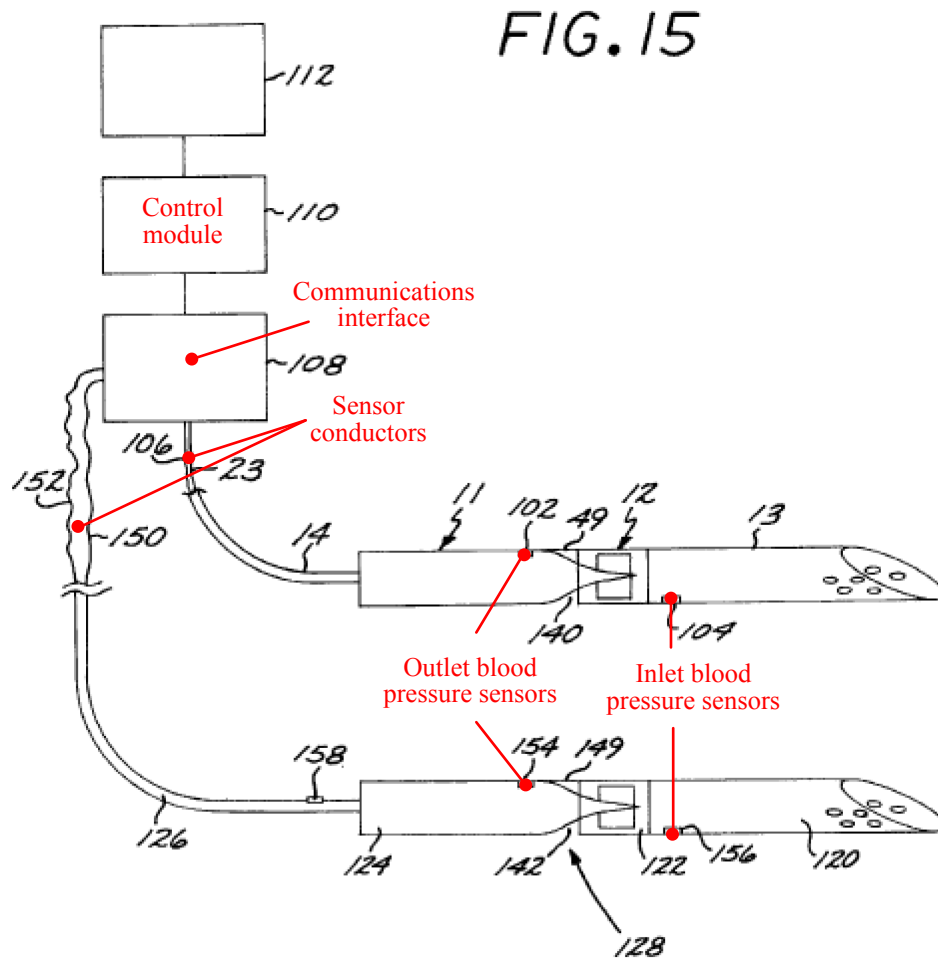


76. Sammler similarly measures pressure of the blood in the pulmonary artery by using a fluid column within a distal catheter extending through the cannula, pump system, and catheter. *See* Sammler at 5:22-25. As FIG. 6 shows, below, Sammler discloses that once the guide wire 51 is removed from the catheter 48, “blood enters the lumen 50 through the opening 52,” filling lumen 50. *See* Sammler at 5:20-25. The lumen 50 within the catheter 48 can connect with a blood pressure measuring instrument, such that “the blood pressure in the pulmonary artery can be measured and influenced, if necessary, during the pumping process.” *See* Sammler at 5:18-25. I explain the details of Sammler’s blood pressure detection mechanism in greater detail in Part VIII below.



77. Siess describes the technique to measure pressure directly by incorporating miniature electronic sensors at the site.⁸ The sensors can be incorporated into the axial flow pump system to provide information about the position of the pump in order to allow adjustment, and to provide information about the performance of the pump and the patient. *See* Siess at 4:28-41. The annotated FIG. 15 of Siess, below, illustrates an embodiment of an intravascular axial flow pump with pressure sensors positioned at the inlet and outlets of the flow pump. The placement of sensors in the pump allows the sensors to discern the position of the pump relative to the heart valve. When properly placed, there will be a substantial pressure differential since the sensors will be sensing conditions on either side of the heart valve through which the blood is being pumped. *See* Siess at 11:23-38.

⁸ Such a technique using sensors to measure pressure directly can be more sophisticated than a fluid column, but a POSITA would still find these techniques interchangeable.



78. A well-known alternative technique determines the differential pressure across the pump by measuring changes in the pump's motor current and speed. The relationship is established because the electrical power that drives the pump (determined by the current and voltage) is converted to the pump's mechanical power (determined by its rotational speed and torque) and finally to the fluid power (determined by the flow rate and pressure) adjusted for known conversion efficiencies. *See Nix at 2:7-11; Konishi at ABSTRACT; Pierce at 757.* Specifically, Nix measures pressure with a sensor on the delivery side of the pump,

and a sensor on the inlet side of the pump, “the control unit controlling the rotational speed of the motor as a function of the signals from both pressure sensors.” Nix at 1:53-55. In addition, Nix uses a single differential pressure sensor to measure the differential pressure, and determine volume flow. *See* Nix at 1:53-2:3. The volume flow can be calculated in view of the differential pressure and the rotational speed of the motor. *Id.* Alternatively, Nix describes how the motor current and speed can be used to determine pressure: “The pressure measuring means need not have one or more pressure sensors. Rather, the pressure may also be determined indirectly via a current measuring means that measures the motor current and calculates the differential pressure between the delivery side and the intake side of the pump from the motor current and the rotational speed.” Nix at 2:6-12.

D. Conventional Guide Mechanisms

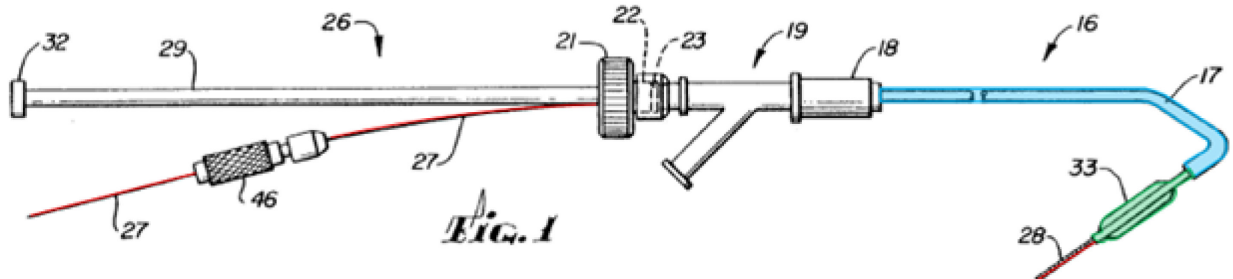
79. Axial flow pumps routinely used the well-known and conventional catheterization techniques of “guide” catheters, “over-the-wire” catheters, and “side-rigger” catheters to place the intravascular blood pump at a desired location within the vasculature. For example, Aboul-Hosn, which I will discuss in detail below, discloses using the over-the-wire technique to place an intravascular blood pump. *See* Aboul-Hosn at 11:24-26, 14:18-15:9, 24:7-14, and 29:17-25. These conventional guiding techniques were originally developed and used widely in

other cardiac applications and angioplasty procedures, long before September 2000. One example was guidance in balloon angioplasty, in which a balloon catheter is guided through the vasculature and placed at a stenosis (a narrowing in a blood vessel). The balloon was then expanded to widen the vessel and then removed, resulting in increased blood flow. *See* Faxon at 59, 66. A later innovation was stenting procedures, where a tube-shaped metal mesh device (i.e. “stent”) is placed over the balloon and expanded after being placed in a stenosis, such as a blocked coronary artery. The expanded stent stays in place after the balloon is removed to hold open the artery to increase blood flow. Starting with guide catheters, the over-the-wire and side-rigger guide mechanisms were later introduced as guide mechanisms for angioplasty. By September, 2000, the over-the-wire and side-rigger approaches have long been the most common modes of placing any catheter-based device into a body using a guide wire. *See, e.g.* Faxon at 57-58 (“The most commonly used balloon type is the over-the-wire catheter system ... Monorails [side-rigger]... are rapidly gaining popularity and now comprise 40% of the angioplasty market.”)

a. Guide Catheters

80. One of the earliest types of guide mechanisms was the guide catheter. For example, Yock, which I discuss in more detail below, describes the use of a “conventional guiding catheter,” a long, flexible tube with a central lumen through

which a guide wire and a balloon dilation catheter can be inserted and slide over the guide wire until the balloon is positioned at a desired location within the patient's body. *See* Yock at 3:56-4:40. Specifically, Yock discloses that “[t]he guiding catheter 17 is inserted into the coronary artery in a conventional manner” (Yock at 3:56-57), then the balloon dilation catheter, which has a guide wire extending distally, is inserted through the guiding catheter into the desired arterial vessel (Yock at 4:32-45), after which the balloon dilation catheter with a deflated balloon is advanced over the guide wire until the balloon reaches a desired location (Yock at 4:46-50). Annotated FIG. 1, below, shows the guide wire 27 (red) and the balloon 33 (green) positioned within the guiding catheter (blue).



81. This same technique, used to advance the guide wire through a guide catheter to position a balloon dilation catheter, has been used to place an axial flow intravascular blood pump, such as the Hemopump. As I previously mentioned, the '068 Patent acknowledges that a guide catheter was a well-known and conventional guide mechanism for intravascular blood pumps. *See* '068 Patent at 2:26-36 and 13:28-29.

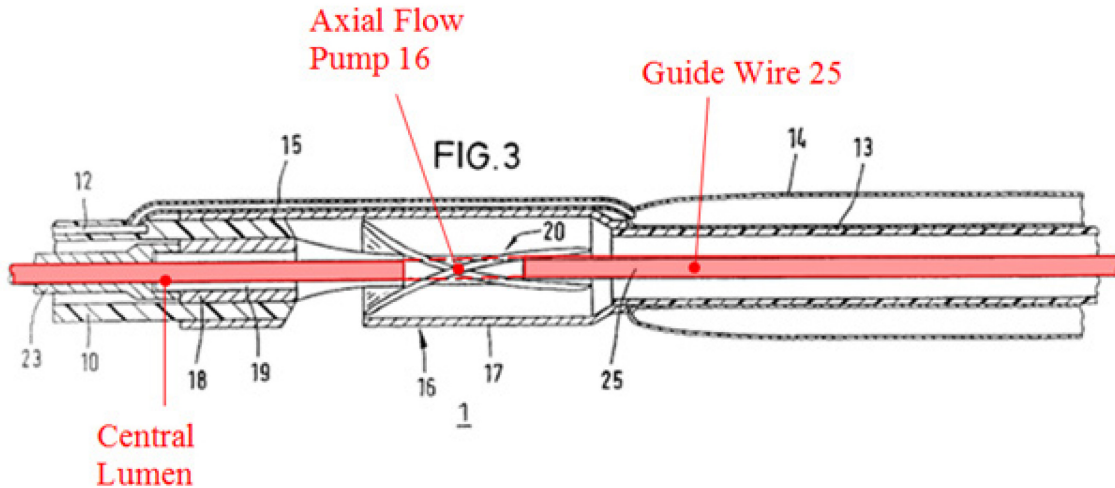
b. Over-the-Wire Catheter

82. A second type of conventional guide mechanism is the over-the-wire catheter. Thomas Fogarty patented one of the first over-the-wire coaxial balloon systems in 1982. *See* Fogarty at 3:4-10. Those systems were then routinely applied in various cardiology applications including blood pumps.

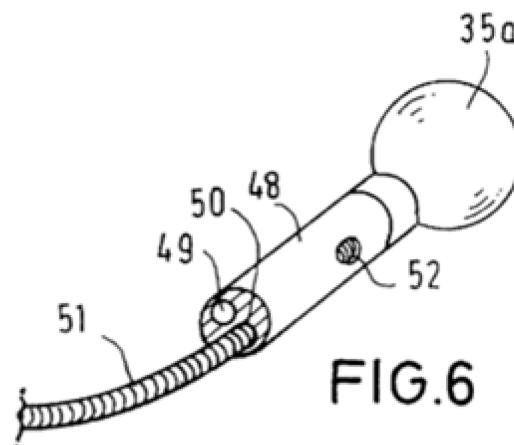
83. A conventional over-the-wire catheter typically includes an elongate catheter with at least one lumen that extends centrally through the catheter, including its interior components, and functions as a guide wire lumen. *See* Fogarty at 2:3-10 *and see* Faxon at 58, Fig. 3 (“Over-the-wire systems have a central lumen to allow independent movement of the wire.”) After introducing the guide wire into a desired location in the body and sliding the guide wire through the guidewire lumen, the catheter can advance over the wire to the desired location in the body. *See* Fogarty at 2:3-10.

84. The over-the-wire guide mechanism was well-known in the art and has been used in intravascular blood pumps. For example, as I discuss in detail below, Aboul-Hosn discloses this mechanism for delivering surgical and percutaneous blood pumps to a patient’s heart. *See* Aboul-Hosn at 11:8-11, 21:19-22:30, 29:17-19, 32:9-13; *and see* Part VI.A. In addition, as shown in annotated FIG. 3, below, Voelker applies the over-the-wire guide mechanism to an axial flow intravascular blood pump, with a central lumen running axially through the drive

shaft and rotor hub. *See Voelker at 3:56-58 (“[T]he guide wire 25 extends coaxially through the flexible shaft 23, the shaft 19 and the impeller wheel 20.”)*

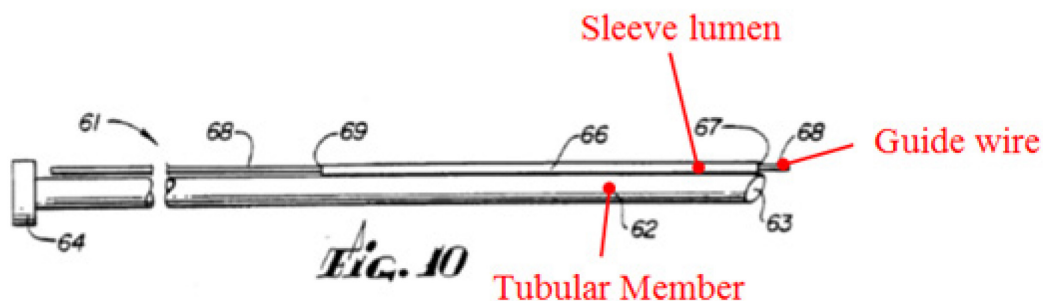


85. Another example is in Sammler, which, as shown in FIG. 6 (below), contains a second lumen 50 “destined for accommodation of a guide wire 51...which also extends through the catheter 17 and the pump 10,” allowing “the operating surgeon to controllably influence the layering of the pump hose.” 5:9-16.



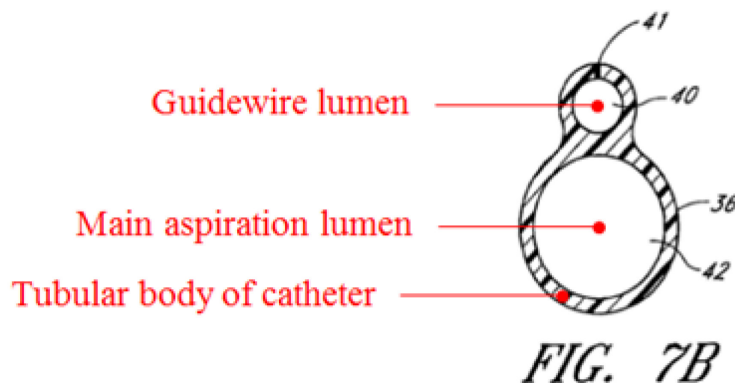
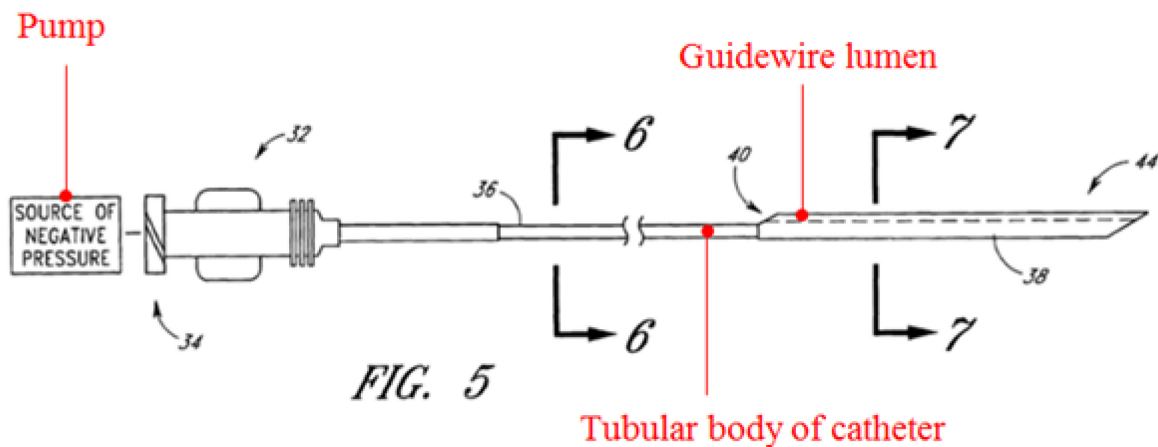
c. Side-Rigger Catheter

86. A third type of conventional guide mechanism is the “side-rigger” type guide mechanism (also sometimes referred to as a “rapid-exchange” or “monorail”). Paul Yock patented a side-rigger catheter in 1991. *See generally* Yock. The conventional side-rigger catheter generally included an elongate tubular member, i.e. a cannula, and a sleeve (with a lumen for the guide wire) secured to the exterior of the tubular member or embedded within the cannula wall itself. *See* Yock at ABSTRACT and Yock at 7:64-8:2. When a guide wire inserts through the sleeve, it would extend in a direction parallel to the flexible tubular member. *See* Yock at FIG. 10 (annotated below); 8:16-19. The catheter can then advance along the guide wire to a desired location in the body. *See* Yock at 8:20-25. This particular orientation of the sleeve in relation to the cannula allows for more rapid exchanges of catheters than over-the-wire configurations.



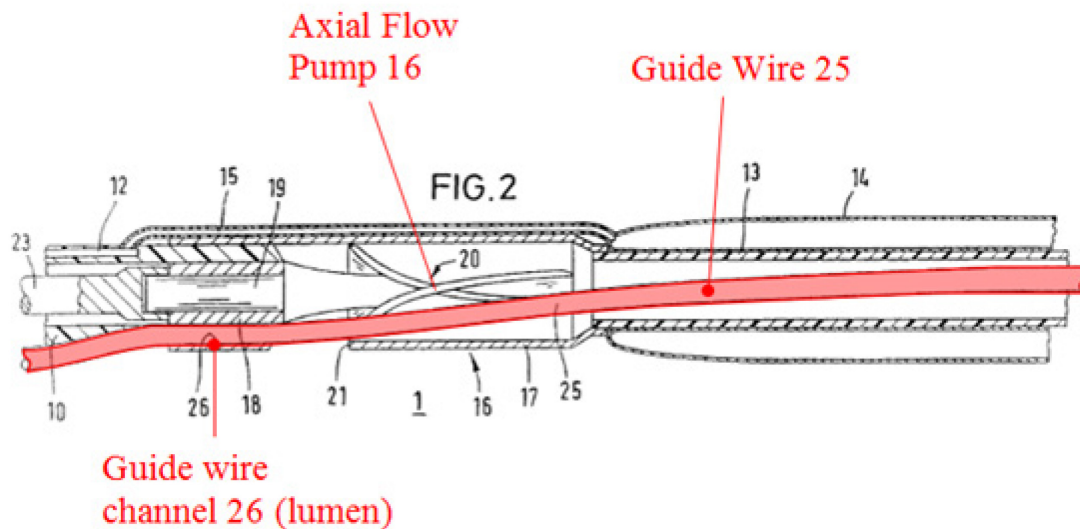
87. Another example is Bagaoisan, which discloses a side-rigger catheter inserted into a patient’s body for use in treatment of an occluded blood vessel and may connect with an extravascular pump. (Bagaoisan at 3:34-43.) As shown in

annotated FIGS. 5 and 7B, below, Bagaoisan discloses “a guidewire lumen 40...apart from the main aspiration lumen 42 of the catheter 30” where “the proximal end of the guidewire 26 is inserted into the distal end of the guidewire lumen 40, and the guidewire lumen 40 is slidably advanced over the guidewire 26.” Bagaoisan at 8:7-11; 8:14-20.



88. A side-rigger guide mechanism has also been used in intravascular blood pumps. For example, annotated FIG. 2 of Voelker, below, shows an axial flow intravascular blood pump in a side-rigger configuration. See Voelker at 3:40-

43 (“In a part of the pump housing 17, a longitudinally extending channel 26 is provided that forms a guide portion (monorail) through which the guide wire 25 is guided into the pump housing 17.”)



89. In fact, a side-rigger guide mechanism has long been used interchangeably with the over-the-wire mechanism, based on design preferences. *See* Faxon at 58-59; Yock at 8:16-25; Bagaoisan at 3:34-43. For example, the balloon angioplasty applications have long accepted the interchangeability of the side-rigger and over-the-wire approaches. *See* Faxon at 57-58 (“The most commonly used balloon type is the over-the-wire catheter system” and “[m]onorails are rapidly gaining popularity and now comprise 40% of the angioplasty market.”) There were, of course, design choices to be made. The over-the-wire approach was known to provide more flexibility in the design choice of guide wire and (in the angioplasty case) balloon size, as compared to older

“fixed wire” techniques, whereas the side-rigger approach was known to be more time-efficient in changing catheters during a procedure and enabling a smaller catheter that was easier to push, and improved visibility. *See Faxon at 57-59.*

90. The Hemopump itself was also delivered by a side-rigger guide mechanism, as taught by Jegaden. According to Jegaden’s disclosure, the guide wire passes through a 5 fr. catheter that extends alongside the cannula, but then enters the lumen of the cannula through a distal port in the cannula wall, and extends out the distal end of the cannula. *See annotated Fig. 2 below.* As shown in Jegaden’s example, below, and as in Voelker FIG. 2, the guide wire does not pass through the drive cable sheath or the rotor hub but, instead, passes along the outside of the cannula. The distal end of Jegaden’s guide wire has a curved shape to aid in placing the cannula in the ventricle.

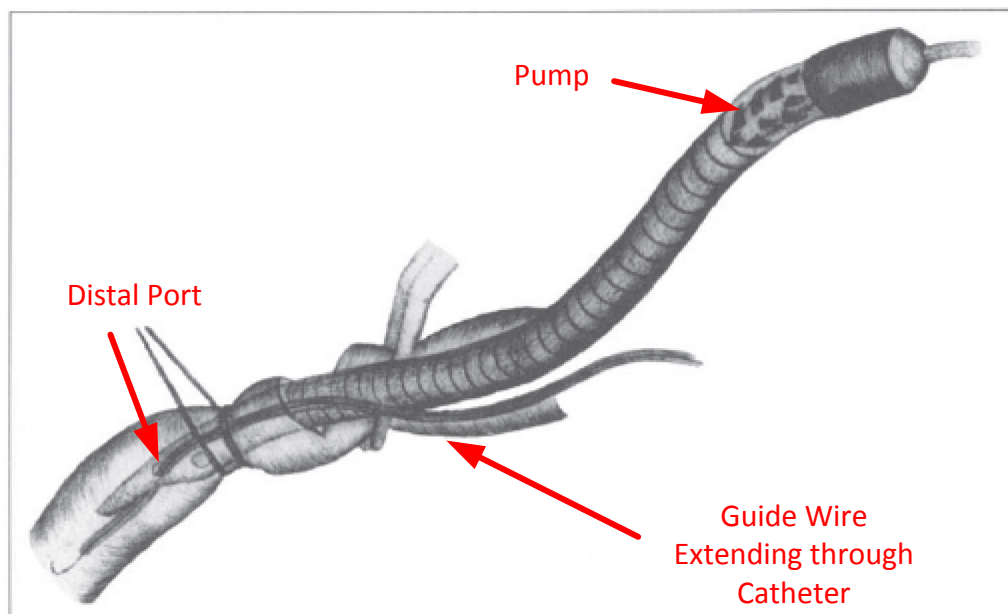


Fig. 2.

91. As depicted above in FIG. 2 of Jegaden, the guide wire is extended through a small guide catheter, and the guidewire and catheters are advanced into the vasculature such that the pump can be slideably advanced along the guide wire within the catheter. For example, Jegaden discloses “a guidewire and a 5F catheter are passed through the distal hole of the cannula and introduced into the femoral artery up to the aorta (Fig. 1). Then the cannula is introduced into the femoral artery and is pushed into the aorta, guided by the vasculature catheter.”

92. The interchangeability of the two approaches—over-the-wire and side-rigger—was also well understood for intravascular blood pump applications. Voelker discloses that the side-rigger approach of FIG. 2 would be a straightforward alternative to the over-the-wire approach of FIG. 3 (which I previously discussed in Part III.D.b). Voelker indicates that in the embodiment of FIG. 2 at least a portion of the guide wire may be guided through a monorail – a side-rigger conduit: “This flexible guide wire 25 extends generally outside the cathater [sic] hose 10. At the distal end of the cathater [sic] hose, preferably on the last 10 cm of the catheter [sic] hose 10 and in a part of the pump housing 17, a longitudinally extending channel 26 is provided that forms a guide portion (monorail) through which the guide wire 25 is guided into the pump housing 17.” Voelker at 3:37-43.

IV. OVERVIEW OF THE '068 PATENT

A. Summary of Alleged Invention of the '068 Patent

93. The '068 Patent describes an intravascular blood pump system that applies a conventional guide mechanism in a standard intravascular blood pump to predictably guide the blood pump to a desired position within the heart and/or vasculature. *See* '068 at 1:21-25; 2:52-56; 6:48-50. The '068 Patent blood pump has many conventional features of the Hemopump, as described earlier. For convenience, this section uses the term “blood pump” or “intravascular pump” to refer to the intravascular blood pump.

94. The '068 Patent acknowledges that it did not invent the intravascular blood pump, nor a guide mechanism for delivering an intravascular blood pump, but rather refers to its invention as an improved guide mechanism over the prior art guide catheters as it “eliminates the need for supplemental guiding mechanisms, such as a separate, large diameter guide catheter as used in the prior art. *See* '068 Patent at 2:26-48; 2:56-60. However, this problem of reducing the size of the catheter had long been appreciated by the art and was already addressed in the prior art, as had the solutions taught by the '068 Patent. *See, e.g.*, Voelker at FIGS. 2; 3; 3:34-65; Bagaosian at FIG. 6, 5:11-16; Faxon at 43, 57-58.

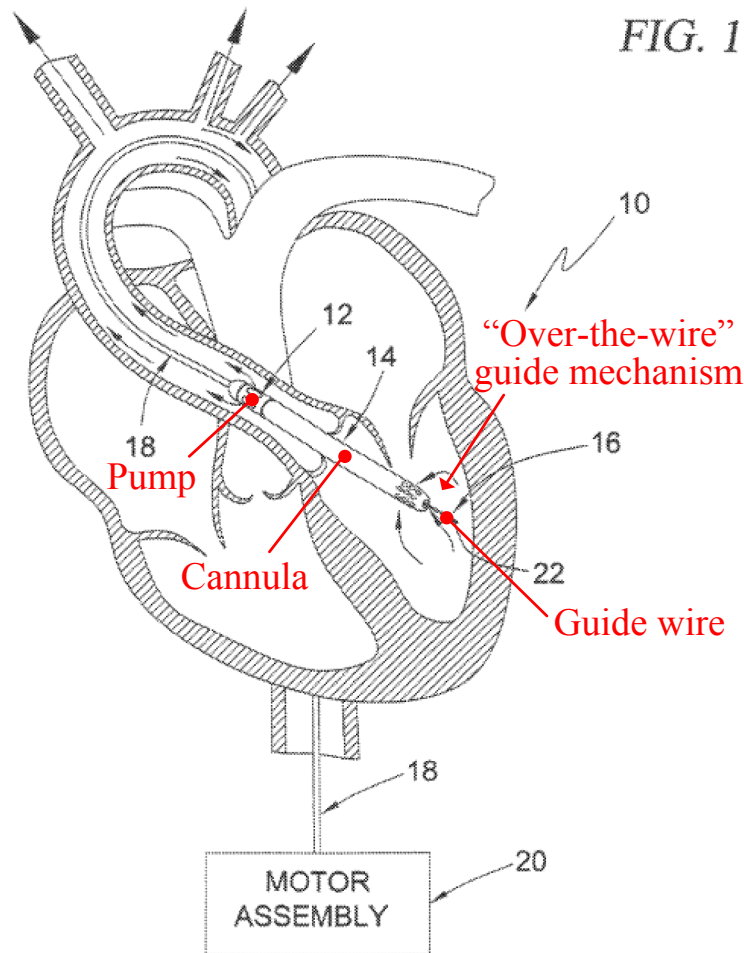
95. The '068 Patent describes three conventional guide mechanism embodiments: (i) an “over-the-wire” type guide mechanism, (ii) a “rapid-

exchange” or “side-rigger” type guide mechanism, and (iii) a “guide-catheter” type guide mechanism. As previously explained, each of these guide mechanism embodiments have been well-known in the art and used for navigating and positioning within the vasculature in many intravascular applications. *See* Part III.D.

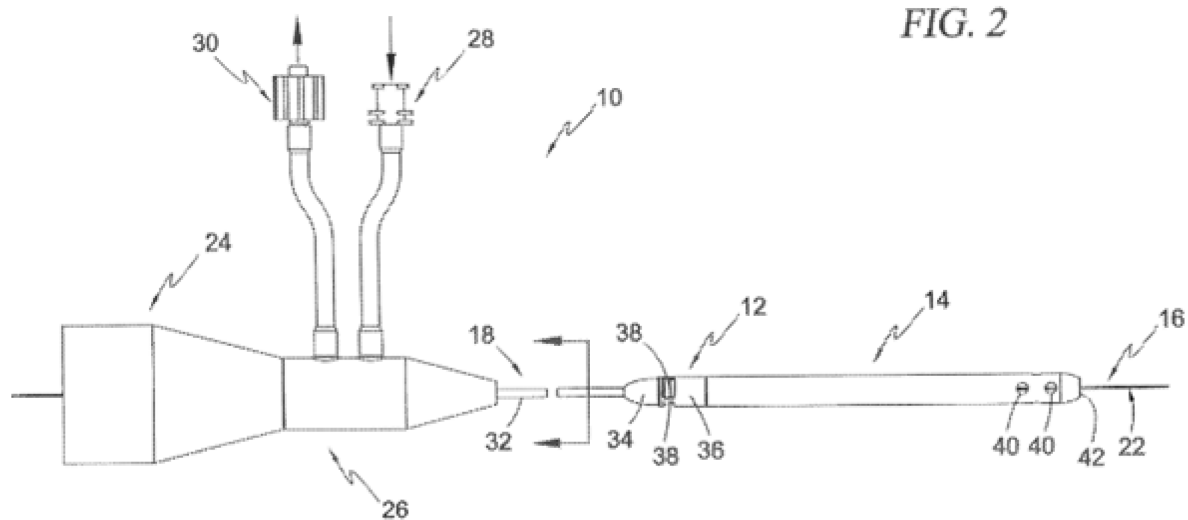
a. Over-the-Wire Guide Mechanism

96. The first embodiment, annotated below in FIG. 1 of the '068 Patent, shows nothing more than a conventional intravascular blood pump system with a conventional over-the-wire type guide mechanism to carry out the predictable result of positioning the pump “in a trans-valvular configuration to provide left-heart assist.” '068 Patent at 5:7-11. The intravascular blood pump system 10 includes a standard intravascular blood pump 12, a cannula 14, and an over-the-wire type guide mechanism 16 with a central lumen that runs through the center of the blood pump rotor, and the other internal components (e.g., the drive cable and cannula). *See* '068 Patent at 7:9-11. A standard drive cable assembly 18 and motor assembly 20 drive the intravascular blood pump 12. *See* '068 Patent at 7:11-13. Consistent with the prior art, the '068 Patent suggests to position the intravascular blood pump and cannula to a desired location by introducing the guide wire 22 into the vascular system of a patient and advancing it within the circulatory system of the patient to a desired location. *See* '068 Patent

at 7:25-37. Once in position, the guide wire 22 is passed through the lumen in the center of the blood pump 12 and exits the distal end of the cannula 14, in the conventional over-the-wire approach, allowing the blood pump 12 and cannula 14 to predictably advance over the guide wire into the desired location. *See* '068 Patent at 7:37-41. As explained in detail below, the over-the-wire guide mechanism disclosed in Aboul-Hosn is the same as the conventional over-the-wire guide mechanism known in the art - none of the components nor the technique shown in this embodiment was new; it was all well-known, indeed it was conventional as of the earliest possible priority date of the '068 Patent. *See* Parts III.D.b and III.D.c.

