

Case No: HP-2015-000035

Neutral Citation Number: [2016] EWHC 2637 (Pat)

**IN THE HIGH COURT OF JUSTICE**  
**CHANCERY DIVISION**  
**PATENTS COURT**

Rolls Building  
Fetter Lane, London EC4A 1NL

Date: 28 October 2016

**Before :**

**MR JUSTICE ARNOLD**

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**Between :**

<b>THORATEC EUROPE LIMITED</b>	<b><u>Claimant</u></b>
<b>- and -</b>	
<b>AIS GMBH AACHEN INNOVATIVE SOLUTIONS</b>	<b><u>Defendant</u></b>

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**Daniel Alexander QC and Joe Delaney** (instructed by **Taylor Wessing LLP**) for the **Claimant**  
**James Mellor QC and Ben Longstaff** (instructed by **Ropes & Gray International LLP**) for  
the **Defendant**

Hearing dates: 5-7, 11-13, 17 October 2016

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**Judgment**

## MR JUSTICE ARNOLD :

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## Introduction

1. This is a claim by the Claimant ("Thoratec") for revocation and a declaration of non-infringement in respect of two patents owned by the Defendant ("AIS"): European Patents (UK) Nos. 2 047 872 ("872") and 2 234 658 ("658") both entitled "Catheter device" (collectively "the Patents"). Thoratec is part of the St Jude Medical group of companies, while AIS is part of the Abiomed group of companies. The Patents are concerned with Ventricular Assist Devices ("VADs"). VADs are devices designed to assist the operation of the human heart, and in particular one or both of the ventricles, in circulating blood. More specifically, the Patents are concerned with VADs which are inserted into the body and driven via catheters. Thoratec seeks a declaration of non-infringement in respect of its HeartMate PHP product.
2. The principal grounds of invalidity relied upon by Thoratec are lack of novelty and/or obviousness over a number of items of prior art, including a prior use of a device called the Reitan Catheter Pump ("RCP") in the Netherlands. Shortly before trial, AIS made a conditional application to amend the claims of 658 to distinguish them from the RCP if necessary. Although there is no counterclaim for infringement, AIS advances a positive case that the HeartMate PHP, at least as described in Thoratec's Product Description, falls within a number of claims of the Patents. No priority is claimed for 872, the filing date of which was 8 October 2007. There is no challenge to the priority date claimed for 658, which is also 8 October 2007. For convenience I shall refer to that date as the "priority date" of both Patents.
3. For the most part, there is no dispute in this case as to the applicable legal principles, which are well established and which I have set out in numerous previous judgments.

I shall therefore not repeat them here. I shall, however, mention the law on two less familiar points.

## Witnesses

### *Factual witnesses*

4. Although Thoratec served witness statements from five factual witnesses in relation to the prior use issue, the only witness it ended up calling was Dr Andreas Dekker. Dr Dekker obtained an MSc in Engineering Physics and Applied Physics from Twente University in the Netherlands in 1998. As part of that degree he studied Biomedical Engineering. From 1998 to 2002 he undertook a Medical Physics Residency at Maastricht University Hospital (“MUH”) in conjunction with Eindhoven University of Technology. In parallel with this, from 1998 to 2003 he carried out research in the cardiothoracic unit of MUH leading to the award of a PhD. Some of the research carried out by Dr Dekker and his co-workers consisted of a study of the RCP which was published in Dekker *et al*, “Efficacy of a New Intraaortic Propeller Pump: An Animal Study”, *Chest*, 123, 2003, 2089-2095 (“Dekker”). Thoratec relies both upon the prior use of the RCP through the supply to Dr Dekker and his colleagues for the purposes of the study and upon Dekker as prior art. Dr Dekker is currently Manager, Research and Education at the Maastricht Clinic, a radiotherapy institute in Maastricht.
5. In addition to the evidence of Dr Dekker, during the course of the trial Thoratec served a hearsay notice in respect of an attendance note of a telephone conversation between a representative of AIS’s solicitors and Dr Öyvind Reitan, the inventor of the RCP, on 6 March 2016. Privilege in the attendance note was waived by counsel for AIS when he put the attendance note to Dr Dekker during cross-examination. In those circumstances AIS sensibly did not resist Thoratec’s application for an extension of time to serve the hearsay notice. Neither side sought to adduce any direct evidence from Dr Reitan.
6. AIS called four factual witnesses in relation to the prior use issue: Markus Ferrari, Sven-René Friedel, Jörg Schumacher and Dr Thorsten Sieß. These individuals all work for companies in the Abiomed group or are otherwise associated with them. It is convenient to describe them in reverse alphabetical order.
7. Dr Sieß obtained a Diploma in Mechanical Engineering from the University of Aachen in 1992 and a PhD in Mechanical Engineering from the same institution in 1998. Thoratec relies upon his PhD thesis (“Sieß”) as prior art. Dr Sieß was the inventor of the Impella device (as to which, see below), co-founder of Impella Cardiotechnik AG in 1998 and Chief Technology Officer of that company from 2000 to 2002. He then performed the same role for Impella Cardiosystems AG until 2005, when it was acquired by Abiomed. Since 2005 he has been Chief Technology Officer at both Abiomed Inc and its subsidiary Abiomed Europe GmbH (“Abiomed Europe”). Since 2014 Dr Sieß has also been Managing Director of both ECP Entwicklungsgesellschaft GmbH (“ECP”), which is now a subsidiary of Abiomed Europe, and AIS, which is now a subsidiary of ECP, ECP and AIS having both been acquired by Abiomed in that year. Dr Sieß is also a shareholder in Abiomed, which continues to market the Impella. He is a named inventor on at least 25 patents.

8. Mr Schumacher studied Mechanical Engineering at university. Since 2008 he has been employed successively as Head of Development, Head of Intellectual Property and Supervisor of Electronics R&D by ECP. ECP was founded in 2007 to develop an expandable catheter-based VAD. ECP obtained an exclusive licence from AIS in respect of the Patents and related know-how, but its development subsequently proceeded in a different direction.
9. Mr Friedel was general manager of both ECP and Berlin Heart GmbH from 2008 to 2014. He is currently Chief Executive Officer of the latter company. Mr Friedel is a businessman rather than a technical person.
10. Dr Ferrari obtained a PhD from the University of Göttingen in Germany for his work on the development of a portable heart lung machine for mobile emergency use. He has worked in the field of mechanical circulatory support (“MCS”) devices since 1989. He has been a consultant to ECP and Abiomed Europe for over 10 years. He has known Dr Reitan for 20 years.
11. All of the factual witnesses were straightforward witnesses, including Dr Sieß. As discussed below, Dr Sieß was also called by AIS as an expert witness and I shall assess his evidence in that capacity separately.

#### *Legal expert witnesses*

12. Both sides adduced evidence from experts in Dutch law. At the time that they did so, neither side had obtained permission to do so, but I granted permission retrospectively at trial. Thoratec’s expert was Professor Willem Hoyng, managing partner of the Dutch law firm Hoyng Rokh Monegier LLP, and Professor of Civil and Intellectual Property Law at the University of Tilburg. AIS’s expert was Gertjan Kuipers, a partner in the Dutch law firm De Brauw Blackstone Westbroek NV. Both experts were well qualified and there was little dispute between them as to the relevant principles of Dutch law. Sensibly, the parties agreed to dispense with cross-examination of these experts. Even so, the money spent on this evidence turned out to have been wasted, since counsel for AIS himself submitted in his closing submissions that there was no relevant difference between English law and Dutch law, even though it was AIS which instigated the introduction of Dutch law into the case.

#### *Technical expert witnesses*

13. Thoratec’s expert witness was Professor James Antaki. Prof Antaki obtained a Bachelor's degree in Mechanical and Electrical Engineering at the Rensselaer Polytechnic Institute in 1985, and a PhD in Mechanical Engineering from the University of Pittsburgh in 1991. From 1991 to 2006 he held a series of academic posts in Mechanical Engineering, Surgery and Biomedical Engineering at the University of Pittsburgh and at Carnegie Mellon University, including being Director of Artificial Heart Research and Development at the former from 1991 to 1999. Since 2006 he has been Professor of Biomechanical Engineering at Carnegie Mellon University. Amongst other posts, he has also been Adjunct Professor in the Departments of Surgery (from 2008 to 2012) and Bioengineering (since 2012) at the University of Pittsburgh. One of the courses he teaches is called “Inventive Problem Solving in Biomedical Engineering”. He has published seven book chapters, over 200 peer-reviewed articles and over 300 abstracts at scientific symposia. In addition to his

academic career, Prof Antaki has worked in various capacities for a number of commercial companies. The majority of his professional career has been devoted to the development of blood-wetted medical devices, particularly in the field of MCS. His research also focuses on the methodology by which such devices are designed and used clinically. Prof Antaki has been involved in the development of a number of VADs that have been marketed, including one that later became the Thoratec HeartMate-II discussed below. He is a named inventor on 24 issued patents and seven pending applications.

14. Prof Antaki was an extremely well-qualified and knowledgeable expert witness. Moreover, he was scrupulously balanced and fair in his testimony. Indeed, on occasion, he conceded points in cross-examination which further enquiry revealed that he did not really agree with. As counsel for AIS pointed out, however, through no fault of his own, Prof Antaki's evidence suffered from two limitations. First, as he readily accepted, he was himself inventive. Moreover, he evidently found some difficulty in distinguishing between his own approach to the prior art and that of the skilled person. Secondly, and perhaps more importantly, it became clear that, at the time of preparing his reports, he had not fully understood the need, when considering whether the steps from the prior art to the claimed inventions would be obvious to the skilled person, to exclude knowledge of the inventions. Rather, he had asked himself whether, knowing the target, the steps were obvious ones. Both these points, and in particular the second one, inevitably diminish the weight that can be placed on Prof Antaki's opinions. On the other hand, his reasoning was fully explored in a lengthy cross-examination, and it is the reasons that are most important.
15. AIS's principal expert witness was Dr Nicholas Gaddum. Dr Gaddum graduated from Canterbury University, New Zealand with a BE in Mechanical Engineering in 2004. He undertook a PhD in Mechanical Engineering at Queensland University, Australia from 2005-2008, which involved the development of a VAD, and in particular a rotary pump BiVAD. In 2010 he spent nine months as technical director of the Innovative Cardiovascular Engineering and Technology Lab at the University of New South Wales and the Prince Charles Hospital in Brisbane, Australia. He has published several papers on VADs stemming from his PhD and post-doctoral research. From later 2010 to 2013 he was a research biomedical engineer at King's College London working on various diagnostic technologies. Since 2015 he has been device and delivery scientist working for a company called Cell and Gene Therapy Catapult in the field of cell-based therapies.
16. Dr Gaddum was a slightly odd choice of expert, both in that he had not completed his PhD in October 2007 and in that he has not worked in the field of VADs since late 2010 (although he did maintain some contact with his previous colleagues in Brisbane after that). Although he was knowledgeable about the field of VADs during the relevant period, some of his knowledge had been gained through research conducted for the purposes of this case. Thus he explained that, although he had heard of the Hemopump (as to which see below) at the time, he had known very little about it. It is common ground between the parties, however, that the design of the Hemopump would have been part of the skilled person's common general knowledge. It follows that Dr Gaddum cannot be regarded as entirely representative of the skilled person. Like Prof Antaki, however, he was a balanced and careful expert witness. Moreover,

it became clear during his cross-examination that he did not really differ from Prof Antaki on many of the key issues.

17. At the time of the case management conference in this case, I gave the parties permission to call two experts each. I did so because it appeared possible that the parties would need to adduce evidence from a biomedical engineer and from a clinician. Unfortunately, the order as drawn up did not specify that the two experts were to be in those fields. As should have been clear, I did not intend to give either party permission to call two experts in the same discipline. It is well established that the Patents Court does not permit duplicative expert evidence to be adduced (or give it any greater weight if it is adduced). In the event neither party saw the need to adduce evidence from a clinician, and accordingly Thoratec only served evidence from one technical expert. AIS served evidence from a second technical expert in addition to Dr Gaddum, namely Dr Sieß. This was purportedly to “supplement” Dr Gaddum’s report, even though Dr Gaddum’s report ran to 148 pages (not including an annex tabulating prior VADs and two annexes dealing with infringement issues) and dealt with every issue in the case.
18. Inevitably, there was overlap between Dr Sieß’s evidence and Dr Gaddum’s evidence. This became particularly blatant in their respective second reports, when both dealt with the topic of synergy. Counsel for AIS elected to rely on Dr Sieß’s evidence on that topic rather than Dr Gaddum’s, which avoided the problem of duplication in that respect. It did not, however, address the other problems with Dr Sieß’s evidence.
19. First, as Dr Sieß accepted, he was not independent, but on the contrary was both a senior manager of AIS and a person with a financial interest in the outcome of the litigation.
20. Secondly, Dr Sieß was not only the inventor of the Impella, but also had spent most of his working life developing, promoting and marketing that device. Inevitably, he was heavily committed to that approach to the design of VADs.
21. Thirdly, on the face of it, the main purposes of Dr Sieß’s first report were (i) to describe the Hemopump in considerable detail and the RCP, Impella and A-Med devices in less detail and (ii) to outline the functional requirements for a catheter-based VAD. It appears that the reason why AIS wanted to adduce this evidence was that Dr Gaddum had had little knowledge of catheter-based devices at the time and even now was not an expert in that sub-field of VADs. Yet both Dr Sieß and Dr Gaddum stated that parts of Dr Sieß’s evidence concerning the Hemopump were not common general knowledge. Moreover, it was Dr Gaddum who gave all the primary evidence on the issues in the case. Thus Dr Sieß’s evidence was not properly integrated into AIS’s case.
22. The fourth and most serious problem with Dr Sieß’s evidence only emerged in cross-examination. At the end of his first report, Dr Sieß stated: “Although I have not considered the Prior Use, in my opinion, it was not obvious to develop any of the documentary prior art into any of the arrangements featured in the claims in the Patents in Suit.” When Dr Sieß was asked the simple question why he had not considered the prior use, he was unable or unwilling to give a straightforward answer. On the contrary, in a painful passage of evidence that extends for 12 pages of the transcript, he stated that he had not written this sentence, it had been written by AIS’s

lawyers; professed not to understand it despite speaking good English; contradicted himself more than once as to whether or not he had in fact considered the prior use; and was unconvincing when he denied that the reason why he had not considered the prior use in his report was that he appreciated that it anticipated or rendered obvious the main claims of the Patents.

