

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**ABBOTT LABORATORIES,
Petitioner**

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

**DECLARATION OF DR. GEORG WIESELTHALER
IN SUPPORT OF PETITIONER's REPLY**

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

Declaration of Dr. Georg Wieselthaler

TABLE OF CONTENTS

	Page
EXHIBIT LIST	4
I. INTRODUCTION	8
II. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE	9
III. LEVEL OF ORDINARY SKILL IN THE ART	14
IV. RELEVANT LEGAL STANDARDS	16
V. TERMINOLOGY	18
VI. THE BOURQUE PUMP	22
A. Bourque discloses a third-generation centrifugal LVAD.	23
B. Like all centrifugal LVADs, the inflow enters the pump along the rotor's central axis and the outflow exits the pump radially.	25
C. The Bourque pump had an elbow so that the pump could use the same peripheral hardware as the prior HeartMate systems.....	26
VII. OBVIOUSNESS.....	26
A. A POSITA would have been motivated to eliminate the elbow in the Bourque pump.	27
1. An inflow elbow is unnecessary in a centrifugal LVAD, because the 90 degree redirection of the blood allows for flexibility during implantation.	27
a. The HVAD	29
b. The Terumo DuraHeart.....	35
c. The Ventracor VentrAssist	37
2. By 2007, placement of an LVAD at the apex would have been preferred over placement in a preperitoneal pocket.	39
B. A POSITA would have had a reasonable expectation of success that eliminating the elbow in the Bourque pump would work.....	42

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

Declaration of Dr. Georg Wieselthaler

1. Numerous LVADs comprising an axially aligned inflow tube already existed.....	42
a. The HeartWare HVAD.....	42
b. The Terumo DuraHeart.....	43
c. The Ventracor VentrAssist	44
d. The MicroMed DeBakey.....	44
e. The Jarvik-2000	44
2. By 2006, Mr. Bourque had already begun redesigning the pump.....	45
VIII. CONCLUSION.....	47

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

Declaration of Dr. Georg Wieselthaler

EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 11,351,356
1002	U.S. Patent No. 11,351,356 File History
1003	Declaration of Peter Crosby
1004	CV of Peter Crosby
1005	U.S. Pat. Pub. No. US 2003/0124007A1 to Heinrich Schima, et al., titled “ <i>Rotary Pump Comprising a Hydraulically Mounted Motor</i> ”
1006	Akamatsu et al., <i>Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump</i> , J Artif Organs 1999, Vol. 2, pp. 3-7
1007	Bourque et al., <i>HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor</i> , ASAIO Journal 2001
1008	U.S. Pat. Pub. No. US 2002/0102169A1 to Richard Wampler, et al., titled “ <i>Sealless rotary blood pump</i> ”
1009	Miracor’s Supplemental Initial Response to Invalidity Contentions, dated September 20, 2014
1010	Frazier et al. <i>Total Heart Replacement with Dual Centrifugal Ventricular Assist Devices</i> , ASAIO Journal 2005
1011	Schob, <i>Centrifugal pump without bearings or seals</i> , World Pumps Vol. 2002, No. 430, pp. 34-37
1012	Rose et al, <i>Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term use of a left ventricular assist device for end-stage heart failure</i> , N Engl J Med. 2001 Nov 15, Vol. 345, No. 20, pp. 1435-43

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

Declaration of Dr. Georg Wieselthaler

1013	HeartMate® II LVAS: Patient Management Guidelines, December 14, 2006
1014	Schulman et al., <i>Comparisons of infection complications between continuous flow and pulsatile flow left ventricular assist devices</i> , The Journal of Thoracic and Cardiovascular Surgery 2007, Vol. 133, No. 3, pp. 841-842
1015	LaRose et al., <i>Heartware – A novel miniaturized passive maglev centrifugal VAD</i> , ASAIO Journal 2004 Mar, Vol. 50, No. 2, p. 137
1016	Qian et al., <i>Permanent magnetic-levitation of rotating impeller: a decisive breakthrough in the centrifugal pump</i> , Journal of Medical Engineering & Technology 2002 Jan/Feb, Vol. 26, No. 1, pp. 36-38
1017	Akamatsu et al., <i>Chronic Animal Experiment with Magnetically Suspended Centrifugal Pump</i> , Artificial Organs 1997, Vol. 21, No. 7, pp. 645-638
1018	U.S. Patent No. 6,050,975
1019	Exhibit 7 of Complaint, dated November 27, 2023
1020	Bottone et al., <i>Magnetos for automobilists, how made and how used</i> , Crosby Lockwood and Son, Ch. 1 (1907) (accessed at https://archive.org/details/magnetosforauto00bottgoog/page/n6/mode/2up)
1021	“Ignition magneto,” accessed via https://en.wikipedia.org/wiki/Ignition_magneto (last accessed October 28, 2024)
1022	Masuzawa et al. <i>Magnetically Suspended Centrifugal Blood Pump with an Axially Levitated Motor</i> , Artificial Organs 2003, Vol. 27, No. 7, pp. 631-638
1023	U.S. Patent No. 6,152,704
1024	U.S. Patent No. 6,589,030

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

Declaration of Dr. Georg Wieselthaler

1025	European Patent No. 0 834 326
1026	Miracor's Response to Exhibit A-1 (Bourque-2001) of Supplemental Invalidity Contentions, dated September 20, 2024
1027	U.S. Pat. No. 5,324,177
1028	Allaire, et al., <i>Prototype Continuous Flow Ventricular Assist Device</i> , J. Artificial Organs 1996, Vol. 20, No. 7, pp.582-690
1029	Kung and Hart, <i>Design Considerations for Bearingless Rotary Pumps</i> , J. Artificial Organs 1997, Vol. 21, No. 7, pp. 645-650
1030	Declaration of Sylvia Hall-Ellis
1032	Declaration of Saranya Raghavan in support of motion for Pro Hac Vice Admissions
1033	Leschinsky, et al., <i>The CorInnova Implantable Cardiac Assist System for Direct Cardiac Compression</i> , Rev. Cardiovasc. Med. 2022; 23(6): 211
1034	Abiomed, Inc., v. WhiteSwell Medical Ltd., PGR2021-00107, Ex. 2006, Declaration of Boris Leschinsky
1035	U.S. Patent No. 10,926,069
1036	Miracor's Supplemental Infringement Contentions, Ex. D - Claim Chart for U.S. Patent No. 11,572,879, dated May 28, 2024
1037	Reserved
1038	Duplicate of Ex. 1015, introduced during cross-examination of Dr. Gallegos
1039	Gallegos, et al., <i>Animal Models for Cardiac Research</i> , In: Iaizzo, P.A. (eds) Handbook of Cardiac Anatomy, Physiology, and Devices. Humana Press (2005).
1040	Transcript of Cross-Examination of Boris Leschinsky (December 10, 2025)
1041	First Declaration of Dr. Wieselthaler

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

Declaration of Dr. Georg Wieselthaler

1042	Second Declaration of Peter Crosby
1043	LinkedIn profile of Kevin Bourque
1044	HeartWare Announcement: First Human Implant of HeartWare's HVAD, March 2006
1045	Transcript of Cross-Examination of Dr. Robert Gallegos (December 15, 2025)
1046	Hoshi, et al., "Third-generation Blood Pumps With Mechanical Noncontact Magnetic Bearings," <i>Artificial Organs</i> 30(5):324–338 (2006)
1047	CV of Dr. Georg Wieselthaler
1048	FEP Medical Policy Manual, Total Artificial Hearts and Implantable Ventricular Assist Devices (January 2024)
1049	Wieselthaler G. <i>My Journey with the HeartWare Ventricular Assist Device- An Obituary. The VAD Journal.</i> 2022; 8(1):e2022813.
1050	Potapov et al., The MicroMed DeBakey VAD—Part I: The Pump and the Blood Flow, <i>JECT.</i> 2003;35:274–283

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

Declaration of Dr. Georg Wieselthaler

I, Dr. Georg Wieselthaler, do hereby declare as follows:

I. INTRODUCTION

1. I am making this declaration at the request of Petitioner in the matter of the *Inter Partes* Review of U.S. Patent Nos. 11,351,356; 11,351,357; 11,376,415; 11,572,879; 11,674,517; and 11,754,077, all to Mohl et al.