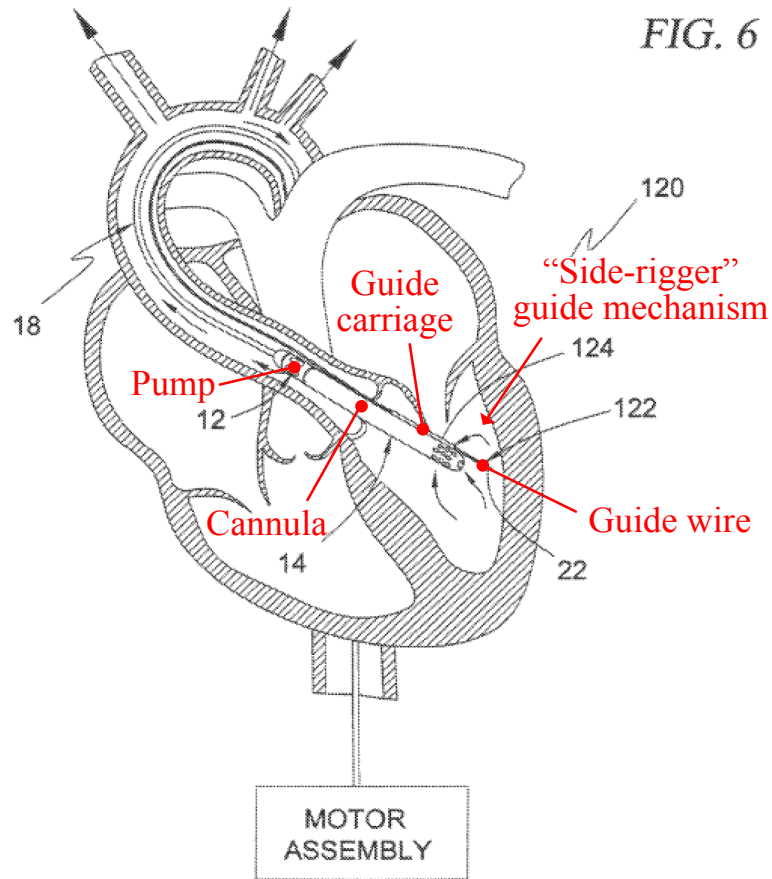


97. FIG. 2 of the '068 Patent, reproduced below, shows a side view of the conventional intravascular blood pump system 10 with its over-the-wire type guide mechanism and conventional purge fluid system 26. Consistent with the prior art such as the Hemopump, the purge fluid delivery system 26 applies a two-way fluid flow where a fluid inlet conduit 28 introduces purge fluid into the blood pump while a fluid outlet conduit 30 withdraws purge fluid from the blood pump. *See* '068 Patent at 7:50-59. This was well-known before the earliest possible priority date of the '068 Patent. *See* Part III.C.c.



b. Side-Rigger Guide Mechanism

98. The side-rigger embodiment of the '068 patent is annotated in FIG. 6 below. It shows nothing more than a well-known intravascular blood pump system having a conventional side-rigger type guide mechanism known in the prior art, predictably “positioned, by way of example, in a trans-valvular configuration to provide left-heart assist.” *See* '068 Patent at 5:29-34. The only difference between this side-rigger embodiment and the over-the-wire embodiment above is the type of guide mechanism used. *See* '068 Patent at 11:47-50. As I have discussed above in Parts III.D.b and III.D.c, both of those mechanisms were conventional in delivering intravascular devices with a guide wire.

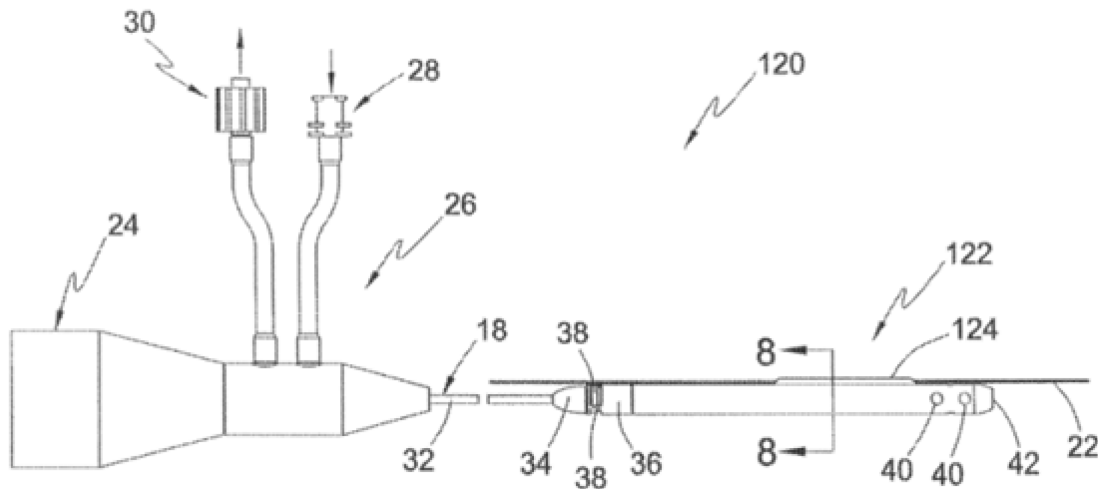


99. As with the over-the-wire system, in this side-rigger embodiment, the intravascular blood pump system 120 includes a standard blood pump 12 and a cannula 14 equipped with a side-rigger guide mechanism 122. *See* '068 Patent at 11:60-64. As opposed to the over-the-wire embodiment, which has a guide mechanism with a central lumen that passes through the center of the blood pump 12 and other components, so the wire exits through the distal end of the cannula 14 lumen, the side-rigger guide mechanism 122 has a conventional guide carriage 124 formed as a lumen along a side portion of the cannula 14 wall, so the wire does not pass through the center of the pump and its components. *See* '068 Patent at 11:64-

67. Once the guide wire 22 is in position in the lumen, the guide wire can predictably “pass slidably through a lumen extending through the guide carriage 124” to advance the blood pump 12 and cannula 14 along the guide wire into a desired location. *See* '068 Patent at 11:67-12:14. As with the over-the-wire technique, this side-rigger approach was already well established in the prior art -- none of the components nor the technique shown in this embodiment was new; it was all well-known, indeed it was conventional as of the earliest possible priority date of the '068 Patent. *See* Parts III.D.b and III.D.c.

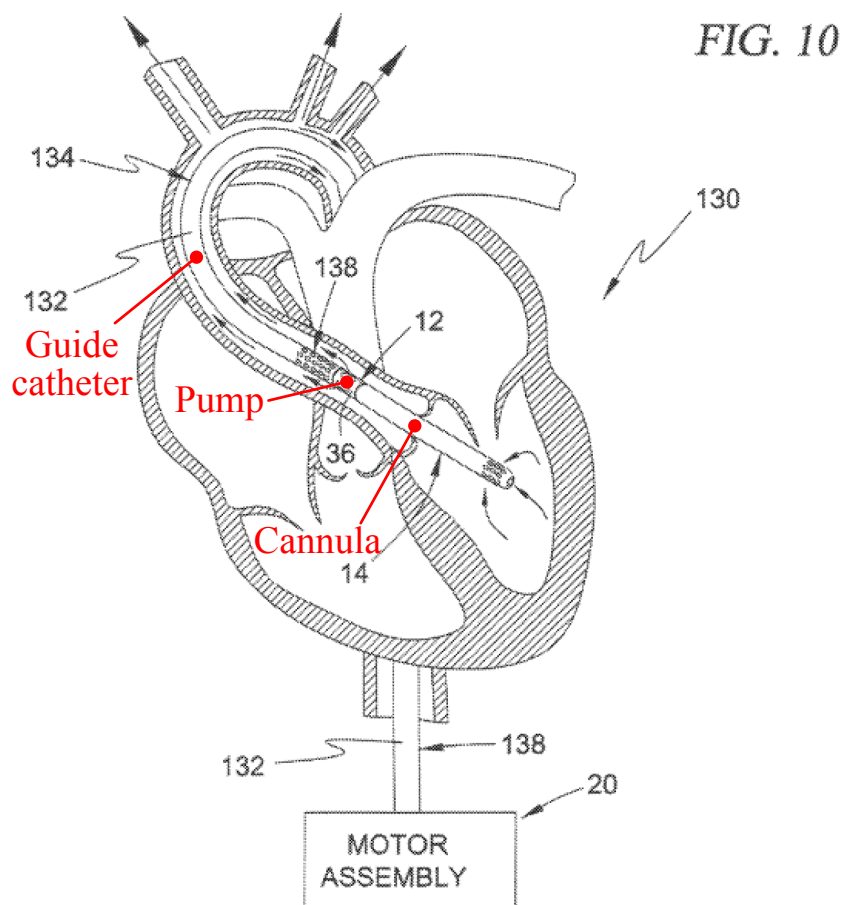
100. FIG. 7, reproduced below, shows a side-view of the intravascular blood pump system with a side-rigger type guide mechanism.

FIG. 7



c. Guide Catheter Guide Mechanism

101. Annotated FIG. 10 of the '068 Patent, below, shows an intravascular blood pump system with a “guide catheter” type guide mechanism “positioned, by way of example, in a trans-valvular configuration to provide left-heart assist.” '068 Patent at 5:47-52. The “guide catheter” embodiment uses many of the same components and features as the over-the-wire and rapid-exchange embodiments. *See* '068 Patent at 12:61-64. In this embodiment, the guide catheter 132 is used to position the pump 12 and cannula 14 at a desired location within the patient's circulatory system.



d. Techniques to Introduce the Intravascular Blood Pump

102. Before reaching the desired location using the various conventional techniques described above, the intravascular blood pump system of the '068 patent must be first introduced into the patient's vasculature. The '068 Patent contemplates that "the guidable intravascular blood pump systems can be introduced into the patient's vasculature to achieve the intravascular access into the right or left heart through any number of access points, including but not limited to the internal jugular vein, the brachiocephalic vein, carotid artery, axillary artery femoral vein, femoral artery, and subclavian artery." *See* '068 Patent at 17:30-36. The '068 Patent explains that the "intravascular blood pump systems of the present invention" can be introduced into the patient's vasculature using either the conventional surgical approach "via direct introduction" into the heart, or alternatively, "[a]s is well known in the art, such intravascular access may be achieved percutaneously." *See* '068 Patent at 17:36-42.

B. Claims 10, 13-15, and 20 of the '068 Patent

103. Claim 10: A method for perfusion a patient with an intravascular blood pump system, the intravascular blood pump system comprising:

(i) an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and at least one blade extending radially outward from the rotor hub, the intravascular blood pump coupled to a catheter on a

proximal end and a cannula on a distal end;

(ii) a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula, wherein the first set of apertures is located in proximity to the rotor and the second set of apertures is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula;

(iii) a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient; and

(iv) a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump;

wherein the elongate lumen (a) is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump; (b) is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and (c) is arranged in series longitudinally with the cannula: the method comprising:

advancing a guide wire to a predetermined location in the circulatory system of the patient; and

advancing the blood pump system along the guide wire to the predetermined location.

104. Claim 13: The method of claim 10, further comprising a plurality of egress flow ports disposed in a shroud of the intravascular blood pump, and a plurality of ingress flow ports disposed at a location spaced apart from and distal to the egress flow ports.

105. Claim 14: The method of claim 13, wherein the ingress flow ports comprise an end port located at the cannula distal end and a plurality of ports located about the cannula and proximal to the end port.

106. Claim 15: The method of claim 10, wherein the first set of apertures are egress ports and the second set of apertures are ingress ports, and wherein the egress ports are configured to direct blood passing through the interior of the cannula and towards the rotor in a direction that is both proximal and radially outward with respect to the rotor hub.

107. Claim 20: A method for perfusion a patient with an intravascular blood pump system, the intravascular blood pump system is configured to be advanced to a predetermined location in a patient's circulatory system and comprises

(i) an intravascular blood pump, the intravascular blood pump comprising a rotor having a generally conical rotor hub tapering in the distal direction, at least two blades extending radially from the rotor hub, the generally conical rotor hub having a distal tip extending distally beyond the blades;

(ii) a cannula extending distally from the intravascular blood pump;

(iii) a plurality of ingress ports located towards the distal region of the cannula and a plurality of egress ports located in proximity to the blood pump such that movement of fluid proximally through an interior region of the cannula is steered towards the egress ports;

(iv) a guide wire having a cross-section substantially smaller than the cannula; and

(v) an elongate lumen, the elongate lumen (a) having a luminal interior sized smaller than an inside diameter of the cannula and sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong, (b) arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and (c) arranged in series longitudinally with the cannula, the method comprising:

advancing a guide wire to a predetermined location in the circulatory system of the patient; and

advancing the blood pump system along the guide wire to the predetermined location.

V. THE PRIORITY CLAIM TO THE '249 PROVISIONAL APPLICATION FAILS

108. Based on my review of the '249 provisional application, it is my opinion that the '249 provisional application does not disclose the claimed subject matter of the '068 Patent. Thus, the earliest priority date of the '068 Patent is the

September 1, 2000 filing date of the PCT application to which the '068 Patent claims priority. My rationale for this conclusion is described below.

109. Independent claim 10 in the '068 Patent requires a lumen “arranged coaxially with at least one of a distal end or a proximal end of the cannula” ('068 Patent at 19:58-60 and at 20:) and independent claim 20 in the '068 Patent requires a lumen “arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula” ('068 Patent at 20:52-54). However, the '249 provisional application does not define or use the term “coaxially.” There is no support in the '249 provisional application for a lumen “arranged coaxially with at least one of a distal end or a proximal end of the cannula,” or “arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula” as claimed. Independent claim 10 also requires a “blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump”. However, the '249 provisional application does not define or use the term “blood pressure detection mechanism.” There is no support in the '249 provisional application for a “blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump,” as claimed.

110. The Examiner also came to the same conclusion regarding features of the related U.S. Patent Application 12/772,810 (issued as U.S. Patent 8,888,728

(“’728 Patent”)) to which the ’068 patent claims priority. In prosecution correspondence involving the ’728 patent, the Examiner stated that claim 15 did not appear “in any correspondence filed with the original priority application 60/152249.” See ’728 File History, Non-Final Rejection 05/08/2013 on pp. 259-280. I understand that when the ’728 Patent issued, claim 15 in the prosecution history became independent claim 1 of the ’728 Patent. The offending features of the ’728 patent are also included in claim 10 of the Challenged Claims, in particular: “a blood pressure detection mechanism comprising a fluid column,” and “the elongate lumen (a) is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump,” and in claim 20 which recites “an elongate lumen, the elongate lumen (a) having a luminal interior sized smaller than an inside diameter of the cannula and sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong.”

111. I understand that claims dependent on an independent claim are entitled to a priority date no earlier than that which the independent claim is entitled.

112. Accordingly, it is my opinion that the ’249 provisional application does not support the claims 10-22 of the ’068 Patent and does not enable a POSITA to practice the alleged invention claimed in the ’068 Patent. Thus, as

mentioned previously, the earliest priority date of the '068 Patent is the September 1, 2000 filing date of the PCT application to which the '068 Patent claims priority.

VI. OVERVIEW OF THE PRIMARY PRIOR ART REFERENCES

A. Overview of Aboul-Hosn

113. This declaration relies on Aboul-Hosn as a primary reference, which is prior art against the Challenged Claims.

114. Aboul-Hosn discloses a minimally invasive intravascular blood pump system that can support or replace the left ventricular function (for example in a beating heart surgery situation), using the same basic components of prior art axial flow pumps discussed in Part III.C. *See* Aboul-Hosn at 7:6-10, 27:3-18, 31:6-9 (“The stablization systems shown in Figs. 23 and 24 illustrate only some of the various types of commercially available *intravascular* and extracorporeal pumps that are compatible or *provided for by the present invention*.”). (Emphasis added). As I will explain in greater detail blow, just like the '068 patent, Aboul-Hosn's minimally invasive intravascular blood pump are miniaturized pumps that are capable of being percutaneously or surgically introduced into the vascular system of the patient. *See* Aboul-Hosn at 6:16-29, 11:8-11, 21:19-22:30, 29:17-19, 32:9-13; '068 patent at 1:56-58, 17:30-32. Aboul-Hosn discloses that the blood pump system can be powered by an external motor or by an integrated motor. *See* Aboul-Hosn generally at 21:24-27; 24:12-19.

115. As shown in annotated FIGS. 1 and 2, below,⁹ the pump components include the rotor 70 and blades (red), located inside the inlet tube 55 (green), with the housing cap 60 (green) to connect the inlet tube to the cannula (blue).¹⁰ *See* Aboul-Hosn at 12:12-14. A drive unit 80 (purple) provides rotational motion to the rotor 70 causing the rotor 70 to spin and generate the axial flow of blood as described in greater detail below.

⁹ I note that FIGS. 1 and 2 show an extracorporeal pump system, however Aboul-Hosn discloses that the intravascular pump system can comprise the same components – namely an inner cannula 20 (blue) coupled to the housing cap 60 and housing body 52 (with inlet 55) (all in green), a rotor 70 (red) within the inlet tube 55, and the drive unit 80 (purple) – but with the components properly sized (i.e. miniaturized) in order to fit into an introducer for positioning within the vascular system of the patient. *See* Aboul-Hosn at FIGS. 3, 4, and 12. I will explain the introduction and positioning of Aboul-Hosn’s intravascular blood pump in greater detail below.

¹⁰ Aboul-Hosn discloses that the housing body 52 and the housing cap 60 may form one “unitary body.” *See* Aboul-Hosn at 12:22-23.

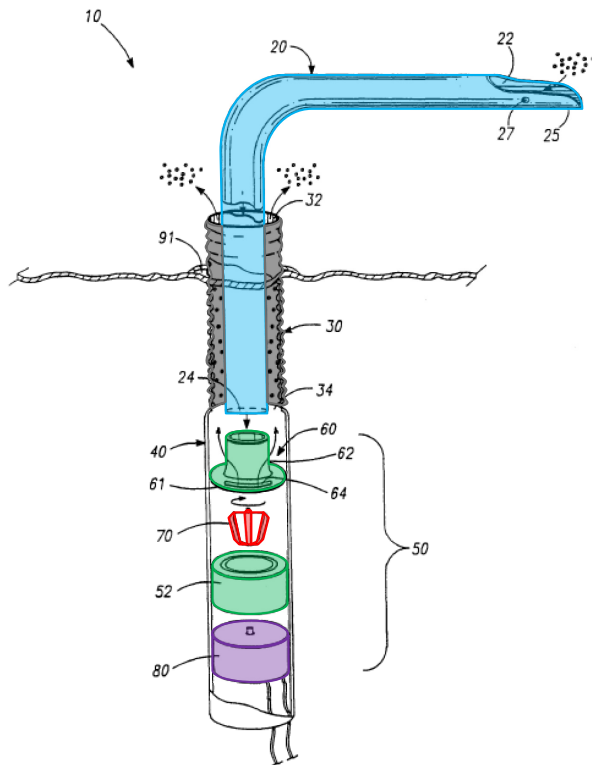


FIG. -1

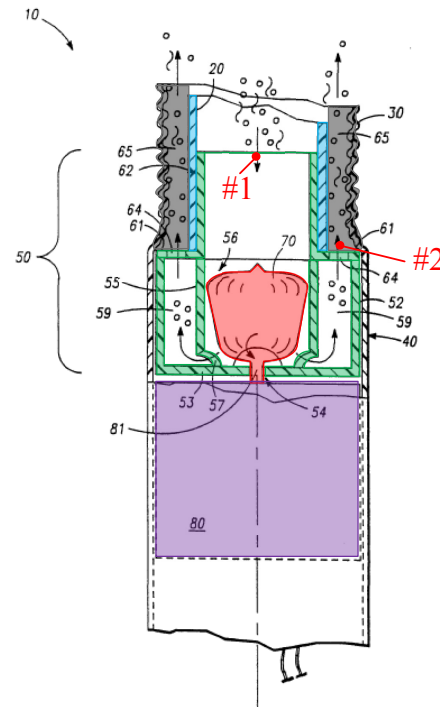


FIG. -2

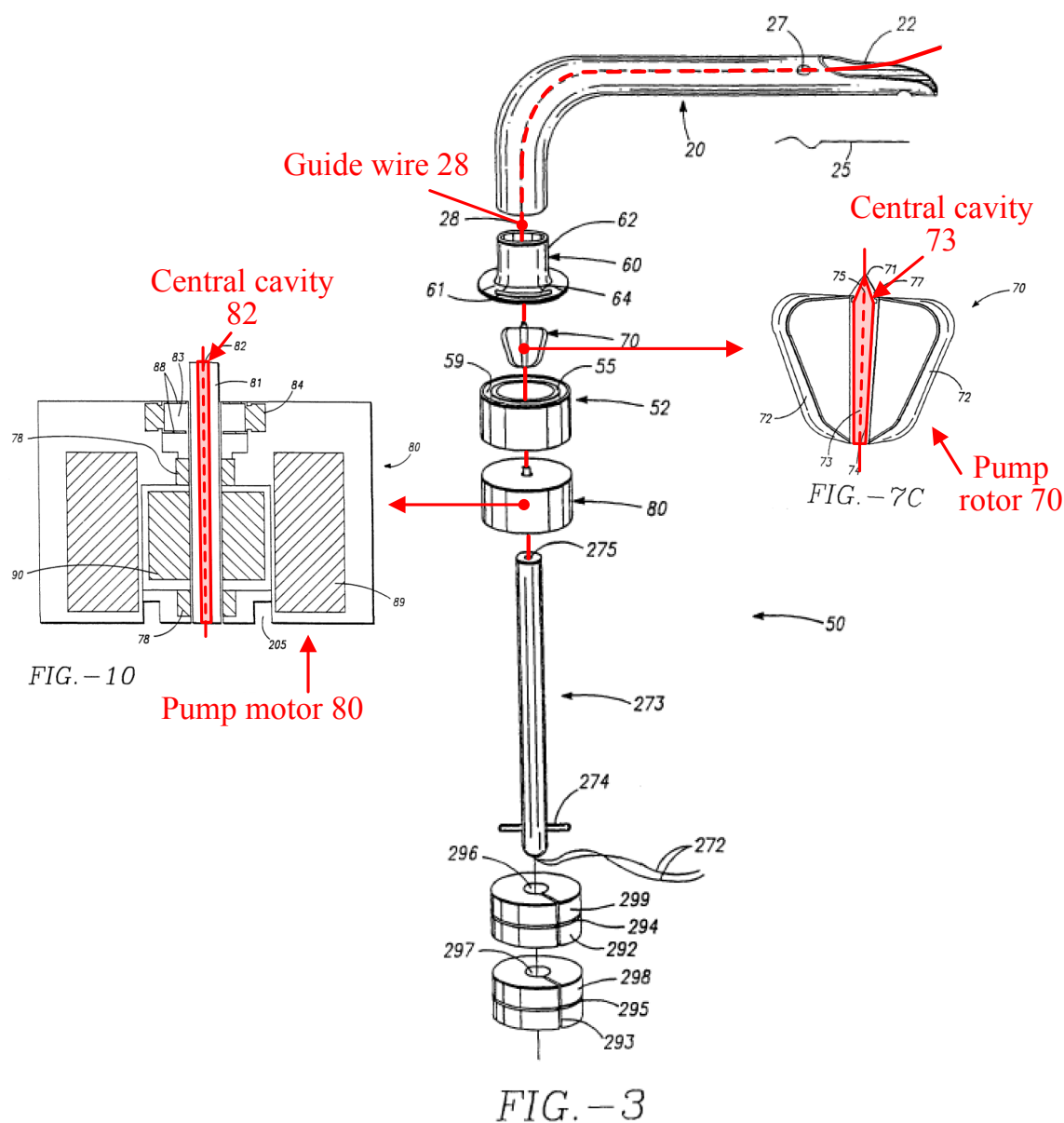
116. The flow path through the pump system configuration shown in FIGS. 1 and 2 of Aboul-Hosn above is a “reverse flow,” in that it has both a conventional axial flow component using a conventional rotor/shroud (*see* Aboul-Hosn at 13:15-18, 18:15-16 (“[e]ach of the illustrated reverse flow pumps essentially consist of an outer pump housing and a rotor”)), followed by reverse flow through ducting which directs the flow through an outer cannula in a reverse direction (*see* Aboul-Hosn at 13:14-18, FIG. 2). As shown by the directional arrow #1 in FIG. 2, above, the axial flow is generated by the rotor 70 and associated blades (red), which draws the blood axially through the distal opening 22 of the inner cannula 20 (blue), into

the rotor 70 (red) and inlet tube 55 (green), as would occur in any conventional axial flow pump. The inlet tube 55 of course is the outer pump housing, also known as a shroud (described further below in Part VIII.A.a regarding limitation 1(c)). The flow is then reversed as it exits the shroud through the radially aligned cut-outs 57 in the inlet tube 55, flowing into the passageway 59 between the inlet tube 55 and the housing body 52. The reversed flow exits through the passageway's outlet windows 64 into the outer cannula 30 along the path shown by the arrows #2. *See* Aboul-Hosn at 18:16-19 (“The pump further consists of an inlet passageway and a separate outlet passageway to direct the flow of fluid as indicated by the arrows included in the figures for purposes of illustration.”).

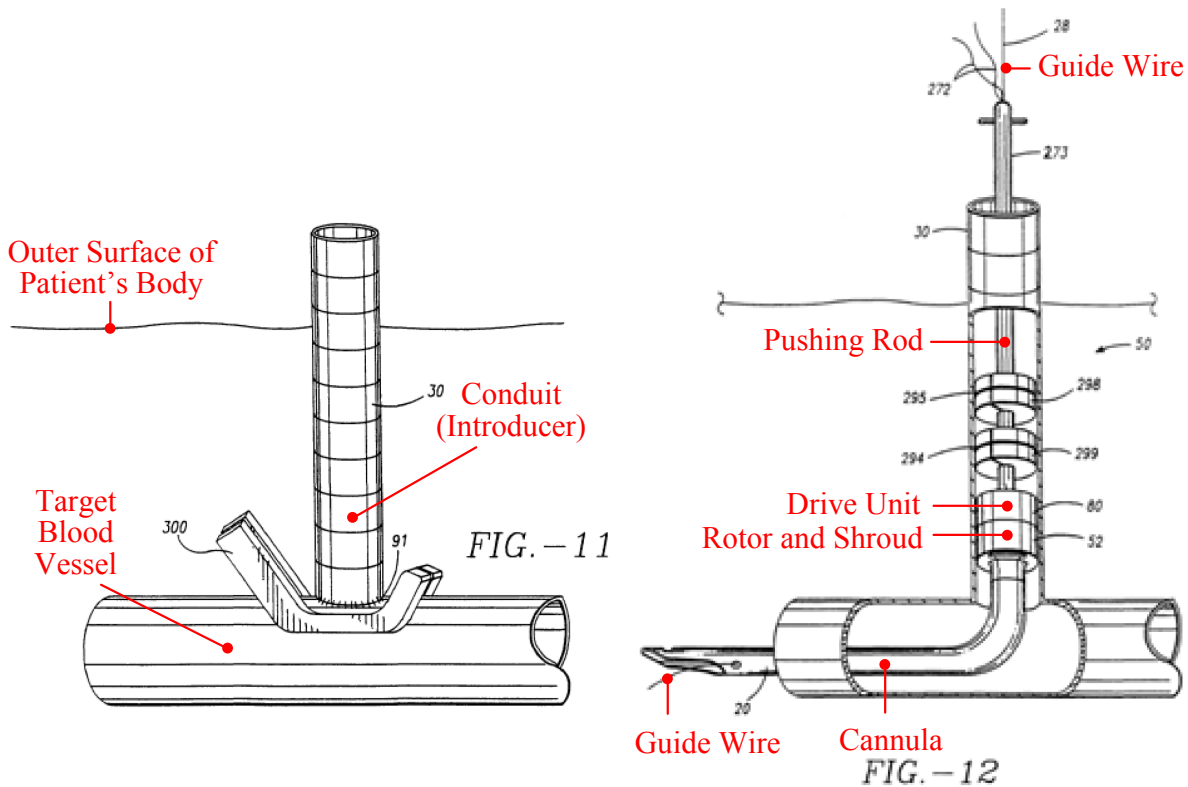
117. Aboul-Hosn discloses that the intravascular blood pump system can be “positioned in a heart chamber or vessel” using a guide wire in the conventional over-the-wire technique—the intravascular blood pump receives the guide wire through a central lumen that extends through the pump components, so the pump can then slide “over” the guide wire into the desired position.¹¹ *See* Aboul-Hosn at 6:26-27, 17:8-22, 20:23-26, 21:6-10, 24:7-14. FIGS. 3, 7C and 10, below, show the over-the-wire technique in connection with the intravascular

¹¹ A POSITA could also readily adapt the pump system to be delivered using the conventional rapid-exchange technique by providing a conventional sleeve along the side of the cannula 20 and passing a guide wire through the sleeve, such that the guide wire runs along the side of the inner cannula 20 and optionally extends into the cannula, as shown in Voelker Fig. 2.

blood pump system in detail. The central lumen extends through the drive unit 80 and the pump components, such as the rotor 70, the housing cap 60, and the inner cannula 20; the guide wire (red) passes through that lumen (i.e. through central cavities 73 and 82), allowing the blood pump to advance along the guide wire into the desired location in the heart using a positioning rod 273. *See* Aboul-Hosn at 14:20-24, 17:8-22, 22:10-21; 24:7-14. As I noted above, the intravascular blood pump system shown in FIG. 3 comprises the same pump components (i.e. the inner cannula 20, housing cap 60 and housing body 52, the rotor 70, the drive unit 80, etc.) as the extracorporeal pump system shown in FIGS. 1 and 2, but with the addition of the pushing rod 273 to push the intravascular blood pump into the patient's body. The positioning rod 273 has "a central passage 275 extending the entire length of the positioning rod 273 and [is] used for passing a guiding element 28, such as a guide wire or a catheter or like devices, through its center." *See* Aboul-Hosn at 14:20-24.



118. FIGS. 11 and 12 of Aboul-Hosn, shown below, illustrates the process of positioning the intravascular blood pump system shown in FIG. 3 within the patient's vasculature using the conventional over-the-wire technique. *See* Aboul-Hosn at 9:12-13.



119. As shown in FIG. 11, an outer conduit 30 is first inserted through a small incision in the patient's skin (denoted by the slightly undulating horizontal line near the proximal end of the outer conduit 30) and attached to "a targeted blood vessel or [heart] chamber using thoracoscopic suturing or microstapling." See Aboul-Hosn at 21:11-18. The outer conduit 30 in Aboul-Hosn effectively functions as what is known in the art as an "introducer" as it can be used to introduce the intravascular blood pump system into the patient's body. See Aboul-Hosn at 12:7-9 ("In a preferred embodiment, the outer conduit 30 is an introducer, or a vascular graft, such as a DacronTM graft, or any other commercially available grafts or synthetic conduits used.") Suturing, stapling, or otherwise attaching the

outer conduit 30 to a target blood vessel as shown in FIG. 11, such as a major artery or vein, allows the intravascular blood pump system to be introduced percutaneously through the patient's vasculature, whereas attaching the outer conduit 30 directly to the target heart chamber allows the intravascular blood pump system to be surgically positioned at the desired location within the patient's heart. Aboul-Hosn describes this as an "endovascular method and system." *See* Aboul-Hosn at 6:24-7:5 ("Another variation of the present invention is directed to an endovascular method and system for preparing the heart for surgical procedures, and particularly for unloading the heart, partially or totally stopping the heart. A reverse flow blood pump system may be passed through a conduit and positioned in a heart chamber or a vessel in preparation to completely or partially stop the heart in order to operate on the organ.").

120. FIG. 12 shows the introduction of an intravascular blood pump system into the patient's vasculature through the introducer (conduit 30). *See* Aboul-Hosn at 9:12-13. After the outer conduit 30 is sutured to the target blood vessel or heart chamber as shown in FIG. 11, a "commercially available high stiffness guide wire" is passed through the outer conduit 30 and placed at a desired location within the patient's vasculature to "assist in the placement of the inner cannula 20" of the intravascular blood pump system. *See* Aboul-Hosn at 21:22-23, 22:10-14. Once the guide wire 28 is in place, the blood pump system is advanced over the guide

wire 28 (i.e. the guide wire 28 passes through the distal opening 22 of the inner cannula 20, through the central passages of the rotor 70, the drive unit 80, and the positioning rod 273 as previously shown in FIG. 3, above) and introduced into the patient's body via the outer conduit 30. *See* Aboul-Hosn at 21:27-29. Silicone plugs 298 and 299 are advanced over the positioning rod 273 into the outer conduit 30 to seal the outer conduit 30 and driving unit 80. *See* Aboul-Hosn at 21:31-22:2.

121. The positioning rod 273, manipulated by the surgeon, pushes the pump 50 and inner cannula 20 over the guide wire 28 into the outer conduit 30 and to the desired location within the patient's vasculature, which can be done with the aid of imaging techniques to ensure proper placement of the intravascular blood pump. *See* Aboul-Hosn at 22:10-18 ("A guide wire 28 may be also advanced with the help of imaging techniques to dispose the distal end of the inner cannula 20 in the desired blood vessel, heart chamber or other body cavity."). After the cannula has been placed at the desired location within the heart, the guide wire 28 may be removed and the pump 50 is activated. *See* Aboul-Hosn at 22:24-25.

122. Using the over-the-wire placement technique shown in FIG. 12, the intravascular blood pump system can be placed in a variety of different configurations to provide both left-heart and right-heart support (such as the configurations shown in FIGS. 14-19 (where the intravascular blood pump system has been positioned surgically) and FIGS. 21 and 23 (where the intravascular blood

pump system has been positioned percutaneously)). *See* Aboul-Hosn at 9:16-31, 10:6-11. For example, FIG. 17 of Aboul-Hosn, below, shows a configuration using two of Aboul-Hosn's intravascular blood pump systems that are positioned surgically to provide both left-heart and right-heart support simultaneously. *See* Aboul-Hosn at 26:21-23 ("Fig. 17 illustrates another variation of the present invention involving the insertion of a left heart pump into the left side of the heart, and simultaneously inserting a second heart pump into the right side of the heart").