23. In these circumstances I do not regard Dr Sieß as a reliable expert witness, and I cannot place any weight upon the opinions expressed in his reports. I do not doubt the accuracy of the purely factual material, however.

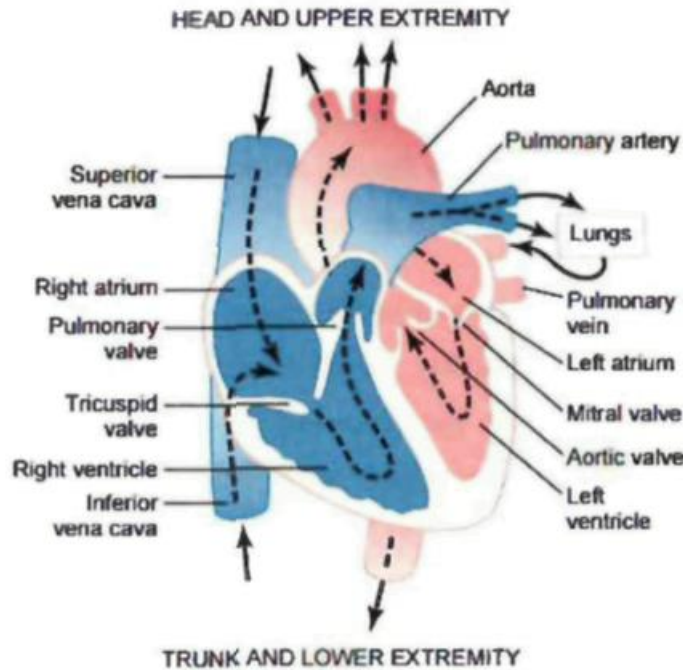
#### Technical background

24. The following account of the technical background is primarily based on the account given by Dr Gaddum in his first report, which I have supplemented with material from Prof Antaki's first report, Dr Sieß's first report and from the oral evidence.

#### *Circulatory anatomy and function*

25. In order to understand why and how VADs are used, it is necessary to understand the human circulatory system, and in particular the structure and normal operation of the heart.
26. *The heart.* The heart acts as a muscular pump with two key circulatory functions: to receive deoxygenated blood returning from the body and brain and pump it to the lungs for oxygenation; and to receive oxygenated blood from the lungs and pump it to the body and brain in order to sustain vital function in all organs and tissues. The heart consists primarily of muscle tissue (myocardium), and it has four main chambers that enable it to perform these functions: the right atrium and right ventricle, and the left atrium and left ventricle.
27. The general anatomy of the heart is shown schematically in the following diagram (from A.C. Guyton and J.E. Hall, *Textbook of Medical Physiology* (11th ed, Elsevier Saunders, 2006)). Note that "left" and "right" refer to patient left and patient right respectively.

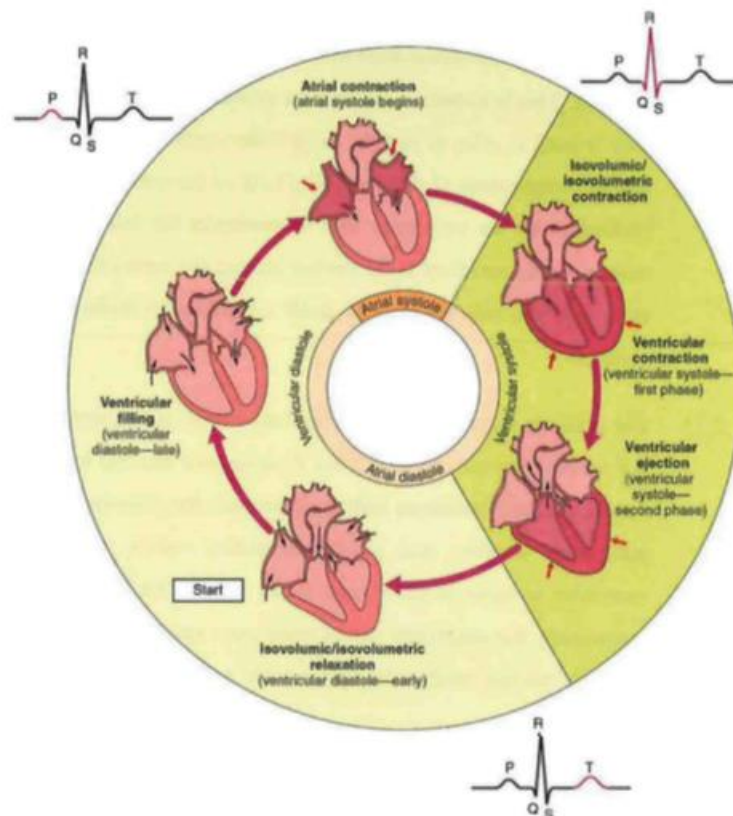




28. Oxygenated blood perfuses through the organs and tissues of the body via the capillaries, the smallest of the blood vessels. These tiny, thin-walled vessels allow the oxygen carried in the red blood cells to diffuse into the tissues. Deoxygenated blood from the capillaries then collects into a network of venules and veins. Veins transport blood back to the heart. The network of veins converges into successively larger vessels as it approaches the heart from all over the body, culminating in the superior and inferior vena cava, which are the veins through which almost all deoxygenated blood finally reaches the heart (deoxygenated blood from the heart muscle itself returns separately via other small veins).
29. All deoxygenated blood enters the heart into the right atrium, which acts as a chamber for receiving blood. From the right atrium the blood is passed to the right ventricle. This chamber in turn pumps the deoxygenated blood out of the heart and to the lungs via the pulmonary arteries. Once the blood has been oxygenated in the capillaries of the lungs (where it also releases waste carbon dioxide), it returns to the heart via the pulmonary veins and enters the left atrium. The left atrium passes the blood to the left ventricle, which finally expels it into the aorta. This is the artery that supplies all oxygenated blood to the rest of the body (including the heart itself) via a network of branching arteries and arterioles. The ventricles are separated from the atria by the tricuspid and mitral valves, and from the pulmonary artery and the aorta by the pulmonary and aortic valves.
30. *Aortic anatomy and branches.* The aorta has an approximately candy-cane shape: it heads upwards a short distance from its root at the left ventricle (the ascending aorta), then curves over (the aortic arch) and heads downwards (the descending aorta) through the torso, following a more or less straight line.
31. In order to supply oxygenated blood from the aorta to the key organs, various smaller arteries branch off the aorta at different distances from the heart. The first such

vessels are the left and right coronary arteries, which supply the heart itself, and consequently branch off near the base of the ascending aorta.

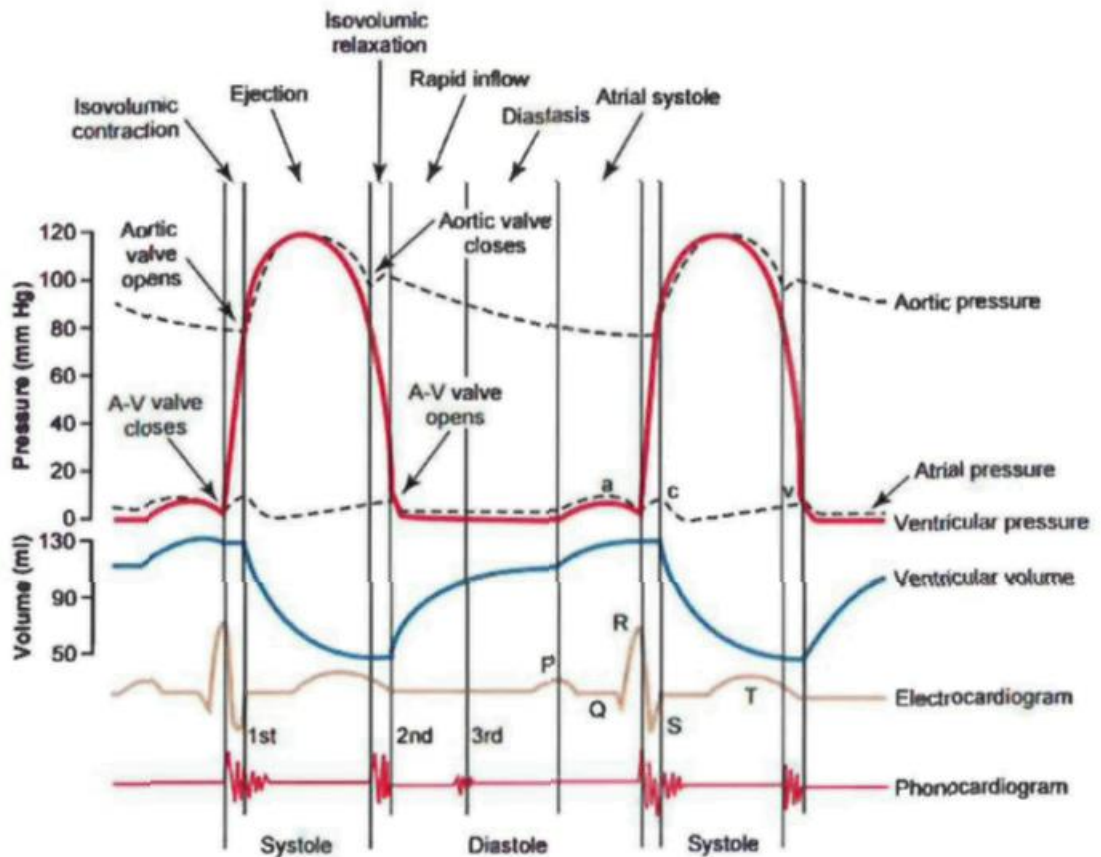
32. Next are three larger arteries that emerge upwards from the aortic arch. Starting closest to the heart these are: (1) the brachiocephalic trunk (which after a short distance divides into the right subclavian artery supplying primarily the right arm, and the right carotid, supplying primarily the head); (2) the left common carotid artery (supplying primarily the head and neck); and (3) the left subclavian artery (primarily the left arm). Moving down the descending aorta, the main three central arteries are the renal to the kidneys, the hepatic to the liver, and the mesenteric to the stomach. The aorta branches into the two femoral arteries at about the level of the pubic bone. These provide blood to the legs.
33. The way in which vessels branch off the aorta (particularly the ascending aorta and aortic arch) is a critical consideration in the placement and operation of VADs, and has a significant bearing on their performance and effect.
34. *The cardiac cycle.* The cardiac cycle refers to the sequence of rhythmic contractions and relaxations of the heart by which it moves blood from one region of the heart to another, and from the heart to other destinations within the body, as outlined above. The cycle is illustrated in the following schematic diagram (from Wikipedia):



35. The cycle may be considered to begin when the heart enters its relaxed state (diastole) in which neither ventricles nor atria are contracting. The aortic and pulmonary valves

(together known as the semilunar valves) close, preventing blood from flowing back into the heart from the aorta and pulmonary arteries, and blood flows into both atria due to the natural pressure of the incoming veins, combined with the relaxation and expansion of the atria themselves. As pressure in the atria increases, the tricuspid and mitral valves (together known as the atrioventricular or AV valves) open and allow blood to flow into the ventricles.

36. Next, the atria contract to force more blood into the ventricles. This is known as atrial systole. At this point, valves in the incoming veins prevent blood from flowing backwards out of the atria. The ventricles are thus filled with blood, ready for expulsion. When the heart is ready to expel this blood, both atria relax, and then both ventricles contract together. This is known as ventricular systole, and the term systole on its own is used to refer to just the ventricular contraction phase, which is the primary contraction of the heart. The bulk of the work done by the heart is performed by the ventricles, and in particular the left ventricle. For this reason the myocardium is far thicker around the ventricles than around the atria, and the left ventricle is itself considerably thicker than the right ventricle.
37. The pressure increase caused by the contraction of the ventricles closes the AV valves, preventing blood from flowing back into the now relaxed atria. As the pressure increases further, it exceeds the pressure in the aorta and pulmonary arteries, and so the semilunar valves open, allowing the ventricles to eject blood into these vessels. Once the ventricles stop contracting, the semilunar valves close once again and all chambers of the heart relax, ready to begin the cycle again.
38. The relationship between pressure in the atria, ventricles and arteries is a very important aspect of the cardiac cycle. The relationship between ventricular and aortic pressure is also highly relevant to the design and operation of any type of device designed to assist with left ventricular function. The approximate pressure relationships for a normal adult heart during the cardiac cycle are shown in the graph below (from Guyton and Hall), together with other features of the cardiac cycle.