2. I am being compensated for my work in this matter at my standard hourly rate. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this proceeding. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

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

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

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

Declaration of Dr. Georg Wieselthaler

II. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE

5. My complete qualifications and professional experience are described in my Curriculum Vitae, a copy of which can be found in Ex.1047. The following is a brief summary of my relevant qualifications and professional experience.

6. I am a cardiothoracic surgeon with more than three decades of experience in cardiac transplantation, mechanical circulatory support, and advanced heart failure surgery, and I currently serve as Chair of the Department of Cardiothoracic Surgery and Chief of Staff at the GAD Heart & Lung Institute in Al-Khobar, Kingdom of Saudi Arabia, following my tenure as Professor of Clinical Surgery (emeritus) at the University of California, San Francisco, where I was the Director and Surgical Chief of Cardiac Transplantation and Mechanical Circulatory Support.

7. My formal training includes a medical degree from the University of Vienna School of Medicine in 1987, followed by internship in surgery at the Military Hospital in Vienna and residency in general surgery at Vienna General Hospital, culminating in fellowships in cardiothoracic and cardiovascular surgery under Professor Ernst Wolner, as well as advanced staff-level fellowships in

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

Declaration of Dr. Georg Wieselthaler

Austria, and later dedicated heart and lung transplant fellowships at the Medical University of Vienna. I hold board certifications from Austria in Surgery (1995), Cardiac Surgery (2000; recertified 2006), Thoracic Surgery (2003), Vascular Surgery (2007), and Cardiac Surgery and Intensive Care (2009), and I have been licensed by the Medical Board of California since 2011.

8. From 1995 to 2011 at the Medical University of Vienna, I progressed from Staff Surgeon to Senior Staff Surgeon, served as Surgical and Medical Director of the Mechanical Circulatory Support Program, and held academic appointments culminating in my habilitation and *venia docendi* in 2003 on the clinical application and impact of continuous-flow blood pumps; I subsequently joined UCSF in 2011, where I led the Cardiac Transplantation and Mechanical Circulatory Support programs through 2023.

9. I am one of the world's leading experts in the use of different forms of mechanical circulatory support systems and cardiac transplantation in the treatment of end stage heart failure patients. Over the years, I have educated and trained colleagues worldwide in the use of all different forms of mechanical assist devices and proctored countless cases worldwide.

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

Declaration of Dr. Georg Wieselthaler

10. Clinically, I have personally implanted around 800 – 1000 implantable left ventricular assist devices and performed more than 900 successful orthotopic heart transplants, reflecting a high-volume surgical practice in durable mechanical circulatory support and transplantation; I have also built and led interdisciplinary teams for the care of advanced heart failure and cardiogenic shock, including ICU-integrated protocols.

11. In 1998, I implanted the world's first miniaturized axial-flow pump (MicroMed DeBakey) in two patients in Vienna, both of whom were later successfully transplanted. In 2006, I implanted the first-in-human cases of the HeartWare HVAD, a third-generation hybrid-magnetically levitated pump that I helped develop as a consultant. I also served later as the principal investigator in the clinical trial for approval of the CE certification.

12. After relocating to the United States, I introduced HVAD clinical use at UCSF and established the institution as the West-Coast Training Center for HeartWare, training and proctoring numerous national and international teams; to reduce surgical trauma and hasten recovery, I pioneered a minimally invasive thoracotomy implantation technique at UCSF in 2013, which led to an FDA-

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

Declaration of Dr. Georg Wieselthaler

supported clinical trial in which UCSF was among the top enrollers, producing multiple peer-reviewed publications.

13. I have served as Principal Investigator for multiple multicenter clinical studies, with responsibilities spanning subject recruitment, clinical oversight, and data integrity; related outcomes and cost analyses, as well as adverse event profiles. For example, I have served as Principal Co-Investigator of the 1999 MicroMed DeBakey, the 2004 Terumo DuraHeart and the 2006 Principal Investigator of the HeartWare HVAD.

14. My scholarly contributions encompass foundational and translational work in rotary blood pumps and LVAD patient management, including first-author clinical reports on the DeBakey axial-flow pump, initial multi-institutional HVAD experience, and systematic reviews on antithrombotic therapy in LVAD patients, along with consensus and methodological publications on infection prevention, thrombosis detection, and device-specific implant strategies. I have additionally authored book chapters on continuous-flow physiology, durable MCS systems, cardiopulmonary bypass pumps, and candidate selection criteria for MCS.

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

Declaration of Dr. Georg Wieselthaler

15. My professional leadership includes longstanding service in major societies such as the International Society for Mechanical Circulatory Support (formerly ISRBP), where I served as Secretary General and President; and the International Society for Heart and Lung Transplantation, where I served on the Board of Directors and program committees. I have also held roles within the European Society for Artificial Organs and the American Association for Artificial Internal Organs, among others. I co-organized the earliest international workshops on rotary blood pumps, beginning in 1988, reflecting deep engagement with device innovation communities over several decades.

16. My work has been recognized with multiple awards, including the Medforte-Olsen Clinical Awards from the International Society for Rotary Blood Pumps (1999, 2001), the Stefan Schuy Award from the Austrian Society for Biomedical Engineering (2002), and the UCSF Health Redefining Possible Award (2017), reflecting clinical innovation, translational research, and contributions to patient outcomes in mechanical circulatory support. I am also a named inventor on patent applications concerning implantation procedures for blood pumps and

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

Declaration of Dr. Georg Wieselthaler

cannula tip designs for VADs, underscoring my contributions to surgical technique and device interface design.

17. In addition to my clinical and research activities, I am an active educator and mentor, having taught at UCSF as Clinical Professor, supervised trainees in the operating room and ICU, and served as career and clinical mentor to numerous postdoctoral fellows and residents who now hold faculty and leadership positions worldwide; I have delivered invited lectures internationally and nationally across leading cardiothoracic and artificial organ forums since at least 2008.

18. A true and correct copy of my curriculum vitae, which includes additional details regarding my positions, clinical activities, trials, publications, and invited presentations, is included as Ex. 1047.

III. LEVEL OF ORDINARY SKILL IN THE ART

19. I understand there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including (1) the levels of education and experience of persons working in the field at the time of the invention; (2) the

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

Declaration of Dr. Georg Wieselthaler

sophistication of the technology; (3) the types of problems encountered in the field; and (4) the prior art solutions to those problems.

20. I understand that Petitioner has argued that a Person of Ordinary Skill in the Art (“POSITA”) as of the February 27, 2007 priority date of the Challenged Patents would have: a) at least a bachelor’s degree in engineering; b) knowledge and experience in the anatomy and physiology of the human circulatory system; and c) at least five years of experience in design and development of *implantable medical devices*.