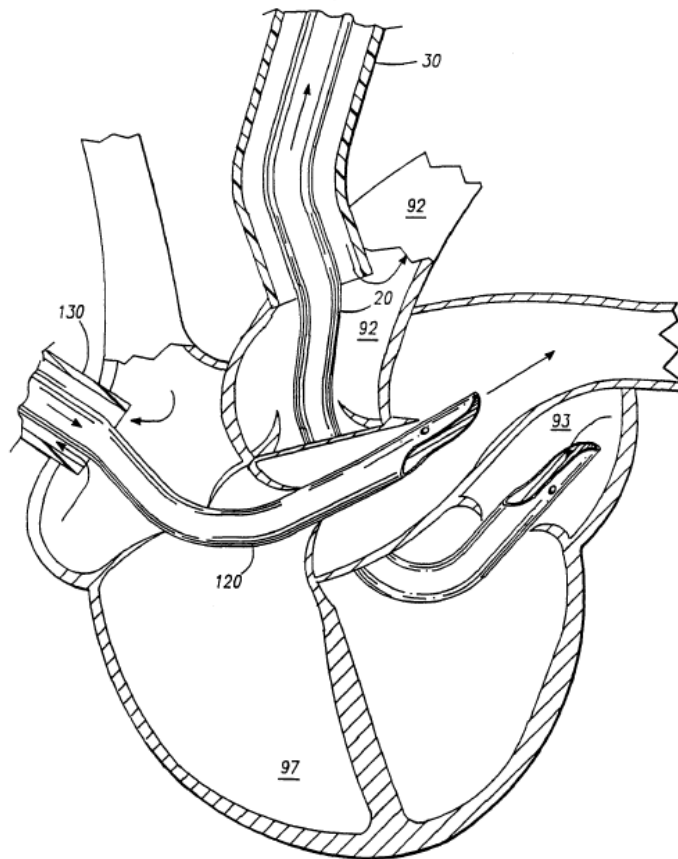


FIG. - 17

123. FIG. 17 is representative of a surgical placement of the intravascular blood pump systems into the patient's heart – in this case an outer conduit can be directly attached to a target heart chamber, such as the right atrium, and the distal portion of the intravascular blood pump system can be advanced into position within the heart over a guide wire (see wire element extending from the distal opening of cannula 20 in FIG. 17 above) in the manner shown and previously discussed in FIG. 12.

124. FIG. 21 of Aboul-Hosn, below, shows an example of a percutaneous placement of an intravascular blood pump system (pump 420 and cannula 410) through the femoral artery 430. *See* Aboul-Hosn at 29:17-29. In the case of FIG. 21, an introducer such as outer conduit 30 is inserted into the patient's body near the leg through an incision and attached to the femoral artery. The intravascular blood pump system is then introduced into the patient's body through the introducer (i.e. an outer conduit 30) and advanced through the femoral artery¹² to the desired position within the patient's heart as shown in FIG. 21.

¹² In the case of FIG. 21, because of the distance the intravascular blood pump will need to travel in order to reach the desired location within the patient's heart from the initial introduction point in the femoral artery within the patient's leg, and to better navigate the curvature of the patient's vasculature, and in particular the aortic arch, an elongate catheter 428 is used in place of the positioning rod 273 (shown in FIG. 12) to advance the blood pump over the guide wire through the femoral artery. A POSITA would readily recognize the catheter 428 as being interchangeable with the positioning rod 273 in percutaneous applications where the positioning rod 273 may not be able to advance the intravascular blood pump

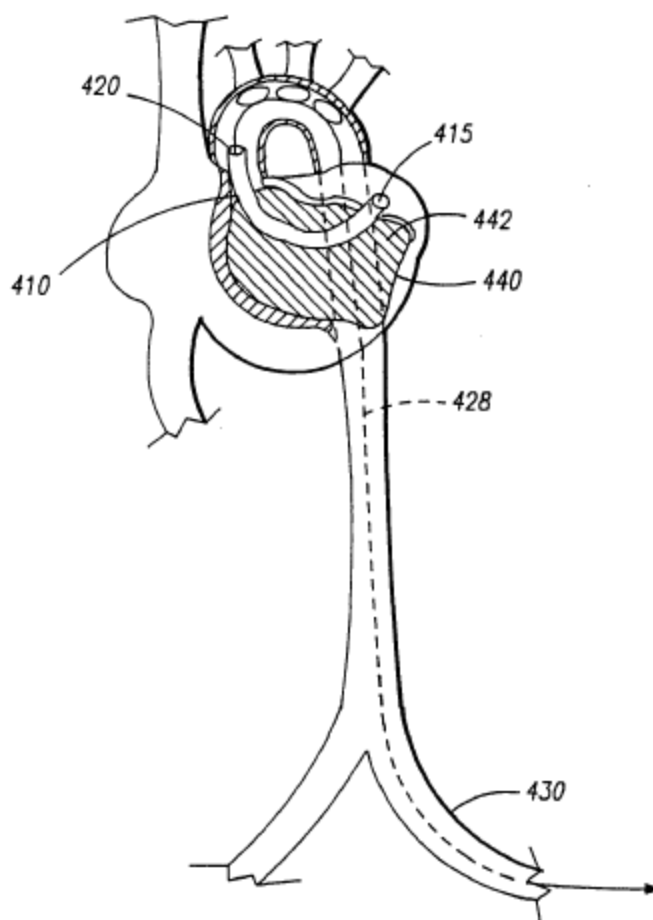


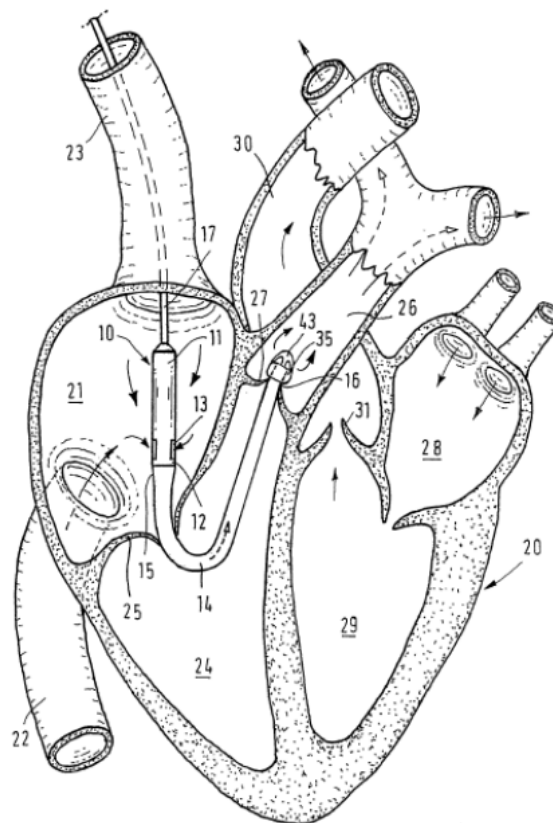
FIG. -21

to the desired location (due to length, navigability, or the like). The catheter 428 would be coupled to the proximal end of the drive unit 80 in the same manner as the positioning rod 273 (i.e. “matched to the groove 205 formed in the drive unit 80 to form a press fit, or to attach to the drive unit by welding, bonding or forming a unitary part,” *see* Aboul-Hosn at 14:28-31). Moreover, like the positioning rod 273 with a central passageway 275 that can pass “wires, tubes or similar accessories needed by the drive unit 80” (*see* Aboul-Hosn at 15:5-6), the catheter 428 “may be a multilumen catheter with separate lumens to drive the pump 420, to measure pressure in the vicinity of the catheter along its entire length, to deliver or remove fluid, to enable the passage of small diameter guides or leads, or to perform other similar functions.” *See* Aboul-Hosn at 29:19-23.

B. Overview of Sammler

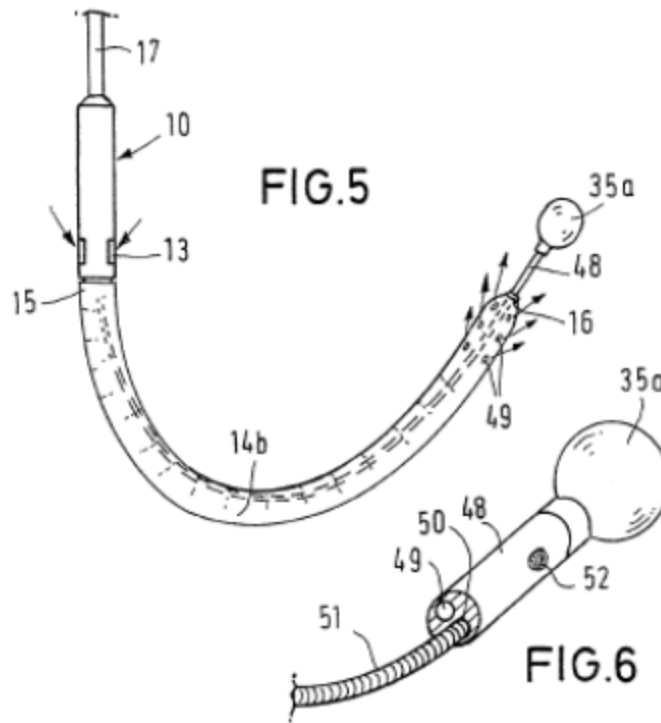
125. This declaration also relies on Sammler as a primary reference, which is prior art against the Challenged Claims.

126. Sammler discloses an intravascular blood pump featuring many of the common components of axial flow blood pumps discussed in Section III.C above. According to Sammler, the blood pump is inserted into the heart from the vasculature and through either the upper vena cava or the lower vena cava into the right atrium of the heart. *See* Sammler at 4:15-18, 4:38-40, FIG. 1 (showing insertion through the upper vena cava 23).

**FIG. 1**

127. Sammler discloses that the internal structure of the pump for moving the blood in axial direction is well-known and described *e.g.* in Rau (WO97/37696). *See* Sammler at 2:18-20, 4:18-19. As shown in FIG. 1, the pump is connected at the distal end to a flexible cannula (pump hose 14) extending from the right ventricle (24) into the pulmonary artery (26) when the pump is positioned in the heart. *See* Sammler at 4:22-23, 4:38-39, 5:9-11. As further shown in FIG. 1, the pump 10 is also connected to the catheter 17 on the proximal end. *See* Sammler at 4:24-26.

128. Sammler discloses an embodiment shown in FIGS. 5 and 6 that includes a guide mechanism with a removable guide wire 51 extending through a lumen 50 within the catheter 48 and cannula 14b, the pump 10, and the catheter 17. *See* Sammler, 3:24-27, 6:3-7, FIGS. 5-6.



129. Sammler also discloses an opening 52 may be “provided on the catheter 48” that can be used “for external pressure measurement.” *See* Sammler at 6:8-10. Once the guide wire 51 is removed, “blood enters the lumen 50 through the opening 52” and the “lumen 50 can be connected to a blood pressure measuring instrument”. *See* Sammler at 6:10-12.

C. Analogous Art

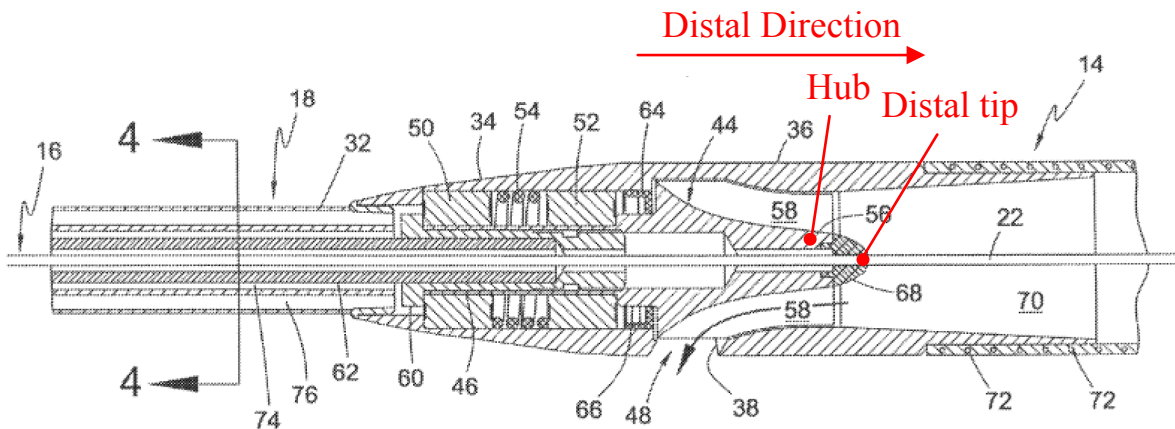
130. It is my opinion that Aboul-Hosn and Sammler are analogous art to the '068 Patent because (1) like the '068 Patent they are directed to intravascular blood pump systems as I explained above in Parts VI.A-B, and (2) they all are directed to the same problem of positioning the intravascular blood pump within the vasculature system of the patient that is being addressed by the '068 Patent. As

such, as I explain in greater detail below, a POSITA would have been naturally motivated when looking at any one of Aboul-Hosn or Sammler to look to the others as well.

VII. CLAIM CONSTRUCTION

131. I have been informed and understand that a claim in *inter partes* review is given the “broadest reasonable construction in light of the specification.” 37 C.F.R. § 42.100(b). I have also been informed and understand that any claim term that lacks a definition in the specification is therefore also given a broad interpretation. The following discussion proposes constructions of and support therefore of those terms. I have been informed and understand that any claim terms not included in the following discussion are to be given their broadest reasonable interpretation in light of the specification as commonly understood by those of ordinary skill in the art.

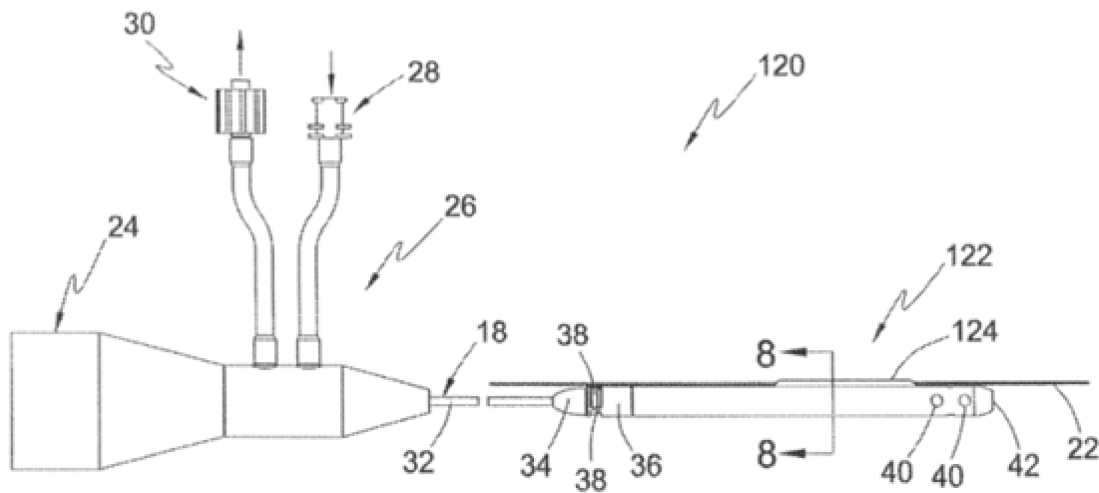
132. A POSITA would understand that “distal” in the ’068 Patent refers to “towards the far end of the cannula relative to the position of the pump.” For example, the ’068 Patent discloses “the purge fluid flows distally around the cable adapter **60**, through the ball bearing assemblies **50**, **52**, and onward past the radial seal **64**.” ’068 Patent at 10:20-23. As shown in FIG. 3 below, this distal flow of the purge fluid runs from left to right, i.e. towards the far end of the cannula relative to the position of the pump.

FIG. 3

133. Moreover, the '068 Patent discloses that the “distal tip” of the hub 56 is where the seal member 68 is attached (right of the hub), whereas the proximal end of the rotor, including the hub, is connected to the drive cable assembly 18 (left of the hub) and to the motor assembly 20 outside of the patient’s body. *See* '068 Patent at 9:25-26; 10:1-3. In other words, the distal tip is the tip away from the outside of the patient’s body, towards the far end of the cannula relative to the position of the pump.

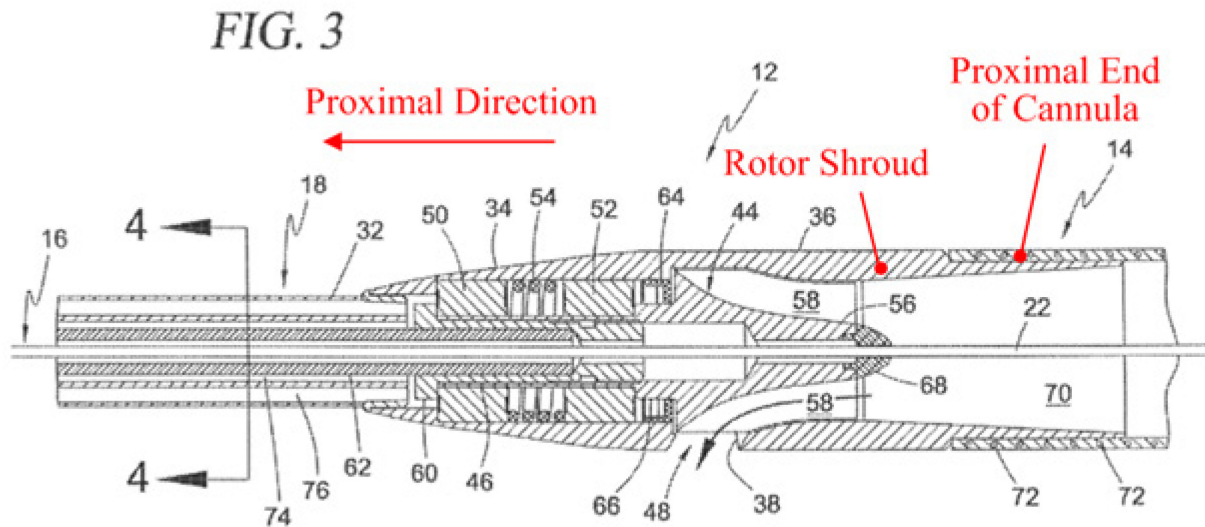
134. Further, the '068 Patent discloses that the “distal region” or “distal end” of the cannula includes “a plurality of ports or fenestrations 40.” '068 Patent 8:14-19. As shown in FIG. 7 below, the “distal region” or “distal end” refers to the far region or end of the cannula relative to the position of the pump.

FIG. 7



135. Based on my understanding of the '068 Patent, “distal” refers to “towards the far end of the cannula relative to the position of the pump.”

136. Similarly, a POSITA would understand that “proximal” in the '068 Patent refers to the opposite of “distal,” i.e. away from the far end of the cannula relative to the position of the pump. For example, the '068 Patent discloses “[t]he cannula **14** is coupled at its proximal end to the rotor shroud **36**.” '068 Patent at 9:47-48. As shown in FIG. 3 below, the proximal end of the cannula is the end opposite the “distal region” of the cannula.



137. Based on my understanding of the '068 Patent, “proximal” refers to opposite of “distal,” i.e., it refers to being directed away from the far end of the cannula relative to the position of the pump. For example, the '068 Patent provides that “[t]he cannula 14 is coupled at its proximal end to the rotor shroud 36,” which is the end opposite the “distal region” of the cannula. (Ex. 1001 ['068 Patent] at 8:16-21, 9:47-52.)

138. Thus, proximal refers to: away from the far end of the cannula relative to the position of the pump.

VIII. SPECIFIC GROUNDS FOR REJECTION:

139. In my opinion, the Challenged Claims are obvious or anticipated in view of the prior art, as they recite nothing more than the same basic intravascular blood pump technology disclosed in the prior art, using a conventional guide-wire delivery mechanism to deliver the blood pump to the vasculature in the same way

taught in the prior art. As I explain below, the intravascular blood pump technology recited in the Challenged Claims (including its components and guide wire delivery technique) was well disclosed in Aboul-Hosn, supplemented by well-known an minor details about what type of blood pressure sensor and where to place it (as taught in Sammler). In the following sections, I explain in detail how the prior art discloses each and every limitation of claims 10, 13-15, and 20 of the '068 Patent and renders those claims obvious.

A. GROUND I: CLAIMS 10, 13-15, and 20 ARE OBVIOUS OVER ABOUL-HOSN IN VIEW OF SAMMLER

a. Independent Claim 10

10(pre): “A method for perfusion [sic] a patient with an intravascular blood pump system, the intravascular blood pump system comprising:”

140. Claim 10 is a method of using an apparatus and specifies that the blood pump is delivered to a location in the circulatory system of a patient over a guide wire. As such, the method is nothing more than a conventional method of delivering an intravascular blood pump, applied to a conventional intravascular blood pump system (as explained below). Aboul-Hosn discloses both minimally invasive intravascular blood pump systems as well as extracorporeal blood pump systems, and methods for using such systems. *See* Aboul-Hosn at 31:6-9.

141. As shown and described in connection with FIGS. 11 and 12 and as I previously explained in Part VI.A, the minimally invasive intravascular blood

pump system can be “positioned in a heart chamber or a vessel” either percutaneously or surgically through a conduit (introducer) attached to a target blood vessel or heart chamber and advanced through the conduit over a guide wire to position the pump at a desired location within the patient’s vasculature, and which Aboul-Hosn describes to be “an endovascular method and system.”¹³ *See* Aboul-Hosn at 21:11-22:30, 6:24-7:5 (“Another variation of the present invention is directed to **an endovascular method and system for preparing the heart for surgical procedures**, and particularly for unloading the heart, partially or totally stopping the heart. **A reverse flow blood pump system may be passed through a conduit and positioned in a heart chamber or a vessel in preparation to completely or partially stop the heart in order to operate on the organ.**”) (emphasis added). Moreover, Aboul-Hosn confirms that the blood pump system is intravascular because he expressly discloses that the “**blood pump system may be passed through a conduit and positioned in a heart chamber or a vessel,**” indicating that the pump system is not merely situated within the conduit, but is positioned within the vasculature. *See* Aboul-Hosn at 6:26-27 (emphasis added).

¹³Stedman’s Medical Dictionary notes that the prefix “Intra” and “Endo” are synonymous. *See* Stedman’s Medical Dictionary at 916 (“intra – Inside, within; opposite of extra-. **SEE ALSO endo-, ento-.** [L. within]) (emphasis added), 590 (“endo-, end-. Prefixes indicating within, inner, absorbing, or containing”). As used in medical terminology, “endovascular” is synonymous with “intravascular.”

142. Thus, Aboul-Hosn discloses a method for perfusing a patient with an intravascular blood pump system.

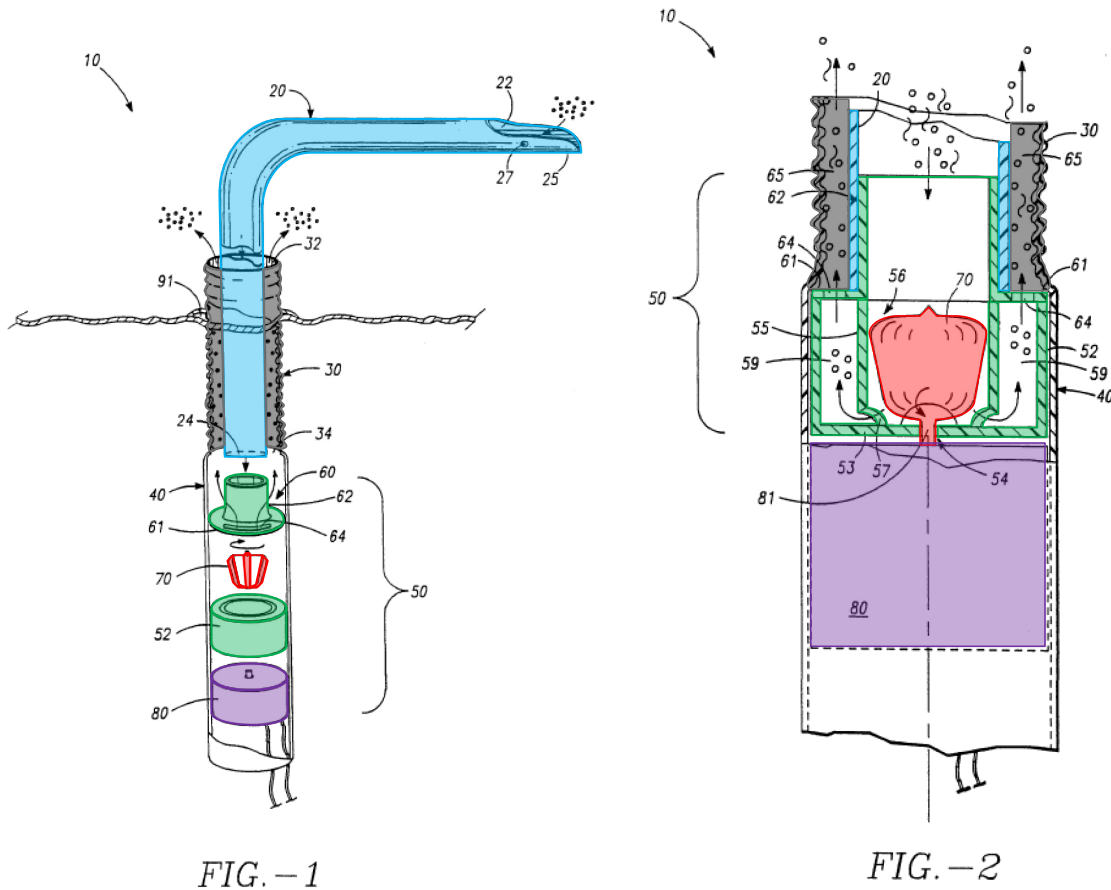
10(a): “(i) an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and at least one blade extending radially outward from the rotor hub.”

143. Aboul-Hosn discloses the intravascular blood pump system comprises an intravascular blood pump. *See* Aboul-Hosn at 1:10-14 (“The present invention is generally directed to related apparatus and methods for the circulation of bodily fluids through the use of a reverse flow pump system.”), 6:6-8 (“The present invention provides a reverse flow pump system that transports fluid between different regions within the body in order to support a wide variety of surgical procedures.”), 6:11-14 (“In one embodiment of the invention, a reverse flow pump for transporting bodily fluids is provided with concentric inner and outer passageways, and an interior compartment that includes a rotor to reverse the directional flow of fluid relative to the pump.”). According to the ’068 patent, “[i]ntravascular blood pumps comprise miniaturized blood pumps capable of being percutaneously or surgically introduced into the vascular system of a patient”. *See* ’068 patent at 1:56-58. Aboul-Hosn’s blood pump is an intravascular blood pump according to the ’068 patent.

144. The components of Aboul-Hosn's blood pump are shown in detail in annotated FIGS. 1, 2, and 12 below. As I previously noted, while FIGS. 1 and 2 of Aboul-Hosn show an extracorporeal pump system (the housing 52 and the drive unit 80 are too large to fit into the conduit 30, and there is no positioning rod to push the blood pump into the patient's body), Aboul-Hosn's intravascular pump system can comprise the same components – namely an inner cannula 20 (blue) coupled to the housing cap 60 and housing body 52 (with inlet 55) (all in green), a rotor 70 (red) within the inlet tube 55, and the drive unit 80 (purple) – but with the components properly sized (i.e. miniaturized) in order to fit into an introducer for positioning within the vascular system of the patient as I will explain in greater detail later in this Section. *See* Aboul-Hosn at FIGS. 3, 4, and 12.

145. The pump includes a rotor 70 (highlighted in red) disposed within an inlet tube 55 of the housing body 52 (highlighted in green), and connected to the drive unit 80 (highlighted in purple). *See* Aboul-Hosn at 12:12-14. An inner cannula 20 (highlighted in blue) is coupled to the inlet neck 62 of the housing cap 60 (also highlighted in green), which can be formed as a “unitary body” with the housing body 52. *See* Aboul-Hosn at 12:22-23, 8:20-21 (“FIG. 1 is an exploded perspective view of a reverse flow system generally showing the reverse flow pump”); 8:24-25 (“Fig. 2 is a sectional side view of the pump portions of a reverse

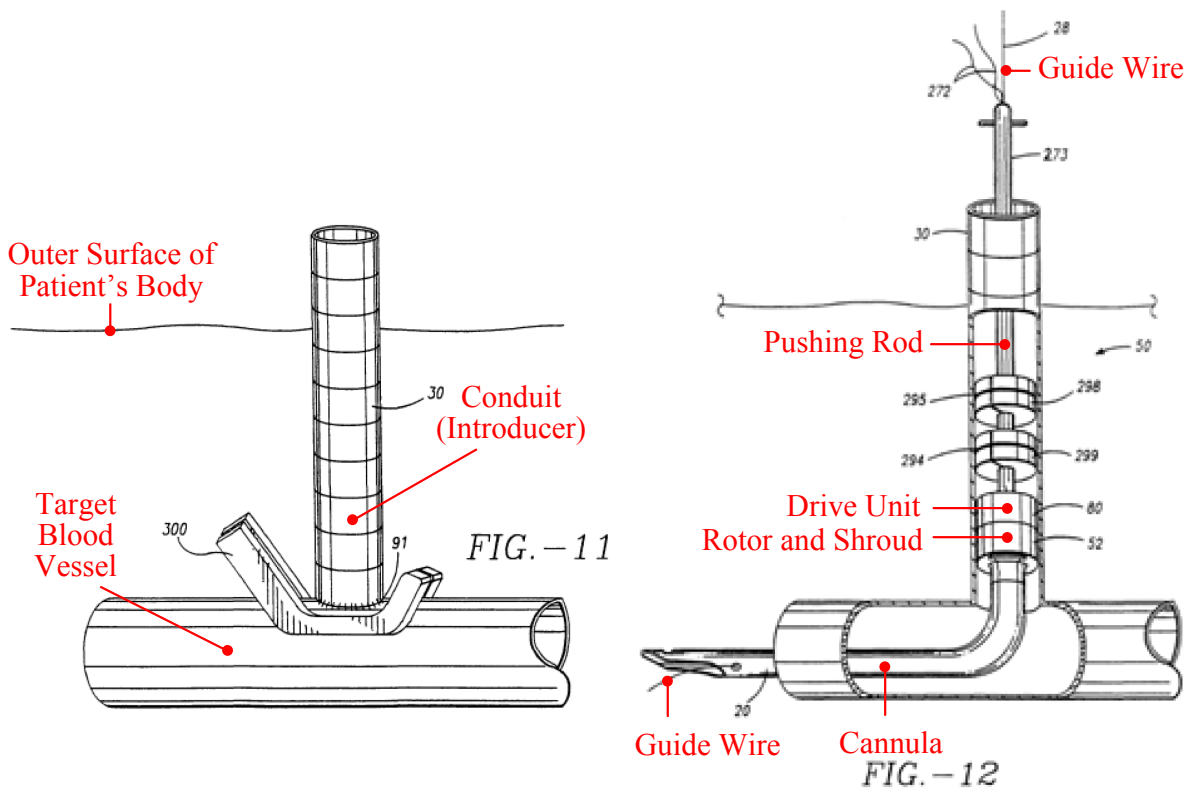
flow system”). The pump components are discussed in more detail in the later limitations.



146. Aboul-Hosn’s blood pump is also intravascular because (1) it is a miniaturized blood pump that is (2) capable of being percutaneously or surgically introduced into the vascular system of the patient. *See* ’068 patent at 1:56-58.

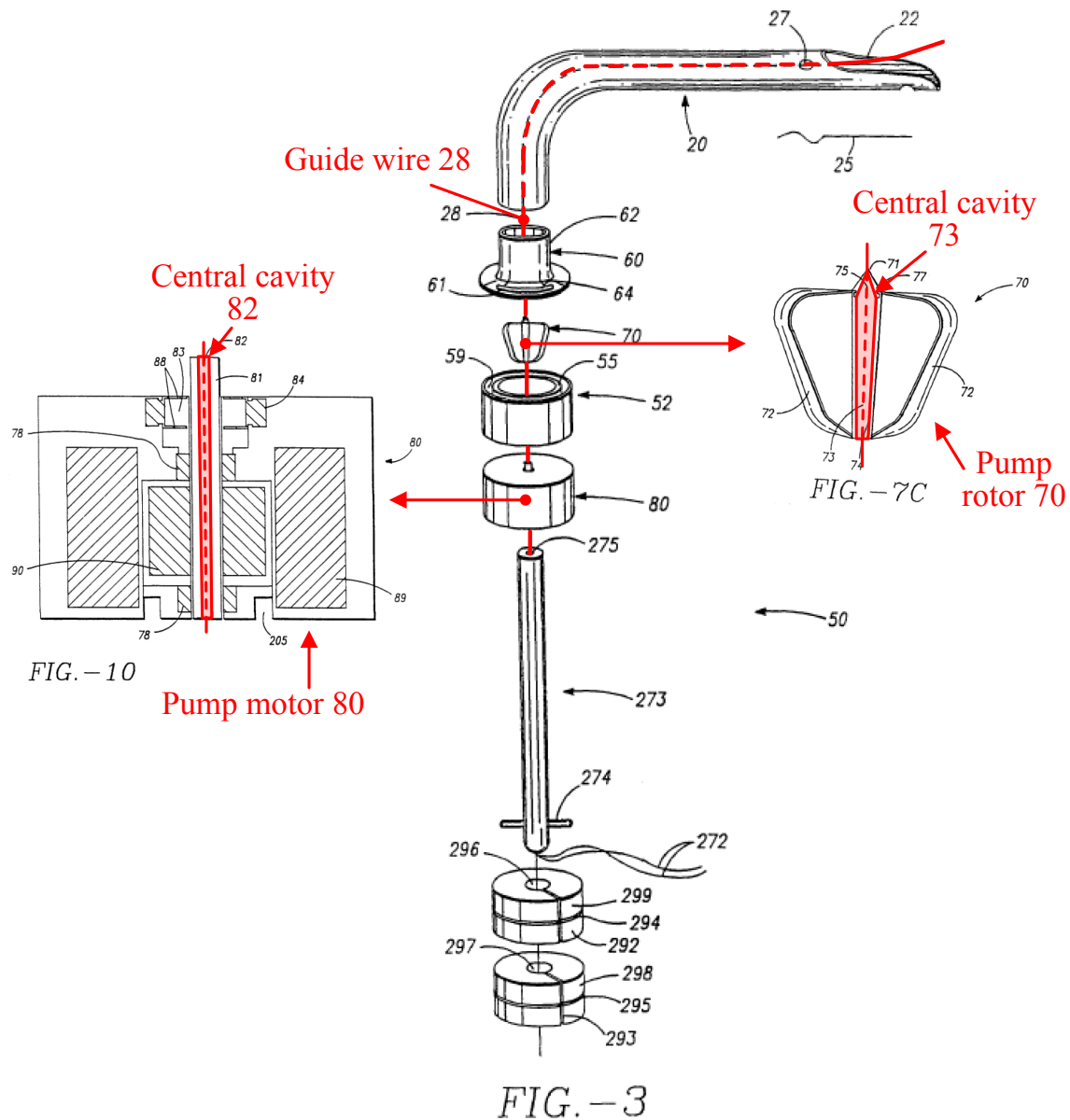
147. First, Aboul-Hosn discloses that the intravascular blood pump is minimally sized in order to fit into an introducer for positioning within the vascular system of the patient. *See* Aboul-Hosn at 6:29-7:2 (“the conduit inserted in the body through a portal of minimal size formed in tissue of a body wall, and

engaging an external surface of a vessel or the heart to limit any significant bleeding”). As I previously explained in Part VI.A, FIGS. 11 and 12 of Aboul-Hosn, shown below, illustrates the process of positioning the intravascular blood pump system shown in FIG. 3 within the patient’s vasculature using the conventional over-the-wire technique. See Aboul-Hosn at 9:12-13.