39. Both atrial and ventricular pressure are substantially lower than aortic pressure except during systole. During systole, the left ventricle has to raise its internal pressure very substantially in order to overcome the aortic pressure and expel a useful amount of blood. In order to eject blood, the pressure in the ventricle has to exceed the afterload, which is the pressure in the aorta.
40. Two important indicators of the heart's performance are the cardiac flow, which is the volume of blood in litres that the left ventricle pump ejects in one minute, and the ejection fraction, which is the ratio of the ejected volume of blood to the starting volume. The starting volume is the volume at the end of diastole, while the ejected volume, also referred to as stroke volume, is the volume at the end of diastole minus the volume at the end of systole. In the diagram above, the ejection fraction appears to be approximately  $(130 - 50)/130$  i.e.  $80/130$ .
41. Normal adult cardiac flow varies between individuals and is roughly correlated with body surface area. Anything in the range of 3.5 l/min for a small adult up to 6.5 l/min for a large adult would not be considered unusual, but a figure of 5 l/min is considered typical.

### *Heart failure*

42. Heart failure refers to the situation in which the heart is no longer able to produce sufficient cardiac flow to meet the needs of the body (including the needs of the heart itself). One cause of heart failure is acute myocardial infarction (heart attack), which occurs when there is a blockage of flow at some point within the arteries of the heart.

This is usually caused by stenosis (narrowing) of the coronary arteries due to build-up of plaque within the vessel, or by bits of that plaque dislodging and causing blockages further downstream. Such a blockage deprives part of the heart muscle of adequate blood flow (and thus oxygen), causing damage or even death to the affected tissue. A heart attack can thus render part of the heart muscle unable to contract effectively. To the extent that this affects the ventricles, they may be left unable to contract powerfully enough to overcome arterial pressure and expel a useful amount of blood.

43. Heart failure may also arise as a result of a variety of other types of disease or conditions, such as acute myocarditis (inflammation of the heart muscle due to infection or other causes) and mitral regurgitation (failure of the mitral valve to prevent blood from flowing back into the left atrium during systole).
44. Heart failure may be acute, such as after a heart attack, where heart function may still be able to recover provided suitable support is provided; or it may be chronic, as in congestive heart failure (“CHF”), where the heart muscle becomes distended and the chances of recovery may be far lower.

#### *Treatment of heart failure by artificial hearts and VADs*

45. Heart failure may be treated to some extent by drugs (notably inotropes, which enhance muscle contraction), but for many patients drug therapy is ineffective or insufficient. For patients with CHF, a heart transplant is often required. By the 1990s, transplantation provided an excellent quality of life with good long-term survival (about 79% at 5 years, 50% at 10 years); but a shortage of donors means that far fewer hearts are available for transplantation than are needed. Even if a donor heart does become available, the patient will often have had to wait some time for it.
46. For these reasons, heart failure is often treated by physical intervention using MCS devices. MCS devices can be divided into two main categories, artificial hearts and VADs.
47. Artificial hearts, as the name implies, are designed to replace the human heart. The first artificial heart was implanted into a human in 1969, but the patient did not survive for very long. In 1981, an improved artificial heart developed by Dr Robert Jarvik called the Jarvik-7 was implanted into a human. This was more successful, but the patient still only survived for 102 days. In 1985, however, Dr Bartley Griffin recognised that, although imperfect and unsuitable for long-term use, the Jarvik-7 could be used temporarily as a “bridge” to transplantation. The success of the first case helped to establish the artificial heart as a viable therapy for patients that are morbidly ill.
48. During the 1960s and 1970s clinicians recognised that many patients with severe heart failure were suffering from failure of only one ventricle of the heart. This led to the developments of VADs, which are intended to assist the function of the left ventricle and/or right ventricle. The aim of such devices is to improve circulatory function by taking over all or part of the pumping action of the heart, and/or by allowing the residual pumping of the heart to be more effective (i.e. resulting in higher cardiac flow).

49. This not only improves circulation, it can also prevent further damage to the heart muscle caused by inability to expel incoming blood. When a person suffers a heart attack, for example, their ejection fraction will usually drop suddenly, but blood is still coming in from the venous system, so the ventricle begins to swell. Although the ejection fraction will tend to remain at the lowered level, because each contraction is starting off with a greater ventricular volume, the heart is able to maintain flow to some extent. This acts as a sort of coping mechanism, but it comes at the expense of distension of the ventricle, which damages the muscle fibres. It is therefore desirable to be able to unload the ventricle in order to treat the heart attack, such as with drug therapy or surgery, and allow the heart time to recover.
50. It is common to distinguish between three main types of therapeutic situation in which VADs may be employed, although there is some overlap between them: bridge-to-recovery (short term, hours or days), bridge-to-transplant (medium term, weeks or months) and destination therapy (long term). Bridge-to-recovery use buys time for the heart to recover from acute heart failure, with or without the help of drugs, so that in due course ventricular support can be withdrawn.

### *Cardiac catheterisation*

51. In general, a catheter is a thin flexible tube that can be inserted into the body to perform a variety of functions, such as delivery or withdrawal of fluids, or performing a medical procedure. Catheters have existed since the dawn of modern medicine, dating back to the 1700s. The applications for catheters include cardiovascular, urological, gastrointestinal, neurovascular and ophthalmic procedures. The procedure of inserting a catheter is known as catheterisation.
52. Cardiac catheterisation is a common medical procedure which is used in various kinds of heart treatment. It is a percutaneous (through the skin) procedure which involves inserting a catheter through a femoral artery in the groin by means of the Seldinger technique. The femoral artery is relatively easy to access and is a commonly used point of entry for such procedures. The Seldinger technique involves puncturing the skin and the blood vessel with a needle, threading an introducer sheath over the needle, withdrawing the needle and then inserting the catheter through the introducer sheath into the artery. The opening stretches around the catheter in a self-sealing fashion.
53. Catheterisation is a minimally invasive procedure which can be performed by an interventional cardiologist (it does not require a surgeon) and which is carried out in a catheterisation laboratory or “cath lab” (it does not require an operating theatre). Since catheterisation is not considered to be surgery, a cath lab has lower sterility requirements, and is often more available than an operating theatre. The Seldinger technique makes insertion simple and quick to perform – it can be done in under five minutes. Thus catheterisation is a very useful procedure for dealing with acute cases.
54. Once the catheter has been inserted, it is navigated through the aorta to the heart. When the catheter is in place, several tests or procedures may be carried out. For example, the tip of the catheter can be used to measure pressure in various parts of the heart, or to inject dye which can be seen on a fluoroscope (a type of x-ray). Catheter tips can also be fitted with small balloons which can be used to open up a clogged artery (most commonly the coronary artery of the heart). In this procedure, which is

called angioplasty, the balloon is used to squeeze the plaque (cholesterol, etc.) against the vessel wall or to eliminate a blood clot. Catheters can also be used to deliver stents (expandable scaffolds) to keep the blood vessel open.

55. In order to be inserted into the femoral artery by the Seldinger technique, a device must be below 6.4 mm in diameter. If the device is of a larger diameter, an arterial graft anastomosed to the artery is required. Anastomosis is the term for the process of stitching the arterial graft to the artery. The introduction of an arterial graft is a surgical procedure conducted in an operating theatre by a surgeon requiring clamping of the artery and the surgical attachment of a conduit through which to insert the device in question.

#### *The intra-aortic balloon pump*

56. The intra-aortic balloon pump, or IABP, was developed in the 1960s in order to assist the heart where there is still some residual function of the left ventricle. It consists of a mechanically inflatable balloon mounted on the end of a long catheter. The balloon is connected to an external gas pump via a thin tube running through the catheter. The pump is designed to inflate and deflate the balloon using helium gas. Thus the IABP is a positive-displacement, pulsatile pump, which works by changing its volume, as opposed to a rotodynamic, continuous pump, which employs some form of rotating impeller, propeller or rotor.
57. To deploy the IABP, the distal end of the catheter (the end remote from the operator, which is the end with the balloon) is inserted into the femoral artery. From there it is advanced up into the descending aorta and finally positioned just below the aortic arch, a short distance below the left subclavian artery (the last of the three arteries branching from the aortic arch). Once in position, the balloon is cyclically inflated and deflated within the aorta.
58. The balloon inflates at the end of ventricular diastole (relaxation) and deflates at the beginning of ventricular systole (contraction). The timing of this counterpulsation is achieved by monitoring the electrical activity of the heart and automatically triggering the pump at the appropriate points of the cardiac cycle.
59. The effects of the counterpulsation are twofold. First, the inflation at the end of diastole increases the pressure in the aorta, displacing blood back up towards the heart and thus pushing it into the coronary arteries and the three arteries of the aortic arch (since it cannot flow back into the heart once the aortic valve shuts). The inflation also pushes blood down the descending aorta to some extent. The increase in pressure above the balloon assists the natural flow in the coronary arteries. The heart itself most readily perfuses with blood when it is relaxed, and so the coronary supply relies to a large extent on the diastolic pressure in the aorta to support this flow in between contractions.
60. Secondly, the deflation of the balloon at the beginning of systole lowers the pressure in the aorta during that deflation. This means that the contraction of the left ventricle can more readily exceed the aortic pressure and thereby expel blood through the aortic valve, even if the left ventricle is not operating at full strength. This increases both cardiac flow and the ejection fraction.

61. Although the IABP can be regarded as a form of VAD, it tends to be treated as a precursor to later VADs. Although the IABP was still in common use for the treatment of acute heart failure in 2007, it was recognised to have inadequacies and drawbacks.

### *Types of VADs*

62. VADs may be categorised in various ways. One distinction is between extracorporeal devices, implantable devices and percutaneous (also known as peripherally-inserted or indwelling) devices. Extracorporeal devices transport blood to a pump outside the patient's body. Implantable and percutaneous devices are designed to promote blood flow without removing the blood from the body.
63. Extracorporeal VADs are clinically complex to set up and run, and involve a substantial amount of equipment outside the body. As such, they are more suited to use in a clinical setting such as an operating theatre or intensive care unit. Extracorporeal devices can be used during operations (e.g. open heart surgery), or for short-to-medium term stabilisation such as extracorporeal membrane oxygenation ("ECMO"). ECMO is where heart and lung assistance is provided outside the body. Thus extracorporeal devices are often incorporated into heart-lung machines.
64. Extracorporeal devices generally require a mini-thoracotomy, a surgical procedure to access the heart via a small incision in the chest, typically between the ribs, as opposed to a full thoracotomy, during which the chest is opened more radically, usually by transecting the sternum and parting the rib cage.
65. Implantable devices are generally designed to be placed inside the chest but outside the heart, bypassing the heart by drawing blood from (say) the left ventricle and pumping it back into the aorta. Implantable devices generally require a full thoracotomy. A full thoracotomy is high trauma and high risk, particularly in view of the condition of the patient. Despite this, implantable devices are more suitable for longer term use than extracorporeal devices.
66. By comparison with extracorporeal and implantable devices, percutaneous devices, and in particular catheter-based devices, reduce trauma and intervention time. Despite this, the vast majority of VADs marketed up to 2007 were extracorporeal or implantable devices.
67. Catheter-based devices can be further sub-divided into devices which are only inserted by means of a catheter and devices which are also driven via a catheter. In the former, the motor is internal to the body, while in the latter the motor is external to the body.
68. Another distinction is between LVADs, which support the left ventricle, RVADs, which support the right ventricle, and BiVADs, which support both the left and right ventricles. Left ventricular support is generally much more important in terms of driving VAD development. A large portion of the heart muscle is devoted to the left ventricle, while the right has a much smaller portion. Most commonly a heart attack will affect the coronaries supplying the left ventricle. Also, the mechanics of the left and right ventricles are coupled, and there is a wall between them, so that when the left ventricle pumps it does work for the right ventricle as well. Therefore while it is



sometimes necessary to provide right ventricular support, and some devices were designed either for that specific task, or to be adaptable to it, left ventricular support is the most common application.

69. Another way of categorising VADs is based on the type of pump they employ. There are two main categories: positive-displacement, pulsatile pumps and rotodynamic, continuous flow pumps. Continuous flow pumps can be further sub-divided into two main categories: axial flow pumps and centrifugal pumps (although there are also mixed flow pumps). Continuous flow pumps employ rotary parts to propel the blood, such as a helical impeller (axial flow pumps), or a disk with vanes that drives the blood by spinning it outwards within a suitable housing (centrifugal pumps).