21. I understand that Patent Owner has argued for a different definition of a POSITA that requires having at least a bachelor’s degree in engineering, knowledge and experience in human circulatory system anatomy and physiology, and at least five years’ experience designing and developing *implantable cardiac assist devices in particular*.

22. I believe I satisfy both Petitioner’s definition of a POSITA and the modified definition proposed by Patent Owner. In particular, I am a medical doctor with significant knowledge of the human circulatory system anatomy and physiology, as well as long work experience exceeding the thresholds noted above

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

Declaration of Dr. Georg Wieselthaler

specifically with regard to designing and developing LVADs. For example, I am also an electrical engineer by training and have worked on different miniaturized centrifugal pump concepts with different bearing configurations in my own bioengineering/animal lab at the Medical University in Vienna. Ex.1049, 2.

23. My opinions expressed here would not change regardless of which party's POSITA definition is adopted.

24. For purposes of this Declaration, in general, and unless otherwise noted, my statements and opinions, such as those regarding my own experience and what a POSITA would have understood or known generally (and specifically related to the references I consulted herein), reflect the knowledge that existed in the relevant field as of the priority date of the Challenged Patents.

IV. RELEVANT LEGAL STANDARDS

25. I am not an attorney. In preparing and expressing my opinions and considering the subject matter of the Challenged Patents, I am relying on certain basic legal principles that counsel has explained to me.

26. I understand that prior art to the Challenged Patents includes patents and printed publications in the relevant art that predate the priority date of the

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

Declaration of Dr. Georg Wieselthaler

Challenged Patents. For purposes of this Declaration, I am applying February 27, 2007, as the priority date.

27. I have been informed by counsel that a claimed invention is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a POSITA. I have also been informed by counsel that the obviousness analysis considers factual inquiries, including the level of ordinary skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed subject matter.

28. I have been further informed by counsel that there are several recognized rationales for combining references or modifying a reference to show obviousness. These rationales include: (a) combining prior art elements according to known methods to yield predictable results; (b) simple substitution of one known element for another to obtain predictable results; (c) use of a known technique to improve a similar device (method, or product) in the same way; (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (e) choosing from a finite number of identified, predictable

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

Declaration of Dr. Georg Wieselthaler

solutions, with a reasonable expectation of success; and (f) some teaching, suggestion, or motivation in the prior art that would have led a POSITA to modify the prior art or to combine prior art teachings to arrive at the claimed invention.

V. TERMINOLOGY

29. The terms Left Ventricular Assist System (LVAS) and Left Ventricular Assist Device (LVAD) are commonly used synonyms, whereas, when you refer to an LVAD you mean in particular the device that supports the failing left ventricle and LVAS refers to the system that supports the left heart that comprises the pump, the driveline, the controller, and the batteries (energy source). The pump consists of several main elements: a) an inflow cannula (tube, or conduit) placed with its opening in the left ventricle or left atrium of the heart; b) the pump itself; c) an outflow cannula from the pump to the circulatory system, typically to the ascending aorta, but also to the left or right subclavian arteries, or the descending aorta.

30. I understand that the Patent Owner's expert, Mr. Leschinsky, has opined that this definition is "overly limiting" because it "include[s] only blood pumps." Ex.2015, ¶33. Further, I understand that Mr. Leschinsky has opined that LVADs include configurations such as direct cardiac compression devices, intra-

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

Declaration of Dr. Georg Wieselthaler

aortic balloons, aortic counterpulsation devices, etc., as well as certain alternative LVAD configurations, such as an inflow cannula placed in the left atrium rather than the left ventricle. Ex.2015, ¶33. I disagree with this overly broad definition, which is inconsistent with how the term “LVAD” is used in the art, whereas some definitions are used in a very general, not very precise way. A cardiac compression device supports left and right ventricular function because both ventricles are compressed from the outside simultaneously and therefore should be more precisely called a bi-ventricular assist / circulatory support-system. See Ex.1033 (B. Leschinsky) (“An implantable direct cardiac compression device ... is designed to provide biventricular support”). A veno-arterial ECMO-system is per definition rather a circulatory- and lung-support system and not an LVAD.

31. An implantable left ventricular assist device (LVAD) is a mechanical device/pump attached to the native heart and vessels to augment cardiac output of the left ventricle. An LVAD differs from a total artificial heart (TAH), which replaces both native ventricles and is attached to the pulmonary artery and aorta when the native heart is typically removed. Mechanical support pumps can also be used to support the right ventricular function and therefore are called RVAD (Right

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

Declaration of Dr. Georg Wieselthaler

Ventricular Assist Device) per definition. A very specific configuration is the surgical implantation of two mechanical support pumps to the native heart to support the left and the right ventricular function, which is per definition a bi-ventricular support configuration, which is different from the Total Artificial Heart, where the native heart is surgically removed.

32. Some circulatory assist devices are placed percutaneously (i.e., are not fully implanted), but also support the failing ventricle. They can be used to support the left as well as the right ventricle and may therefore be referred to as percutaneous-VADs (pVADs), pLVAD and pRVAD. Ex.1048, 5. For example, the Impella is a catheter based device introduced through a peripheral artery (in most cases via the femoral artery, but also via the subclavian artery, or the ascending aorta). In this device, a small pump is contained within the catheter-tip placed into the left ventricle (pLVAD). Blood is pumped from the left ventricle, through the device, and into the ascending aorta. There is a similar device available for the support of the right ventricular function (pRVAD). For these pVAD devices, many of the system's components are external to the body so they are mainly for short-term use (6 hours to 28 days). Ex.1048, 5.

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

Declaration of Dr. Georg Wieselthaler

33. An implantable LVAD is also different than other mechanical circulatory support (MCS) strategies such as intra-aortic balloon pump (IABP), direct cardiac compression devices, and extracorporeal membrane oxygenation (ECMO). Ex.1048 7–8.

34. An intra-aortic balloon pump (IABP) generally consists of a balloon placed in the descending thoracic aorta that inflates during diastole to increase coronary perfusion and deflates during systole to reduce afterload, improving to some extent left heart function and subsequently slightly increase cardiac output. IABPs are typically inserted percutaneously and synchronized with the cardiac cycle using ECG or arterial pressure signals.

35. A direct cardiac compression device is a mechanical system designed to physically squeeze the heart to restore or augment circulation during cardiac arrest or severe pump failure. These devices apply rhythmic external or internal compression to mimic the pumping action of both ventricles, improving blood flow to vital organs. External compression devices are typically used in emergency or surgical settings as a temporary measure when conventional resuscitation is insufficient. Implantable cardiac compression devices are surgically placed in the

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

Declaration of Dr. Georg Wieselthaler

pericardium and compressing the heart from the outside and squeeze both ventricles simultaneously and therefore are called per definition bi-ventricular circulatory support systems. Recent developments are under investigation also for long-term use.

36. Extracorporeal Membrane Oxygenation (ECMO) is an advanced life-support technique that temporarily takes over the function of the heart and lungs in patients with severe cardiac and/or respiratory failure. It is mainly applied in a veno-arterial cannulation mode, circulates blood through an external circuit where it is oxygenated and carbon dioxide is removed before returning it to the body. ECMO is typically used in critical care settings for short-term use as a bridge to recovery, bridge to transplant, or other interventions when conventional therapies are insufficient.