148. As I also previously explained in Part VI.A, FIGS. 3, 7C, and 10 below show the details intravascular blood pump system 12 with the guide wire 28 extending through the central passageways of the cannula 20, rotor 70, and positioning rod 275. As shown in FIG. 3, the intravascular blood pump comprises the same components as that of the extracorporeal blood pump system shown in

FIGS. 1 and 2 and are denoted by the same element labels (i.e. the rotor 70, the housing body 52 and housing cap 60, etc.).



149. As shown in FIG. 12, all of the components that comprise the intravascular blood pump system, including the intravascular blood pump, must be sized smaller than the conduit 30 that is “inserted in the body through a portal of

minimal size” so that the pump system can be pushed through the conduit 30 to position the “distal end of the inner cannula 20 in the desired blood vessel, heart chamber or other body cavity.” *See* Aboul-Hosn at 6:29-7:2, 22:10-12, 22:16-18 (“While positioning the distal end of the inner cannula 20, the pump 50 may need to be advanced in the outlet conduit 30 by pushing the positioning rod 273 into the outer conduit or graft.”). FIG. 12 of Aboul-Hosn showing the introduction of the intravascular blood pump system into the patient’s body, beneath the skin, stands in stark contrast to FIG. 13 showing an extracorporeal blood pump system, below. *See* Aboul-Hosn at 24:15-19 (“This variation includes the use of a pump 50 that is kept outside the skin of a patient 94”).

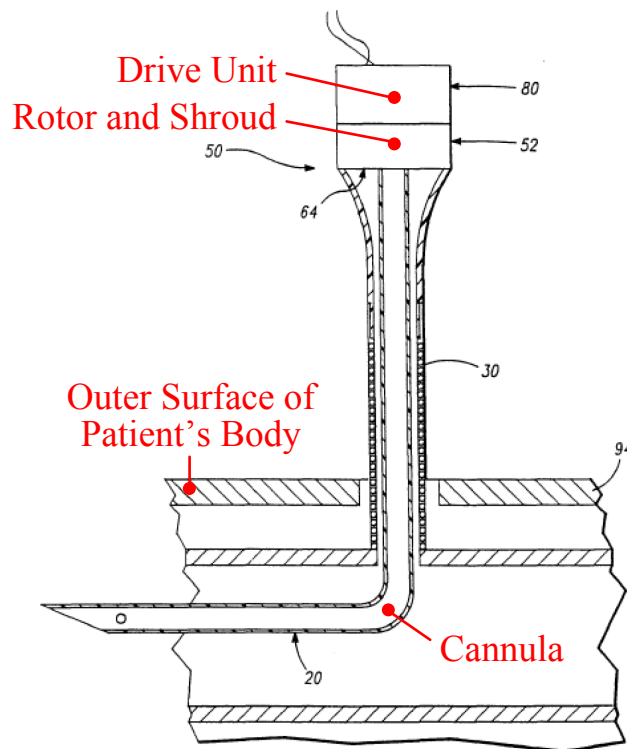


FIG. - 13

150. Aboul-Hosn expressly contrasts the extracorporeal pump shown in FIG. 13 (i.e. the “pump 50 that is kept outside the skin of the patient 94”) with the intravascular blood pump shown in connection with the intravascular blood pump system shown in FIG. 12 by explaining that “[a]n advantage offered by this embodiment of the present invention,” (referring to the extracorporeal pump of FIG. 13) “is the use of a pump 50 that is kept outside the skin 94” which “effectively avoids the requirement for **both the pump housing body 52 outside diameter** and the outside diameter of the drive unit 80 to be smaller than the inside diameter of the outer conduit 30” (referring to the introducer conduit 30 shown in

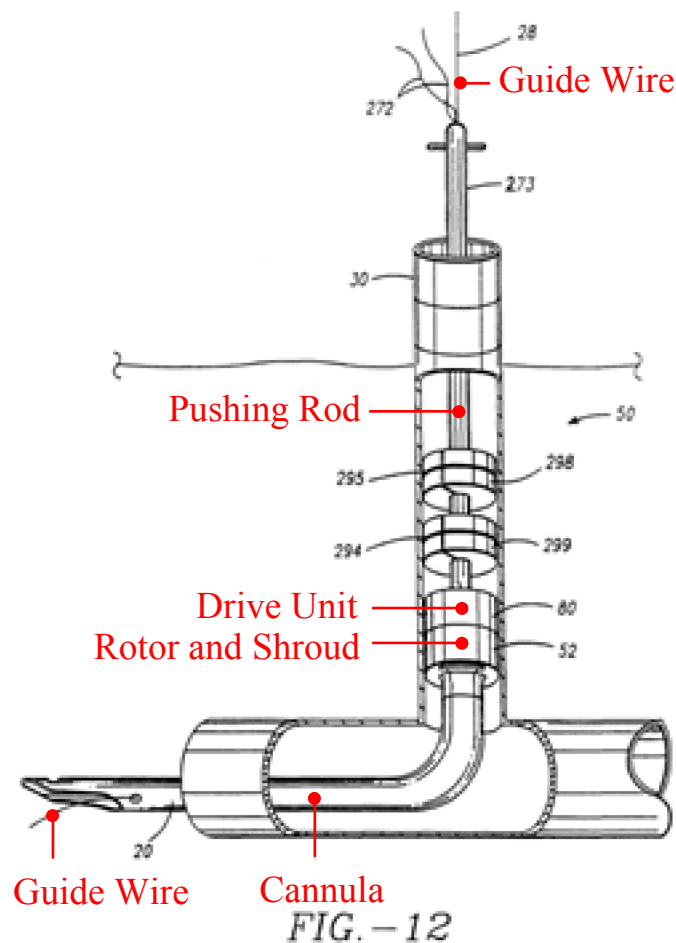
FIG. 12). *See* Aboul-Hosn at 24:24-29 (emphasis added). Aboul-Hosn goes on to explain that “[t]he **outer diameter of the pump rotor and all internal parts dimensions may therefore be larger than described earlier, which may simplify the pump designs and may enable the device capacity to be increased significantly without increase in pump design sophistication.**” *See* Aboul-Hosn at 24:29- 25:1 (emphasis added).

151. Aboul-Hosn thus expressly recognizes that the blood pump can be sized as desired, to either be placed into the patient or remain outside. Indeed, Aboul-Hosn recognizes a straight forward trade-off between the intravascular blood pump of FIG. 12 that is “passed through a conduit and positioned in a heart chamber or vessel” and the extracorporeal blood pump of FIG. 13 that “is kept outside the skin 94” – that the pumping capacity is reduced in the intravascular blood pump of FIG. 12 as compared to the extracorporeal blood pump of FIG. 13 because the intravascular blood pump of FIG. 12 has a “requirement for both the pump housing body 52 outside diameter and the outside diameter of the drive unit 80 to be smaller than the inside diameter of the outer conduit 30” in order to be pushed through the conduit 30. Aboul-Hosn 24:27-29. Thus, the intravascular blood pump of the intravascular blood pump system shown in FIG. 12 is minimally sized (i.e. it is a miniaturized) in order to fit into an introducer for positioning within the vascular system of the patient at the expense of significant increased

device capacity. *See* Aboul-Hosn at 6:29-7:2 (“the conduit inserted in the body through a portal of minimal size formed in tissue of a body wall, and engaging an external surface of a vessel or the heart to limit any significant bleeding”). Making the blood pump within a certain size, to comport with the desired design (i.e. smaller to fit within the conduit for introduction into the patient’s body or larger in the extracorporeal application for increased pumping capacity), would be straight forward to a POSITA.

152. Second, the intravascular blood pump is capable of being percutaneously or surgically introduced into the vascular system of the patient. As I previously explained in Part VI.A and with respect to claim 1.pre, Aboul-Hosn’s intravascular blood pump system can be “positioned in a heart chamber or a vessel” either percutaneously or surgically through a conduit (introducer) attached to a target blood vessel or heart chamber and advanced through the conduit over a guide wire to position the pump at a desired location within the patient’s vasculature. *See* Aboul-Hosn at 21:11-22:30, 6:24-7:5. As shown in FIG. 12, reproduced again below, the intravascular blood pump is still in the process of being advanced through the conduit 30 – the distal end of the cannula 20 has not yet been positioned “in the desired blood vessel, heart chamber or other body cavity” because the distal opening of the cannula and the outflow windows of the intravascular blood pump are not separated by a structure such as a heart valve, and

if operated in this condition will draw in blood and pump out blood into the same blood vessel which would not unload the heart in preparation for surgery or otherwise “transports fluids between **different regions** within the body in order to support a wide variety of surgical procedures” which is the purpose of Aboul-Hosn’s intravascular blood pump system. *See* Aboul-Hosn at 6:6-8 (emphasis added), 6:19-20.



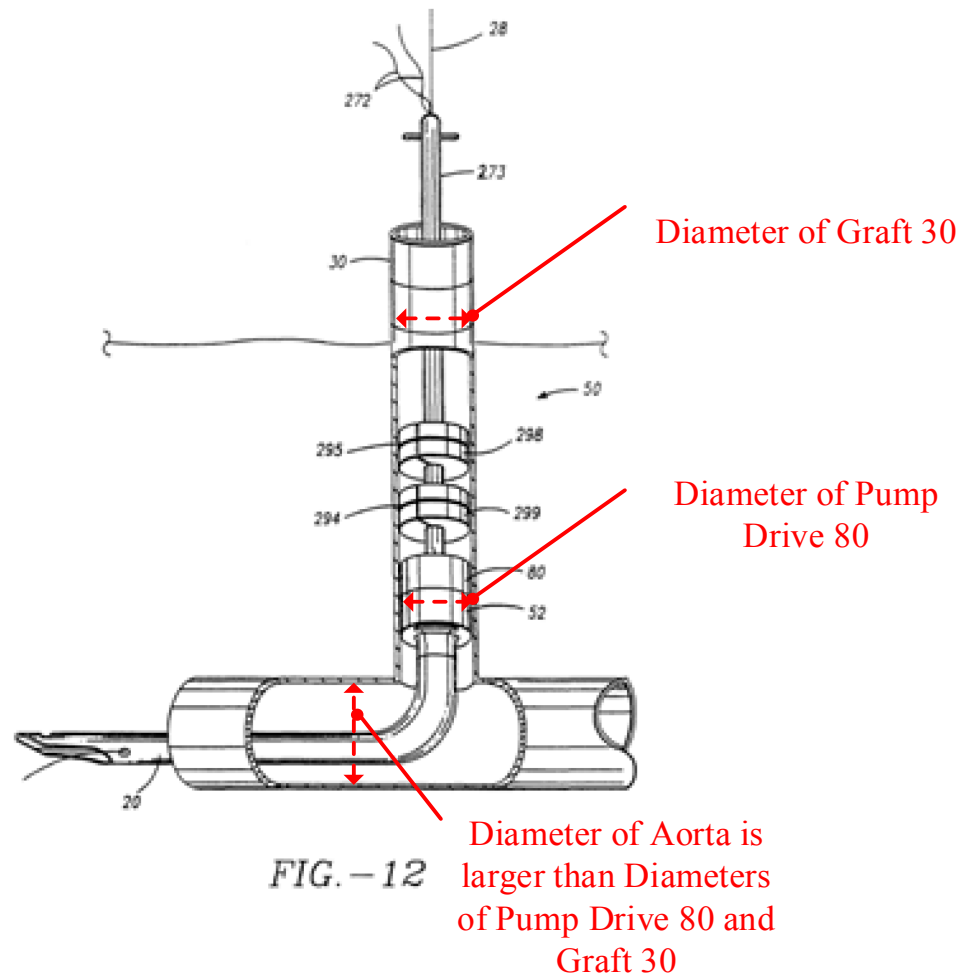
153. For instance, the pump would need to be advanced even further through the conduit 30 until the distal end of the cannula is positioned across a

heart valve to transport blood from one heart chamber to another chamber or vessel. *See e.g.* Aboul-Hosn at FIGS. 14-19.

154. Moreover, Aboul-Hosn discloses that the conduit 30 used to introduce the intravascular blood pump system into the patient's body can be a "DacronTM graft, or any other commercially available grafts or synthetic conduits." *See* Aboul-Hosn at 12:7-9. A Dacron graft is typically used to extend or replace a portion of the patient's vascular system. For example, a Dacron graft can be used to replace or repair a blood vessel that has been damaged due to disease or injury. The Dacron graft forms a part of the patient's vascular system. The conduit 30, which Aboul-Hosn discloses can be a Dacron graft, would also be an extension of the patient's vascular system – similar to that of a branching blood vessel as blood would flow from the target blood vessel that the conduit 30 has been attached to into the conduit (hence the need for silicon plug 298 to "seal the outer conduit 30 and the driving unit 80," *see* Aboul-Hosn at 21:31-22:1). Thus, even where the intravascular blood pump remains within the conduit 30 as shown in FIG. 12 – a POSITA would understand that the pump is within the vascular system of the patient.

155. A POSITA would also understand that commercially available Dacron grafts can have stated diameters of 7-10mm – which are consistent and compatible to use as introducers for intravascular blood pumps, which as I previously

explained in Part III.B have diameters of 7-9mm (or smaller). *See* Wampler '712 at 3:52-54; Voelker at 1:56-61. Compared to the aorta, which has a cross-sectional area of about 2.5cm^2 (250mm^2), or an even larger heart chamber, the Dacron graft used to introduce the intravascular blood pump system would be much smaller in size. *See* Guyton at Chapter 14, p 151. Indeed, Aboul-Hosn discloses that “the conduit [is] inserted in the body through **a portal of minimal size** formed in tissue of a body wall and engaging an external of a vessel or the heart **to limit any significant bleeding**.” *See* Aboul-Hosn at 6:31-7:2 (emphasis added). As such, the intravascular blood pump that must be sized to have an outer diameter smaller than the inner diameter of the conduit in order to be pushed through the conduit (*see* Aboul-Hosn at 24:26-29) would be more than capable of being introduced into the vascular system of a patient, such as in the aorta or a heart chamber, which are going to be larger than the conduit. As shown in annotated FIG. 12 of Aboul-Hosn below, the diameters of both the graft and the drive unit of the pump are much smaller than the diameter of the aorta. Although there is no indication that FIG. 12 is drawn to scale as a whole, a POSTIA would understand, based on Aboul-Hosn’s teaching of a Dacron graft, that FIG. 12 still provides the correct relative size comparison, indicating that the pump has been in fact miniaturized sufficiently, and is “capable” of being pushed further into the aorta.



156. Further, there are well-known advantages of inserting the intravascular blood pump system into the vascular system of the patient. In order for the distal end of the cannula to be positioned across a heart valve to transport blood from one heart chamber to another chamber or vessel, either (1) the position of the drive unit may be fixed and the length of the cannula increased to reach a desired position within the heart, or alternatively (2) the length of the cannula may be fixed but the drive unit must be moved further within the vasculature, i.e. closer to the heart. As an example, in Aboul-Hosn FIG. 12, to achieve the desired blood

transport between chambers without displacing the drive unit 80 and rotor 52, the cannula 20 would have to be extended to a length such that the distal end of the cannula could be positioned across a heart valve. However, to reach a heart valve this configuration would result in an extremely long cannula, and a POSITA would readily understand that increasing the length of the cannula detrimentally increases hydrodynamic losses.

157. Indeed, a POSITA would be familiar with frictional head loss in a pipe, and the fact that frictional head loss is a function of (1) the characteristics of the internal flow, i.e. transitional or turbulent (high Reynolds number) and viscous for blood, but also (2) a function of the pipe geometry, both diameter and length, and a friction factor which is itself a function of the pipe shape, i.e. the cannula shape. *See* White Chapter 6.3, describing frictional head loss and the Darcy friction factor. *See also* Siess Thesis, Chapter 5.8.4 Viscosity Effect, describing channeling friction losses. To avoid these increased frictional losses associated with an increased cannula length which would in turn require a larger pump, a POSITA would likely favor a short cannula over a lengthy one. Aboul-Hosn appreciates this with his use of intravascular blood pumps and extracorporeal blood pumps, as I explained above. Intravascular blood pumps enable one to insert the pump system, e.g. the pump 50, further distally, i.e. closer to the heart, thus shortening the length of the cannula while still reaching the desired position across

a heart valve. A shorter cannula would be preferable to minimize the hydrodynamic losses mentioned above without increasing pump size, and a shorter cannula would therefore yield a beneficial increase in pump output without increasing the pump size.

158. Finally, Aboul-Hosn expressly contemplated that intravascular blood pumps are capable of being introduced into the vascular system of the patient. As I previously explained in Part VI.A, FIGS. 21 and 23 of Aboul-Hosn, below, show an example of a percutaneous placement of an intravascular blood pump system including an intravascular blood pump through the femoral artery. *See* Aboul-Hosn at 29:17-19, 30:21-24. As shown below in FIGS. 21 and 23, to place the distal end of the cannula into the left atrium where the intravascular blood pump system was inserted into the femoral artery, the intravascular blood pump system including the blood pump 420 is advanced through the femoral artery 430 (using the multilumen catheter 428 in the place of the positioning rod 273 due to the distance that the intravascular pump system needs to travel through the artery as I explained above in footnote 10). *See* Aboul-Hosn at 29:17-19.

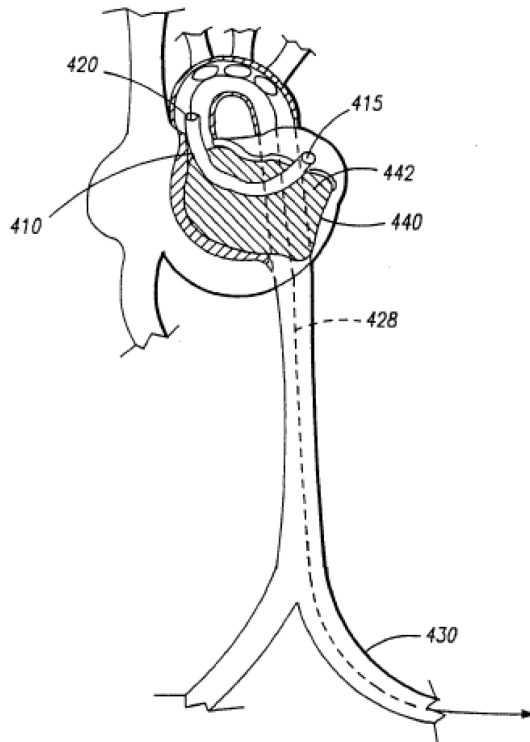


FIG. -21

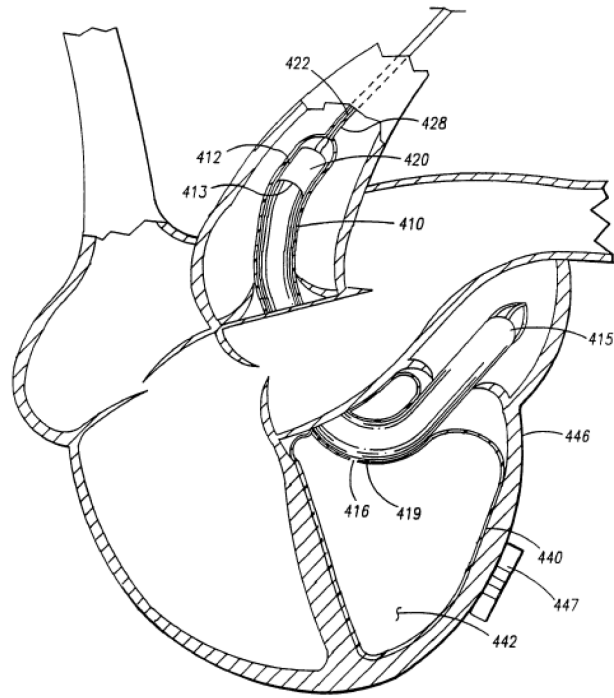
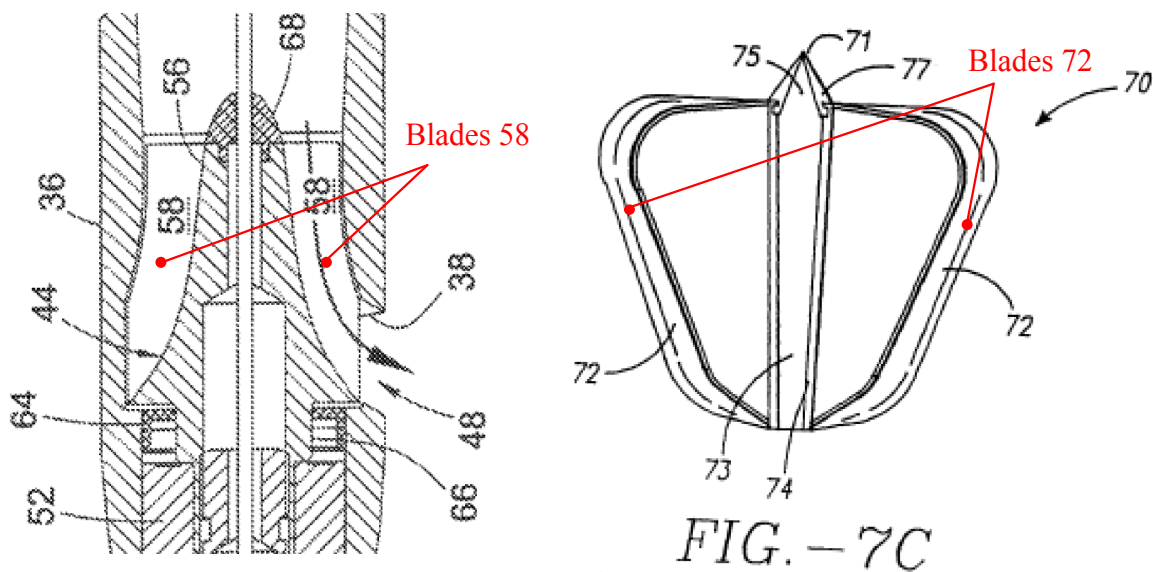


FIG. -23

159. Thus, when considering Aboul-Hosn in its entirety, Aboul-Hosn expressly discloses the blood pumps of FIGS. 1-4, applied as in FIG. 12, as being an intravascular blood pump for the reasons I explained above.

160. Aboul-Hosn discloses a rotor 70 with a rotor hub 74 tapering in the distal direction, with at least one blade 72 extending radially outward from the rotor hub 74. *See* Aboul-Hosn at 16:30-17:6 (“As shown in FIG. 7A-C, the rotor 70 may comprise a single or multiple blades 72 extending from a longitudinally aligned central hub 74.”). As previously discussed in Part VII, the distal direction is the direction towards the far end of the cannula relative to the position. FIG. 7C of Aboul-Hosn (right) shows a rotor 70 having a central hub 74 tapering in the

distal direction, with blades 72 extending “radially outward” from central hub 74 in the same manner as blades 58 extend from hub 56 in the '068 Patent (left). Aboul-Hosn discloses that “the rotor 70 may comprise a single or multiple blades 72 extending from a longitudinally aligned central hub 74.” *See* Aboul-Hosn at 17:1-2.



161. As annotated FIG. 7C below shows, the rotor hub has a distal end that extends distally beyond the most distal portion of the blade.

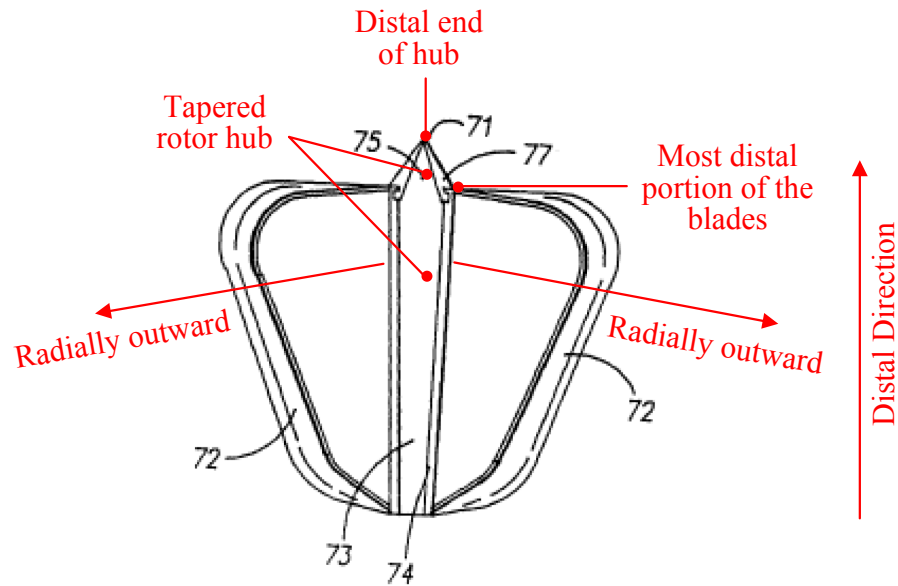


FIG. - 7C

162. Thus, Aboul-Hosn illustrates a rotor design that meets this limitation: (1) an intravascular blood pump (2) comprising a rotor 70 with a central hub 74 with an end tapering in the direction towards the far end of the cannula relative to the position of the pump and (3) blades 72 extending radially outwards from the rotor hub.

163. Accordingly, Aboul-Hosn discloses an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and at least one blade extending radially outward from the rotor hub.

10(a)(2): “the intravascular blood pump coupled to a catheter on a proximal end and a cannula on the distal end;”

164. The '068 Patent does not disclose the phrase “coupled to a catheter on a proximal end and a cannula on the distal end” nor does it identify what it means

for the intravascular blood pump to be “coupled to” a catheter or cannula, and thus under a broadest reasonable interpretation in light of the specification, this limitation requires that the blood pump have a catheter connected to the proximal end and a cannula connected to the distal end. *See* '068 Patent at 1:61-63, 3:30-35.

165. Aboul-Hosn discloses intravascular blood pump with a cannula connected to its distal end. As detailed in annotated FIGS. 1 and 2, below, inner cannula 20 (blue) is directly coupled to the pump housing cap 60 (green) fitted over the housing body of the pump 52; this would occur in the proximal end region of the cannula 20, where that region would fit concentrically about the inlet neck 62 – in the distal end region of the pump. *See* Aboul-Hosn at 12:12-14.

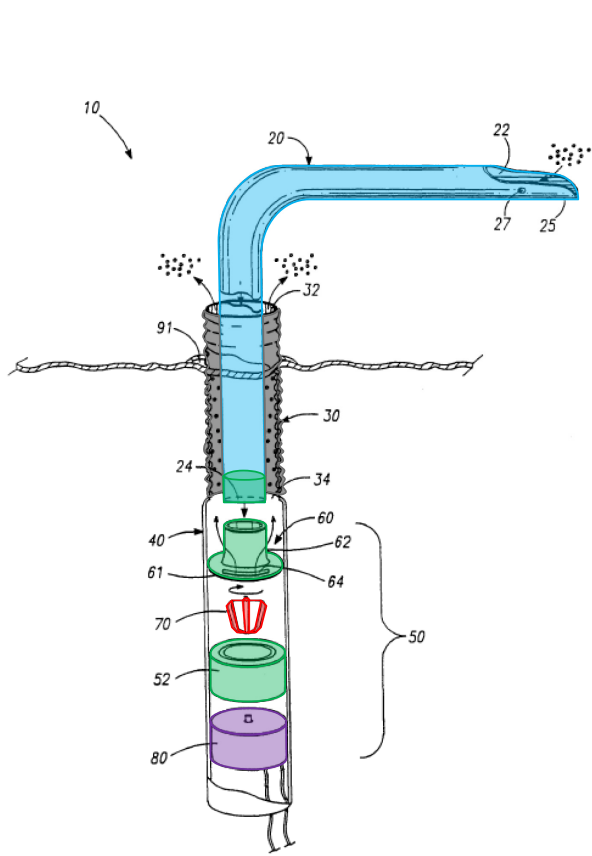


FIG. -1

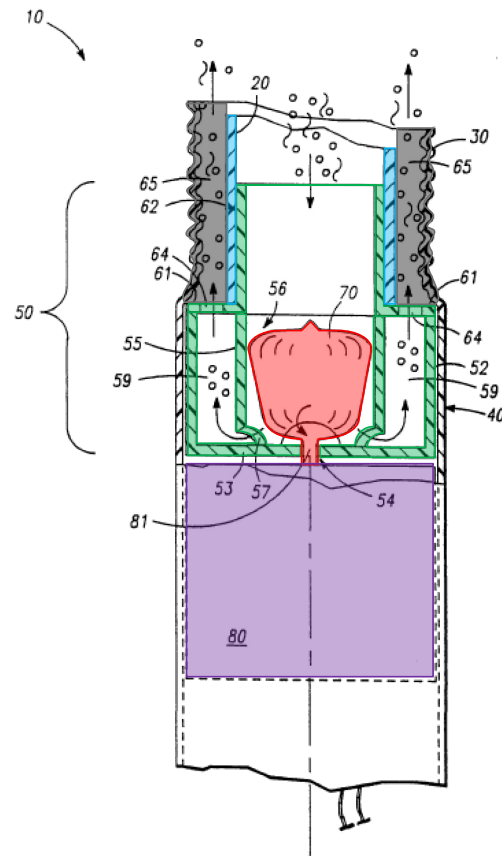


FIG. -2

166. Aboul-Hosn discloses a direct coupling of the cannula to the pump because the pump housing body 52 and the housing cap 60 may form a unitary body. *See* Aboul-Hosn at FIG. 2 (above), 12:22-23. As discussed in Part VI.A., the intravascular blood pump system shown in FIG. 3 comprises the same pump components (i.e. the inner cannula 20, housing cap 60 and housing body 52, the rotor 70, the drive unit 80, etc.) as the extracorporeal pump system shown in FIGS. 1 and 2, but with the addition of the pushing rod 273 to push the intravascular

blood pump into the patient's body. Thus, Aboul-Hosn discloses an intravascular blood pump coupled to a cannula on a distal end.

167. Aboul-Hosn also discloses a catheter attached to the proximal end of the blood pump. Specifically, FIG. 12 of Aboul-Hosn shows the positioning rod 273 interfaces with the proximal end of the drive unit 80, which is in turn connected to the housing body 52 attached to the distal end of the drive unit 80. Aboul-Hosn at 20:21-23 ("The proximal face of the drive unit 80 may comprise a groove 205 for attachment to the distal end of a positioning rod 273"); 16:11-12: ("The housing body 52 proximal end may be attached to the distal end of drive unit 80").

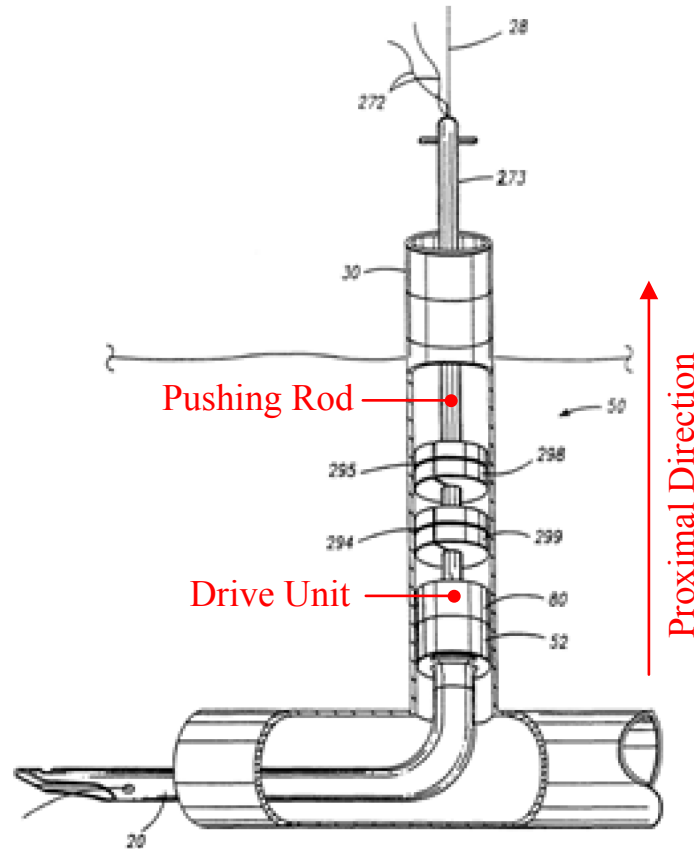


FIG. -12

168. As shown above in FIG. 12, the positioning rod 273 links the intravascular blood pump and the drive unit to the exterior of the patient's body – it contains a central passageway 275 “for passing wires, tubes or similar accessories needed by the drive unit 80” when the blood pump system is positioned within the patient's vasculature. *See* Aboul-Hosn at 15:6-9. As also shown above, the positioning rod 273 extends in the proximal direction in relation to the blood pump.