#### *First generation VADs*

70. VADs are often said to fall into three broad generations based on certain features of their design and deployment.
71. The first generation of VADs were positive-displacement, pulsatile pumps. The pump mechanism of these devices typically used two chambers separated by a diaphragm, with air pressure on one side being used to flex the diaphragm. This would allow the other chamber to fill passively under natural blood pressure, and then the diaphragm could be used to apply positive pressure to pump the blood back into the body.
72. This first generation of VADs started to appear in the 1960s. Some of these devices showed limitations for certain applications. The diaphragms were prone to fatigue failure from repeated flexing. They were also very large devices, and the extracorporeal pumps (as opposed to implantable devices) required lines to and from the body. Another problem was clotting – blood would stagnate in the diaphragm, and thus be liable to clot. That could then lead to small clot fragments dislodging and blocking the vessels of the body or brain. Despite these problems, first generation devices were used successfully, particularly in extracorporeal applications.
73. A resurgence in the development of VADs occurred in the 1980s with the development of further first generation devices, as well as the emergence of the second generation VADs (as to which, see below). The development of these new devices with modern materials and computer control eventually led to the REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) trial conducted in 2000-2001 by the US National Heart, Lung and Blood Institute. This was a dedicated comparison of MCS (with a first generation, implantable LVAD), with what was then “optimal medical management” (i.e. pharmacological management). The outcome was that an LVAD decreased the risk of death by half, with a significant increase in quality of life. This conclusion was a pivotal point for the development of MCS devices, and in particular VADs.

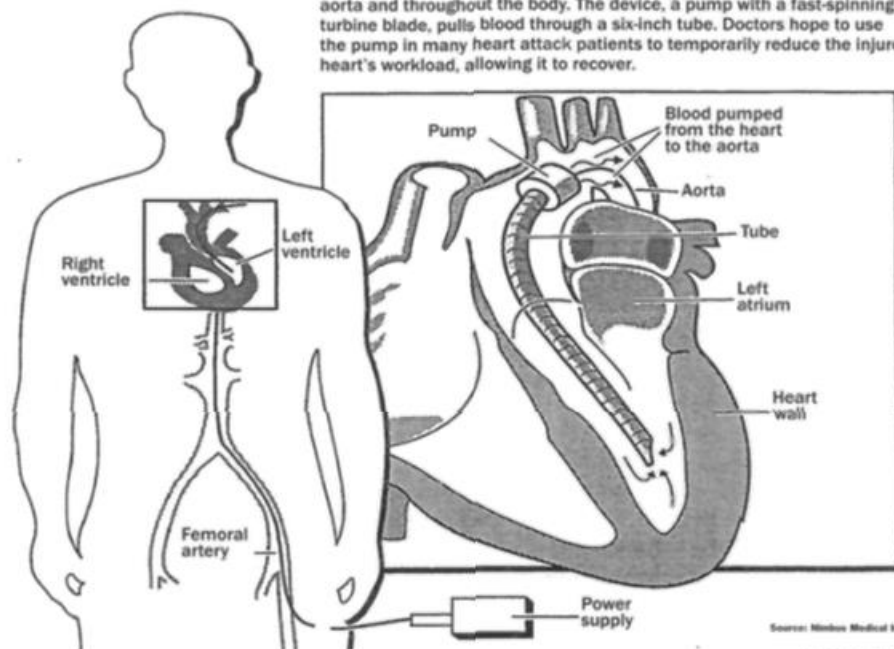
#### *Second generation VADs*

74. The second generation of VADs began to appear in the 1980s. Instead of positive-displacement, pulsatile pumps, these devices used rotodynamic, continuous pumps. The second generation devices also featured blood-immersed bearings or seals. A common example in an axial flow pump would be a mechanical thrust bearing to limit the position of the impeller axially and thus provide axial stability.

75. Second generation VADs were mainly extracorporeal or implantable devices. Examples of such devices included the Thoratec HeartMate-II and the BioMedicus (later Medtronic) BioPump (both discussed below).
76. The second generation of VADs also saw the first catheter-based devices. Like the IABP, these were inserted percutaneously. They were more suited to short term, bridge-to-recovery, use.
77. *Hemopump*. The best known catheter-based second generation device was the Hemopump, which was developed by Dr Richard Wampler and colleagues and distributed by Johnson & Johnson. The Hemopump comprised a catheter which incorporated a miniature rotodynamic pump with an axial flow impeller. The pump was driven by means of a drive cable which passed through the catheter. The drive cable was driven by an extracorporeal motor. In use, the Hemopump was positioned through the aortic valve, drawing blood from inside the left ventricle through a silicone cannula and discharging it into the descending aorta. The Hemopump was reported in the *New York Times* in May 1988, when the device was first used in man, from which the illustration below is reproduced.

### Tiny Pump Assists an Ailing Heart

Threaded to the heart from the femoral artery in the groin, a small device draws oxygenated blood from the left ventricle and pumps it into the aorta and throughout the body. The device, a pump with a fast-spinning turbine blade, pulls blood through a six-inch tube. Doctors hope to use the pump in many heart attack patients to temporarily reduce the injured heart's workload, allowing it to recover.

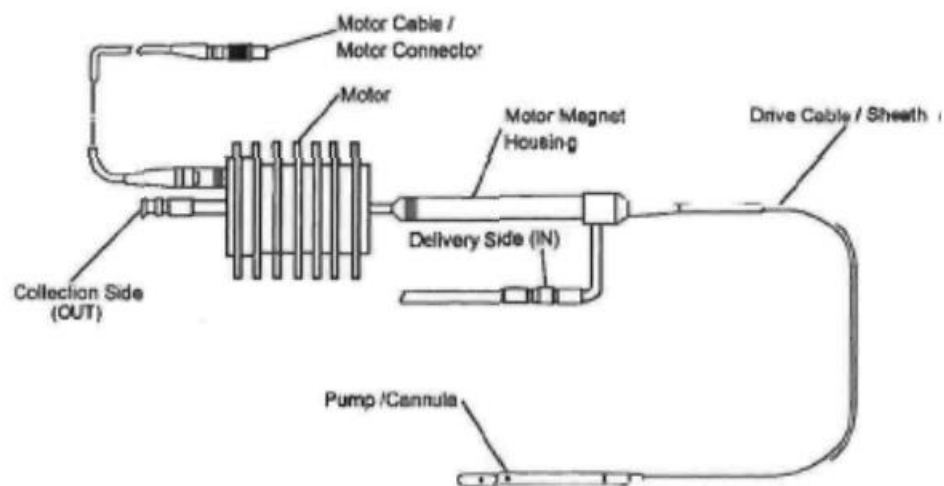


Source: Nitrox Medical Inc.

The New York Times/May 5, 1988

78. The Hemopump was intended to assume up to 80% of the workload of the resting heart for up to seven days. The introduction of this device demonstrated that it was feasible to provide circulatory support with an indwelling impeller operating at very high speeds (in excess of 10,000 revolutions per minute) without destroying the blood cells.

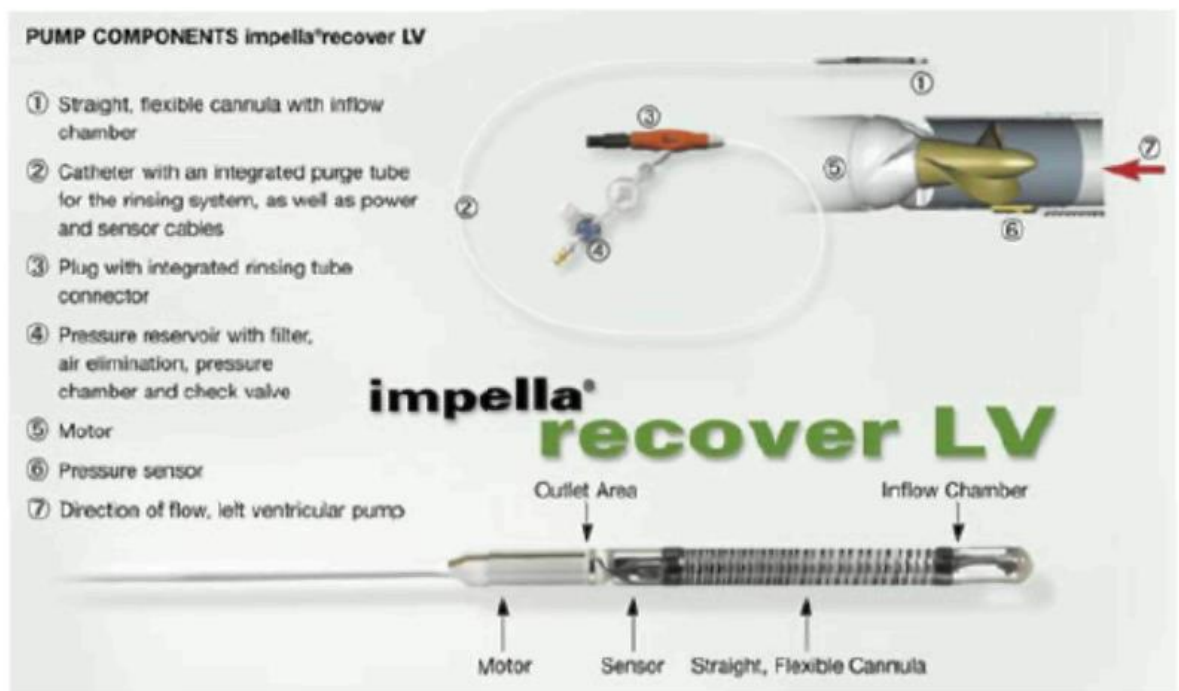
79. The Hemopump employed a brushless motor arrangement (as to which, see further below), in which the motor stator was reusable, but the motor rotor, catheter, pump and cannula were designed to be disposed of after a single use. The schematic diagram reproduced below (from W. Aboul-Hosn and R. Wampler, *The Hemopump: Clinical Results and Future Applications* (Springer, 1995)) shows the motor partially disassembled, with the housing containing the motor rotor (labelled “motor magnet housing”) displaced from its operating position within the motor stator (labelled “motor”).



80. The electromagnetic stator generated a rotating magnetic field, which drove the permanent magnets in the rotor. This magnetic coupling enabled the motor to be separated into a “dry” side (the stator) and a “wet” side (the rotor in its housing). The rotor rotated on journal bearings. The drive cable was sealed from blood by a seal in the pump head. The bearings, drive cable and seal were lubricated and flushed with a glucose solution purge fluid. The purge fluid was pumped into the motor magnet housing through the inlet marked “Delivery Side (IN)” and exited through the outlet marked “Collection Side (OUT)”. The flow of purge fluid resulted in some purge fluid entering the patient’s blood stream through the pump head. The flow of the purge fluid from inside the pump across the seal and into the blood stream kept the seal gap free of blood. Otherwise, fibrin would build up in the gap, leading to a reduction in the pressure of the purge flow. That would gradually allow more blood to enter into the gap which would lead to pump failure.
81. There were a number of different models of Hemopump. The first was the Hp21, which was subsequently followed by the Hp14. The Hp21 had a 7.4 mm diameter pump and a curved cannula, and it was inserted by means of an arterial graft, while the Hp14 had a 4.6 mm pump with a straight cannula which was inserted by the Seldinger technique. Between the Hp21 and Hp14 there was the Hp31, which had an 8mm pump with a straight cannula inserted by means of a sternotomy (transthoracic, open chest surgery). The Hp21 had certain advantages, in particular that it was significantly more powerful than the IABP, but it also suffered from certain drawbacks, notably that the drive shaft fractured quite frequently. The Hp14 attained a peak flow rate of about 2.3 l/min at a pressure of 70 mmHg, which was less than the

Hp21 and Hp31, but it had the advantages that it suffered less from drive cable fractures and could be used by an interventional cardiologist.

82. The Hemopump was discontinued in 1998 for undisclosed reasons. (According to Dr Sieß, this was because, although the Hemopump received a CE marking and was used clinically in Europe, it did not receive approval from the US Food and Drug Administration.) Nevertheless, the Hemopump continued to be discussed extensively in the academic literature and at conferences. (Indeed, by October 2007 over 800 articles had been published which referred to it at least in citations.)
83. *Impella*. A more recent catheter-based device was the Impella, which first received CE mark approval in January 2003. It was intended for temporary circulatory support in patients with acute heart failure. Like the Hemopump, this device utilised a small axial flow blood pump that was inserted percutaneously through a femoral artery and positioned in the ascending aorta with a cannula placed across the aortic valve and the tip within the left ventricular cavity. But unlike the Hemopump, the Impella utilised an intracorporeal miniature motor that directly drove the pump. The motor was connected by electrical wires in the catheter to an external console that monitored and controlled the device. The catheter also provided a conduit for a lubricant/purge fluid from outside the body that maintained the integrity of the bearings of the pump. The pump seal was continuously purged with a solution of glucose and heparin.
84. A number of different versions of the Impella had been marketed by October 2007, and in particular the Impella 5.0, which was designed to produce a flow rate of 5 l/min, and the Impella 2.5, which was designed to produce a flow rate of 2.5 l/min. The general arrangement of the Impella devices is shown in the illustration reproduced below.