VI. THE BOURQUE PUMP

37. Bourque et al., *HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor* (Ex.1007, “Bourque”) was published in the American Society for Artificial Internal Organs (ASAIO) Journal in 2001.

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

Declaration of Dr. Georg Wieselthaler

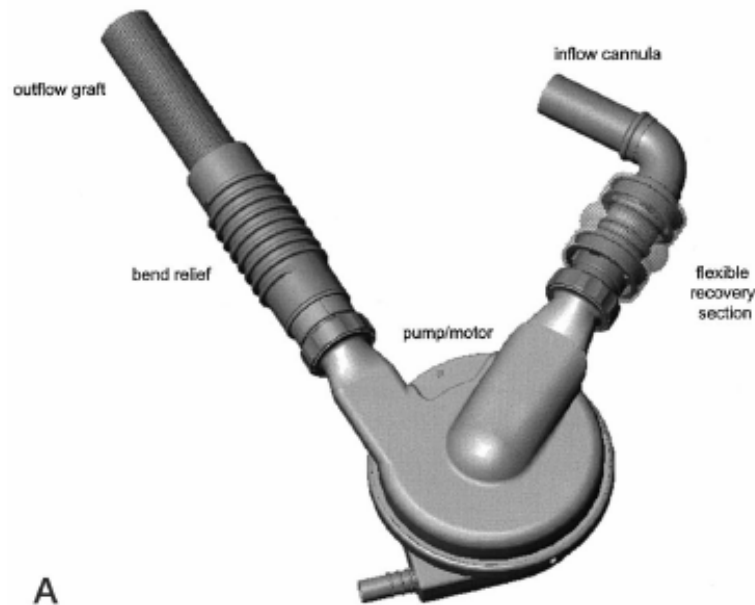
A. Bourque discloses a third-generation centrifugal LVAD.

38. Bourque describes the design and testing of a “long-term, compact left ventricular assist device (LVAD),” known as the HeartMate III. Ex.1007, 1. Bourque describes that first-generation LVADs that were clinically available at the time were positive-displacement-type pumps that “contain[ed] mechanical parts that wear, such as ball bearings, flexible diaphragms or sacs, and valves.” Ex.1007, 1. The “second generation of LVADs” (*e.g.*, HeartMate II) were “continuous flow-type pumps,” which have “inherently fewer mechanical parts” and “additional benefits” such as a smaller size, no noise, no compliance chamber, and lower cost. Ex.1007, 1. The third-generation HeartMate III features “a centrifugal pump with an active magnetically levitated rotor” and “[t]he rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely.” Ex.1007, 1.

39. Figure 1A of Bourque illustrates an overall view of the HeartMate III pump:

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

Declaration of Dr. Georg Wieselthaler



Ex.1007, Fig. 1A.

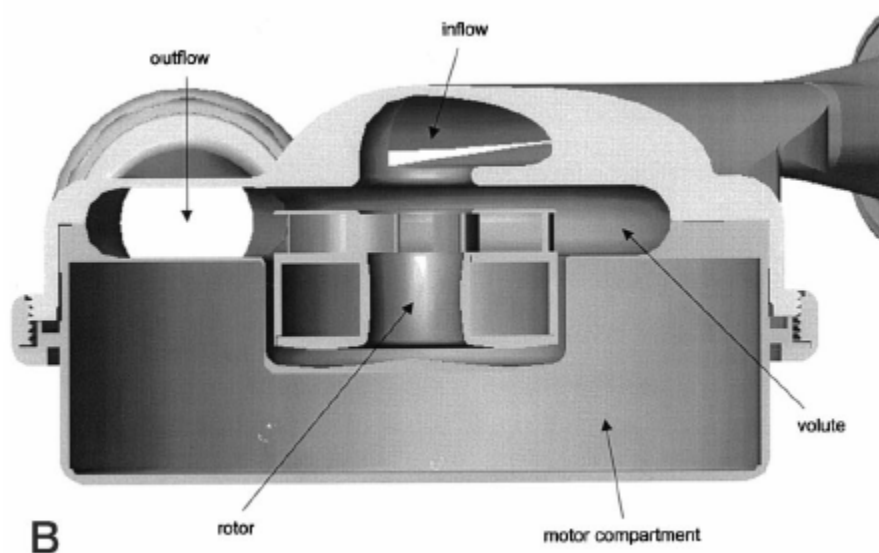
40. The HeartMate III pump described in Bourque includes an “upper housing that includes the inflow and outflow channels and the upper half of the volute; a lower housing that includes the lower half of the volute and a cavity for the rotor, in which the motor is enclosed; a rotor that includes an impeller and passively magnetic elements; an inflow subassembly that includes a left ventricular (LV) cannula”; an “outflow subassembly”; “an electronic cable to be exteriorized percutaneously”; and additional subcomponents and hardware. Ex.1007, 1.

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

Declaration of Dr. Georg Wieselthaler

B. Like all centrifugal LVADs, the inflow enters the pump along the rotor's central axis and the outflow exits the pump radially.

41. Figure 1B of Bourque illustrates a cross-sectional view of the HeartMate III pump:



Ex.1007, Fig. 1B.

42. Bourque explains that flow “enters the impeller,” then “exits the backswept blades of the impeller into a volute of uniformly increasing width,” which directs “the flow ... toward the outflow.” Ex.1007, 2. Said another way, the blood enters the pump along the rotor's central axis and exits the pump radially.

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

Declaration of Dr. Georg Wieselthaler

C. The Bourque pump had an elbow so that the pump could use the same peripheral hardware as the prior HeartMate systems.

43. Bourque describes that the HeartMate III was designed, in part, so that it could borrow the peripheral hardware from the earlier generation HeartMate devices:

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

Ex. 1007, 5.

44. Due, at least in part, to this decision to borrow the peripheral hardware from the earlier generation HeartMate devices, the Bourque pump comprised an “elbow”—a “bend in the flow before it enters the impeller.” Ex. 1007, 2.

VII. OBVIOUSNESS

45. I understand that Petitioner has argued and that Mr. Crosby has opined that a POSITA would have been motivated with a reasonable expectation of

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

Declaration of Dr. Georg Wieselthaler

success to modify the HeartMate III “inflow subassembly” (Ex.1007) to serve as the “inflow cannula...placed into the apex of the left ventricle” as taught by Wampler (Ex.1008, [0075]), which would result in an axially aligned inflow tube. I agree with this assessment.

A. A POSITA would have been motivated to eliminate the elbow in the Bourque pump.

46. A POSITA would have been motivated to eliminate Bourque’s “flow-restrictive elbow fitting,” because an inflow elbow is unnecessary in a centrifugal LVAD given that the 90 degree redirection of the blood allows for flexibility during implantation. Ex.1008, [0076].

1. An inflow elbow is unnecessary in a centrifugal LVAD, because the 90 degree redirection of the blood allows for flexibility during implantation.

47. The Bourque pump, like all centrifugal LVADs, has an inflow that enters the pump along the rotor’s central axis and an outflow that exits the pump radially. Said another way, by design, a centrifugal pump provides 90 degree redirection of the blood, in contrast to an axial flow pump, where impeller outflow is directed parallel to axis of rotation. Accordingly, a POSITA would have recognized that an inflow elbow is unnecessary in Bourque pump.