169. As discussed in Part VIII.A.a., and as I will explain in further detail below with respect to the positioning of Aboul-Hosn's intravascular blood pump system within the vasculature, Aboul-Hosn expressly contemplated that intravascular blood pumps are capable of being introduced into the vascular system of the patient through percutaneous placement of an intravascular blood pump system including an intravascular blood pump through the femoral artery. *See* Aboul-Hosn at 29:17-19, 30:21-24. As shown below in FIGS. 21 and 23, to place the distal end of the cannula into the left atrium where the intravascular blood pump system was inserted into the femoral artery, the intravascular blood pump system including the blood pump 420 is advanced through the femoral artery 430 (using the multilumen catheter 428 in the place of the positioning rod 273 due to the distance that the intravascular pump system needs to travel through the artery as I explained above in footnote 10). *See* Aboul-Hosn at 29:17-19.

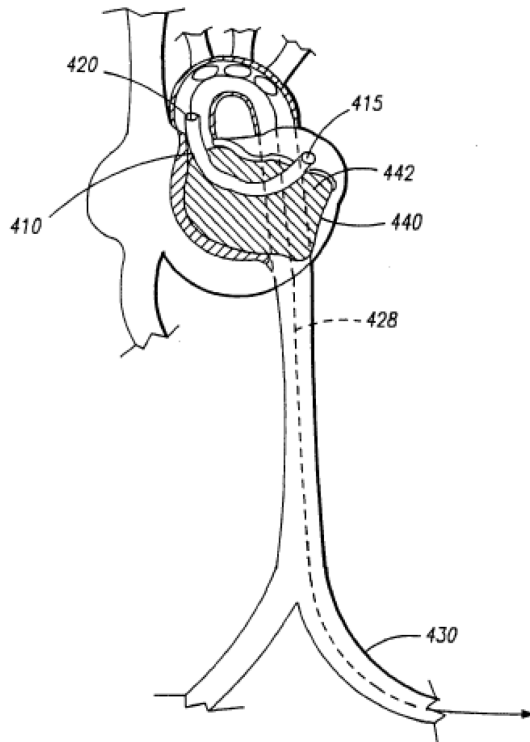


FIG. -21

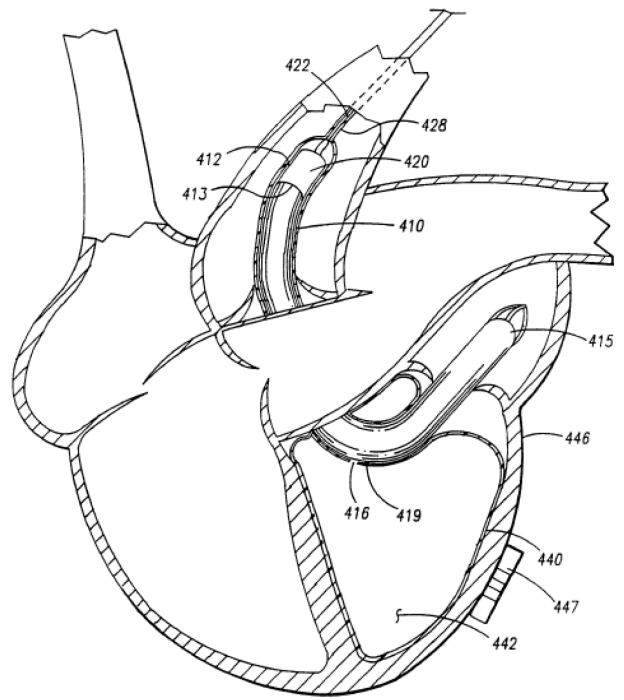


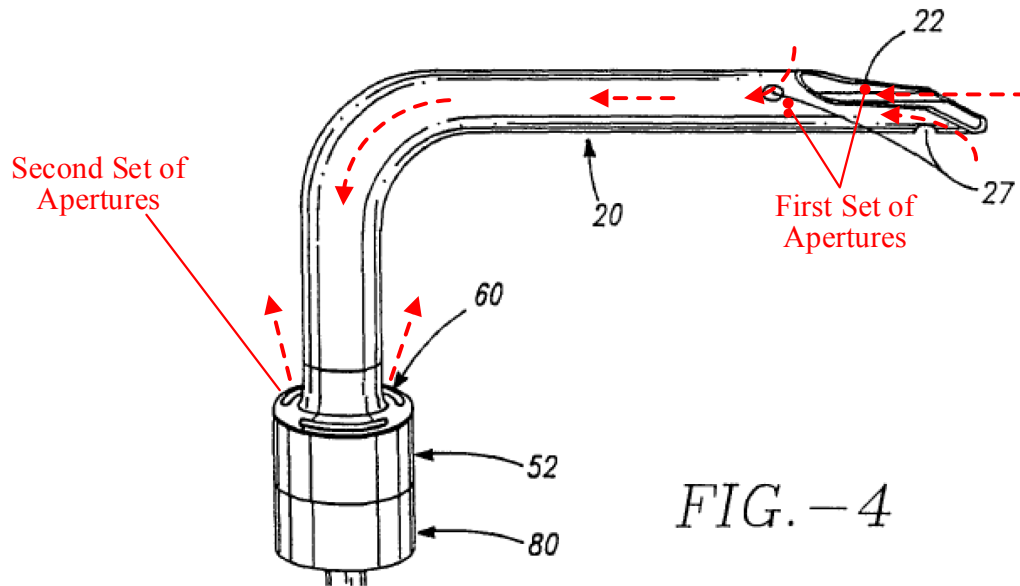
FIG. -23

170. A POSITA would understand that there is no functional difference between Aboul-Hosn's positioning rod 271 shown in FIG. 12 and multilumen catheter 428 shown in FIG. 23 and that catheter 428 would readily be interchanged for the positioning rod 271 in FIG. 12 in applications where the intravascular pump is positioned further from the insertion point. In the configuration where multilumen catheter 428 is interchanged with positioning rod 271, the multilumen catheter similarly interfaces with the proximal end of the drive unit 80, which in turn connects to the proximal end of the blood pump. As such, the positioning rod 273 and the multilumen catheter 428 are catheters that are coupled to the proximal end of the intravascular blood pump.

10(b): “(ii) a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula, wherein the first set of apertures is located in proximity to the rotor and the second set of apertures is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula”

171. This claim element recites that the first and second sets of apertures establish fluid communication in and out of the cannula. According to the claim, the second set of apertures is distal to the first set of apertures, and the set of first apertures is closer to the rotor than is the second set of apertures. As I discussed above in the brief description of the technology, conventional axial flow pumps commonly included multiple holes in the cannula that allow blood to flow into and out of the cannula when the pump is activated in vivo. *See* Part III.C.a.

172. This claim element is disclosed in Aboul-Hosn- the distal opening 22 along with one or more of the openings 27 would be a second set of apertures, and the multiple cut-outs 57 or the outflow windows 64 under housing cap 60, or both, would be a first set of apertures. The first set of apertures and the second set of apertures establish fluid communication between an interior and an exterior of the cannula, and those two sets of apertures are spaced apart from each other with the second set located distal of the first.



173. As explained previously with respect to the preamble of claim 10, annotated FIG. 2 along with FIG. 4 of Aboul-Hosn, below, illustrates an embodiment of the intravascular blood pump for use in the intravascular blood pump system shown in FIGS. 3, 4, and 12. *See* Part VIII.A.a; Aboul-Hosn at 8:20-9:13. Specifically, FIGS. 2 and 4 show how the blood enters and exits through the intravascular blood pump system during use – blood enters through the holes 22 and 27 of the distal end of the cannula 20 and exits through the cutouts 57 into passageway 59, then out the outlet windows 64 into passageway 65 and into the blood stream.

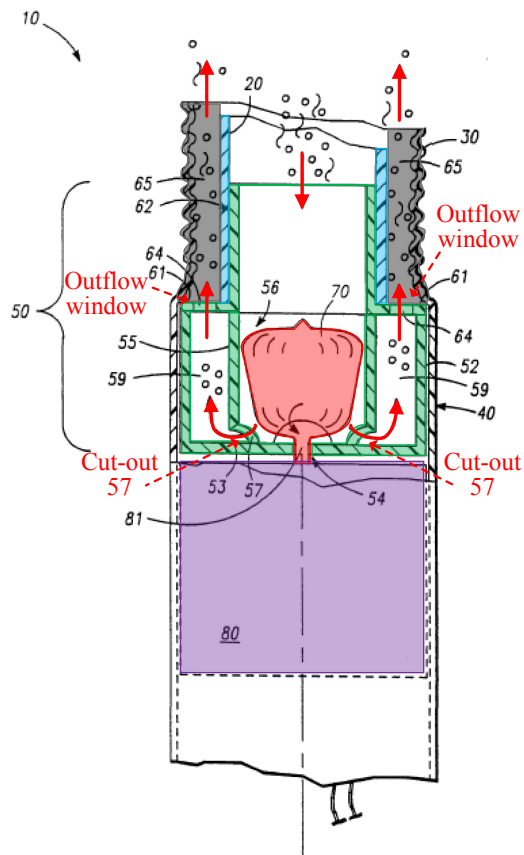


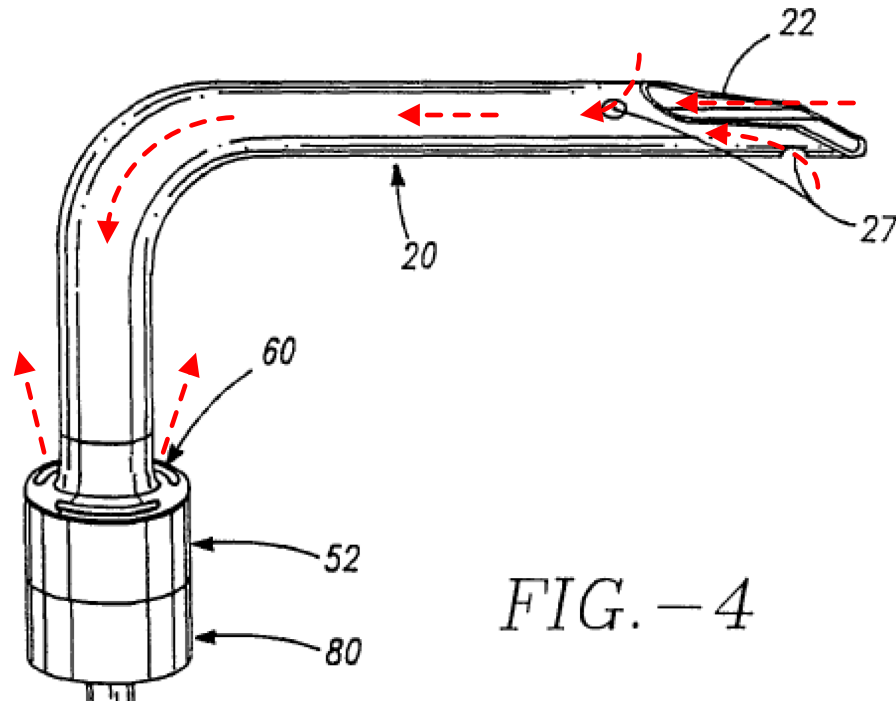
FIG. -2

174. Annotated FIG. 2 above shows the blood flow (highlighted as the red arrows) path when the rotation of the rotor 70 – blood enters through the distal end of inner cannula 20 (i.e., through holes 22 and 27, see FIG. 4 below) and flows towards the blood pump 50, then passes through the rotor 70 and exits through multiple cut-outs 57 formed in the inlet tube 55. See Aboul-Hosn at 13:11-13 (“A plurality of radially aligned cut-outs 57 may also be formed along various portions of the inlet tube 55 to permit the passage of fluid.”); 13:15-18 (“During operation of the fluid control apparatus in this configuration, the rotor 70 is rotated by the

driving unit 80 through an opening or hole 54 in order to direct fluids such as blood from the inlet tube out through the cut-outs 57.”); 15:24-26 (“The inlet tube 55 may comprise multiple cut-outs 57 at its proximal end to connect the passage 59 with the inlet tube 55.”).

175. The blood then flows through the outflow windows 64 formed in the housing cap 60, and outwards along the exterior surface of the inner cannula 20 and out of the pump 50. *See* Aboul-Hosn at 13:6-7 (“The outflow windows 64 may be radially aligned around an inlet neck 62 formed in the base member 61 of the housing cap 60.”).

176. Aboul-Hosn explains that the openings 27 formed near the cannula 20 distal tip can include a “plurality of openings 27”, as shown in the close-up view of FIG. 4, annotated below to show the flow path (red) of the patient’s blood. *See* Aboul-Hosn at 11:21-24 (“The inner cannula 20 may also have a plurality of openings 27 formed near its tip 25 to allow blood to flow into the inner cannula 20, particularly when the distal opening 22 may become occluded or otherwise obstructed.”).



177. Together, the distal opening 22 and the openings 27 along with the multiple cut-outs 57 and the plurality of outflow windows 64, establish a flow of blood from outside the inner cannula 20, through the interior of the inner cannula 20, and back outwards to the exterior of the inner cannula 20. In other words, the distal opening 22, openings 27, multiple cut-outs 57 and the plurality of outflow windows 64 establish fluid communication between an interior and exterior region of the inner cannula 20.

178. A POSITA would readily associate the cut-outs 57 (alone or together with the outflow windows 64) as the first set of apertures (“located in proximity to the rotor”), and the inlet openings 22 and 27 as the second set (“spaced apart from

and located distal to the first set of apertures towards a distal region of the cannula”).

179. Annotated FIG. 4 above also shows the positioning of the openings in their proximal/distal relationship – distal opening 22 and the openings 27 are located at the distal region, i.e. towards the far end of the inner cannula 20 relative to pump 50, whereas the multiple cut-outs 57 and outflow windows 64 are located adjacent the rotor 70 within the housing body 52. The distal opening 22 and the openings 27 are thus located distal to the multiple cut-outs 57 and the plurality of outflow windows 64, towards the far end of the inner cannula 20 relative to pump 50, and are spaced apart and located distal from the multiple cut-outs 57 and the plurality of outflow windows 64.

180. Therefore, the distal opening 22 along with one or more of the openings 27 would be a second set of apertures, and the multiple cut-outs 57 or the outflow windows 64, or both, would be a first set of apertures, the first set of apertures and the second set of apertures establish fluid communication between an interior and an exterior of the cannula, and those two sets of apertures are spaced apart from each other with the second set located distal of the first.

181. Aboul-Hosn thus discloses this element of the claim.

10(c)(1): “(iii) a guide mechanism configured as an elongate lumen”

182. Aboul-Hosn discloses a guide mechanism configured as an elongate lumen in the same manner as disclosed in the '068 Patent. As explained previously in Part VI.A, Aboul-Hosn discloses extending a guide wire through a central lumen through the blood pump, drive unit, and cannula to place a blood pump system in a desired location in the heart. This is illustrated in annotated FIG. 3 (below), which is an exploded view of the conventional over-the-wire arrangement used in Aboul-Hosn's intravascular blood pump system – showing the guide wire 28 passing through the central passages in the various pump components (through the drive unit 80, rotor hub 74, and housing cap 60) and through the cannula 20, exiting at the distal end of the cannula 20. *See* Aboul-Hosn at 14:20-26; 22:12-14.

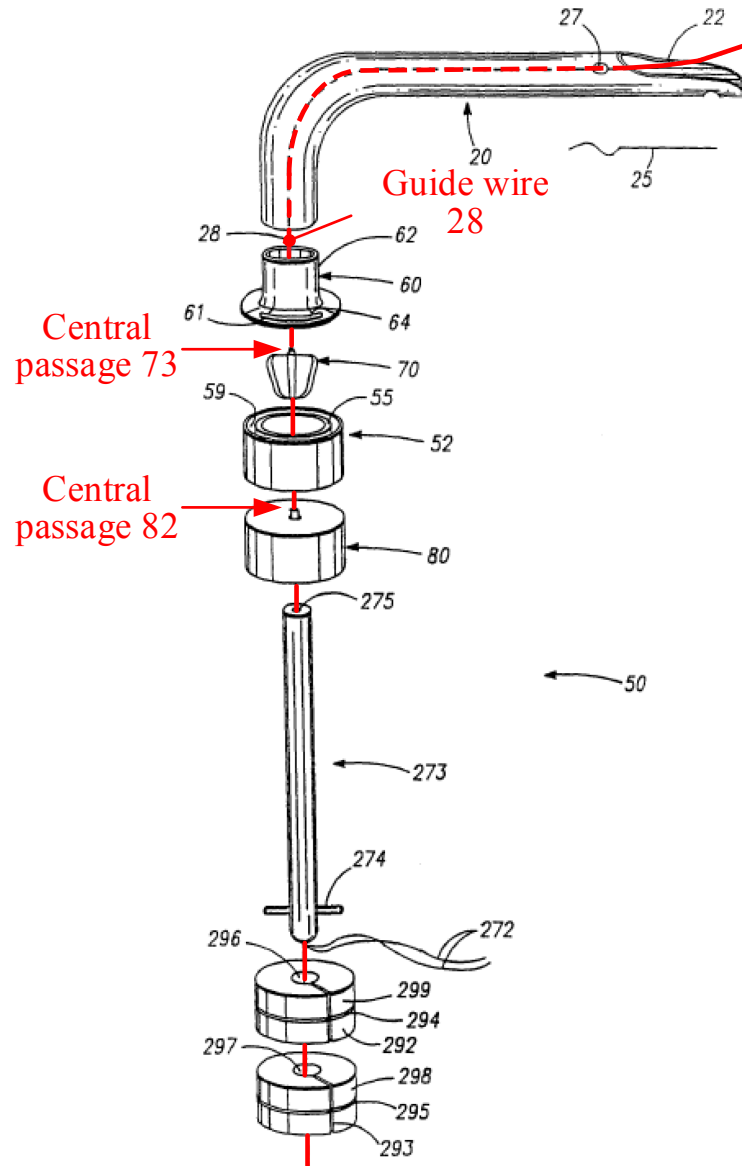
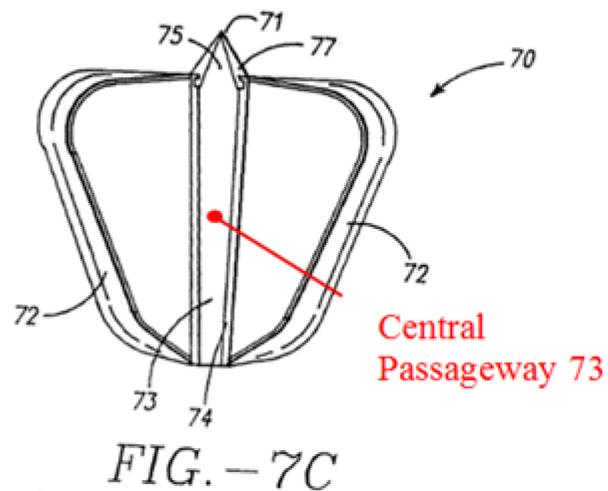


FIG. -3

183. I note that Aboul-Hosn separately refers to the central passage within each component, but when the components are combined into the functioning blood pump, a single central passage extends through the components. That single central passage extending through at least the intravascular blood pump, as described above, would be the “elongate lumen” recited in the claim.

184. Aboul-Hosn confirms that the rotor 70 includes “a central rotor passage 73” that extends “the entire length of the rotor” and “forms a continuation of central passage 82 of drive unit 80.” Aboul-Hosn at 17:8-10, and see annotated FIG. 7C below.



185. The central passage also extends through the drive shaft. As annotated FIG. 10 shows below, the drive unit 80 includes a central passage 82 that “extend through the entire length of the shaft 81.” Aboul-Hosn at 20:23-25. These passages 73 and 82 also connect with the central lumen 275 and the positioning rod 273 and the lumen of the cannula 20, forming the continuous central guide wire lumen.

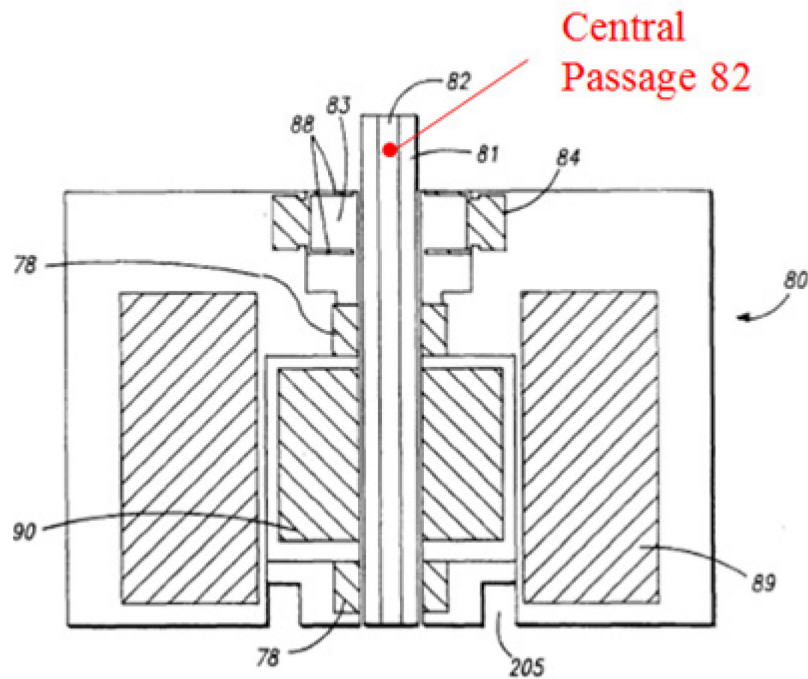
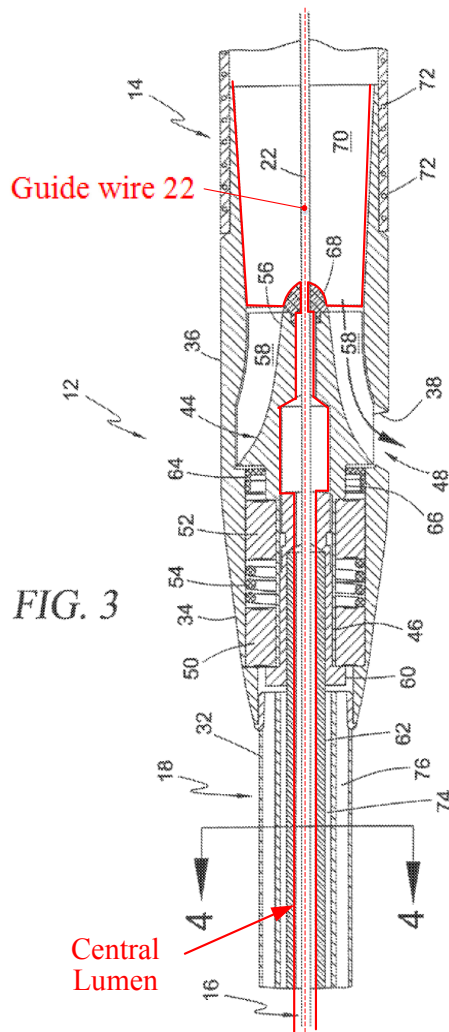
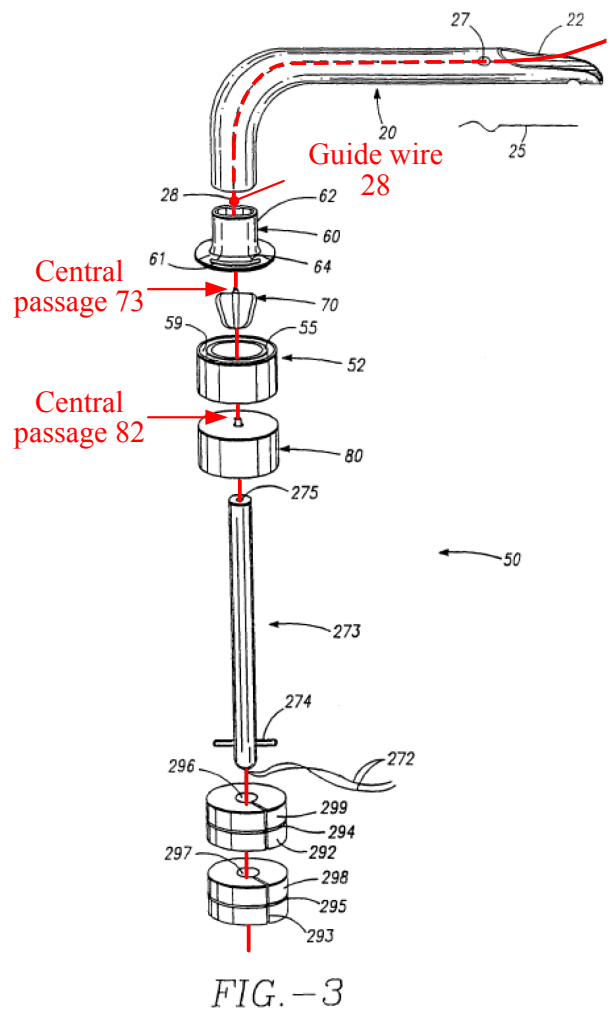


FIG. -10

186. Further, as shown below in the side-by-side comparison of FIG. 3 of Aboul-Hosn and FIG. 3 of the '068 Patent, the continuous lumen disclosed in the Aboul-Hosn embodiment (right) has essentially the same configuration as the guide mechanism in the over-the-wire embodiment of the '068 Patent (left). The '068 Patent explains that the central lumen "is established by forming and co-aligning the individual central lumens within each of the drive cable 62, the cable adapter 60, the shaft 46 and hub 56 of the rotor 44, and the cannula 14." '068 Patent at 10:36-39.



'068 Patent



Aboul-Hosn

187. As shown in the side-by-side comparison of FIG. 3 of Aboul-Hosn and FIG. 3 of the '068 Patent, the configuration of the '068 Patent is the same as the intravascular blood pump system in Aboul-Hosn.

188. In the '068 Patent the guide wire 22 runs through the central lumen 16, which includes the central passage through each of the co-aligned components – e.g., drive cable 18, blood pump 12, and cannula 14; similarly in Aboul-Hosn the

wire 28 extends through the central passage 275 of the positioning rod 273 (or through a lumen within the multilumen catheter 428 where the intravascular blood pump is inserted into the graft at a position away from the heart as shown in FIGS. 21 and 23), the central passage 82 of drive unit 80, and central rotor passage 73 of the rotor 70, and on into the cannula 20.

189. In Aboul-Hosn, the proximal end of the “elongate lumen” would be at or near the proximal end of the positioning rod 273 or the catheter 428, located exterior of the patient’s body, and the distal end of the “elongate lumen” would be the distal end of the cannula 20 (consistent with the teaching of the ’068 Patent 10:38). *See* Aboul-Hosn at FIGS. 3 and 21. Accordingly, Aboul-Hosn discloses the same elongate lumen configuration as in the ’068 Patent.

190. Thus, Aboul-Hosn discloses this element of the claim.

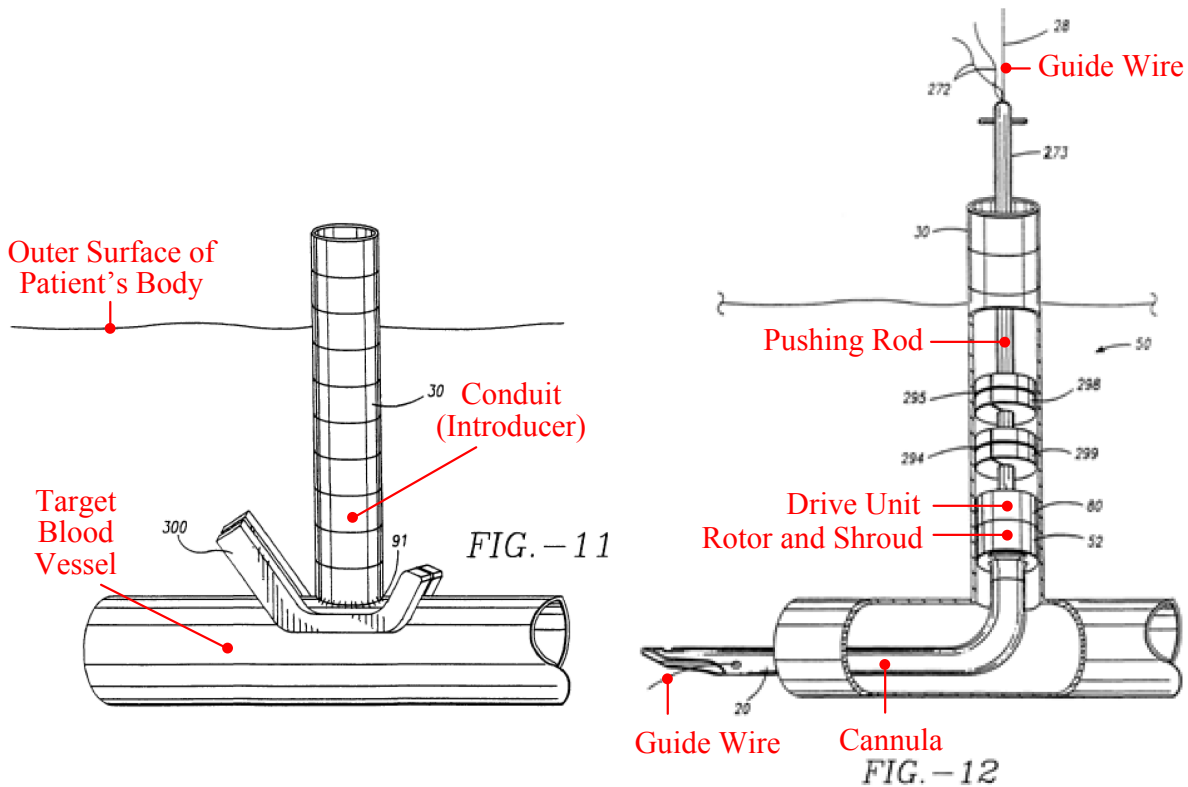
1(c)(2): “and [the guide mechanism] adapted to guide said intravascular blood pump, cannula , and catheter to a predetermined location within the circulatory system of a patient; and”

191. As discussed above with respect to limitation 10(c)(1), Aboul-Hosn discloses the guide mechanism as the continuous over-the-wire lumen extending through the length of the system, including the positioning rod or catheter, the drive unit, the central passages of the pump components, and the length of the cannula. Aboul-Hosn explains that “[i]n preparation for insertion of a fluid transport system

into a patient, a commercially available high stiffness guide wire 28 may be used and passed through the central passage of the positioning rod 273 proximal end, to the distal end of the rotor 70, passing through the gland valve 77, and through the cannula 20.” Aboul-Hosn at 24:8-12.

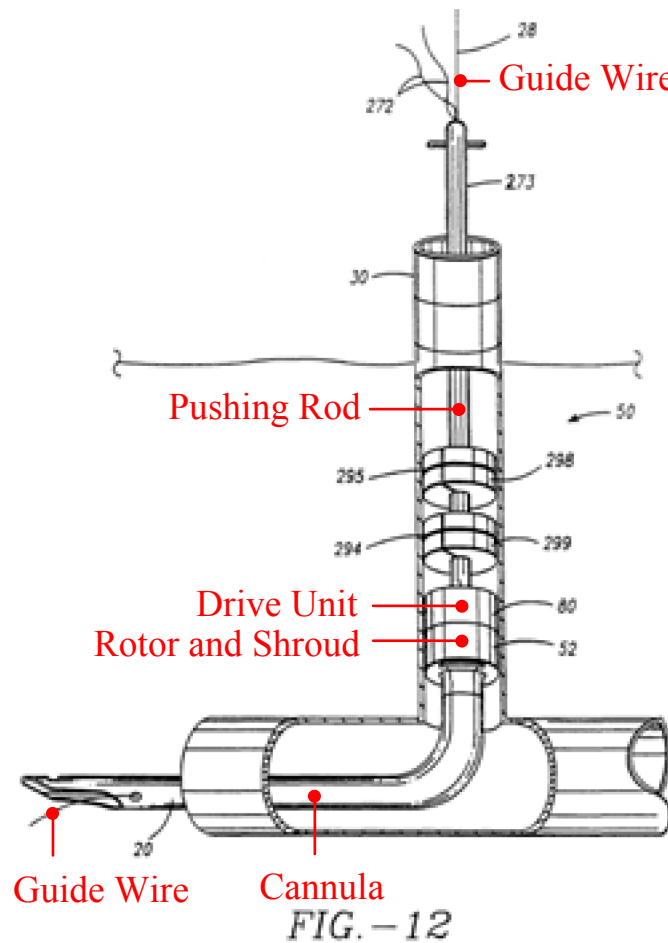
192. As Aboul-Hosn further explains, the guide wire is used to guide the pump, cannula, and catheter/positioning rod to the desired location within the circulatory system. See Aboul-Hosn at 22:10-12 (“A guide wire 28 may be also advanced with the help of imaging techniques to dispose the distal end of the inner cannula 20 in the desired blood vessel, heart chamber or other body cavity”), 22:13-21 (“the distal end of the inner cannula 20 may be guided to a location before removing the guide wire 28. While positioning the distal end of the inner cannula 20, the pump 50 may need to be advanced in the outlet conduit 30 by pushing the positioning rod 273 into the outer conduit or graft” until “pump 50 reaches the desired position”).

193. As I explained in Part VI.A, the intravascular blood pump system can be delivered over-the-wire using the placement technique as shown in FIGS. 11 and 12 of Aboul-Hosn, below.



194. The positioning rod 273 pushes the pump 50 and inner cannula 20 over the guide wire 28 into the outer conduit 30 and to the desired location within the patient's vasculature, which can be done with the aid of imaging techniques to ensure proper placement of the intravascular blood pump. See Aboul-Hosn at 22:10-18 ("A guide wire 28 may be also advanced with the help of imaging techniques to dispose the distal end of the inner cannula 20 in the desired blood vessel, heart chamber or other body cavity."). After the intravascular blood pump system has been placed at the desired location, the guide wire 28 may be removed and the pump 50 is activated. See Aboul-Hosn at 22:24-25.