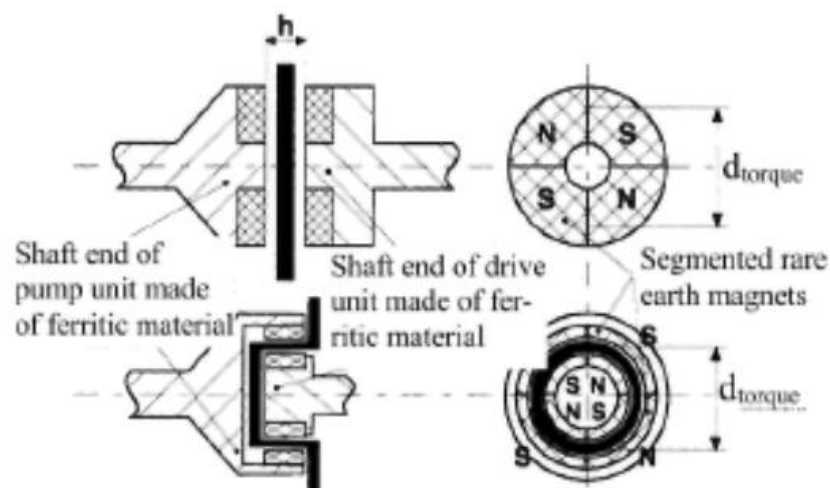


*Third generation VADs*

85. The third generation of VADs was relatively new in 2007. They were characterised by replacing the seals and bearings of the second generation with contactless drive mechanisms usually including magnetic or non-contacting hydrodynamic bearings. The rotor in these devices would be “levitated” in the pump housing using any combination of magnet arrangements, or hydrodynamic bearings, to rotate the rotor element while keeping it axially and radially supported. This combination of magnetic drive and magnetic and/or hydrodynamic bearings would allow the impeller to levitate while pumping blood, thus not coming into contact with any other part of the pump. These third generation or “mag lev” VADs were implantable devices.

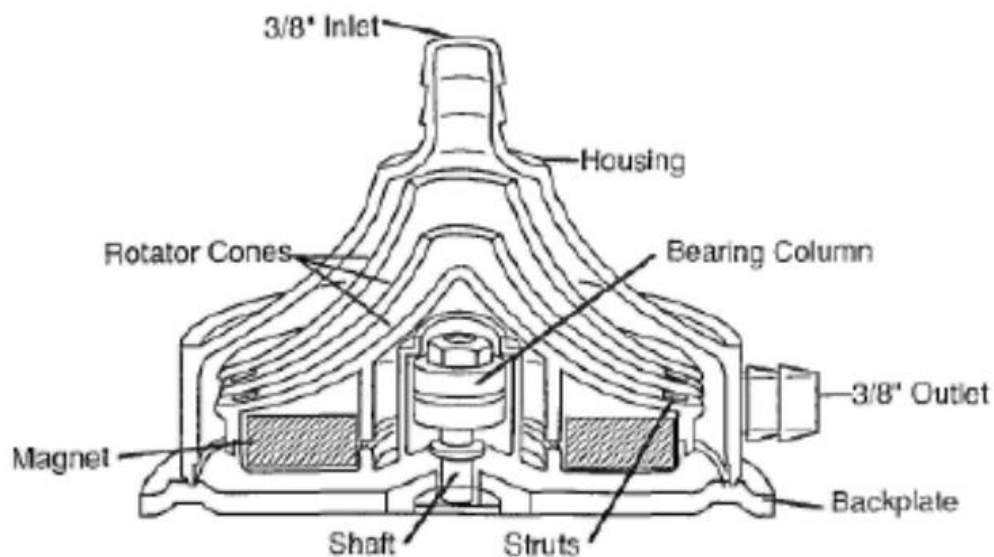
### *Magnetic couplings*

86. The simplest means of coupling a motor to an impeller is a direct connection, using a drive shaft. However, this necessitates the use of a shaft seal to prevent blood from infiltrating the motor, or in other words, to maintain a “wet” and “dry” side of the drive train. This approach was adopted by several manufacturers of VADs, including the Impella. In 2007, shaft seals were known to have a number of disadvantages, including wear, heat generation and thrombosis that both limited the durability of the device and posed serious risk of adverse effects to the patient.
87. An alternative method which was used in VADs (and other fields) was a magnetic coupling, which has the advantage of not requiring a physical connection. This allows the impeller to be hermetically separated from the motor without having to include a seal around a drive shaft. Within this category of magnetic couplings, two primary geometries of magnets were known: face-to-face and concentric. These geometries are helpfully depicted in Figure 3.2 of Sieß, which is reproduced below. Face-to-face is at the top and concentric at the bottom.



88. The first arrangement involves a pair of disc-shaped magnets, positioned face-to-face. The space between these two faces is called the air gap. In this case, the magnetisation of each disc would typically be in the axial (thin) dimension, with alternating poles around their periphery.

89. A well-known example of a (second generation) VAD that employed a face-to-face magnetic coupling was the BioMedicus (later Medtronic) BioPump. This was an extracorporeal, centrifugal pump, which used a ball-bearing to support the rotor, and a face-to-face magnetic disc coupling to separate the blood circuit hermetically from the drive unit. The BioPump was introduced in 1978 and was used extensively throughout the world in heart-lung machines. It remained in use in October 2007. The schematic cross-sectional diagram reproduced below shows the disposable pump head, containing a disc magnet with alternating poles at its base. In use this was placed adjacent to a mating disc magnet (also with alternating poles) within a drive unit containing the motor. Note that this diagram also shows the (unlabelled) seal on the shaft.

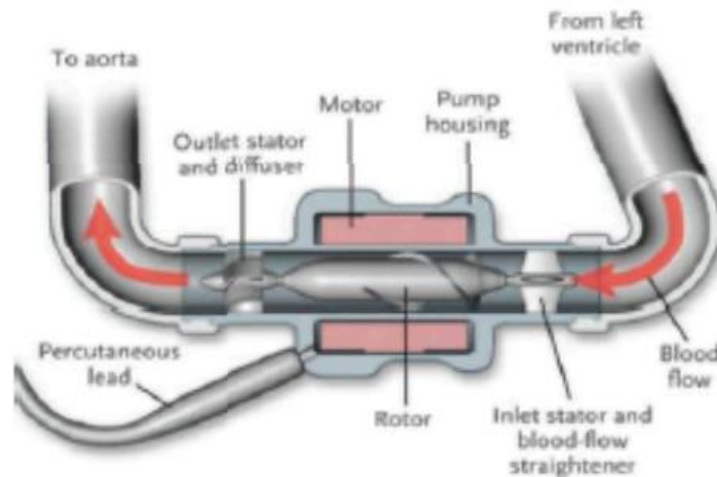


### *Brushless motors*

90. A variety of different types of electric motors had been used in VADs by 2007. A type of motor which was frequently employed in third generation devices, but also in some second generation devices, was a brushless motor. A brushless motor is a type of electric motor that uses a static arrangement of wire coils (the stator) to generate a rotating magnetic field that imparts torque to permanent magnets arranged on the rotating part (the rotor). Such motors are said to be “brushless” in contrast to “brushed” motors, in which the coils are instead mounted on the rotor, typically sitting inside a stator of permanent magnets. In the latter arrangement, the coils are supplied with current by brushes mounted on the rotor that make contact with stationary electrical contacts as they pass. As the brushes rotate they meet electrical contacts with alternating polarity. This means that the current in the coils alternates in synchrony with the spinning of the rotor, so that the magnetic fields generated by the coils are always in the right alignment to create torque against the magnetic fields of the stator. In a brushless motor, the timing and manipulation of the alternating magnetic fields needed to create and sustain torque is generated not by the spinning of electrical contacts in the rotor, but by separate electronic control systems that switch

electrical current between the coils of the stator. Even for a simple brushless motor, this requires sophisticated electronics and careful design of the physical components, to ensure that the fields in the stator engage most efficiently with those in the rotor, and that the fields move at a suitable pace to apply the desired torque at all times.

91. In third generation VADs which employ brushless motors, the stator comprises an arrangement of coils in the non-blood-contacting side of the pump, and the rotor comprises the impeller itself, in which the permanent magnets are mounted. In such VAD devices, the motor stator can be arranged around the periphery of the impeller, creating a concentric magnetic configuration, or arranged above/below the impeller, creating a face-to-face configuration. Normally, additional magnetic/hydrodynamic components would be required above/below, or around the periphery respectively to ensure that both axial and radial stability is provided, as well as rotational drive.
92. A well-known example of a (second generation) VAD with a brushless motor in 2007 was Thoratec's HeartMate-II, which is illustrated below.



93. The HeartMate II was a second generation, rather than a third generation, device because the impeller was mounted on bearings on either end. The part labelled "motor" in the diagram is the stator which drives the rotor on which an axial flow impeller is mounted.

#### *Design constraints*

94. The skilled person designing a VAD, and in particular a catheter-based VAD, in October 2007 would be aware of a number of constraints upon the design, including the following:
  - i) The pump must be able to achieve a suitable flow rate against a given head of pressure. What flow rate was acceptable would depend on the clinical application which was envisaged, however. For example, the Impella 2.5

demonstrated that there was a market for a device that only produced a flow rate of 2.5 l/min.

- ii) Insertion of a device at the end of a catheter by the Seldinger technique would limit the diameter of the device. This would place constraints upon the design of the pump and of the motor if the motor was to be located within the body.
- iii) The pump must be designed to have an adequate life span, and hence to be able to withstand the mechanical stresses involved for that period. For short-term use, however, this would be less of an issue than for medium- or long-term use.
- iv) Blood is sensitive and prone to damage if overstressed, in particular by excessive shear, which is apt to cause haemolysis (the rupture of blood cells). Nevertheless, the Hemopump and the Impella had shown that high rotational speeds could be achieved without high levels of haemolysis.
- v) The design and placement of the device should minimise the risk of thrombosis (formation of blood clots), which can lead to strokes and other complications. I shall return to this point below.
- vi) Blood should preferably not encounter the mechanical parts of the device, for the reasons explained above in relation to the Hemopump.
- vii) The characteristics of the drive unit must match the characteristics of the pump, in particular in terms of the speed, torque and power required. Subject to that, however, the skilled person would appreciate that it would be possible to “mix and match” different drive units and pumps.

### The Patents

- 95. The authentic text of both Patents is in German, but there are agreed certified translations into English. There is little difference between the specifications of the two Patents, and for present purposes it is convenient to focus on 872.
- 96. The specification starts at [0001] by stating that the invention relates to a catheter device, and in particular a catheter device with an elongated drive shaft. The specification goes on to describe the background to the invention. At [0002]-[0003] it refers to the increasing use of implantable blood pumps to treat patients with heart disease, and in particular blood pumps designed to provide short term support for the heart inserted by minimally invasive means.
- 97. The specification then describes a number of items of prior art, beginning with the IABP (at [0004]) and the Hemopump (at [0005]). The Hemopump is described as “a promising concept for effecting adequate relief of systemic heart strain”, but is said to have the disadvantage that “the transfemoral implantation, due to the large diameter of the rotor, is possible only through an operation involving a femoral arterotomy and if necessary by a graft coupling”. (This statement is true of the Hp21, but not the Hp14.)
- 98. The specification continues:



“[0012] The present invention is based on the problem of creating a catheter device with a drive shaft extending over virtually the whole catheter device and which may be driven at high rotary speed.

[0013] The problem is solved by a catheter device according to claim 1. Advantageous developments of the invention are set out in the dependant claims”.

99. After a consistory clause corresponding to claim 1 ([0014]), the specification goes on:

“[0015] Because of the separation of the output-side clutch element up to the distal end of the catheter device, it is not necessary to guide the drive shaft to the outside via a hole. Any such feed-through would require sealing, but such sealing limits the speed. Since this catheter device has no corresponding sealing of a drive shaft feed-through, very high speeds may be transmitted to the drive shaft.

[0016] The contribution of the transmittable torque is limited by the magnet ring bearing and the magnetic connection of the two magnet units. As soon as the settable torque is exceeded, the two magnet units separate.”

100. The specification then describes some of the features of the subsidiary claims. This section includes the following passages:

“[0020] In accordance with a development, an additional magnet ring bearing is provided. On the one hand this provides further and especially radial support for the output-side clutch element, and on the other hand it is able to counteract the forces exerted by the magnet units, so that the force with which the output-side clutch element is pressed against the sliding bearing is reduced.

[0021] The maximum torque transferable by the magnetic clutch is determined by both the distance between the two magnet units set by the sliding bearing and by the force with which the magnet ring bearing acts on the clutch element in the axial direction.

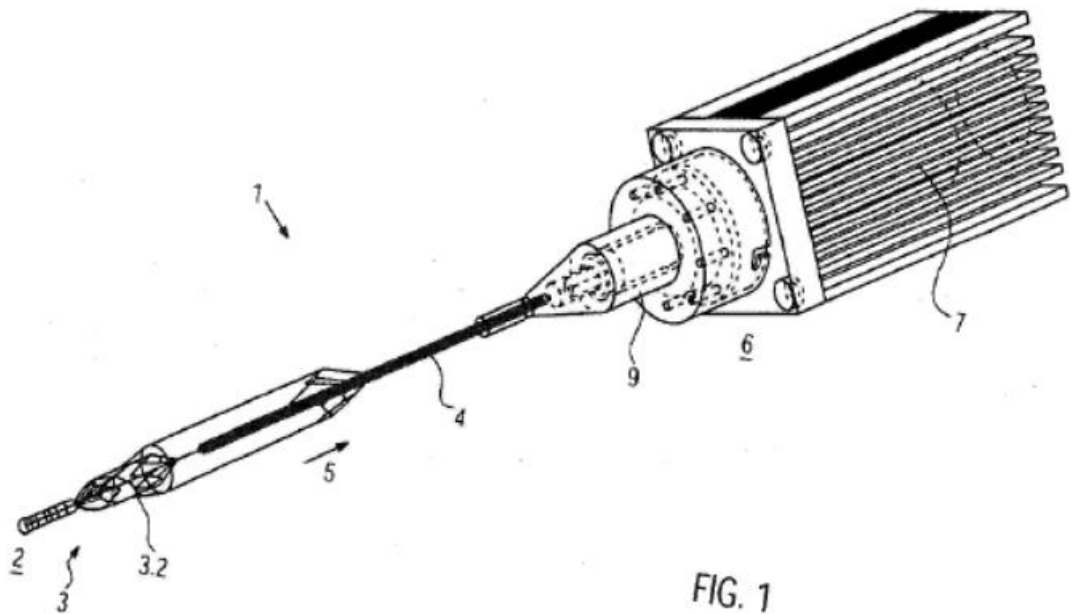
...