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

Declaration of Dr. Georg Wieselthaler

48. Wampler expressly taught that an inflow elbow is unnecessary in a centrifugal LVAD:

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

Ex.1008, [0076]. Put simply, because a centrifugal pump already provides 90 degree redirection, an elbow is unnecessary and flow restrictive, in contrast to the HeartMate II, which is an axial flow pump.

49. A POSITA would have recognized that the Bourque pump’s elbow was flow restrictive and causes shear forces. The computational fluid dynamics analysis “reveals a slight degree of swirling flow in the elbow,” including “a small pocket of pre-swirl [that] is induced from the impeller and migrates upward into the elbow.” Ex. 2005, 5. A POSITA would have been motivated to eliminate the elbow to reduce shear forces, because excessive shear stress can damage blood cells, particularly

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

Declaration of Dr. Georg Wieselthaler

causing hemolysis and platelet activation, as well as cause von Willebrand's-factor degradation. Eliminating the elbow would reduce shear, which would help maintain blood integrity and minimize thrombotic and hemorrhagic events, ensuring safer long-term circulatory support.

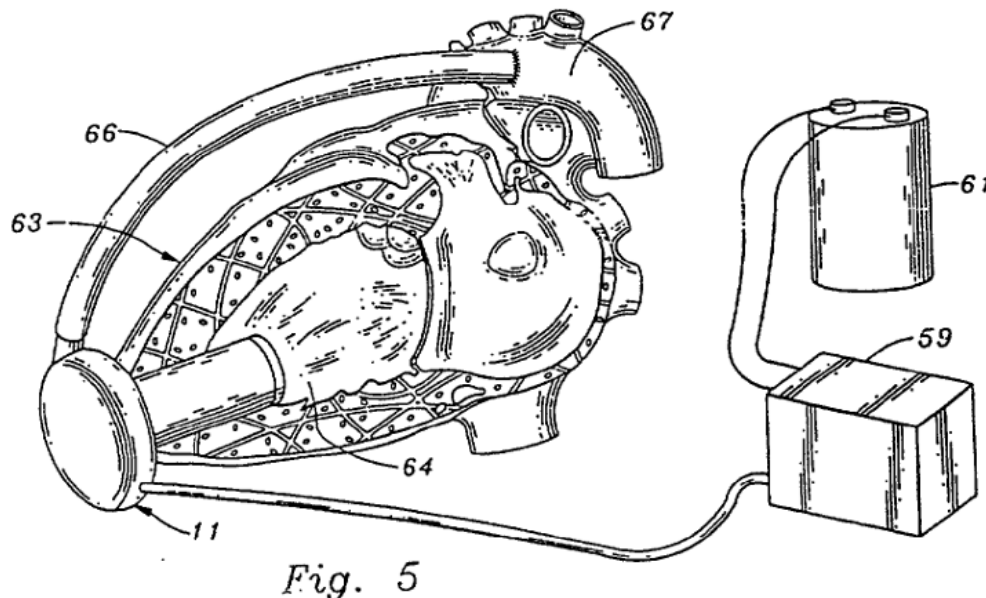
50. By 2007, a POSITA would have appreciated that there were at least three implantable centrifugal LVADs that adhered to these teachings to eliminate an elbow—the HVAD, the DuraHeart, and the VentrAssist. The existence of these devices would have further motivated a POSITA to eliminate the elbow in the Bourque device.

a. The HVAD

51. Unlike the Bourque pump, the HVAD did not have an elbow. A great feature of the HVAD was the integrated inflow cannula into the pump housing, which dramatically reduced the size of the pump and allowed for placement at the apex of the heart. Ex.1015; Ex.1049, 1–2. The HVAD was implanted above the diaphragm at the apex of the heart, as illustrated in one of Wampler's patents:

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

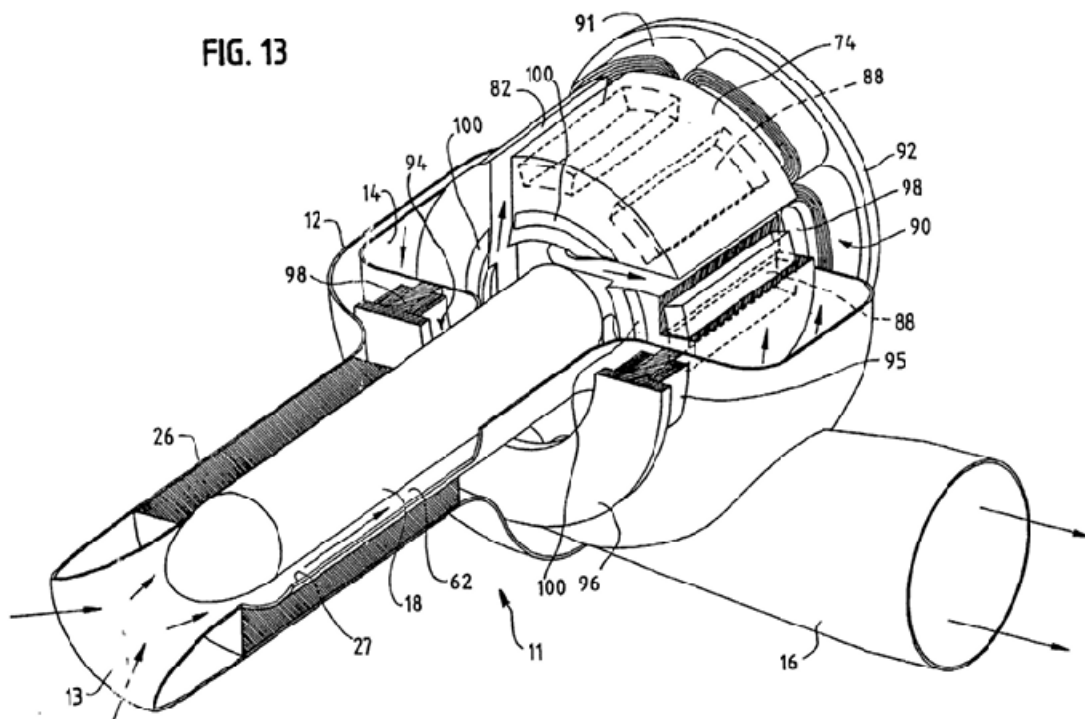
Declaration of Dr. Georg Wieselthaler



Ex.1008, Fig. 5.

52. In June 2003, I was asked if I would be interested in meeting with a start-up company to set up a roadshow for a new, striking LVAD pump. Ex. 1049, 1. I met with this new start-up company called HeartWare, which was formed out of a bankrupted company named Kriton, Inc. (Sacramento, California). Ex.1049, 1. Richard Wampler, the inventor of the famous Hemopump, was working with Kriton on a prototype of a blood pump with a hydrodynamic/passive magnetic suspension. Ex.1049, 1-2.

FIG. 13



Ex. 1008, Fig. 13.

54. The prototype of this miniaturized centrifugal pump weighed only 145 grams. Ex.1015. Jeff LaRose, the engineer behind the final pump design, explained the striking technology—a combination of hydrodynamic and passive magnetic

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

Declaration of Dr. Georg Wieselthaler

bearings, which resulted in a wear-less blood pump with a very thin and flexible driveline with only five leads. Ex.1049, 2.

55. In late 2003, I agreed to a consultancy role with HeartWare, Inc. to develop the HVAD. Ex.1049, 2. The intention of our team was to develop the best and most user-friendly pump with a wear-less pump technology so that patients could be supported for years and years. Ex.1049, 4.