195. As discussed above in Part VIII.A.a., FIG. 12 illustrates the intravascular blood pump still in the process of being advanced through the conduit 30. The distal end of the cannula 20 has not yet been positioned “in the desired blood vessel, heart chamber or other body cavity” because the distal opening of the cannula and the outflow windows of the intravascular blood pump are not separated by a structure such as a heart valve, and if operated in this condition will draw in blood and pump out blood into the same blood vessel which would not unload the heart in preparation for surgery or otherwise “transports fluids between **different regions** within the body in order to support a wide variety of surgical procedures” which is the purpose of Aboul-Hosn’s intravascular blood pump system. *See* Aboul-Hosn at 6:6-8 (emphasis added), 6:19-20.



196. The pump would need to be advanced even further through the conduit 30 until the distal end of the cannula is positioned across a heart valve to transport blood from one heart chamber to another chamber or vessel, such that the intravascular blood pump and the positioning rod 273 or a multilumen catheter 428 (depending on the position of the graft and the distance the intravascular blood pump system needs to travel to reach the patient's heart as discussed above) are also positioned within the circulatory system. *See e.g.* Aboul-Hosn at FIGS. 14-19. Aboul-Hosn confirms this is the case as he expressly states that “[a] **reverse flow**

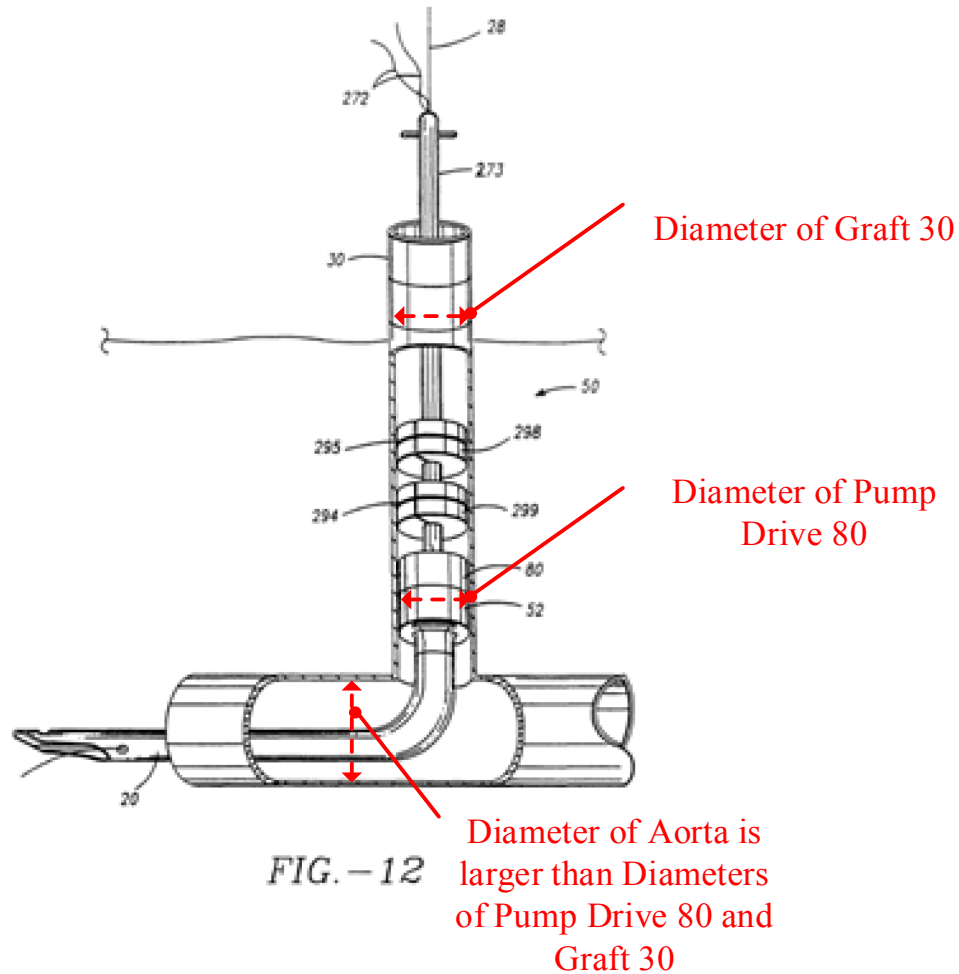
blood pump system may be passed through a conduit and positioned in a heart chamber or vessel in preparation to completely or partially stop the heart in order to operate on the organ.” *See* Aboul-Hosn at 6:26-29 (emphasis added). Notably, Aboul-Hosn does not state that only the cannula or a portion of the blood pump system is passed through the conduit, or that the pump is positioned in the conduit – rather, he makes it clear that the **“blood pump system is passed through the conduit and positioned in a heart chamber or vessel.”** *See* Aboul-Hosn at 6:26-29 (emphasis added).

197. As also discussed above in Part VIII.A.a., Aboul-Hosn discloses that the conduit 30, used to introduce the intravascular blood pump system into the patient’s body, can be a “DacronTM graft, or any other commercially available grafts or synthetic conduits.” *See* Aboul-Hosn at 12:7-9. The conduit 30 would act as an extension of the patient’s vascular system, similar to that of a branching blood vessel as blood would flow from the target blood vessel into the conduit (hence the need for silicon plug 298 to “seal the outer conduit 30 and the driving unit 80,” *see* Aboul-Hosn at 21:31-22:1). Thus, even where the intravascular blood pump remains within the conduit 30 as shown in FIG. 12 – a POSITA would understand that the pump is within the vascular system of the patient.

198. As also discussed above in Part VIII.A.a., a POSITA would also understand that commercially available Dacron grafts can have stated diameters of

7-10mm, which are consistent and compatible to use as introducers for intravascular blood pumps, which as I previously explained in Part III.A have diameters of 7-9mm (or smaller). *See* Wampler '712 at 3:52-54; Voelker at 1:56-61. Compared to the aorta, which has a cross-sectional area of about 2.5cm^2 (250mm^2), or an even larger heart chamber, the Dacron graft used to introduce the intravascular blood pump system would be much smaller in size. *See* Guyton at Chapter 14, p 151. Indeed, Aboul-Hosn discloses that “the conduit [is] inserted in the body through **a portal of minimal size** formed in tissue of a body wall and engaging an external of a vessel or the heart **to limit any significant bleeding.**” *See* Aboul-Hosn at 6:31-7:2 (emphasis added). Accordingly, the intravascular blood pump (which must be sized to have an outer diameter smaller than the inner diameter of the conduit in order to be pushed through the conduit), *see* Aboul-Hosn at 24:26-29, would be more than capable of being introduced into the vascular system of a patient, such as in the aorta or a heart chamber, which are going to be larger than the conduit. As shown in annotated FIG. 12 of Aboul-Hosn below, the diameters of both the graft and the drive unit of the pump are much smaller than the diameter of the aorta. Although there is no indication that FIG. 12 is drawn to scale as a whole, a POSTIA would understand, based on Aboul-Hosn’s teaching of a Dacron graft, that FIG. 12 still provides the correct relative size comparison,

indicating that the pump has been in fact miniaturized sufficiently, and is “capable” of being pushed further into the aorta.



199. As also discussed above in Part VIII.A.a., there are well-known advantages of inserting the intravascular blood pump system into the vascular system of the patient. In order for the distal end of the cannula to be positioned across a heart valve to transport blood from one heart chamber to another chamber or vessel, either (1) the position of the drive unit may be fixed and the length of the cannula increased to reach a desired position within the heart, or alternatively (2)

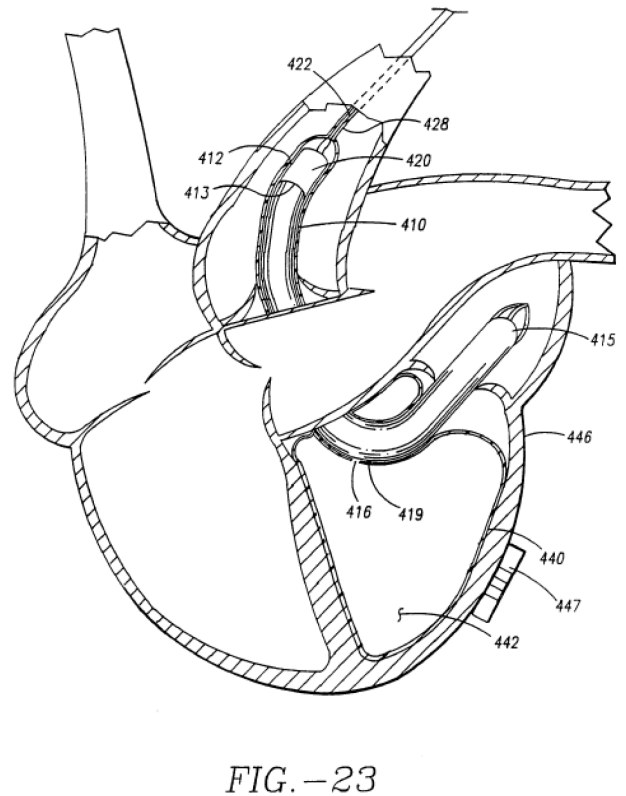
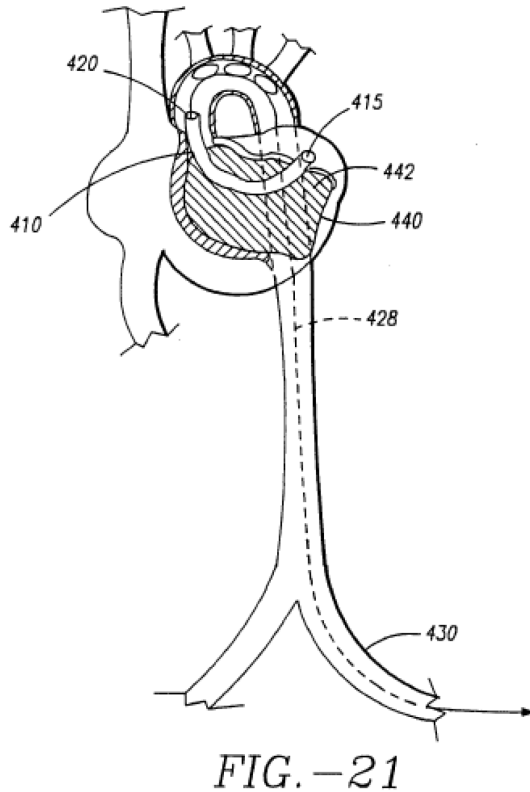
the length of the cannula may be fixed but the drive unit must be moved further within the vasculature, i.e. closer to the heart. As an example, in Aboul-Hosn FIG. 12, to achieve the desired blood transport between chambers without displacing the drive unit 80 and rotor 52, the cannula 20 would have to be extended to a length such that the distal end of the cannula could be positioned across a heart valve. However, to reach a heart valve this configuration would result in an extremely long cannula, and a POSITA would readily understand that increasing the length of the cannula detrimentally increases hydrodynamic losses.

200. Indeed, a POSITA would be familiar with frictional head loss in a pipe, and the fact that frictional head loss is a function of (1) the characteristics of the internal flow, i.e. transitional or turbulent (high Reynolds number) and viscous for blood, but also (2) a function of the pipe geometry, both diameter and length, and a friction factor which is itself a function of the pipe shape, i.e. the cannula shape. *See* White Chapter 6.3, describing frictional head loss and the Darcy friction factor. *See also* Siess Thesis, Chapter 5.8.4 Viscosity Effect, describing channeling friction losses. To avoid these increased frictional losses associated with an increased cannula length which would in turn require a larger pump, a POSITA would likely favor a short cannula over a lengthy one. Aboul-Hosn appreciates this with his use of intravascular blood pumps and extracorporeal blood pumps, as I explained above. Intravascular blood pumps enable one to insert the

pump system, e.g. the pump 50, further distally, i.e. closer to the heart, thus shortening the length of the cannula while still reaching the desired position across a heart valve. A shorter cannula would be preferable to minimize the hydrodynamic losses mentioned above without increasing pump size, and a shorter cannula would therefore yield a beneficial increase in pump output without increasing the pump size. This is particularly true where the graft is attached to a target blood vessel for introduction of the intravascular blood pump system at a location that is away from the heart, such as the femoral artery as shown in Aboul-Hosn's FIG. 21. In this case, if the blood pump were to stay within the graft, then the cannula would need to extend the length of the patient's body to reach the heart, which would exceed any reasonable pumping capacity of the miniaturized blood pump positioned within the graft, and would not work. Rather, a POSITA would readily understand the intravascular blood pump is inserted into the circulatory system, using a shorter cannula, and the blood pump and cannula is advanced through the artery until the distal end of the cannula is positioned across a heart valve or other suitable structure for pump the blood through the blood pump system.

201. Aboul-Hosn expressly contemplated that intravascular blood pumps are capable of being introduced into the vascular system of the patient. As I previously explained in Part VI.A, FIGS. 21 and 23 of Aboul-Hosn, below, show

an example of a percutaneous placement of an intravascular blood pump system including an intravascular blood pump, cannula, and catheter through the femoral artery. *See* Aboul-Hosn at 29:17-19, 30:21-24. As shown below in FIGS. 21 and 23, to place the distal end of the cannula into the left atrium where the intravascular blood pump system was inserted into the femoral artery, the intravascular blood pump system including the blood pump 420 is advanced through the femoral artery 430 (using the multilumen catheter 428 in the place of the positioning rod 273 due to the distance that the intravascular pump system needs to travel through the artery as I explained above in footnote 10). *See* Aboul-Hosn at 29:17-19.



202. Aboul-Hosn expressly confirms this to be the case. With respect to FIGS. 21 and 23, Aboul-Hosn discloses that “Fig. 21 is a stabilization system provided **in accordance with the present invention** that is introduced through a femoral artery,” and “[t]he stabilization systems shown in Figs. 23 and 24 illustrate only some of the various types of commercially available intravascular and extracorporeal pumps that **are** compatible or provided **for by the present invention.**” *See* Aboul-Hosn at 10:6-7, 31:6-9 (emphasis added). Aboul-Hosn further discloses “the present invention provides a reverse flow pump system that transports fluid between different regions within the body in order to support a wide variety of surgical procedures” which, as previously discussed in this Part, includes the intravascular blood pump system as shown in FIGS. 3, 4, and 12 that is inserted into the patient’s vasculature through the graft and shares the same components as the extracorporeal blood pump system shown in FIGS. 1, 2, and 13, such as the rotor 70, the housing 52 the housing cap 60, and the drive unit, that are miniaturized for introduction into the patient’s body. *See* Aboul-Hosn 6:6-8, 6:24-29, 21:9-22:18, 24:26-25:1. Aboul-Hosn thus expressly discloses that the “stabilization system” shown in FIGS. 21 and 23 (which he states is “provided by the present invention”) uses the intravascular blood pump of FIGS. 3, 4, and 12 (which Aboul-Hosn states is “the present invention” – “a reverse flow blood pump

system that transports fluid between different regions within the body”). *See* Aboul-Hosn at 6:6-8, 10:6-7, 31:6-9.

203. When considered in its entirety, Aboul-Hosn expressly discloses the intravascular blood pump, cannula, and catheter are guided to a predetermined location within the circulatory system of the patient.

204. Not only does Aboul-Hosn expressly disclose this, it would have also been obvious to a POSITA to use Aboul-Hosn’s intravascular blood pump system to provide the “stabilization system” as shown in FIGS. 21 and 23.

205. As I quoted above, Aboul-Hosn discloses that the “stabilization system” shown in FIG. 21 is “provided in accordance with the present invention” and shown in FIG. 23 is “provided for by the present invention,” respectively. *See* Aboul-Hosn 10:6-7, 31:6-9. These statements by Aboul-Hosn when describing the “stabilization system” shown in FIGS. 21 and 23 would have naturally motivated a POSITA to look at the blood pump systems expressly disclosed by Aboul-Hosn in the document to determine what the “present invention” is that provides for the “stabilization system” shown in FIGS. 21 and 23. In doing so, a POSITA would have come across both Aboul-Hosn’s extracorporeal blood pump system as shown in FIGS. 1, 2, and 13, and Aboul-Hosn’s intravascular blood pump system as shown in FIGS. 3, 4, and 12. *See* Aboul-Hosn at 10:25-15:18, 21:11-22:18, 24:15-25:1.

206. When considering Aboul-Hosn's extracorporeal blood pump system as shown in FIGS. 1, 2, and 13, a POSITA would have recognized that the extracorporeal blood pump system would not have been used as an intravascular blood pump system shown in FIGS 21 and 23 due to the larger pump components that are not sized to be inserted through a graft and into the patient. *See* Aboul-Hosn at 24:26-25:1. In contrast, it would have been immediately understood by a POSITA that Aboul-Hosn's intravascular blood pump shown in FIGS. 3, 4, and 12 is "the present invention" that is used for the "stabilization system" shown in FIGS. 21 and 23 because, as previously discussed, the blood pump of Aboul-Hosn's intravascular blood pump system is miniaturized so that it can be introduced through a graft that is attached to a target blood vessel, and inserted into the patient's circulatory system. *See* Aboul-Hosn] 21:11-22:18, 24:26-25:1.

207. This is also entirely consistent with Aboul-Hosn's disclosure of the rotor in FIGS. 7A-7C, which is used in Aboul-Hosn's intravascular blood pump system shown in FIGS. 3, 4, and 12. Aboul-Hosn expressly states that "Figs. 7A-C and 8 illustrate various configurations of a rotor 70 that may be used in a reverse flow pump or any other type of fluid transport apparatus," which indicates to a POSITA that the rotor 70 of Aboul-Hosn's intravascular blood pump system shown in FIGS. 3, 4, and 12 can be used in **"any other type of fluid transport apparatus."** *See* Aboul-Hosn at 16:30-31 (emphasis added). The "stabilization

system” shown in FIGS. 21 and 23 certainly qualifies as “any other type of fluid transport apparatus.”

208. Based on Aboul-Hosn’s statement regarding the rotor, a POSITA would have been expressly motivated to use rotor of FIGS. 7A-7C in the “stabilization system” of FIGS. 21 and 23 because the rotor 70 can be used in “any ... type of fluid transport apparatus,” which includes the “stabilization system” of FIGS. 21 and 23. In addition, the rotor 70 would not be able to generate the flow of blood without its corresponding shroud, the housing 52, housing cap 60, inlet 55 within the housing 52, and so forth, as I explained previously in Part III.C.b, it is the rotor shroud in conjunction with the rotor that provides the axial flow of blood for the blood pump. Thus, it would have been logical and straightforward to a POSITA to use the corresponding housing 52, housing cap 60, and so forth, which together form the shroud for the rotor 70 along with the rotor 70 in the stabilization system of FIGS. 21 and 23. *See* Aboul-Hosn at 16:30-31.

209. Notably, it is the shroud and the rotor that makes up the blood pump portion of Aboul-Hosn’s intravascular blood pump system. As recited by this claim, the “intravascular blood pump” only requires the “intravascular blood pump comprising a rotor.” A POSITA would readily be motivated to use Aboul-Hosn’s intravascular blood pump (i.e. the rotor and shroud) shown in FIGS. 3, 4, and 12 in the “stabilization system” shown in FIGS. 21 and 23. *See* Aboul-Hosn at 10:6-7,

31:6-9. Aboul-Hosn does not provide any specific details of the pump 420 used in the “stabilization system” shown in FIGS. 21 and 23, which signals to a POSITA to look elsewhere in the specification to discern the details of the pump 420. This which would lead them to Aboul-Hosn’s express teachings to use the rotor 70, which Aboul-Hosn discloses can be used in “any type of fluid transport apparatus,” and the corresponding shroud of the intravascular blood pump of FIGS. 3, 4, and 12, which are miniaturized so as to be capable of being inserted into the vasculature as previously discussed, and use them for the “stabilization system” shown in FIGS. 21 and 23 for the reasons I discussed above.

210. Moreover, Aboul-Hosn does not expressly limit or otherwise constrain the exact location in which the graft to introduce the intravascular blood pump system in the patient can be sutured or attached. Quite the contrary, Aboul-Hosn broadly states that the graft can be attached to a portal that “is created in the desired blood vessel or body cavity.” *See* Aboul-Hosn at 21:19-23. Aboul-Hosn expressly discloses that intravascular blood pumps can be introduced percutaneously through the femoral artery, as shown in FIG. 21. *See* Aboul-Hosn at 29:17-19. As such, where Aboul-Hosn’s intravascular blood pump system is introduced into the patient’s femoral artery through the graft, a POSITA would have been motivated to advance the intravascular blood pump system – the cannula, blood pump, and positioning rod 273 or multilumen catheter 428

depending on the distance the pump system needs to travel within the vasculature – through the graft and into the patient’s circulatory system for to obtain the same advantages discussed above in this Part, including a shorter cannula length to reduce hydrodynamic losses and to maintain sufficient pumping capacity with the miniaturized pump components of the intravascular pump.

211. As I also explained in Part III.D, these teachings and techniques were already well-known in the art. Percutaneously inserting and positioning intravascular blood pumps within the patient’s vasculature such that the pump system is inserted closer to the patient’s heart is evidenced by Sammler which discloses positioning an intravascular blood pump system through the upper vena cava and into the right side of the heart over a guide wire. *See* Sammler 4:38-40, 6:5-7, FIGS. 1, 5, and 6. Siess and Walpler also discloses the same. *See* Siess at FIG. 1, 5:55-58, Wampler ’712 at FIG. 1a.) Positioning Aboul-Hosn’s intravascular blood pump, catheter, and cannula in the manner shown in FIGS. 21 and 23 – through the femoral artery and into the heart – in the manner as shown in FIG. 12 – using a graft attached to the femoral artery and pushing the blood pump over the guide wire into the patient’s femoral artery – is not only consistent with Aboul-Hosn’s teachings and disclosures, it is also generally consistent with the teachings and techniques that were already well-known in the art.

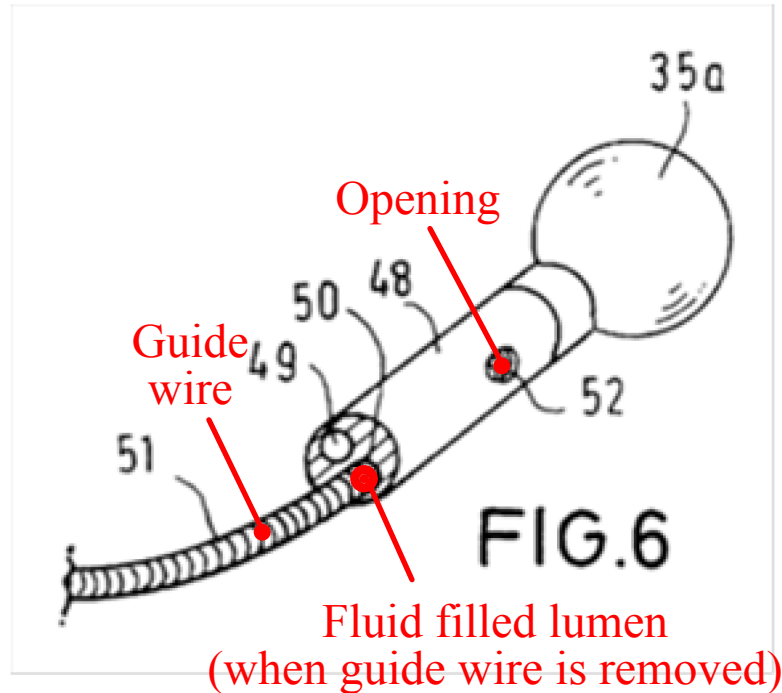
212. Thus, Aboul-Hosn, both expressly and in view of its teachings in its entirety to a POSITA, discloses a guide mechanism adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient.

10(d): “(iv) a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump;”

213. The '068 patent provides no details as to what is meant by “detect[ing] the pressure of the blood proximate the intravascular blood pump,” or any details about what constitutes a fluid column, or how that fluid column would detect the pressure of the blood and thus under a broadest reasonable interpretation in light of the specification, this limitation requires a fluid column for transmitting blood pressure near the blood pump.

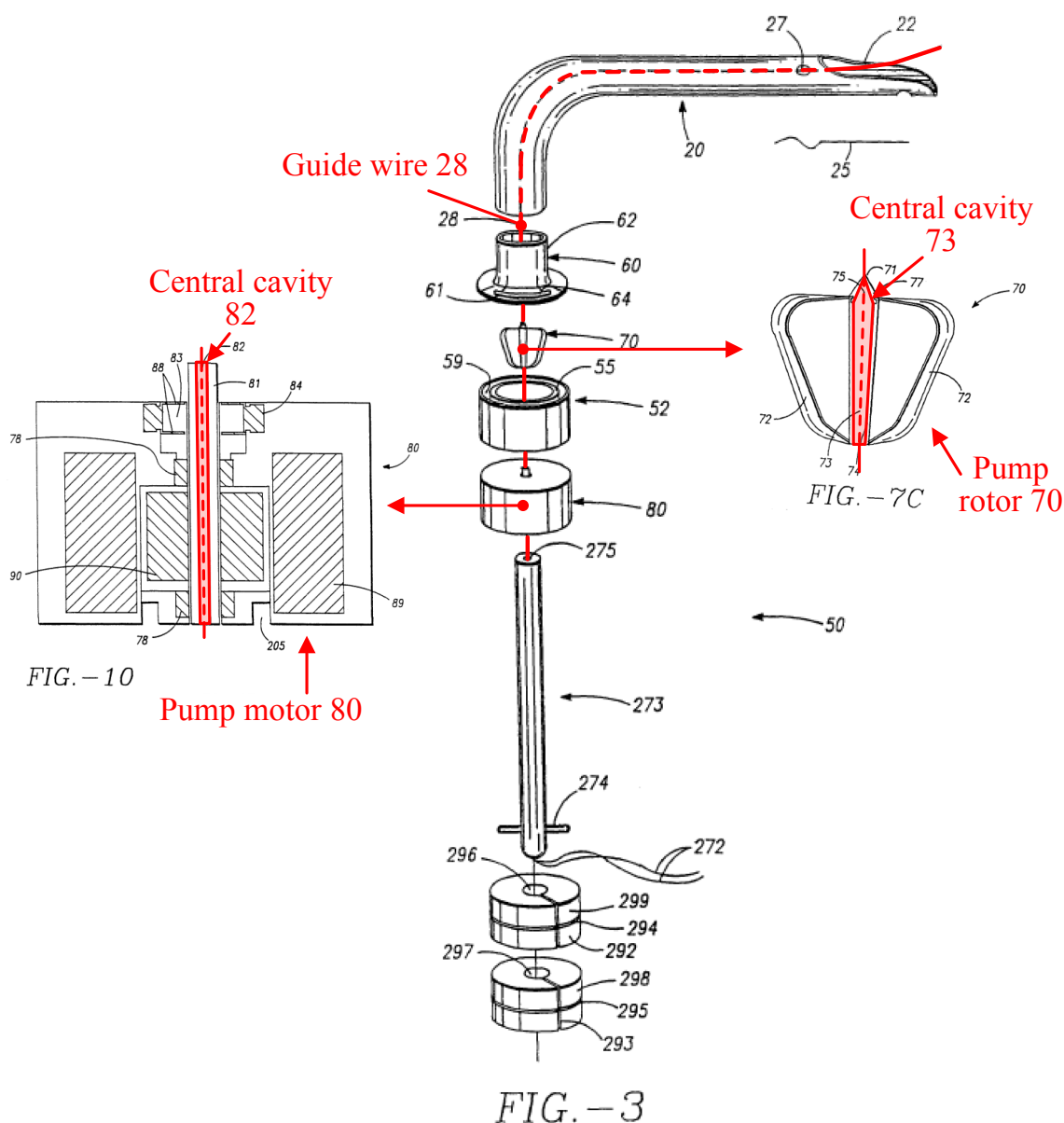
214. As I explained above in Part III.C.d, it was well known to use a fluid column in the form of a fluid-filled lumen to transmit fluid pressure to a distant location at which it can be measured. Measuring blood pressure in this way, with a port near the intravascular blood pump, relies on the basic prior art principle of a hydrostatic pressure tube. As I also explained above in Part VI.B, Sammler discloses measuring pressure of the blood in the pulmonary artery using a fluid-filled lumen. *See Sammler at 6:8-12.* As FIG. 6 shows, below, Sammler discloses

that once the guide wire 51 is removed from the pump, “blood enters the lumen through the opening 52,” filling the lumen 50. *See* Sammler at 5:9-10. The lumen 50 would be connected to a blood pressure measuring instrument such that “the blood pressure in the pulmonary artery can be measured and influenced, if necessary, during the pump process.” *See* Sammler at 6:10-12. The pressure is measured “at the site 52” where the opening is formed in the catheter 48. *See* Sammler at 6:13-14. A POSITA would readily understand that the catheter 48, which contains the lumen 50, connects to the cannula 14b at its distal end and extends through the cannula and connects to the catheter 17 extending proximally with respect to the intravascular blood pump to reach outside the patient to connect to “a blood pressure measuring instrument” for “external pressure measurement.” *See* Sammler at 5:39-41, 6:3-12. These connections would form a single fluid lumen, or “column,” that reached outside the patient. If no such single lumen were formed, the fluid would leak within the cannula and catheter before reaching the pressure gauge. *See* Sammler at 5:39-41, 6:3-12 (“an additional lumen 50 to accommodate a guide wire 51 and, after removal of the guide wire, **for external pressure measurement.**”) (emphasis added). As such, Sammler discloses measuring the blood pressure using the same well-known hydrostatic measurement techniques I previously discussed in Part III.C.d.



215. Sammler's teaching of using a fluid filled lumen to measure blood pressure can be readily applied to Aboul-Hosn's intravascular blood pump to measure the blood pressure proximate the blood pump. Like Sammler, Aboul-Hosn discloses passing a guide wire through a lumen that extends through the intravascular blood pump system to help position the blood pump at a desired location within the patient's vasculature. *See* Aboul-Hosn at 21:19-22:16 ("The guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20. As a result, the distal end of the inner cannula 20 may be guided to a location before removing the guide wire 28."); Sammler at 3:24-26 ("A second lumen may be additionally provided, into which a guide wire is inserted, which facilitates

fasting the advancing of the pump hose through the vascular system.”). As I previously explained above in Part VIII.A.a, Aboul-Hosn’s guide wire extends through a central passage of the intravascular blood pump system that includes the co-aligned central passageways 73, 82, and 275 of the pump rotor 70, drive unit 80, and the positioning rod 273, respectively, as shown in annotated FIGS. 3, 7C, and 10 below. *See* Aboul-Hosn at 17:8-22, 20:23-26, 21:6-10, 24:7-14.



216. Once Aboul-Hosn's intravascular blood pump is positioned in the desired location with the patient's vasculature, and the guide wire 28 has been removed (*see* Aboul-Hosn at 22:14-16 ("As a result, the distal end of the inner cannula 20 may be guided to a location before removing the guide wire 28.")), the central passageways 73, 82, and 275 extending through the pump rotor 70, drive

unit 80, and positioning rod 273 can be similarly used as a passageway for a fluid filled lumen to detect the blood pressure at an opening that is exposed by the removal of the guide wire as taught by Sammler. *See* Aboul-Hosn at 15:4-6 (“the central passage 275 of the positioning rod 273 may ... provide for passing wires, tubes or similar accessories needed by the drive unit 80.”); Sammler at 3:26-27 (“After removal of the guide wire, said second lumen may be used as a pressure measuring lumen.”), 6:8-12 (“According to Fig. 6, an opening 52 can be provided on the catheter 48, which is connected to the lumen 50 and which is blocked by the guide wire 51. After the guide wire 51 is withdrawn from the lumen 50, blood enters the lumen 50 through the opening 52. The lumen 50 can be connected to a blood pressure measuring instrument, so that the blood pressure in the pulmonary artery can be measured and influenced, if necessary, during the pumping process.”).

217. As with Sammler, blood can enter the central passageways of Aboul-Hosn’s intravascular blood pump system through the opening at the distal end of the passage 73 through the pump rotor 70 (shown above in annotated FIG. 7C) (*see* Sammler at 6:8-12 (“[a]fter the guide wire 51 is withdrawn from the lumen 50, blood enters the lumen 50 through the opening 52”), which Aboul-Hosn expressly discloses “**may be left open** or closed at the distal end with a glad valve 77,” after the guide wire 28 is removed. *See* Aboul-Hosn at 17:11-12 (emphasis added). In

this manner, Aboul-Hosn's intravascular blood pump system can be configured to detect the blood pressure proximate the intravascular blood pump (i.e. at the distal end of the pump rotor 70) using a fluid-filled lumen extending through the central passages 73, 82, and 275 and outside of the patient's body and can be connected to a blood pressure measuring instrument as taught by Sammler. *See Sammler at 3:26-27, 6:8-14.* As I previously discussed with respect to the first part of this claim (6.a), the positioning rod is an "elongate catheter" and so the central passage 275 is a part of the fluid-filled lumen that is used to measure the pressure of the blood proximate the pump as previously explained in this paragraph.

218. It would have been obvious to a POSITA, and a POSITA would have been naturally motivated to, use Aboul-Hosn's intravascular blood pump system in the manner taught by Sammler to detect the blood pressure proximate the blood pump. Like Sammler, Aboul-Hosn expressly discloses that the "pump 50 may also be equipped for sensing devices (not shown) for measuring various body conditions such as the blood pressure, the presence of blood, or other parameters that would suggest the need for altering the flow rate of the fluid transport apparatus 10." *See Aboul-Hosn at 23:4-8; Sammler at 6:10-12* ("The lumen 50 can be connected to a blood pressure measuring instrument, so that the blood pressure in the pulmonary artery can be measured and influenced, if necessary, during the pumping process."). Aboul-Hosn provides an example of one configuration of a

blood pressure sensing device – “[f]or example, the apparatus may include pressure sensors along the inner cannula 20 so that a preset pressure change would signal the need to change the capacity of [the] apparatus.” *See* Aboul-Hosn at 23:8-10.