[0023] The element rotating due to the drive shaft may be a rotor, a milling tool or another tool.

[0024] Such a rotor is preferably designed to unfold automatically. It may be provided with a pump housing which, like the rotor, is compressible to a small diameter. ...

[0025] The combination of an automatically unfolding pump head with the magnetic clutch explained above forms a catheter device with which on the one hand, owing to the high speed and the large rotor, a high pump performance is obtained, and on the other hand a high life expectancy of several hours to several days is achieved.”

101. There is then a lengthy description of a specific embodiment of the invention by reference to 25 figures. Figure 1, which I reproduce below, shows a schematic overview of the device, with a motor (7), clutch (9), drive shaft (4), and pump head (3) with expandable rotor (3.2). These form the basic components of the device, details of which are then explained in turn, along with certain other features.



102. The pump head and its components are described at [0029] to [0056]; the drive shaft is described (along with associated parts) at [0057] to [0062]; the expandable rotor is described at [0063] to [0074] (again along with associated parts) and its expansion is described at [0081] to [0084]; an outlet hose is described at [0075] to [0079]; the clutch is explained at [0086] to [0124]; the motor assembly is described at [0125] to [0136] and the method of coupling with the magnetic clutch is explained at [0138] to [0147].
103. For present purposes most of these details do not matter, but I do need to refer to three passages which describe the magnetic clutch and the magnet ring bearing. These refer to Figures 14 and 15 which I reproduce below.

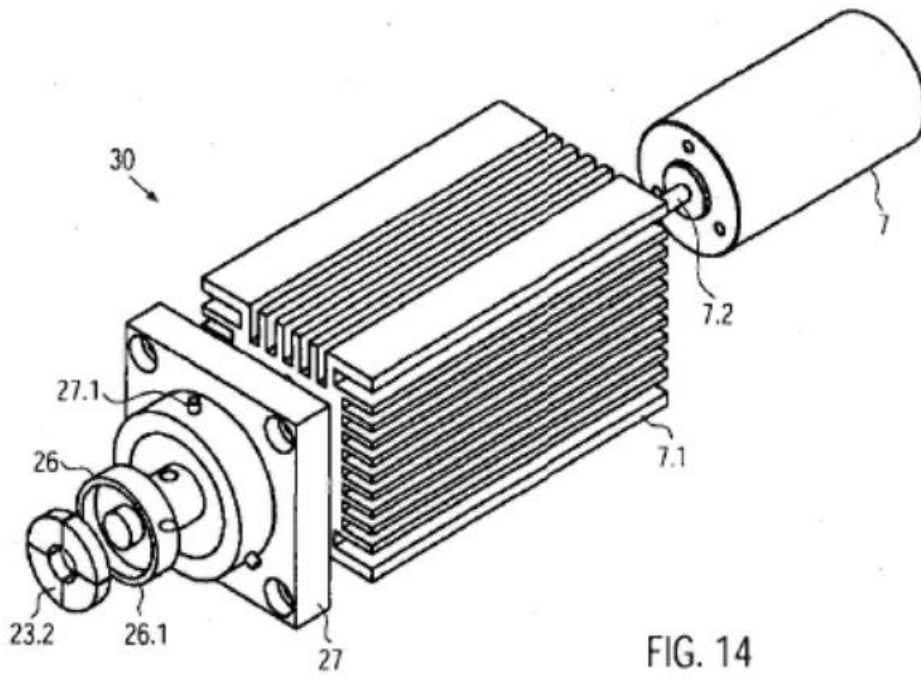


FIG. 14

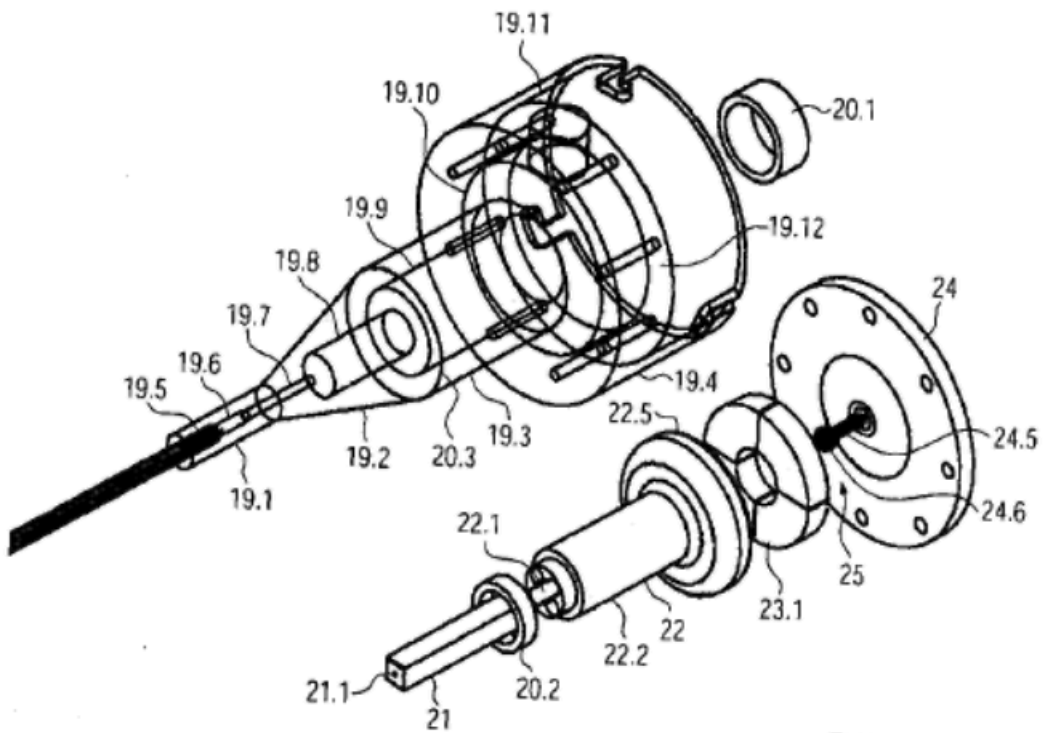


FIG. 15

104. The first passage states:

“[0086] The clutch 9 is a magnetic clutch (Fig. 14, Fig. 15). The clutch 9 has a clutch housing 19 with a distal magnet unit 23.1. The clutch housing 19 is connected to the proximal catheter body element 8.2, which forms a continuous hollow space. The clutch housing 19 separates the proximal catheter body element 8.2 hermetically from a motor assembly 30. The motor assembly 30 has a proximal magnet unit 23.2. The proximal magnet unit 23.2 is connected by tension to the motor 7. The distal magnet unit 23.1 is connected to the drive shaft 4 via a clutch element 22.

[0087] The distal magnet unit 23.1 and the proximal magnet unit 23.2 are coupled securely to one another through magnetic forces. A tension connection with non-contact rotational force transfer is ensured by the two magnet units 23.1, 23.2.”

105. The second passage states:

“[0108] At the distal end and at the periphery of the cylindrical section 22.2 of the clutch element 22, a shoulder 22.4 is formed. Mounted on this shoulder 22.4 is a second inner ring magnet 20.2. The shoulder 22.4 accommodates the inner ring magnet 20.2 in such a way that its outer surface lies flush with the cylindrical surface of the cylindrical section 22.2. This forms, in combination with the outer ring magnet 20.1 similarly encompassing it in the bearing section 19.9 of the clutch housing 19, a magnet ring bearing 20.3.

[0109] In the magnet ring bearing 20.3, the two ring magnets 20.1, 20.2 are so arranged that e.g. the north pole of the outer ring magnet is oriented towards the distal end and the south pole towards the proximal end. The north and south poles of the inner ring magnets are correspondingly opposite one another. Similarly, the north and south poles of the two ring magnets may also be reversed. The magnet ring bearing 20.3 centers the drive shaft 4 axially and radially. The radial centering is effected through the radial attraction forces in the radial direction. The axial centering is effected by means of magnetic restoring forces generated by a slight offset of the inner ring magnet 20.2, which pull the inner ring magnet 20.2 into a position coinciding axially with the position of the outer ring magnet 20.1 with a greater offset, however, repelling forces occur between the two magnet rings 20.1 and 20.2, causing them to be pressed apart.”

106. The third passage states:

“[0143] In the event of jamming of the rotor 3.2, the friction connection between motor 7 and drive shaft 4 must be broken, to prevent ‘winding-up’ of the drive shaft 4 while the rotor is stationary. ‘Winding-up’ of the drive shaft 4 could lead to a

change in position of the pump head 3, resulting in damage to the heart and/or the aorta and veins.

[0144] As soon as the rotor 3.2 jams, the drive shaft 4 twists and shortens, and the resistance at the distal magnet unit 23.1 increases. The magnetic fields between the proximal and the distal magnet units 23.2, 23.1 do not overlap completely in operation, since the distal magnet unit 23.1 always trails the proximal magnet unit 23.2 a little. If now the torque required at the distal magnet unit 23.1 increases, the north and south poles of the magnet units 23.1, 23.2 no longer overlap but instead abut one another. By this, the distal magnet unit 23.1 is pressed away from the proximal magnet unit 23.2 in the distal direction. The magnetic connection between the two magnet units 23.1, 23.2 is broken and the drive shaft 4 comes immediately to a stand.

[0145] Due to the displacement of the clutch element 22 in the distal direction, the inner ring magnet 20.2 of the clutch element 22 is similarly shifted in the distal direction; the north and south poles of the two ring magnets 20.1, 20.2 of the magnet ring bearing 20.3 no longer overlap but instead abut one another. By this means, the clutch 9 is held in the decoupled state, resulting in a lasting decoupling of motor 7 and drive shaft 4.

[0146] The amount of transferable torque is limited by the magnet ring bearing 20.3 and the magnetic connection of the two magnet units 23.1, 23.2. As soon as the set torque is exceeded, the two magnet units 23.1, 23.2 separate. Owing to the rapid rotary motion, the distal magnet unit 23.1 can no longer follow the proximal magnet unit 23.2, since the magnetic binding forces are no longer adequate. Because of this, the north and south poles no longer overlap and the magnet units 23.1, 23.2 repel one another. The connection of the magnet units 23.1, 23.2 is broken and the maximum transferable torque is limited. The magnet units 23.1, 23.2 are held in the decoupled state by the magnet ring bearing 20.3 through the mutual repulsion of the ring magnets 20.1, 20.2.”

107. It can be seen from these passages and the accompanying figures that, in the specific embodiment, the proximal magnet unit 23.2 and the distal magnet unit 23.1 are arranged face-to-face, separated by the wall 24, and mounted on sliding bearing 24.5. In normal operation, the alignment of the magnetic poles on the respective magnet units keeps the units attracted to one another. If the rotor jams, however, the poles on the distal magnet unit move out of alignment with the poles on the proximal magnet unit, generating a repulsive force that drives the units apart. They are held in the decoupled state by the inner ring magnet 20.2 and outer ring magnet 20.1 comprising magnet ring bearing 20.3.
108. The remainder of the specification discusses further details of a variety of different aspects of the device, including method of deployment, fluid flushing, benefits of the

invention, and certain further distinctions over earlier pump devices. Again these details do not matter for present purposes.

### The claims

109. As a consequence of the close relationship between the Patents, the claims in 658 are essentially the same as a subset of those in issue in 872. There are some minor differences in the translation of certain words of the claims as between the Patents, but neither side suggested that these differences had any technical significance. I shall therefore focus on the claims of 872.

110. Omitting reference numerals and broken down into integers, claim 1 of 872 is as follows:

“[1] Catheter device comprising

[a] a motor located at the proximal end of the catheter device

[b] a drive shaft, extending from the proximal end section to the distal end section of the catheter device, for driving

[c] a rotating element located at the distal end of the catheter device,

characterised in that

[2] at the proximal end of the catheter device, the drive shaft is connected to the motor by a clutch, and

[3] the clutch is a magnetic clutch with a proximal and a distal magnet unit,

[4] wherein

[a] the proximal magnet unit is connected to the motor, and

[b] the distal magnet unit to the drive shaft, and

[5] the distal magnet unit is

[a] supported in a clutch housing and

[b] physically separated from the proximal magnet unit by a wall.”

111. The claims alleged by AIS to be independently valid are claims 1, 5, 7, 8, 11, 19, 20, 21 and 22 of 872 (claims 1, 4, 6, 7, 9 and 15 of 658). Of these, only claims 1, 5, 8, 21 and 22 of 872 (claims 1 and 4 of 658) are alleged to be infringed, and therefore I shall follow the parties’ example in concentrating on these claims. The only other claim in respect of which Thoratec pursued its arguments on invalidity was claim 7 of 872.