56. From 2004 to early 2005, the first animal experiments were performed at the Texas Heart Institute in Houston. At the end of 2005, after successfully finishing the good laboratory practice animal experiments, we started to prepare everything for the first human implantation. Ex.1049, 5.

57. I performed the first clinical implantation of the HVAD at my home institution in Vienna. Being the Clinical Director for Mechanical Circulatory Support at the Medical University in Vienna, I received IRB and competent authority approval for an implant in February 2006, and in March, I found the perfect patient. A 48-year old former opera singer with end-stage heart failure, who suffered from nonischemic cardiomyopathy, was the first patient to receive HeartWare's HVAD on March 22, 2006. Ex.1049, 5.

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

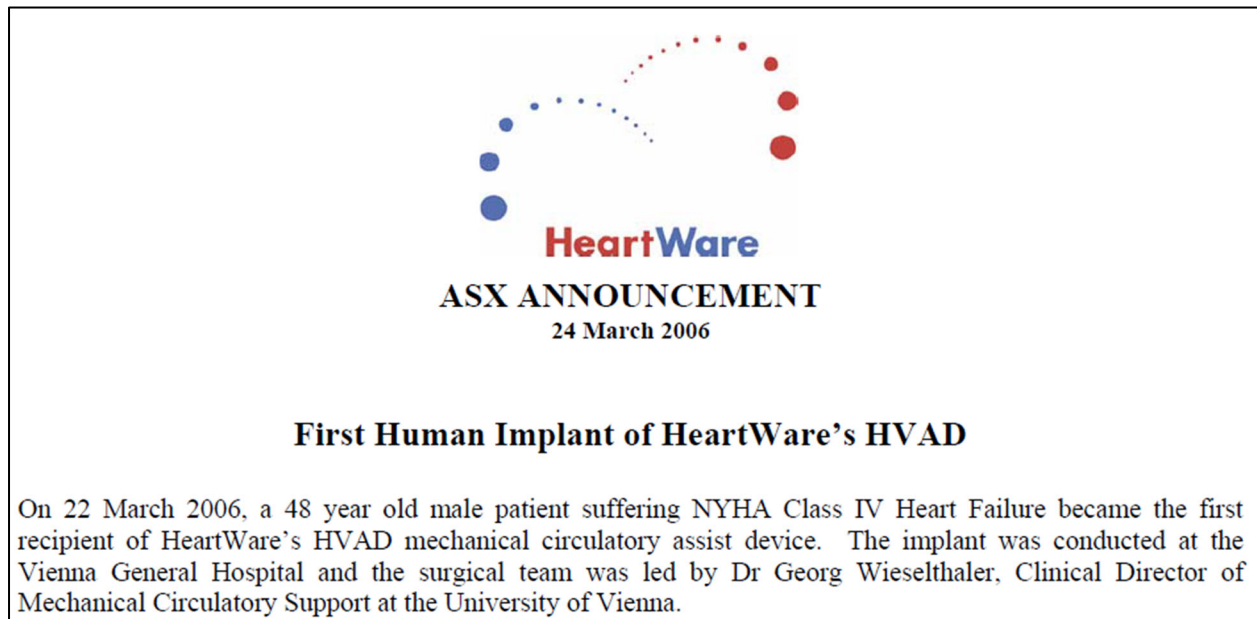
Declaration of Dr. Georg Wieselthaler

58. The operation was successful; it was fast and uneventful. The size of the device coupled with the perpendicular relationship of outflow to the inflow allowed for intrapericardial pump placement and fast implantation. Ex.1015. The patient was extubated seven hours after surgery and moved to the floor after four days. Although the patient was bed-ridden before surgery, he recovered quickly and was put on a very intense mobilization program by our well-trained physical therapy staff. While on the HVAD support he started singing once again and went back on stage to perform professionally. He was successfully transplanted after a year on the pump. Ex.1049, 5-6.

59. The company shared the exciting news of our first clinical implantation with the world:

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

Declaration of Dr. Georg Wieselthaler



Ex.1044, 1.

60. A month after this first patient, I implanted the second HeartWare pump into a 35-year-old patient, who also did very well. An additional two more implants followed in 2006. Overall, 23 patients were enrolled in this clinical trial, and excellent results were achieved. Specifically, a 91% survival rate at 6-months and an 89% 1-year survival were reported—the best results in a clinical LVAD trial at that time. Ex.1049, 6.

61. After achieving the CE-mark in Europe, the HVAD was immediately adopted at many centers in Europe, Australia, and Asia Minor as the primary LVAD to be used. Ex.1049, 6.

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

Declaration of Dr. Georg Wieselthaler

b. The Terumo DuraHeart

62. The Terumo DuraHeart also did not have an elbow such as the Bourque pump. In 2004, I was Principal Co-Investigator of the TERUMO DuraHeart CE-mark trial. Ex.1047, 29.

63. In 1999, the Terumo team, including Chisato Nojiri, Tetzuzo Akutsu, and Teruaki Akamatsu, reported on the “[i]ntrathoracic implantation” of the pump (which became the DuraHeart). Ex.1006, 2-3. These studies “demonstrated excellent anatomical fit in a small [sheep] weighing 45 kg.” Ex.1006, 4. Because of these successful sheep studies, a POSITA would have understood that the **pump** (outlined in blue) was being designed for implantation at the apex of the **heart** (outlined in red) with its **inlet port** (outlined in green) being inserted into the apex of the left ventricle, as shown in Figure 1:

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

Declaration of Dr. Georg Wieselthaler

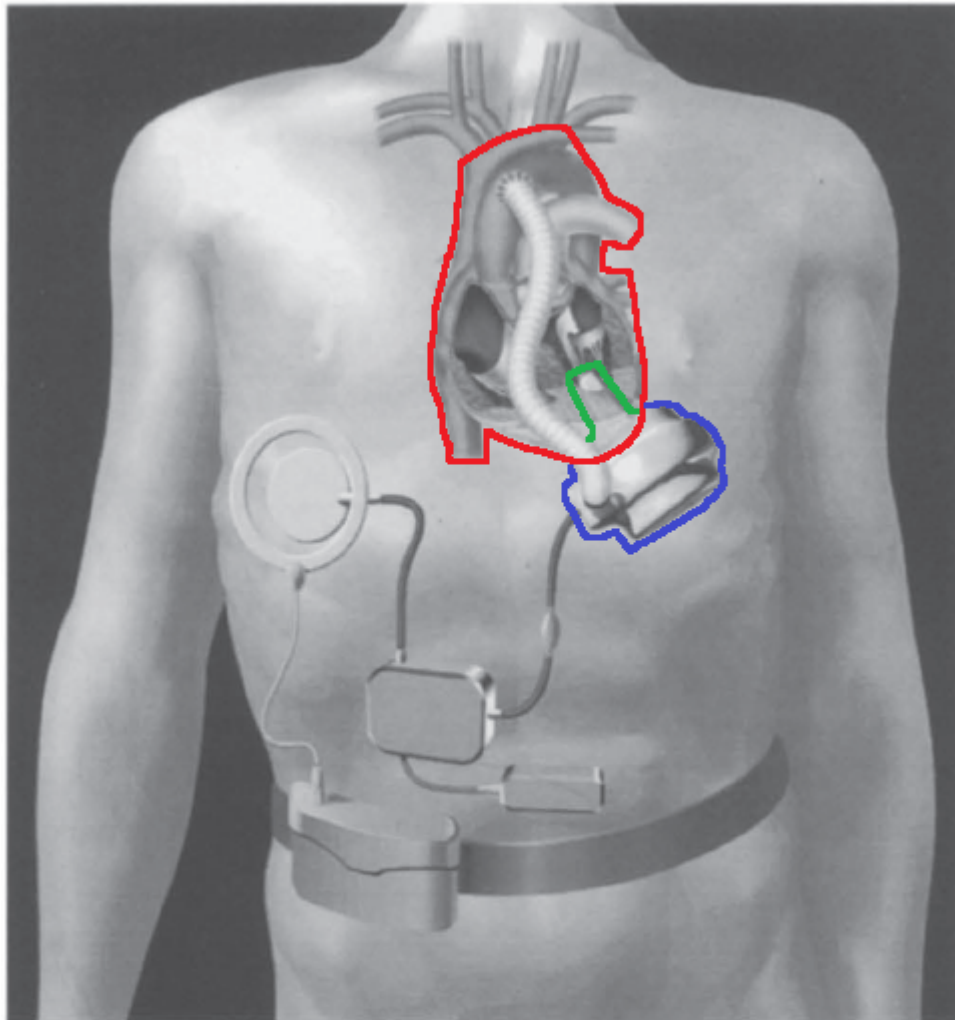


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

64. By 2006, the DuraHeart pump had been implanted in 20 patients.

Ex.1046, 4.

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

Declaration of Dr. Georg Wieselthaler

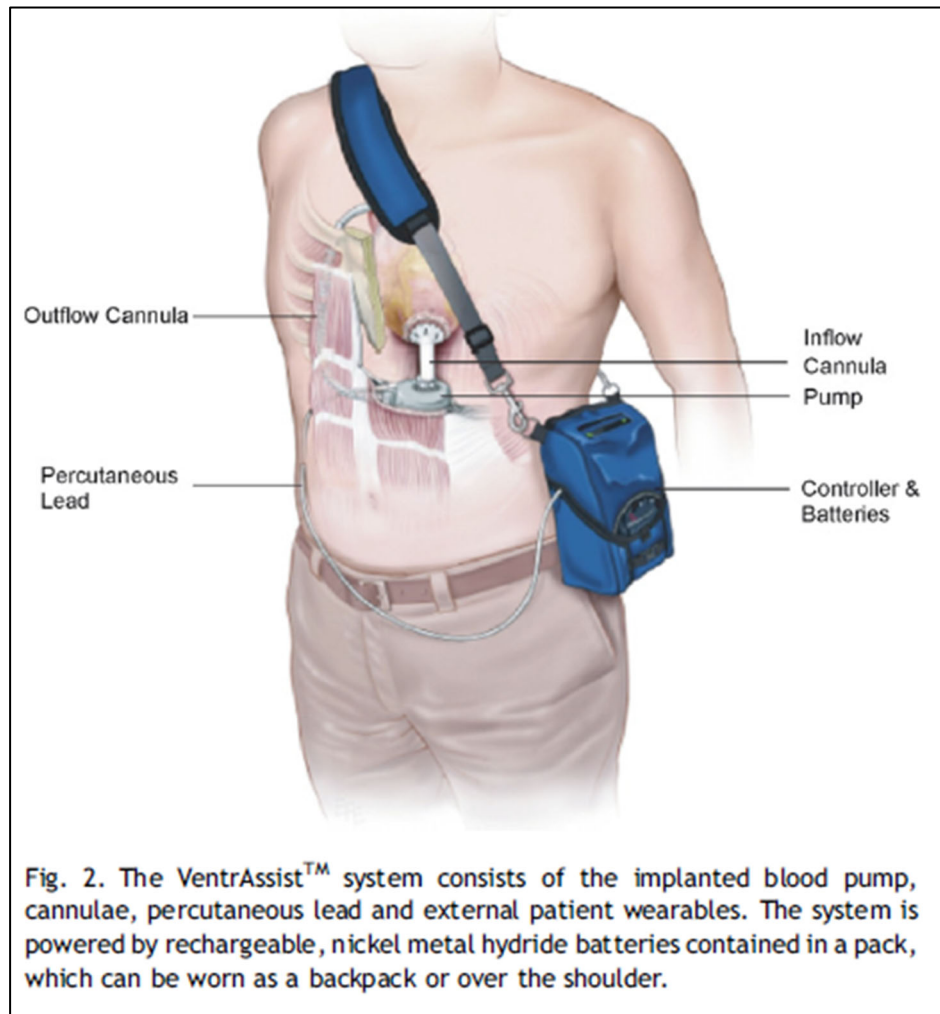
c. The Ventracor VentrAssist

65. Like the Bourque 2001 design, the VentrAssist was intended for implantation below the diaphragm in a preperitoneal pocket. Unlike the Bourque design, however, the VentrAssist did not use an inflow elbow.

66. The VentrAssist comprises an “inflow cannula” “attached from the failing left ventricle [that] delivers blood from the heart to the VentrAssist,” as shown below:

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

Declaration of Dr. Georg Wieselthaler



Ex.2013, 2, Fig. 2.

67. Unlike the Bourque pump, there is no elbow present where the inflow enters the pump. As shown in Fig.1 and Fig. 3, a 90 degree redirection of the blood is effected without the necessity of an elbow fitting:

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

Declaration of Dr. Georg Wieselthaler



Fig. 1. The VentrAssist™ blood pump is encased in a welded titanium shell and features a silicone percutaneous lead.

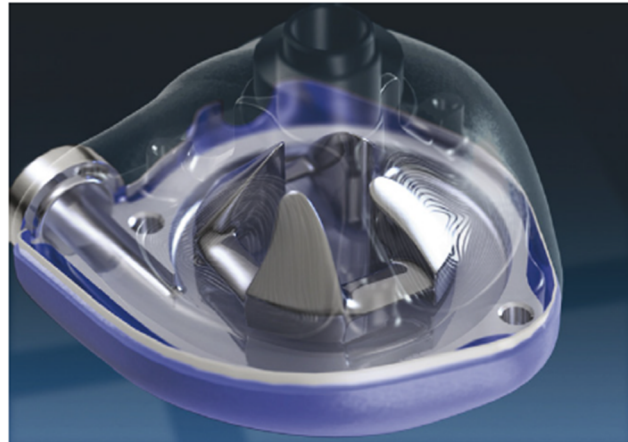


Fig. 3. Schematic view of the blood pump showing the upper bearing surface of two of the four rotor blades. The rotor integrates pumping motor and hydrodynamic bearing functions, and is coated in a black diamond-like carbon to enhance blood compatibility.

Ex.2013, Figs.1, 3.

68. By 2007, the VentrAssist was “approved for use in Europe (‘CE Marked’)” and “87 patients ha[d] been implanted with the VentrAssist.” Ex.2013, abstract, 2, 8.

2. By 2007, placement of an LVAD at the apex would have been preferred over placement in a preperitoneal pocket.

69. By 2007, instead of designing a pump to borrow parts from the predecessor HeartMate systems, a POSITA would have prioritized “[g]ood anatomic compatibility,” as taught by Wampler, so that the device “fit[s] well between the apex of the heart and the adjacent diaphragm,” eliminating the need

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

Declaration of Dr. Georg Wieselthaler

for a peritoneal pocket dissection associated with increased rates of infection.

Ex.1008, [0076].