219. In view of Sammler’s teachings, a POSITA would have readily understood that rather than add additional components to the intravascular blood pump system, such as “pressure sensors along the inner cannula 20,” to detect the blood pressure (which would increase the complexity and cost of the intravascular blood pump system as a result of attaching and routing the sensors through the pump system), the pre-existing central passageways 73, 82, and 275 extending through the pump rotor 70, drive unit 80, and positioning rod 273, respectively, can be used to receive passage of a fluid-filled lumen for the same purpose – to detect the pressure of the blood in the inner cannula at the distal opening of the central passageway 73 of the pump rotor 70 – once the blood pump system is positioned and the guide wire is removed as I explained above. A POSITA would have been naturally motivated to apply Sammler’s teachings to Aboul-Hosn because it provides a more efficient way of measuring the blood pressure within the inner cannula using the pre-existing structure of Aboul-Hosn’s intravascular blood pump system without the need to significantly reconfigure the system or its components.

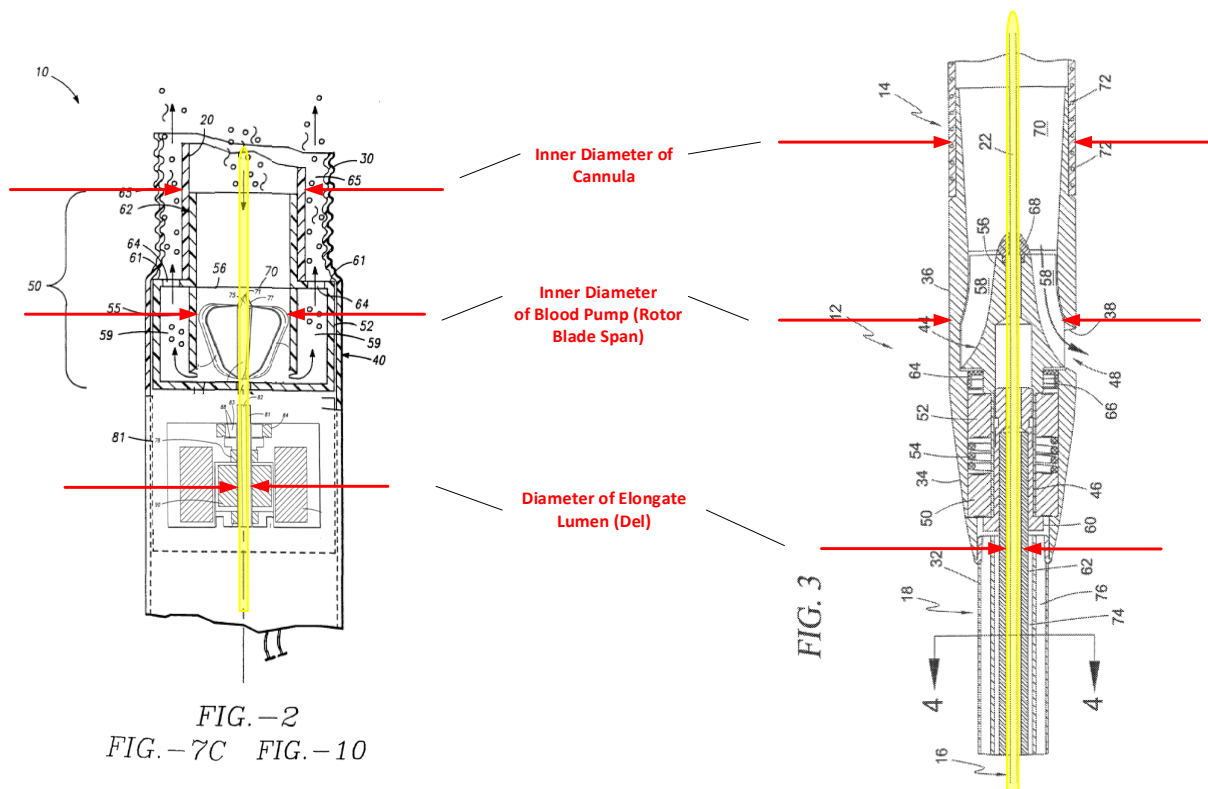
220. Thus, Aboul-Hosn in view of Sammler discloses a blood pressure detection mechanism comprising a fluid column disposed within the catheter and configured to detect the pressure of the blood proximate the intravascular blood pump.

10(e)(1): “wherein the elongate lumen (a) is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump;”

221. This claim requires two comparisons involving the elongate lumen – a first comparison to the inner diameter of the cannula and a second comparison to the inner diameter of the intravascular blood pump.

222. The '068 patent does not identify or disclose what it means for the elongate lumen to be “substantially smaller” than “an inner diameter of the cannula and intravascular blood pump.” The '068 Patent does not define “substantially smaller,” but as shown in the side-by-side comparison of annotated FIGS. 2, 7C and 10, and FIG. 3 of the '068 Patent and annotated FIG. 3 of Aboul-Hosn below, regardless of how the '068 Patent would define “substantially smaller”, at any point along the pump and cannula, Aboul-Hosn discloses the same relative size shown in the '068 Patent between the inner lumen diameter and the pump inner diameter and the cannula inner diameter. *See '068 Patent FIG. 2 and see Aboul-Hosn FIG. 3.*

223. This element of the claim is disclosed in Aboul-Hosn, however “substantially smaller” is defined.



224. As explained above with respect to limitations 10(c)(1) of claim 10, the elongate lumen of Aboul-Hosn includes the central guide wire passage that extends through the drive shaft 81, through the rotor hub 74 and through the cannula 20.

225. In regard to the first comparison required by the claim element, Aboul-Hosn discloses that the elongate lumen is sized substantially smaller than an inner diameter of the cannula.

226. The above configuration is consistent with a POSITA's well understood dimensions of conventional cannulas. A POSITA would know that conventional dimensional ranges for the diameter of the cannula would be on the

order of 6-9mm. For example, the '068 patent discloses that “the pump 12 and cannula 14 may be dimensioned to any suitable diameter for intravascular applications. For example, the range of sizes may include, but is not necessarily limited to 9 French to 30 French, although the range is more preferably from 14 French to 24 French, and most preferably from 18 French to 20 French.” '068 Patent, 8:28-33. Since the French size is three times the diameter in millimeters, the preferred range for the pump and cannula diameter would be 6 to 6.7 mm. Sammler '216 also discloses conventional cannula diameters: “[t]he pump hose [cannula] is approximately 12 cm long and has an outside diameter of approximately 8 mm. Its wall thickness is 0.05 mm to 0.2 mm.” Sammler '216, 3:40-42. This would lead to a cannula inner diameter of 7.9 mm to 7.6 mm. Accordingly, a POSITA reading Aboul-Hosn would likely assume conventional dimensional ranges for the diameter of the cannula, i.e. on the order of 6-9mm.

227. The elongate lumen in Aboul-Hosn is sized substantially smaller than these conventional dimensional ranges for the diameter of the cannula. Aboul-Hosn indicates that the guide wire passage has a diameter of “approximately 0.040 inches,” or about one millimeter. *See* Aboul-Hosn at 20:23-25; 17:16-19. Thus, in Aboul-Hosn the inner diameter of the guidewire passage is substantially smaller than the inner diameter of the cannula: 16% (1/6) to 11% (1/9) of the size of the inner diameter of the cannula.

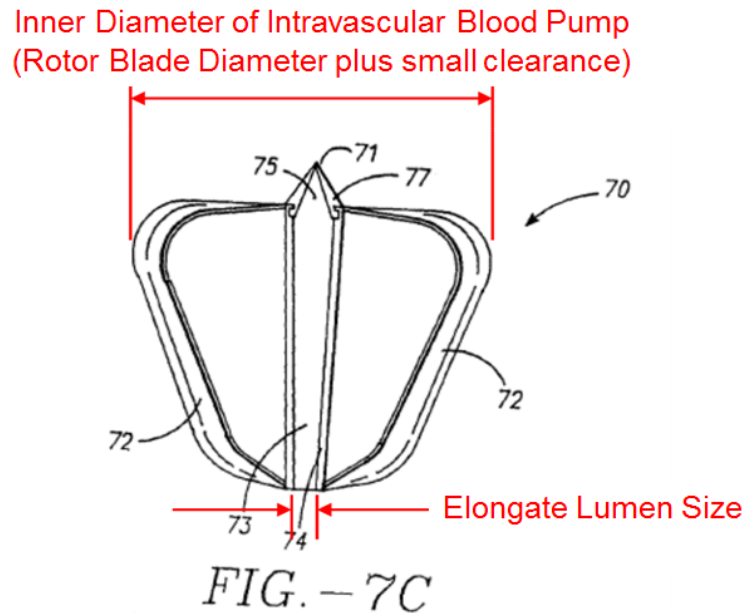
228. Second, Aboul-Hosn also discloses that the elongate lumen is sized substantially smaller than an inner diameter of the intravascular blood pump.

229. According to the claim, as discussed with respect to claim element 10(a) above, the intravascular blood pump includes the rotor hub and its blades, and the inner diameter of the blood pump would refer to the diameter of the rotor blades, plus a small clearance. A POSITA determining the inner diameter of the pump would know to consider the diameter of the rotor blades (plus a small clearance) as the inner diameter of the pump, because this rotor blade diameter, along with blade tip speed, importantly provides an indication of what the pump performance will be. *See e.g.*, Wu at 444.

230. FIG. 7C of Aboul-Hosn shows that the central passage 73 is substantially smaller than the pump inner diameter (rotor blade diameter plus a small clearance) – the central passage 73 is located within the rotor central hub 74, which is the smallest portion of the pump except for the guidewire itself and substantially smaller in diameter than the diameter of the blades (and the pump housing within which the blades reside).

231. As illustrated in Fig. 7C below the guidewire inner lumen 73 fits within the rotor hub (74) and is smaller than the rotor hub diameter. The outer diameter of the rotor hub is substantially smaller than the outer diameter of the blades in order for the blades to pump the blood. As shown in annotated FIG. 7C

below, the elongate lumen size is substantially smaller than the inner diameter of the intravascular blood pump (the pump blades plus a small clearance).



232. This claim element is thus disclosed in Aboul-Hosn.

10(e)(2): “(b) [the elongate lumen] is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and”

233. Aboul-Hosn discloses that the elongate lumen is arranged coaxially with at least one of a distal end or a proximal end of the cannula. As I explained earlier with respect to limitation 10(c)(1) of claim 10, the guide mechanism includes the elongate lumen extending through the length of the multi-lumen catheter 428, the central passages within the drive unit and the pump components (including the rotor hub 74 and drive unit 80), and the length of the cannula 411. As I also explained in Part VI.A, cannula 411 simply includes the inner cannula 20 (and outer

conduit 30 in the reverse flow mode) adapted for percutaneous access. *See* Aboul-Hosn at 14:13-16. The guide mechanism has an axis through the central passages of the components of the intravascular blood pump system because the various components of the intravascular blood pump system align to form the elongate lumen, as shown in annotated FIG. 3 below. *See* Part VI.A. *See also* Aboul-Hosn at 12:28-13:1; 13:7-9; 13:23-24.

234. Annotated FIG. 3 below identifies where each feature of this claim element is found. As in the '068 Patent first embodiment, the elongate lumen extends through the catheter, the drive unit 80, the rotor hub 74 and a portion of the cannula (in green), and the guide wire extends through the elongate lumen.

235. The elongate guide lumen is coaxial (concentric) with at least one of a distal end or a proximal end of the cannula over a portion (indicated with a green bracket), because the elongate guide lumen is coaxial (concentric) with the proximal end of the cannula over this portion.

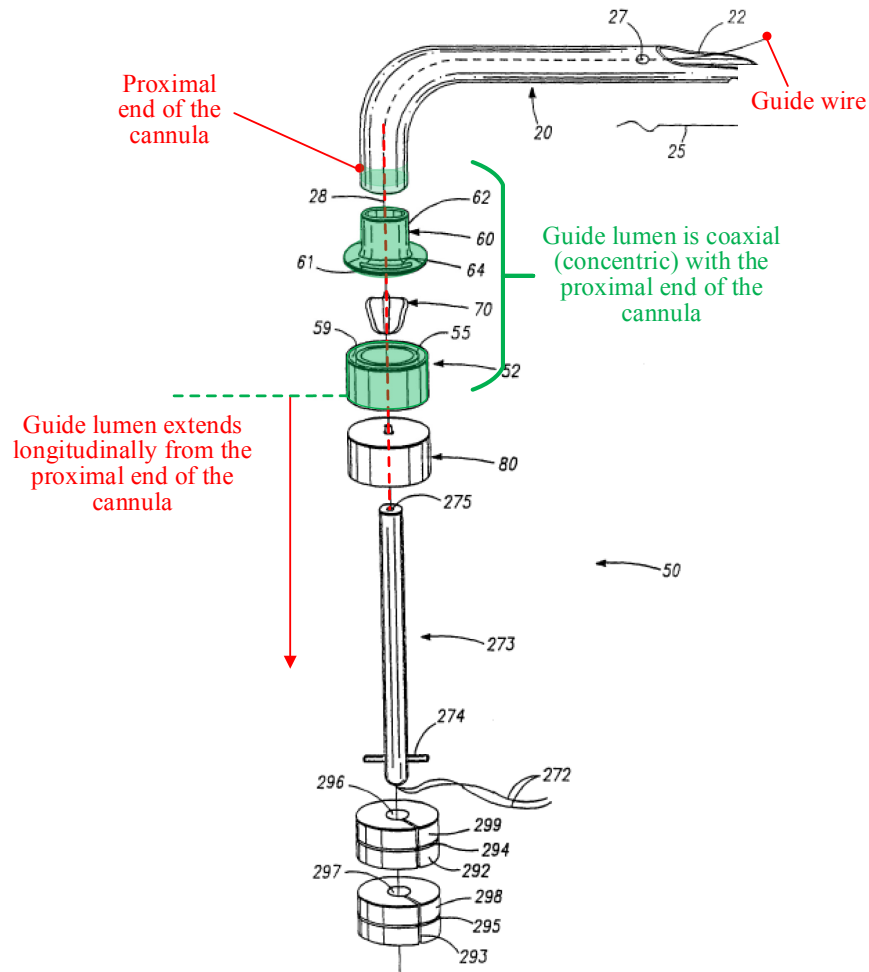


FIG. -3

236. The proximal end of the cannula is concentric with the components of the pump in the region of the housing cap 60 (i.e., the housing cap 60 fits within the distal end of the cannula 20 (or cannula 411)) and shares a common axis within that region. This is illustrated in FIG. 3 by the green highlighted regions, where the proximal end of the cannula would fit concentrically around the housing cap 60. *See Aboul-Hosn at 13:27-29.* In other words, two components are locally coaxial if they are concentric to each other at that location, as in the structure of a coaxial

cable. In the case of the standard axial flow mode (i.e., without the reverse flow components) (*see* Part VI.A), the same analysis applies and the proximal end of the cannula would fit concentrically about inlet tube 55 (shroud) (*see* Part VI.A and VIII.A.a).

237. Annotated FIG. 3 above also shows with a red arrow that below the portion of the pump (indicated with a green bracket) where the guide lumen is coaxial (concentric) with the proximal end of the cannula, the elongate guide lumen extends longitudinally away from the proximal end of the cannula.

238. Thus, Aboul-Hosn discloses that the lumen is arranged coaxially with at least one of a distal end or a proximal end of the cannula.

10(e)(3): “(c)[the elongate lumen] is arranged in series longitudinally with the cannula:”

239. Aboul-Hosn also discloses that the cannula and the lumen are arranged in series longitudinally. As annotated FIG. 3 above shows, the cannula is aligned in series longitudinally with the elongate lumen - the various components of the intravascular blood pump system align to form an elongate lumen that extends from the cannula through the pump components and through the rod 273 (or the catheter lumen in the case of the percutaneous embodiment, and the cannula connects to the pump elements, covering part of the pump elements, e.g., the housing cap 60. *See* Part VI.A; *see also* Aboul-Hosn at 29:17-25, 30:20-27.

240. Thus, Aboul-Hosn discloses that the cannula and lumen are arranged in series longitudinally.

10(f): “the method comprising: advancing a guide wire to a predetermined location in the circulatory system of the patient; and”

241. This method step recites nothing more than the conventional step of delivering a guide wire to the circulatory system. As discussed in Part VI.A and limitation 10(c)(2), Aboul-Hosn discloses that the guide wire is inserted into a desired location in the body before the cannula is advanced over the guide wire into a position in the body. *See* Aboul-Hosn at 22:12-14 (“The guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20.”). Thus, Aboul-Hosn teaches that the guide wire is first positioned in the circulatory system of the patient to later guide the cannula into position, for example in any chamber or vessel in the heart.

242. Aboul-Hosn discloses that the guide wire may be advanced to a particular location in the vasculature of a patient using imaging techniques to place the guide wire. *See* Aboul-Hosn 22:10-14:

A guide wire 28 may be also advanced with the help of imaging techniques to dispose the distal end of the inner cannula 20 in the desired blood vessel, heart chamber or other body cavity. The guide wire 28 may be inserted

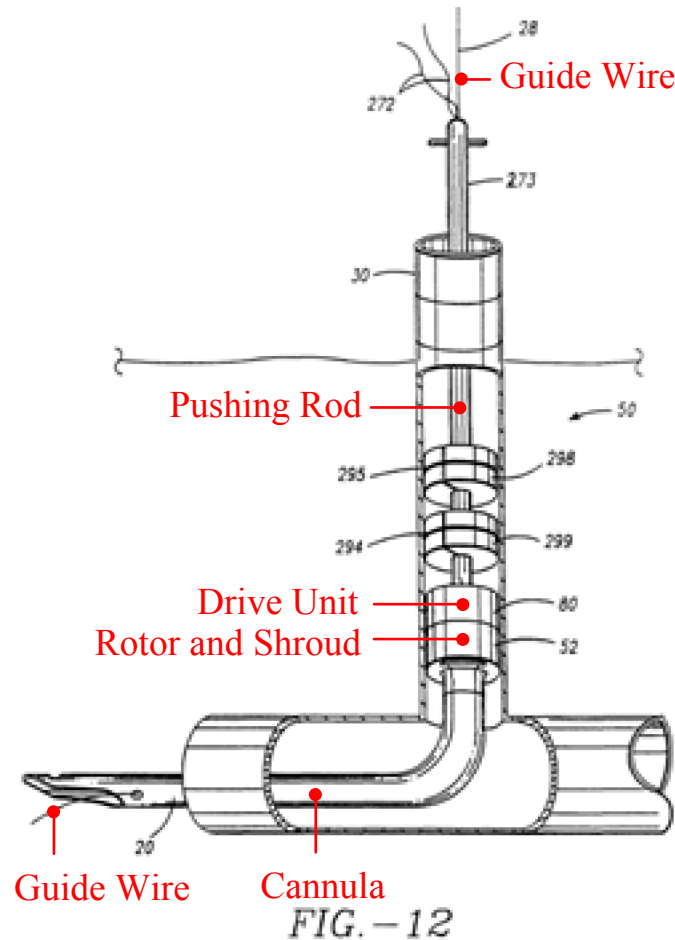
and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20.

243. Thus, Aboul-Hosn discloses a method of advancing a guide wire to a predetermined location in the circulatory system of the patient.

10(g): “advancing the blood pump system along the guide wire to the predetermined location”

244. This method is also nothing more than a conventional step – moving a blood pump system along a guide wire. Aboul-Hosn also teaches this conventional step - after the guide wire has been positioned (conventionally, of course) in the vasculature, the cannula can be guided into a position over the guide wire. *See* Aboul-Hosn at 22:12-16 (“The guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20. As a result, the distal end of the inner cannula 20 may be guided to a location before removing the guide wire 28.”).

245. As discussed in Section Part VI.A and limitations 10(c)(2) and 10(f) Aboul-Hosn discloses that the guide mechanism allows the guide wire to be slideably advanced through the guide mechanism to position the cannula within the vasculature of the patient. The cannula can be advanced over the guide wire to a location within the body by sliding the cannula over the guide wire in the guide mechanism. *Id.*



a percutaneous placement of an intravascular blood pump with the distal end of the cannula in the left atrium. See Aboul-Hosn at 29:17-19, 30:21-24.

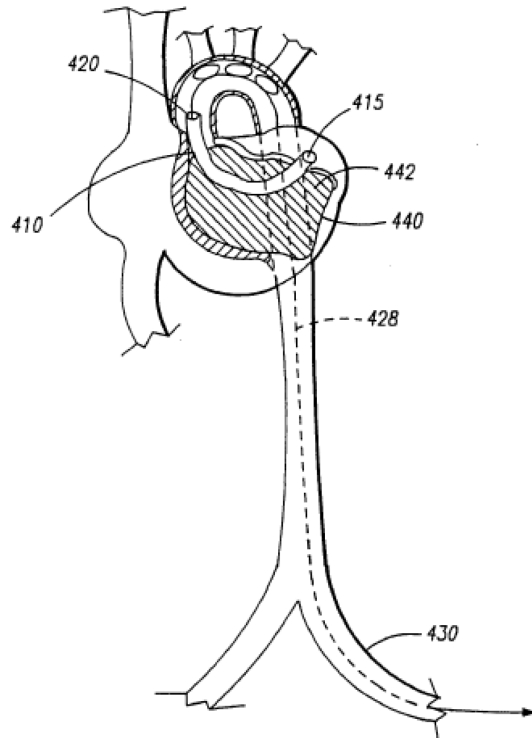


FIG. -21

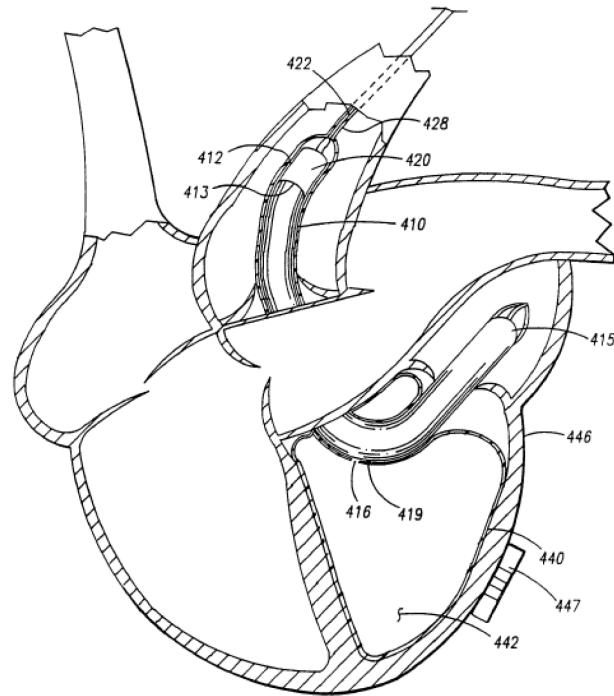


FIG. -23

248. Thus, Aboul-Hosn discloses this method step

b. Dependent Claim 13

“The method of claim 10, further comprising a plurality of egress flow ports disposed in a shroud of the intravascular blood pump, and a plurality of ingress flow ports disposed at a location spaced apart from and distal to the egress flow ports.”

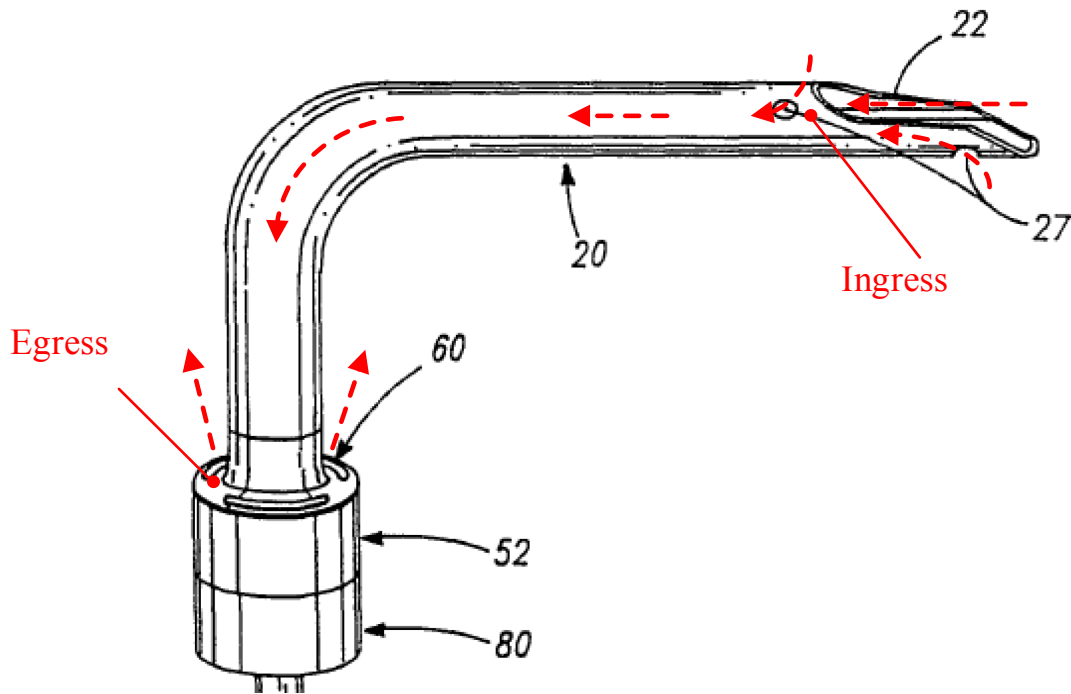
249. This claim element requires one set of holes in the shroud and another set located distal to that first set, along with egress and ingress. A POSITA would

understand that “ingress” refers to the flow of fluid into the blood pump and “egress” refers to the flow of fluid out of the blood pump.

250. Aboul-Hosn discloses both sets of flow ports – the ingress flow ports are openings 22 and 27, and the cut-outs 57 (by themselves or together with the outflow windows 64) are the egress ports.

251. As explained previously with respect to limitation 10(b) of claim 10, Aboul-Hosn discloses that (1) blood flows into the inner cannula 20 (and therefore into the blood pump) through the distal opening 22 along with the openings 27 formed in the distal region of the inner cannula 20, and (2) blood flows out of the blood pump through the multiple cut-outs 57 of the inlet tube 55 and the outflow windows 64 of the housing cap 60. *See* Part VIII.A.a. As I discuss above in Part VIII.A.a, a POSITA would associate the cut-outs 57 (alone or together with the outflow windows 64) with the first set of apertures, and the inlet openings 22 and 27 with the second set. Thus, in addition to being the first set and second set of apertures, the distal opening 22 and openings 27 are also ingress flow ports, as blood flows through them into the intravascular blood pump system when the pump is actuated in vivo, and the multiple cut-outs 57 (alone or taken together with the plurality of outflow windows 64) are also egress flow ports, as blood flows out of them (to exit the intravascular blood pump system) when the pump is actuated, as

shown in annotated FIG. 4, below. *See* Aboul-Hosn at 11:21-24; 13:11-13; 13:15-18; 15:24-26.



252. Accordingly, as disclosed in Aboul-Hosn, and annotated below, the egress ports (i.e., cut-outs 57) are also located in the inlet tube 55 which is the shroud. *See* Part VIII.A.a. As annotated FIG. 2 (below) shows, Aboul-Hosn discloses that rotor 70 is “axially aligned inside a cylindrical-shaped housing body 52,” or more specifically, that “[a] rotor 70 may be disposed longitudinally inside the inlet tube 55” that is within the housing body 52. *See* Aboul-Hosn at 12:30-13:1, 13:14-15.

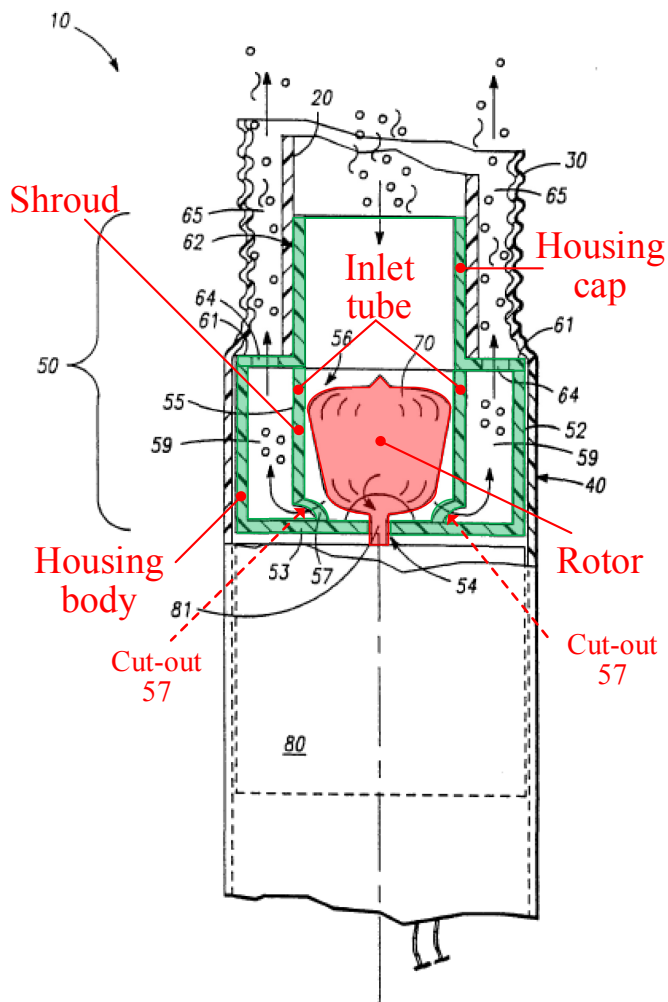


FIG. -2

253. Aboul-Hosn further explains that the inlet tube 55 (shroud) “may vary in shape to match the outside profile of the rotor 70” (15:26-27) and “[a] clearance between the inlet tube 55 profile and the rotor 70 should exist to permit the rotor 70 to rotate without contacting the walls of the inlet tube 55.” Aboul-Hosn at 15:30-16:1. It would be understood that the blood flowing through the rotor

would move axially, being constrained radially by the walls of the inlet tube 55, and that the inlet tube 55 protects the rotor.

254. Further, that same assessment would apply even in the situation where “[t]he distal opening of the housing body 52... [is] covered with a housing cap 60” (Aboul-Hosn at 13:2-4) in such a manner that the housing body 52 and the housing cap 60 forms one “unitary body” (Aboul-Hosn at 12:22-23). In this configuration, the inlet neck 62 and inlet tube 55 would also be a unitary body, meaning that the inlet tube 55 and inlet neck 62 together would form a “shroud.” In other words, the inlet tube 55 within the housing body 52 is part of the shroud of the intravascular blood pump.

255. Therefore, Aboul-Hosn’s multiple cut-outs 57 (either alone or taken together with windows 64) are a plurality of egress flow ports that are disposed in the shroud of the intravascular blood pump, and the openings 22 and 27 formed in the distal region of the inner cannula 20 are a plurality of ingress flow ports.

256. Moreover, as previously explained with respect to claim 10(b) of claim 10, the openings 22 and 27, i.e. ingress flow ports, spaced apart from and located distal to multiple cut-outs 57 and window 64, i.e. egress flow ports - the ingress flow ports are formed near the distal tip 25 of the inner cannula 20, whereas the egress flow ports are formed near the proximal end of the cannula. *See* Part VIII.A.a; Aboul-Hosn at 11:21-24 (“The inner cannula 20 may also have a plurality

of openings 27 formed near its tip 25 to allow blood to flow into the inner cannula 20, particularly when the distal opening 22 may become occluded or otherwise obstructed.”).

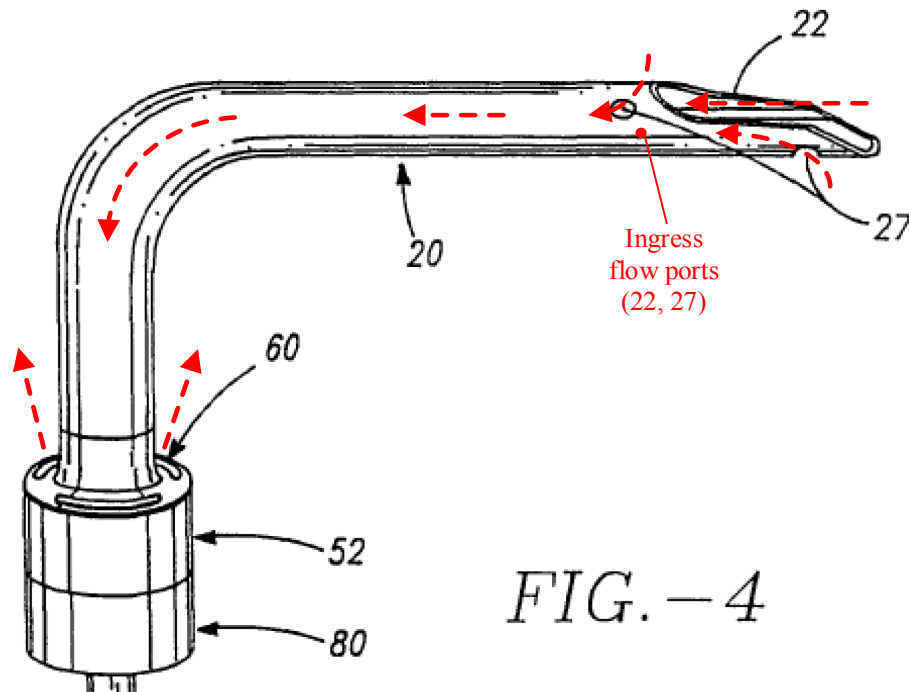
257. This claim element is thus disclosed in Aboul-Hosn.

c. Dependent Claim 14

14: “The method of claim 10, wherein the ingress flow ports comprise an end port located at the cannula distal end and a plurality of ports located about the cannula and proximal to the end port.”