112. Claim 5 (claim 4 of 658) specifies that “the clutch housing has a rinsing bore for the connection of a pump for the introduction of a rinsing medium into the clutch housing and the catheter body”.
113. Claim 7 (claim 6) specifies that “the drive shaft is fastened non-rotatably at its proximal end, within the clutch housing, to a profiled rod, and the profiled rod is held so as to be axially slidable but non-rotatable in a recess of a clutch element located within the clutch housing”.
114. Claim 8 specifies that “the clutch element is rotatably mounted via a sliding bearing in the clutch element”. Claim 7 of 678 includes the same requirement except that the official English translation uses the words “friction bearing” rather than “sliding bearing”.
115. Claim 21 (also with no equivalent in 658) specifies that “a pump housing is provided and encompasses the rotor with a tubular pump section, wherein the pump housing is formed by a mesh, the openings of which are closed by an elastic covering, at least in the area of the pump section”.
116. Claim 22 specifies that the mesh is made of a memory material.
117. The conditional amendments proposed to 658:
  - i) limit the “rotating element” in claim 1 to a “rotor situated in a pump housing”, “wherein the rotor and pump housing are compressible, and the rotor is designed to unfold automatically from a compressed state”;
  - ii) introduce a new claim 2 which specifies that the pump housing is “a tubular mesh structure of memory material”; and
  - iii) replace the term “friction bearing” in claims 7 and 8 with “sliding bearing”, which is a better translation of the German term “*Gleitlager*”, and is the term used in the claims of 872.

#### The skilled person

118. There is no dispute as to the identity of the skilled person to whom the Patents are directed. The skilled person is a medical device engineer working as part of a team in either industry or academia with at least a master’s level qualification in mechanical or biomedical engineering and with some experience in the general field of VADs.

#### Common general knowledge

119. There is little, if any, dispute that all the matters I have set out under the heading “technical background” (apart from the parentheses in paragraph 82) would have been part of the skilled person’s common general knowledge, and in any event I so find.
120. Although counsel for AIS submitted in his closing submissions that common general knowledge was one of the most important issues in the case, the dispute between the parties is not really as to what was or was not common general knowledge, but rather as to the attitudes and perceptions of the skilled person at the priority date, and hence

the approach he (or she) would adopt to the development of a VAD. It is convenient to address these questions in the context of obviousness below.

### Construction

121. There are a number of issues of construction of the claims. It is convenient to note that these are all relevant to infringement, and have little impact on validity.

#### *A magnetic clutch with a proximal and a distal magnet unit*

122. AIS contends that the skilled person would understand a “magnetic clutch” to be a form of clutch in which torque is transmitted between two magnet units when they are engaged but which ceases to transmit torque above a certain threshold at which the magnet units are disengaged. Although at one stage Thoratec appeared to be contending that the skilled person would also understand that the disengagement occurred through axial separation of the two magnet units, counsel for Thoratec did not argue that this requirement was conveyed merely by the use of the expression “magnetic clutch”. Accordingly the issue is what the skilled person would understand from the words “with a proximal and a distal magnet unit”.
123. It is common ground that the words “proximal” and “distal” are frequently used in medicine and biomedical engineering to refer to the parts of something that are closer to and further way from a reference point (such as the centre of the body). The issue is as to how the skilled person would understand them in this context. AIS contends that the skilled person would understand them simply to denote the relative positions of the magnetic units within the device as a whole, and thereby to cover any arrangement of magnet units which achieves the other requirements of claim 1. Thoratec contends that the skilled person would understand them to denote magnet units which are face-to-face as shown in Figure 3.2 from Sieß (see paragraph 87 above), and thus not to cover concentric magnet units. It is common ground that the only arrangement described in the specific embodiment is face-to-face as shown in Figures 14 and 15 of the Patents, but AIS contends that it does not follow that the claims are restricted to that arrangement.
124. Counsel for AIS advanced the following main arguments in support of the broader construction. First, he argued that it is evident the words “proximal” and “distal” are used in claim 1, and generally in the specification, to denote the general arrangement of the components of the catheter device and not to define any precise spatial relationship of particular components of the device.
125. Secondly, he argued that it is clear that the words “proximal” and “distal” are used in integer [1] of claim 1 to denote the relative topological positions of the motor and the rotating element in the catheter device, and that there was no reason to interpret them differently in integer [3].
126. Thirdly, he argued that the skilled person would appreciate that the claim did not employ wording, such as “face-to-face”, which described the physical orientation of the magnet units with respect to each other, and thus was not limited to any particular physical orientation.



127. Fourthly, he argued that the skilled person would appreciate that orientations other than face-to-face could satisfy the four requirements of the claim with respect to the magnet units, namely that (i) together they form a magnetic clutch (which can be engaged and disengaged), (ii) the proximal magnet unit is connected to the motor, (iii) the distal magnet unit is connected to the drive shaft (and thence to the rotating element) and (iv) they are physically separated by a wall.
128. Fifthly, he argued that, as a result of foregoing considerations, the skilled person would understand that the words “proximal” and “distal” were simply a naming convention to make it clear which magnet unit was which: the magnet unit connected to the motor or the magnet unit connected to the drive shaft.
129. Counsel for Thoratec advanced the following main arguments in support of the narrower construction. First, he argued that the skilled person would consider that “proximal” and “distal” were a natural way to describe an axially-disposed, face-to-face arrangement in which one face was connected to the motor and the other to the drive shaft, whereas it was not a natural way to describe a radially-disposed, concentric arrangement. By contrast, the skilled person would consider that it would be natural to describe a radially-disposed, concentric arrangement of magnet units as “inner” and “outer”, language which the Patents use when describing the ring magnets comprising the magnet ring bearing (see [0109] of 872 quoted in paragraph 105 above and claim 12).
130. Secondly, he argued that the skilled person would consider that this interpretation was reinforced by the requirement that the magnet units be physically separated by a “wall”, which would be a natural way to describe a planar element between face-to-face magnet units.
131. Thirdly, he argued that the skilled person would consider that, had the patentee wanted to cover other arrangements, more general language would have been employed, such as “driver” and “driven”.
132. Fourthly, he argued that the skilled person would interpret the claim in the light of the description, and would note that the only arrangement described or shown was face-to-face, which would reinforce his understanding.
133. Fifthly, he argued that, when considering the patentee’s technical purpose in requiring one magnet unit to be “proximal” and the other “distal”, the skilled person would note that together they formed a magnetic clutch and would appreciate from [0016] and [0144] (quoted in paragraphs 99 and 106 above) that they enabled the magnetic clutch to be axially separated upon torque overload. Without such axial separation, it would be more difficult to ensure that there was no “chatter” between the driver and follower magnets if they fell out of radial alignment.
134. Sixthly, he argued that this understanding was supported by the presence in some of the subsidiary claims of the magnet ring bearing, which enabled the magnet units to be held apart once they axially disengaged.
135. Lastly, he argued that the effect of AIS’s construction was to render the words “proximal” and “distal” in integer [3] redundant, since on that construction they

simply meant “connected to the motor” and “connected to the drive shaft” respectively, but those requirements were specified in integers [4][a] and [b].

136. Despite the skill with which counsel for Thoratec presented these arguments, in my judgment AIS’s construction is the correct one for the reasons given by counsel for AIS. In short, I consider that the skilled person would understand the words “proximal” and “distal” to denote which magnet unit was which by reference to their relative topological positions in the device, rather than their physical orientation with respect to each other. Moreover, the skilled person would appreciate that the four technical requirements specified in claim 1 could be achieved by means of orientations other than face-to-face.

*Sliding bearing/friction bearing*

137. I do not understand there to be any dispute that “sliding bearing” is a more accurate translation of the German than “friction bearing”, and so I will proceed on the basis that the English versions of claims 7 and 8 of 678 are amended as proposed.
138. AIS contends that the skilled person would understand “sliding bearing” to mean any bearing in which one surface slides over another. Thoratec contends that the skilled person would understand that the function of the claimed sliding bearing was to provide both radial support and an axial thrust to counteract the axial attraction of the proximal and distal magnet units, as occurs in the specific embodiment.
139. In my judgment AIS’s construction is the correct one. The words “sliding bearing” are general words, and the skilled person would appreciate that other arrangements were possible than the one employed in the specific embodiment.

*Mesh*

140. AIS contends that the “mesh” of claim 21 covers any expandable lattice-like or net-like arrangement of filaments or struts. Thoratec contends that the expression is limited to an arrangement with apertures in the shape of polygons, as in the specific embodiment.
141. In my judgment AIS’s construction is the correct one. The word “mesh” is a general one, and the skilled person would appreciate that other forms of mesh could be employed than the one in the specific embodiment.

*Relationship between the features of claims 1, 5, 7 and 8 and the features of claims 21 and 22.*

142. Apart from claims 3 and 4, which respectively specify that the rotating element is “a milling head or other tool” or “a rotor”, claims 1-18 of 872 are essentially concerned with the features of the proximal end of the catheter device, and in particular the magnetic clutch and associated elements. By contrast, claims 19-20 and claims 21-22, which in both cases are dependent on claims 4-18, are concerned with the distal end of the catheter device, and in particular the frame structure of the rotor (claims 19 and 20) and the mesh of the pump housing (claims 21 and 22). The parties are divided as to the consequences of this.

143. Thoratec relies upon the following statement of principle by Lord Hoffmann in *Sabaf SpA v MFI Furniture Centres Ltd* [2004] UKHL 45, [2005] RPC 10:

“24. .... before you can apply s.3 and ask whether the invention involves an inventive step, you first have to decide what the invention is. In particular, you have to decide whether you are dealing with one invention or two or more inventions. Two inventions do not become one invention because they are included in the same hardware. A compact motor car may contain many inventions, each operating independently of each other but all designed to contribute to the overall goal of having a compact car. That does not make the car a single invention.

25. Section 14(5)(d) of the Act provides (following art.82 of the EPC ) that a claim shall ‘relate to one invention or to a group of inventions which are so linked as to form a single inventive concept’. Although this is a procedural requirement with which an application must comply, it does suggest that the references in the Act to an ‘invention’ (as in s.3) are to the expression of a single inventive concept and not to a collocation of separate inventions.

26. The EPO guidelines say that ‘the invention claimed must normally be considered as a whole’. But equally, one must not try to consider as a whole what are in fact two separate inventions. What the Guidelines do is to state the principle upon which you decide whether you are dealing with a single invention or not. If the two integers interact upon each other, if there is synergy between them, they constitute a single invention having a combined effect and one applies s.3 to the idea of combining them. If each integer ‘performs its own proper function independently of any of the others’, then each is for the purposes of s.3 a separate invention and it has to be applied to each one separately. ...”

144. Part G, Chapter VII-9, section 7 of the current *Guidelines for Examination in the EPO* (November 2015 edition) is to the same effect:

“... A set of technical features is regarded as a combination of features [as opposed to mere aggregation of features] if the functional interaction between the features achieved a combined technical effect which is different from, e.g, greater than, the sum of the technical effects of the individual features. In other words, the interactions of the individual features must produce a synergistic effect. If no such synergistic effect exists, there is no more than a mere aggregation of features ...”

145. On the face of the specifications, the features of claims 19-22 appear to be entirely distinct from the features of claims 1-18 and to perform their own proper function independently of the latter. In summary, claims 19-20 are directed to a rotor with an

elastic-covered framework structure made of memory material that enables the rotor forcibly to be compressed and then to unfold while claims 21-22 are directed to a pump housing formed by an elastic covered mesh made of a memory material. The advantage of these features is that they enable the rotor and pump housing to be inserted through the catheter in a compressed conformation which has a narrow diameter and to expand to a larger diameter in situ. This would appear to be useful regardless of how the rotor was driven. By contrast, claims 1-18 are directed in essence to a magnetic clutch for use with any catheter device. This would appear to be useful regardless of the nature of the rotating element at the distal end. Indeed, as noted above, claim 3 specifically covers devices in which the rotating element is a milling head or other tool.