70. First-generation LVADs were volume displacement pumps, had a large artificial surface, were bulky and heavy, and therefore excluded small patients from implantation. They were too large for implantation into the chest and therefore, they needed a large space for pre- or intraperitoneal implantation. The large wound created led to an increased risk of bleeding and infections with subsequently increased morbidity.” Ex. 1050, 1 (cleaned up). With the transition to continuous-flow technology, LVADs featured significant miniaturization. These devices had “smaller artificial surface” and “smaller weight and size” compared to the earlier generation devices, and allowed for the first time implantation into the chest. Ex. 1050, 2 (cleaned up).

71. Further on, these advances enabled implantation using less invasive approaches—such as thoracotomy-only or partial sternotomy—eliminating the need for full median sternotomy and reducing dissection size considerably. For example, the MicroMed DeBakey LVAD “is implanted into a pericardial space above the diaphragm” and “connected with the apex of the left ventricle via a

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

Declaration of Dr. Georg Wieselthaler

titanium inflow cannula and with the ascending aorta by a Dacron graft,” as shown in Figure 2:

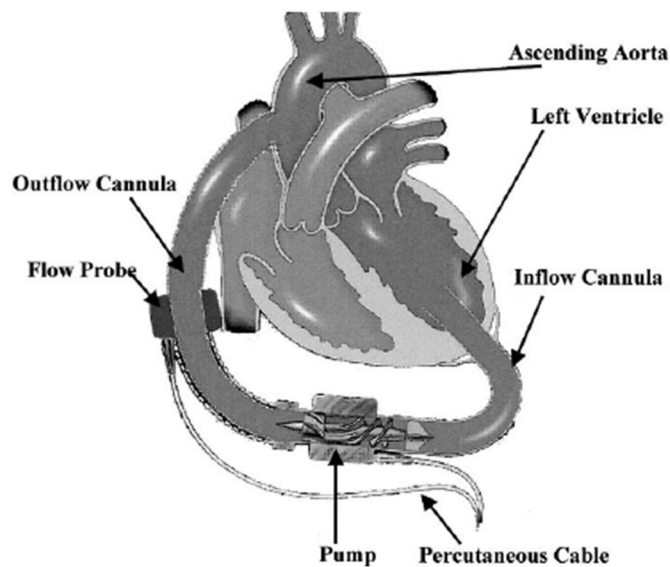


Figure 2. Implantation of the MicroMed DeBakey VAD. The titanium inflow cannula is connected to the apex of the left ventricle and the Dacron outflow cannula to the ascending aorta (published with permission of MicroMed Inc., Woodlands, TX).

Ex.1050, 3.

72. Similarly, as previously discussed, the small size of the HVAD allowed even for “intrapericardial pump placement.” Ex. 1015. Placement at this position is consistent with Wampler’s teaching that “good anatomic compatibility is possible since the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm.” Ex.1008, [0076], Fig. 5.

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

Declaration of Dr. Georg Wieselthaler

B. A POSITA would have had a reasonable expectation of success that eliminating the elbow in the Bourque pump would work.

73. By 2007, a POSITA would have reasonably expected that modifying the Bourque 2001 elbow to serve as the “inflow cannula...placed into the apex of the left ventricle” as taught by Wampler (Ex.1008, [0075]), would work. I discuss at least two reasons below. First, by 2007, numerous similarly designed devices—using an inflow tube inserted into the left ventricle—had already been clinically implanted either below or above the diaphragm. Second, by 2006, Mr. Bourque had already begun redesigning the prototype from 2001 to eliminate the elbow, which strongly suggests that by 2007, a POSITA would have reasonably expected that design change would work.

1. Numerous LVADs comprising an axially aligned inflow tube already existed.

74. A POSITA would have had a reasonable expectation that eliminating the elbow in the Bourque pump and using an axially aligned inflow tube would be successful because of the existence of several similar LVADs.

a. The HeartWare HVAD

75. By 2006, HeartWare had begun a clinical trial implanting the device in patients above the diaphragm at the apex of the heart:

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

Declaration of Dr. Georg Wieselthaler



Ex.1044, 1.

76. As explained above, the HVAD's "small size"—due its "short integrated inflow cannula and an axial height less than one inch ... coupled with the perpendicular relationship of outflow to the inflow"—allowed for an "optimized fit" "between the apex of the heart and the adjacent diaphragm."

Ex.1015; Ex.1008, [0076].

b. The Terumo DuraHeart

77. As I discussed above, in 1999, Terumo reported on the "[i]ntrathoracic implantation" of the DuraHeart. Ex.1006, 2-3. These studies "demonstrated excellent anatomical fit in a small [sheep] weighing 45 kg."

Ex.1006, 4. Because of these successful sheep studies, Terumo designed its pump

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

Declaration of Dr. Georg Wieselthaler

for implantation at the apex of the heart. Ex.1006, Fig. 1. By 2006, the DuraHeart pump had been implanted in 20 patients. Ex.1046, 4.

c. The Ventracor VentrAssist

78. As I discussed above, the VentrAssist comprises an “inflow cannula” “attached to the apex of the failing left ventricle [that] delivers blood from the heart to the VentrAssist.” Ex.2013, 2, Fig. 2. By 2007, the VentrAssist was “approved for use in Europe (‘CE Marked’)” and “87 patients ha[d] been implanted with the VentrAssist.” Ex.2013, abstract, 2, 8.

d. The MicroMed DeBakey

79. The MicroMed-DeBakey-pump was the first implantable, miniaturized axial-flow pump to be implanted in patients at our institution in November 1998. Although the first implants were performed at the German Heart Center in Berlin 3 days before our implants, our two patients were the first long-term survivors in the world with a completely nonpulsatile blood pressure.

e. The Jarvik-2000

The “Jarvik-2000” was directly inserted into the apex of the left ventricle and small enough to sit within the apical wall of the ventricle, protruding into the ventricle. Ex.2020, 6.

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

Declaration of Dr. Georg Wieselthaler

2. By 2006, Mr. Bourque had already begun redesigning the pump.

80. By 2006, Mr. Bourque had already begun redesigning the prototype from 2001 to eliminate the elbow and make other enhancements to miniaturize the device so that the HeartMate 3 could be implanted directly to the apex of the heart. The fact that in 2006, Mr. Bourque had already begun this redesign strongly supports that by 2007, a POSITA would have reasonably expected such a modification would be successful.

81. In an interview, Mr. Bourque explained that “in 2006,” he understood the elbow of the 2001 prototype was unnecessary:

[W]e don’t need to implant it down here (in the abdomen), we can go right in the chest. And that took away this whole business about creating a pocket for the pump and then requiring a conduit between the heart and the pump. We just put this (the inflow cannula, if you’re scoring at home) right in the heart. So that made it smaller as well.

Ex.2007, 7.

82. Mr. Bourque appreciated that there were enhancements to make the device smaller that were available in 2006 which would help its placement at the

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

Declaration of Dr. Georg Wieselthaler

cardiac apex. For example, by 2006, “the electronics themselves,” such as the “[c]hips” were “smaller.” Ex.2007, 7. With these and other modifications, Mr. Bourque miniaturized the 2001 prototype. Ex.2007, 5-6.

83. Like Mr. Bourque in 2006, a POSITA in 2007 would have also reasonably expected that eliminating the elbow of the 2001 Bourque prototype would enable the pump to be developed as a compact device that would fit at the apex of the heart, similar to the HVAD.

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

Declaration of Dr. Georg Wieselthaler

VIII. CONCLUSION

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

Dated: Monday, December 22, 2025



Dr. Georg Wieselthaler