258. Aboul-Hosn discloses the distal opening 22 which is an ingress flow port formed as an end port, and the plurality of openings 27 which are also ingress flow ports formed in the inner cannula proximal to the distal opening 22

259. As previously explained with respect to claim 13, the distal opening 22 along with the openings 27 formed in the distal region of the inner cannula 20 allow blood to flow into the inner cannula 20, and as such, are ingress flow ports. *See Part VIII.A.b.* As shown in annotated FIG. 4, below, the distal opening 22 is formed at the distal tip (far end) of the inner cannula 20. *See Aboul-Hosn at 11:8-9 (“The inner cannula 20 in FIG. 1 may be formed with a distal opening 22 and a proximal opening 24.”).*



260. FIG.4 also shows the plurality of openings 27 are formed in the distal region of the inner cannula 20, near the distal opening 22 and inwards of the distal opening 22, i.e. farther away from the far end of the inner cannula than the distal opening 22. *See* Aboul-Hosn at 11:21-24 (“The inner cannula 20 may also have a plurality of openings 27 formed near its tip 25 to allow blood to flow into the inner cannula 20, particularly when the distal opening 22 may become occluded or otherwise obstructed.”).

261. FIG. 4 shows two openings 27 thus corresponding to a plurality of openings as the claim requires. Notwithstanding, a POSITA would recognize that there can be as many openings 27 as are needed to ensure that there is sufficient flow of blood into the inner cannula 20, in light of Aboul-Hosn’s disclosure of (1)

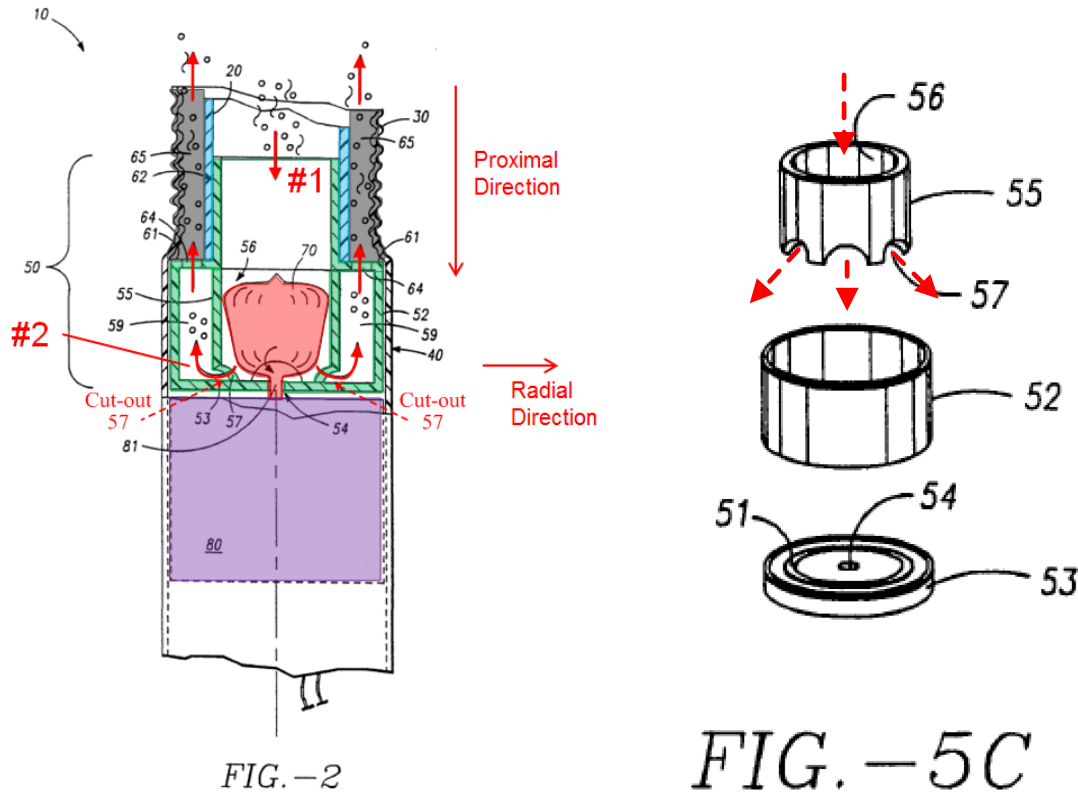
“a plurality of openings 27” (Aboul-Hosn at 11:21-224), which means two or more openings, and (2) the need to allow blood to flow into the inner cannula “when the distal opening 22 may become occluded or otherwise obstructed” (Aboul-Hosn at 11:21-24).

262. Thus, the distal opening 22 is an ingress flow port formed as an end port, and the plurality of openings 27 are also ingress flow ports formed in the inner cannula proximal to the distal opening 22.

d. Dependent Claim 15

15: “The method of claim 10, wherein the first set of apertures are egress ports and the second set of apertures are ingress ports, and wherein the egress ports are configured to direct blood passing through the interior of the cannula and towards the rotor in a direction that is both proximal and radially outward with respect to the rotor hub.”

263. As previously explained with respect to limitation 10(b) of claim 10 and claim 13, Aboul-Hosn’s multiple cut-outs 57 (alone or together with windows 64) are a first set of apertures that are also egress flow ports, and the openings 22 and 27 formed in the distal region of the cannula 20 are a second set of apertures that are also ingress flow ports. *See* Parts VIII.A.a and VIII.A.b. As shown in annotated FIGS. 2 and 5C, below, blood flows through the multiple cut-outs 57 from the cannula 20 in a proximal direction as well as in a radially outward direction with respect to the hub of the rotor 70.



264. As shown above, the arrow #1 indicates that blood would flow proximally through the cannula 20, and the arrows #2 indicate that the flow proceeds radially through the cut out 57 into the passageway 59. Aboul-Hosn explains that the “radially aligned cut-outs 57” formed at the bottom of the inlet tube 55 “permit the passage of fluid” from the inlet tube 55. *See* Aboul-Hosn at 13:11-13. Thus, the multiple cut-outs 57 provide a path for the blood to flow from the inside of the blood pump to outside. By placing the multiple cut-outs 57 past the rotor 70, the blood flow is directed in a proximal direction from the distal end of the cannula 20 toward the rotor 70 (and its associated rotor hub), before the blood can exit the inlet tube 55 through the cut-outs 57.

265. Thus, Aboul-Hosn discloses this element.

B. GROUND II: CLAIM 20 IS ANTICIPATED OR RENDERED OBVIOUS BY ABOUL-HOSN

a. Independent Claim 20

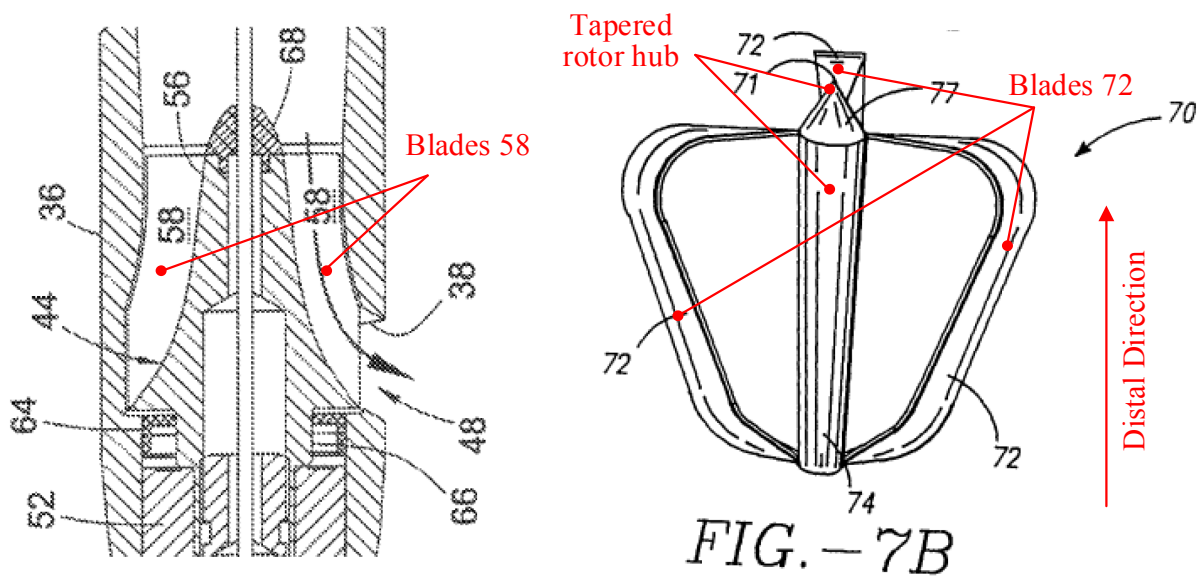
20(pre): “A method for perfusion [sic] a patent [sic] with an intravascular blood pump system, the intravascular blood pump system is configured to be advanced to a predetermined location in a patient’s circulatory system and comprises: (i) an intravascular blood pump,”

266. As explained previously with respect to the preamble of claim 10, Aboul-Hosn shows a blood pump system that can be positioned in predetermined location in the vasculature of the patient, such as the heart. *See Part VIII.A.a.*

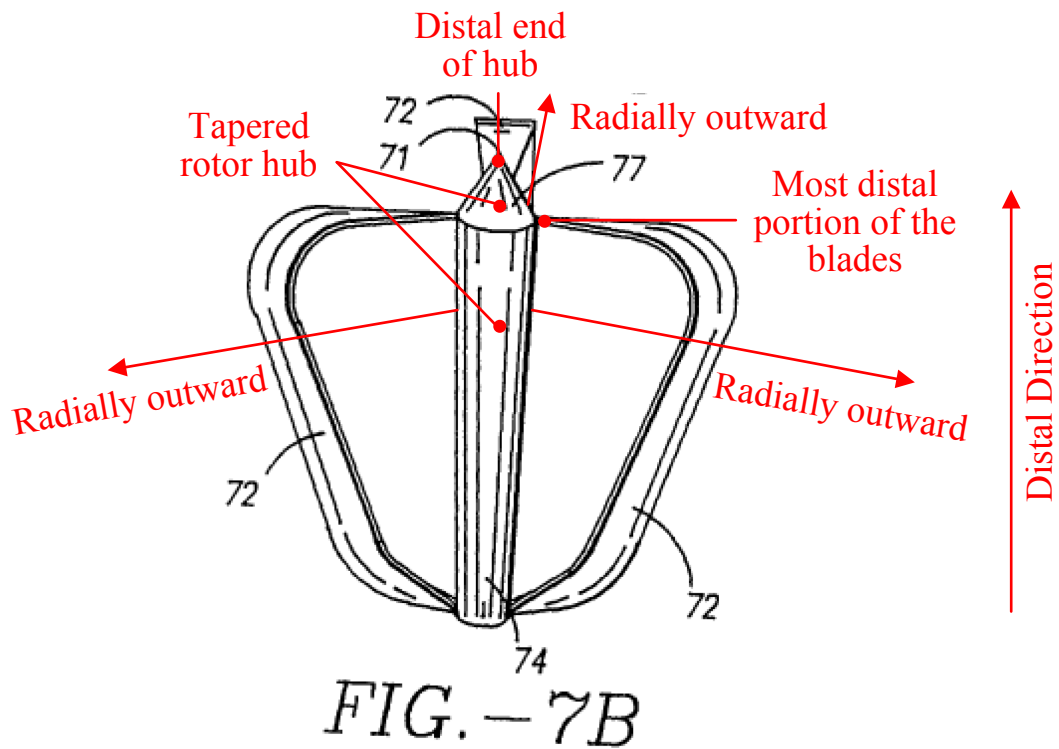
20(a): “the intravascular blood pump comprising a rotor having a generally conical rotor hub tapering in the distal direction, at least two blades extending radially from the rotor hub, the generally conical hub having a distal tip extending distally beyond the blades;”

267. As explained previously with respect to limitation 10(a)(1) of claim 10, Aboul-Hosn discloses a rotor having: (1) a rotor 70 with a central hub 74 with an end tapering in the distal direction, and (2) three blades 72 extending radially outwards from the rotor hub. Aboul-Hosn also discloses (3) the rotor hub being generally conical, and (4) the distal tip of the rotor hub extending distally beyond the rotor blades.

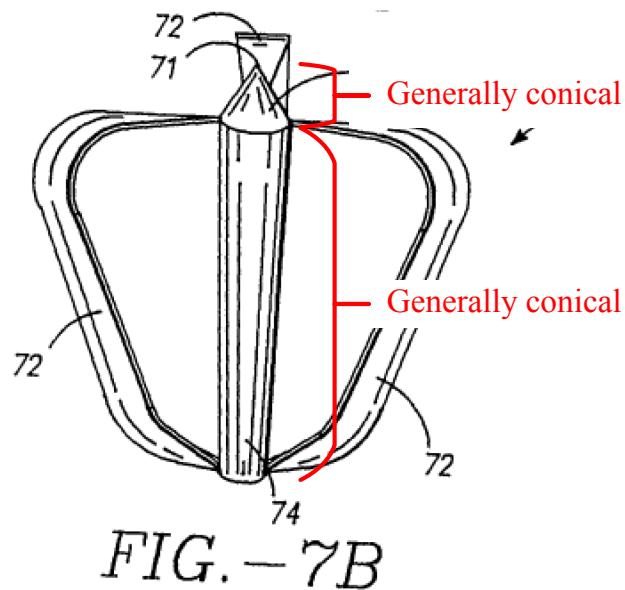
268. Aboul-Hosn discloses that “the rotor 70 may comprise a single or multiple blades 72 extending from a longitudinally aligned central hub 74.” *See* Aboul-Hosn at 17:1-2. As previously discussed in Part VII, the distal direction is the direction towards the far end of the cannula relative to the position. FIG. 7B of Aboul-Hosn (right) shows a rotor 70 having a central hub 74 tapering in the distal direction, with three blades 72 extending “radially outward” from central hub 74 in the same manner as blades 58 extend from hub 56 in the ’068 Patent (left).



269. As annotated FIG. 7B below shows, the rotor hub has a distal end that extends distally beyond the most distal portion of the blade.



270. As annotated in FIG. 7B below, the rotor hub is generally conical.



271. Moreover, this general rotor configuration was conventional—a rotor hub tapering in the distal direction, with blades of various shapes and orientations

extending from the surface of a central hub, and the distal end of the hub extending distally beyond the most distal portion of the blades. *See* Part III.C.b for discussion of conventional rotor designs. Aboul-Hosn also expressly recognizes that the specific configuration of the rotor is not limited to the design shown in FIG. 7B, and that a variety of suitable configurations may be used. Aboul-Hosn at 16:30-31, 17:27-28, 19:14-15.

272. Thus, Aboul-Hosn discloses this claim element.

20(b): “(ii) a cannula extending distally from the intravascular blood pump;”

273. As explained previously with respect to limitation 10(a)(2) of claim 10, Aboul-Hosn discloses a cannula extending from the blood pump. Moreover, as explained earlier, “distal” refers to “towards the far end of the cannula relative to the position of the pump.” *See* Part VII. The cannula, therefore, extends distally from the intravascular blood pump.

20(c): “(iii) a plurality of ingress ports located towards the distal region of the cannula and a plurality of egress ports located in proximity to the blood pump such that movement of fluid proximally through an interior region of the cannula is steered towards the egress ports;”

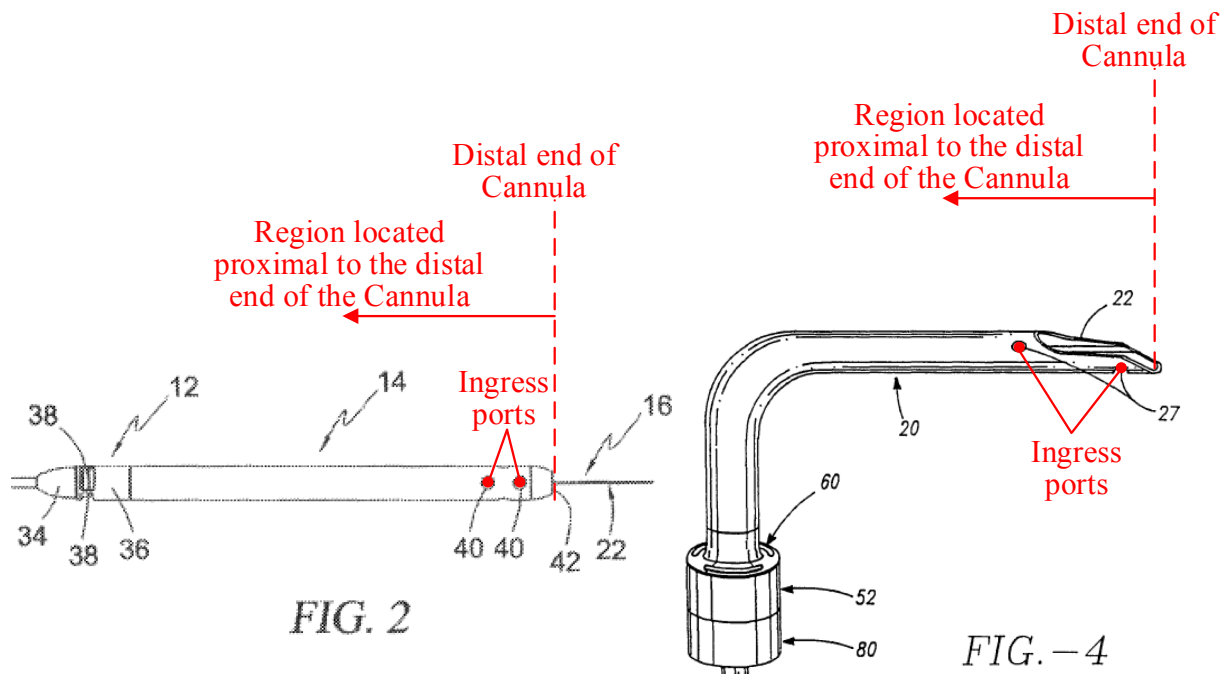
274. As is the case with claim 13, this claim element recites a set of ingress and a set of egress flow ports. It also recites that blood is steered proximally through the cannula to the egress ports. A POSITA would understand that

“ingress” refers to the flow of fluid into the blood pump, and “egress” refers to the flow of fluid out of the blood pump.

275. Aboul-Hosn discloses this element. As explained above in relation to Claim 13, the openings 27 formed in the distal region of the inner cannula 20 are a plurality of ingress ports in that blood is pumped through them into the blood pump, and the multiple cut-outs 57 of the inlet tube 55 and the outflow windows 64 are a plurality of egress ports through which the blood flows out of the blood pump. *See* Part VIII.A.b.

276. The openings 27 satisfy the ingress ports limitation at least because the plurality of openings 27 are located proximal along the cannula relative to the distal end of the cannula. In fact, a comparison with the '068 Patent confirms this. Below is a side-by-side comparison of annotated FIG. 2 of the '068 Patent (left) and annotated FIG. 4 of Aboul-Hosn (right), both of which show the location of the ingress ports in the same location on the cannula relative to the distal end.¹⁴ As the figures below show, the plurality of openings 27 in Aboul-Hosn and the ports 40 of the '068 Patent are formed in a region located in the distal region of the cannula as compared to the egress ports that are located nearer the blood pump.

¹⁴ The ingress ports, i.e. ports 40, are in the same location on the cannula relative to the distal end in each of the three major embodiments—over-the-wire, rapid exchange, and guide catheter—of the '068 Patent, i.e. FIGS. 2, 7 and 13.



277. Further, as previously discussed with respect to claim 13 and as shown in annotated FIG. 2, below, as shown by the red directional arrows, blood flows proximally through the cannula 20 towards the blood pump 50, passes through the rotor 70 exits through multiple cut-outs 57 into the passageway in the housing body 52 and flows out through outflow windows 64. *See* Part VIII.A.b. In other words, blood flows in a proximal direction through ingress ports into the interior of the cannula 20 is steered towards the egress ports.

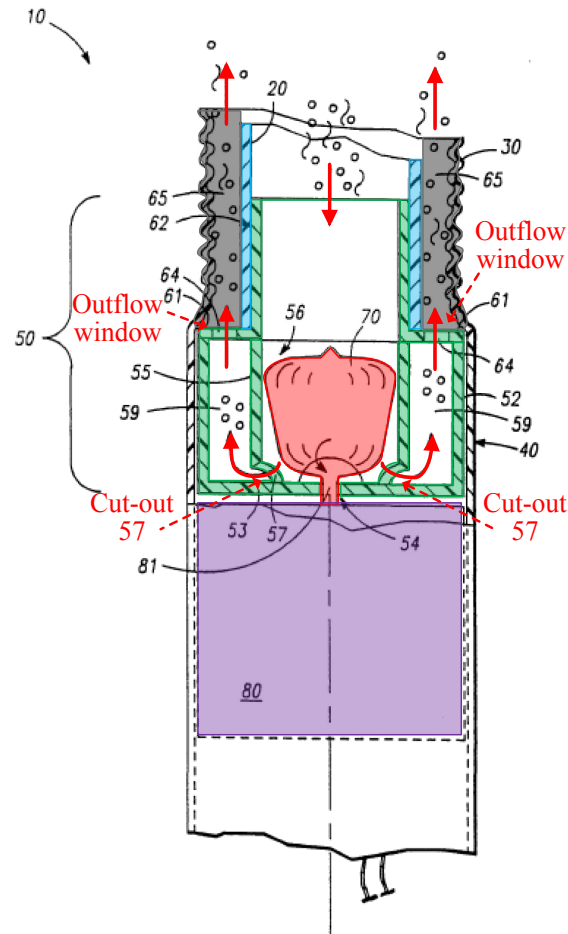


FIG. -2

278. Thus, Aboul-Hosn discloses this claim element.

20(d): “(iv) a guide wire having a cross-section substantially smaller than the cannula; and”

279. As explained previously with respect to limitation 10(e)(1) of claim 10, the elongate lumen which is advanced along the guide wire in Aboul-Hosn’s disclosure is significantly smaller than the diameter of the inner cannula. *See Part*

VIII.A.a. As such, Aboul-Hosn's guide wire has a cross-section that is substantially smaller than the cannula.

20(e)(1): “(v) an elongate lumen, the elongate lumen (a) having a luminal interior sized smaller than an inside diameter of the cannula and sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong,”

280. This element requires a comparison between the interior lumen of the elongate guide wire lumen and the inside diameter of the cannula, where the guide wire lumen is smaller than the cannula diameter. As explained previously with respect to limitation 10(c)(1) of claim 10, Aboul-Hosn discloses an elongate lumen that accommodates the guide wire and extends through the catheter lumen (or the positioning rod lumen 273), and the central passage of the drive unit 80, through the rotor hub 74 and through the cannula 20. *See* Part VIII.A.a. Aboul-Hosn indicates that that central passage has a diameter of “approximately 0.040 inches,” or about one millimeter. *See* Aboul-Hosn at 20:23-25; 17:16-19. In contrast, the cannula of a conventional blood pump for intravascular applications, such as disclosed in the '068 Patent, has diameters in the range of 9 French to 30 French (i.e. 0.12 to 0.40 inches). *See* '068 Patent at 8:28-35.

281. As explained previously with respect to limitation 10(e)(1) of claim 10, Aboul-Hosn's cannula would at least be as large as a conventional cannula – i.e., at least 0.12 inches in outer diameter. *See* Part VIII.A.a. Even assuming that

the inside diameter of the conventional cannula is a bit smaller than that (i.e., accounting for the thickness of the cannula wall itself), the inside diameter would still be orders of magnitude larger than the 0.040 inch diameter of the central passage through the drive unit 80 and the rotor hub 74. The elongate lumen would also have a sufficiently large diameter to accommodate the guide wire when the guide wire is advanced along the elongate lumen, as shown for example in Aboul-Hosn's FIG. 3. Thus, Aboul-Hosn discloses this claim element.

20(e)(2): “(b) [the elongate lumen] arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and (c) arranged in a series longitudinally with the cannula,”

282. As previously explained with respect to limitation 10(e)(2), Aboul-Hosn discloses its guide wire lumen (the central passages) arranged coaxially with the proximal end of the cannula and the lumen and the cannula arranged in series longitudinally. *See Part VIII.A.a.*

20(f): “the method comprising: advancing a guide wire to a predetermined location in the circulatory system of the patient; and”

283. As previously discussed with respect to limitation 10(f) of claim 10, this step is a conventional method step and is disclosed in Aboul-Hosn. Aboul-Hosn discloses that a method of using the intravascular blood pump system includes advancing a guide wire to a predetermined location in the circulatory system of a patient. *See Part VII.A.a.*

20(g): “advancing the blood pump along the guide wire to the predetermined location.”

284. Also, as previously discussed with respect to limitation 10(g) of claim 10, Aboul-Hosn discloses the conventional method of advancing the blood pump along the guide wire to the predetermined location to place the blood pump in the patient. *See* Part. VII.A.a.

IX. CONCLUSION

285. Based on the foregoing, claims 10, 13-15, and 20 of the '068 Patent are unpatentable because they are disclosed by, and rendered obvious, in view of the prior art.

X. AVAILABILITY FOR CROSS EXAMINATION

286. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allocated for cross examination.

XI. RIGHT TO SUPPLEMENT

287. I reserve the right to supplement my opinions in the future to respond to any arguments that Patent Owner raises and to take into account new information as it becomes available to me.

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

Dated: September 22, 2017



John M. Collins, Ph. D.
Lexington, MA

John M. Collins, Ph.D.

Summary

A tested leader in technology-driven businesses with more than 35 years of international experience focused on the accelerated design, development and commercialization of innovative technologies, products and services. Experiences integrate a broad geographic and technology base across industries from clean energy/tech to consumer durables, with a career long focus on medical devices. A proven ability to form and lead high performance project and operational teams, create and manage strong intellectual property portfolios, as well as develop, structure, and drive collaborative business relationships with companies ranging from start-ups to premier multi-national organizations. Maintains a hands-on approach and an intimate working knowledge of technologies, operations, and user needs.

Experience

2008 to Present	CIMIT: Consortia for Improving Medicine with Innovation and Technology	Boston, MA
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Chief Operating Officer

CIMIT is a consortium of the greater Boston area's premier clinical, research and academic institutions with a growing network of affiliates (www.CIMIT.org). Based at the Mass General Hospital, its mission is to improve patient care by facilitating collaboration among clinicians, engineers and entrepreneurs to catalyze the discovery, development and implementation of innovative technologies and procedures/systems that improve patient care. As COO, responsible for ensuring CIMIT's Finding, Funding and Facilitation functions are effective. A particular focus is to assist investigators move technologies from the lab into commercialization and scale the CIMIT network through the web-based CoLab® platform.

2008 to Present	Reed Collins LLC	Lexington, MA
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Chief Technology & Innovation Officer

Technology, intellectual property, commercialization and business development consulting services for research teams, start-ups, IP law firms and risk capital organizations. In addition, strategic consulting to non-profits with a focus on innovation and healthcare.

2002 to 2008	TIAX LLC	Cambridge, MA
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President

In close collaboration with CEO and owner, Dr. Kenan Sahin, formed TIAX from the Arthur D. Little T&I group. Established TIAX as a 150-person strong, privately held technology development and commercialization business, successfully blending services work for government and commercial clients with technology development and licensing. TIAX (www.TIAXLLC.com) is a unique technology "transformation" organization focused in several core technology areas, including clean energy and materials, health and wellness, appliances and HVAC systems, and enhanced security. TIAX has one of the most successful records in SBIR wins, with more than 40 Phase I grants, most of which proceed to subsequent phases and collaborative commercial relationships. The World Economic Forum recognized TIAX as a Technology Pioneer in 2002 and as a New Champion in 2007.

Promoted to President in 2005 after having served as Executive Vice President since the company founding in 2002. In addition to an integral role in managing the transition and building a new business infrastructure, key accomplishments include attracting and hiring over 60 exceptionally qualified staff members, developing key technology platforms and intellectual property portfolios, and establishing several significant collaborative business relationships and licensing agreements.

1999 to 2002	Arthur D Little, Inc	Cambridge, MA
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Senior Vice President, Technology & Innovation (T&I) Directorate

Reporting to the President and serving on the company's Executive Leadership Team, reestablished Arthur D. Little, Inc. (ADL) as a leader in technology consulting, linking strategy, innovation, and technology development. Architected and drove the turnaround of the technology business, reversing a declining revenue trend that persisted over several years to generate an average of ~20% annual growth. Successfully built a strong leadership team and focused the business on the integrated services of technology-based consulting, technology and product development, and intellectual property management. Grew the business to about 300 staff members and operated above target profitability levels (20% contribution margin). Drove a number of large commercial relationships that created significant success for clients. Board member of Cambridge Consultants Ltd. (a wholly owned subsidiary based in Cambridge U.K.), Nuvera Fuel Cells (an ADL spin-out with interests held by Gruppo De Nora and Amerada Hess, based in Cambridge, MA) and Strategic Food Solutions (a joint venture between ADL and TNO, the Netherlands research organization).

1996 to 1999	Arthur D Little, Inc	Sydney, Australia
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Managing Director, Asia Pacific Management Consulting Directorate

Reporting to the President and serving on the company's Executive Leadership Team, restructured Arthur D. Little's Management Consulting business in Asia during the currency crisis of the late 90's. Aligned the offices in Sydney, Melbourne, Singapore, Tokyo, Seoul, Kuala Lumpur and Hong Kong to achieve services revenues of about \$30mm. Enabled the growth of ADL's three lines of business (Technology, Environment and Management Consulting) by expanding/extending relationships with multi-national corporations based in the US and Europe.

Initially, served as the Managing Director of the Sydney office and a member of the Asia Pacific Leadership team for two years before being promoted. In that time, opened an office in Melbourne and doubled the in-country revenues, returning the Australian operation to profitability, while also leading the expansion of the Technology & Innovation Management and the Organizational Learning practice across Asia Pacific.

1988 to 1996	Arthur D Little, Inc	Cambridge, MA
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Vice President, Technology and Product Development

Joined Arthur D. Little, Inc. after completing Ph.D. to help establish the medical products group. Held a variety of positions of increasing responsibility while also maintaining an active hand in creating and managing engagements with clients. Created and implemented ADL's Product Development Process.

1982 to 1986	Booz, Allen & Hamilton	Cleveland, Ohio
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Senior Consultant

Held a variety of positions of increasing responsibility, transitioning from being a contributor in technology and strategy assignments to being a project leader.

Education

Ph.D. – MIT 1987 to 1988	Doctorate in Mechanical Engineering from Massachusetts Institute of Technology, with a concentration in fluid mechanics and heat/mass transfer. Minor concentration in Technology & Innovation Management.
M.S. – MIT 1980 to 1982	Masters in Mechanical Engineering from Massachusetts Institute of Technology, with a concentration in fluids mechanics and heat/mass transfer. Minor concentration in Technology & Innovation Management.
B.S. – RPI 1976 to 1980	Bachelors in Mechanical Engineering from Rensselaer Polytechnic Institute, with a minor in Economics. General Motors Scholar/Intern.

Other

Patents	Over 20 US patents, with numerous corresponding international patents (attached below)
Publications	See recent publications below
Security Clearance	DoD Top Secret (no longer active)

Issued US Patents

Patent Number	Date Issued	Title
Trocars		
US05350364	09/27/1994	Universal seal for trocar assembly
US05342315	08/30/1994	Trocar seal/protector assemblies
US05314417	05/24/1994	Safety trocar
US05209736	05/11/1993	Trocar method and apparatus
US05197955	03/30/1993	Universal seal for trocar assembly
Automated Fryer		
US05319939	06/14/1994	Frozen food storage and dispensing system
US05230279	07/27/1993	Frying apparatus
US05224415	07/06/1993	Frozen food storage and dispensing system
US05305615	04/26/1994	Frozen food storage & dispensing system
US05142968	09/01/1992	Automated deep fat fryer
Blood/Fluid Warmer		
US06047108	04/04/2000	Blood warming apparatus
US05846224	12/08/1998	Container for use with blood warming apparatus
Rug Cleaner		
US04712740	12/15/1987	Venturi spray nozzle for a cleaning device
US04570856	02/18/1986	Liquid and detergent mixing chamber and valves
Catalytic Coating Process		
US04550034	10/29/1985	Method of impregnating ceramic monolithic structures with predetermined amounts of catalyst
US04609563	09/02/1986	Metered charge system for catalytic coating of a substrate
Ergonomic Table		
US04637322	01/20/1987	Adjustable computer work table
US04890561	01/02/1990	Extendable keyboard support assembly
Tendon/Ligament Repair		
US06106556	08/22/2000	Tendon and ligament repair system
US06080192	06/27/2000	Tendon and ligament repair system
US05800544	09/01/1998	Tendon and ligament repair system

Recent Publications

Accelerating the Healthcare Innovation Cycle

IEEE Pulse, December 3, 2013

A description of the CIMIT Model for stimulating and accelerating healthcare innovations into practice

Facilitating Translational Research

Journal of Investigative Dermatology, May 1, 2015

An overview of the need for and CIMIT's approach to facilitating translational medical research.

Deep Innovation in the Medical Domain a la Boston's CIMIT

Venture Findings #3, November 25, 2015

An overview of how the CIMIT Model supports innovation

National Institute of Biomedical Imaging and Bioengineering Point-of-Care Technology Research Network: Advancing Precision Medicine

IEEE Journal of Transnational Engineering in Health and Medicine, August 16, 2016

This paper describes the Point-of-Care Technology Research Network and the three Centers funded by NIBIB as examples of academic-based organizations that support collaborations across disciplines, institutions, and geographic regions to successfully drive innovative solutions from concept to patient care.

Healthcare Commercialization Programs: Improving the Efficiency of Translating Healthcare Innovations from Academia Into Practice

IEEE Journal of Transnational Engineering in Health and Medicine, September 28, 2016

The article describes Healthcare Commercialization Programs (HCPs) which offer institutions and funders an additional option to improve the efficiency with which the healthcare projects translate into products and services that improve people's health. It describes programs such as CIMIT's CRAASH course that get teams out of the lab to interface with customers and stakeholders.