146. Despite this, AIS contends that the skilled person would consider that the presence of both sets of features had a synergistic effect, or at least that the two interacted with each other. So far as the specification is concerned, AIS relies on [0025] (quoted in paragraph 100 above). This says that the combination of an automatically unfolding pump head with the magnetic clutch enables a high pump performance and a high life expectancy to be achieved. It does not state that the combination is a synergistic one, however. Nor, more importantly, does it explain how the two aspects interact with one another to produce these benefits.
147. Prof Antaki's evidence was that the extent to which a magnetic clutch influences pump performance due to its impact on the speed of rotation would be the same, irrespective of whether or not the rotor was foldable. Equally, the contribution of a foldable rotor to pump performance would also be the same, irrespective of how it was driven, e.g. through a drive shaft connected to the motor directly or via a magnetic clutch. Although both were beneficial, the two aspects functioned independently.
148. Counsel for AIS submitted that Prof Antaki had failed to consider in his report the combined effect of the two features upon life expectancy, as opposed to pump performance. When he was cross-examined about this, however, Prof Antaki did not accept that there was any synergistic effect on life expectancy either.
149. As explained above, AIS relied upon Dr Sieß in relation to this issue rather than Dr Gaddum. As I have said, I do not regard Dr Sieß as reliable expert witness. In any event, I found his evidence on this point unpersuasive. In his second report, he gave three reasons for saying that the combination of a magnetic clutch with all the features of claim 22 would be synergistic. First, because the expandable pump head would enable the use of a larger rotor, which would increase the flow rate, but also the torque. The magnetic clutch would avoid over-stressing the drive shaft. Secondly, because a self-expanding pump could jam when partially deployed. Again, the magnetic clutch would avoid overstressing the drive shaft. Thirdly, because both the magnetic clutch (which would avoid the need for a seal) and the expandable pump head (which could operate at a lower speed) would reduce power losses.
150. Even on its face, this evidence does not support the synergy argument in relation to claim 21 (claims 19 and 20 are not alleged by AIS to be both independently valid and infringed anyway). Furthermore, I do not find any of the three reasons convincing. So far as the first point is concerned, claim 22 does not specify the size of the rotor. In any event, any large rotating element would increase the torque. The ability of the

magnetic clutch to disengage if the set torque is exceeded is advantageous regardless of the nature of the rotating element. As to the second point, Prof Antaki explained that the failure mode of a rotor jamming was not unique to expandable pumps: all rotors (and all rotating elements) can jam in theory. Indeed, the Patents envisage (at [0143 quoted in paragraph 106 above) a situation in which they jam due to coming into contact with the walls of the heart or blood vessel. Moreover, the ability of the magnetic clutch to disengage if the set torque is exceeded is advantageous regardless of the reason why the torque is exceeded. Turning to the third point, no doubt it is correct that a magnetic clutch would lose less power than an arrangement with a seal and that a large rotor which achieves higher flow rates at lower speeds will lose less power than less efficient rotors, but these effects are independent of each other.

### The prior art

#### *The RCP*

151. As explained above, two of the items of prior art relied upon by Thoratec, namely Dekker and the prior use, concern the RCP. It is convenient to put them into context by first saying a little more about the RCP.
152. As noted above, the RCP was invented by Dr Reitan. It appears that he started work on developing the device before 1994, which is when Dr Sieß first became aware of the RCP. By 1998 em-tec GmbH, a German company, was developing a controller for the RCP. By 2000 the RCP was being marketed by Jomed AB, a Swedish company founded by Lars Sunnanväder, and its subsidiaries in other countries. Although there is no dispute that (i) Dr Reitan promoted the RCP at conferences, (ii) Jomed marketed the RCP, (iii) a number of other academic articles were published about the RCP and (iv) investigations into the potential clinical utility of the RCP continued until after the priority date, Thoratec only relies upon Dekker and upon the prior use of the RCP through the supply of an RCP, including a number of catheter units, by Jomed to Dr Dekker and his colleagues for the purposes of carrying out the work which led to Dekker. For its part, AIS contends that the prior use was confidential, but also contends that, if it was not, the skilled person would conduct a literature search for information about the RCP which would lead him to (among other things) Dekker. I will consider the latter point when dealing with obviousness.
153. Jomed became insolvent in late 2003 and the rights to the RCP were acquired by CardioBridge GmbH, in which Mr Sunnanväder was also an investor, in 2004. CardioBridge has continued to market and develop the device since then.

#### *Dekker*

154. Dekker reports an animal study comparing the efficacy of the RCP, called the “PP” in the paper, and the IABP. The study entailed short-term introduction of the device into nine calves with an induced heart condition (mitral regurgitation). The authors measured the effect of the RCP and the IABP on blood pressure and blood flow. Dekker states that the study was “financially and technically supported by Jomed”.
155. The authors introduce the RCP (at 2089) as follows:

“In 2000, the intraaortic propeller pump (PP) [Reitan catheter pump; Jomed; Helsingborg, Sweden], a new device designed to continuously reduce afterload, was developed.<sup>4</sup> It is a propeller-based pump that is placed in the high descending aorta with propeller rotational speeds of  $\leq 14,000$  revolutions per minute (rpm). Like the IABP, the aim of the intraaortic PP is to reduce pressure proximal to the pump, thereby reducing the afterload of the left ventricle. A secondary proposed benefit is the augmentation of perfusion distal to the pump. In the first human application of the PP, excellent results were reported.<sup>5</sup>”

156. It is convenient to note here that reference 4 is Ö. Reitan *et al*, “Hydrodynamic properties of a new percutaneous intra-aortic axial flow pump”, *ASAIO J*, 2000, 323–329 (“Reitan 2000”) and reference 5 is U. Lönn, “Human use of the Jomed Reitan catheter pump” in Jomed’s Annual Report 2000.

157. The RCP is described in the materials and methods section of Dekker in a subsection titled “Intraaortic PP” (at 2090-2091) as follows:

“The new intraaortic PP is a support device with a deployable propeller (Fig 2), which is driven by a flexible central driveshaft.<sup>4</sup> The other end of the driveshaft is a permanent, disk-shaped magnet, which is placed in the driving unit. The driving unit consists of a rotating magnet that can be set between zero and 14,000 rpm. The PP can only operate continuously, so no triggering is needed.

The PP is placed in the descending aorta in a position similar to the intraaortic balloon. Once this position is reached, the propeller is deployed (Fig 2) and is ready for use. A solution of 20% glucose and 5 IU/mL heparin was used at 25 mL per hour to purge and lubricate the pump.

The propeller is guarded by a basket (Fig 2), which prevents contact between the propeller and the aortic wall. However, the aorta should have a diameter of at least 21 mm to prevent stenting. For this reason, the aortic diameter was measured with fluoroscopy before insertion of the PP. In all animals, the diameter was between 21 and 24 mm.”

158. Figure 2 shows the pump head of the RCP with the propeller in its undeployed and deployed states. It does not show the “permanent, disk-shaped magnet” at the end of the drive shaft or the driving unit with its “rotating magnet”. Although Reitan 2000 includes a photograph of the drive unit (Fig 1B on 324), and describes it as containing a DC motor, it does not provide any further detail concerning the magnets.

159. In the study the authors found that the RCP reduced mean ascending aortic pressure, but without any significant increase in mean cardiac flow. It also reduced the mean diastolic coronary and carotid flow. Thus the RCP reduced the afterload in the left ventricle, but did not increase the overall cardiac output. Moreover, it reduced perfusion of the brain and heart. In contrast, the IABP improved cardiac flow, and

carotid and diastolic coronary flow. Accordingly the authors concluded that the IABP provided better circulatory support than the RCP in this animal model.

*The prior use*

160. As noted above, Thoratec relies upon the disclosure of the RCP by Jomed to Dr Dekker and his co-workers (Koen Reesink, Dr Erik van der Veen, Dr Vincent van Ommen, Gijs Geskes, Cecile Soemers and Dr Jos Maessen) for the purposes of carrying out the study reported in Dekker in 2001-2002. At the time, Dr Dekker and his colleagues were all employed by MUH.
161. By the end of the trial, there was no serious dispute as to the construction of the RCP which was the subject of the prior use. Like the Hemopump, the RCP had a disposable catheter unit incorporating a pump head and drive cable and a reusable extracorporeal drive unit. In use, the drive cable was magnetically coupled to the drive unit. There was a ring of six magnets behind the end wall of the catheter unit which were driven by corresponding magnets in the drive unit. Thus the two magnet units formed a magnetic clutch separated by a wall. The RCP also incorporated a purge system. All of these features would have been apparent to a skilled person in the position of Dr Dekker and his colleagues.
162. It is common ground that the legal burden lies on the party relying on a prior use of a product to establish that the prior use made the construction of the product in question (so far as relevant) available to the public, but that the evidential burden of establishing confidentiality may shift to the other party: see *Dunlop Holdings Ltd's Application* [1979] RPC 523.
163. In the present case, AIS does not allege that Dr Dekker and his colleagues were subject to any express obligation of confidence, but it contends that they were subject to an implied obligation of confidence under Dutch law.
164. The relevant principles of Dutch law may be summarised as follows:
  - i) Like English law, Dutch law recognises that duties of confidence can arise not only from express agreements, but also impliedly from the circumstances in which information is obtained or received.
  - ii) The test is an objective one.
  - iii) There is, in general, a rebuttable *prima facie* presumption that research carried out by a university or other academic institution for a third party is confidential.
  - iv) In determining whether that presumption has been rebutted, all the relevant circumstances are to be taken into account, including any documentary evidence available as to the terms under which the institution undertook to perform the work and the testimony of witnesses.
165. There is no documentary evidence as to the terms on which Dr Dekker and his colleagues carried out the study reported in Dekker. The available evidence falls into the following categories. First, there is the testimony of Dr Dekker. He is the only

person who gave oral evidence with first-hand knowledge of the relevant circumstances. Secondly, there is the hearsay evidence of Dr Reitan. Thirdly, there is the evidence of Messrs Ferrari, Friedel, Schumacher and Sieß. As I will explain, however, none of these witness was involved in, or had any direct knowledge of, the relevant circumstances. Fourthly, there is a body of circumstantial documentary evidence.

166. Before turning to analyse the evidence, it is important to stress that what matters for present purposes is whether the arrangement of the magnetic coupling in the RCP (not precise details of the magnets, dimensions or tolerances etc) was made available to the public. Accordingly, the key question is whether Dr Dekker and his colleagues were free to disclose that information to others, or whether they were subject to an implied obligation to keep it confidential.
167. Dr Dekker explained that, at the time, he was working on his PhD thesis under the supervision of Dr van der Veen. Dr van der Veen's group had established a laboratory which was equipped to carry out studies of the effect of medical devices on heart function in animals such as those reported in Dekker and had established a reputation for carrying out such work. As a result, Dr van der Veen was frequently approached by medical device companies who wanted studies to be carried out. The group's general practice was to publish the results of their experiments in the scientific literature. In the case of the study of the RCP, this was not only intended to be published, but also to form part of Dr Dekker's PhD thesis. It was academic work, and not a consultancy project. Thus the design of the study was carried out by the group, as well as the actual experiments. Prior to publication in *Chest*, the group presented a poster on the work at the European Society of Cardiology conference in Berlin in 2002. Since the results of the study were not very positive for the RCP, Dr Dekker believed that it was likely that someone had shown Dr Reitan or Jomed the results before publication; but he was not aware that either Dr Reitan or Jomed had ever objected to publication. Dr Dekker was very clear that he did not sign any confidentiality agreement, was not told that the work was confidential and did not consider that it was confidential.
168. Dr Dekker's evidence is supported by the contents of Dekker. While this acknowledges financial and technical support from Jomed, it contains details of the pump head, some information about the drive unit (which is slightly amplified by the reference to Reitan 2000) and details of the results of the experiments. This is hardly suggestive of confidentiality.
169. Counsel for AIS relied upon Dr Dekker's acceptance during cross-examination that he would have considered it wrong if a stranger had come into the lab and copied all the raw data from the experiments. I am not impressed with this point, for a number of reasons. First, Dr Dekker said that the reason for this was the information was "our property" i.e. the van der Veen group's property, not Jomed's or Dr Reitan's. Secondly, and consistently with this, Dr Dekker went on to say that he would have felt free to hand the data to someone else if he thought they would make better use of it. Thirdly, I understood Dr Dekker's answer to relate to the position prior to the publication of the paper, not afterwards. Fourthly, even if the data from the experiments was confidential, it does not necessarily follow that the arrangement of the magnetic couplings was. (I should add that, of course, even if the data from the



experiments was not confidential, it does not necessarily follow that the arrangement of the magnetic couplings was not.)

170. Counsel for AIS also relied upon Dr Dekker's evidence that, nowadays, it is common practice to include express provisions in the agreements covering such studies allowing a window of time for the sponsor to apply for patent protection if they wished. Again I am not impressed with this point, for a number of reasons. First, Dr Dekker was clear that, in this respect, practice had changed since 2001-2002. Secondly, Dr Dekker was also clear that, where such provisions were included, anything which was not expressly designated confidential was not confidential and that the same applied in the absence of such provisions. Thirdly, it is commonplace for information to be confidential for a limited period of time although intended to be, and in fact, made public later. Examples include stock market announcements and draft judgments of English courts. Once made public, the information ceases to be confidential. Fourthly, again this is about the results of the experiments, not the arrangement of the magnetic coupling.

171. Turning to the hearsay evidence of Dr Reitan, the relevant part of the attendance note reads as follows:

“[Dr Reitan] indicated that Jomed was not hiding anything about the product in 2001. In fact they had already patented everything they thought was inventive (he did not think that was the case with the drive unit) and that they were really trying to generate interest in the product.

They had been demonstrating the RCP at conferences since 1997. At these conferences people could have looked at, picked up and inspected the product.

At the time the interesting aspect of the product was the pump head. This was the focus of the exhibitions and conferences.”

172. This evidence is clearly supportive of Dr Dekker's evidence that the supply of the RCP by Jomed to the van der Veen group was not subject to any obligation of confidentiality, and in particular that the arrangement of the magnetic coupling was not confidential.

173. As for the evidence of Messrs Ferrari, Friedel, Schumacher and Sieß, this mainly concerned dealings between Abiomed, ECP, em-Tec and CardioBridge relating to the RCP at various times between 2005 and 2012. This evidence has no direct bearing on the supply of the RCP by Jomed to the van der Veen group in 2001-2002, and therefore I do not propose to go into details concerning it. Nevertheless, some of Dr Sieß's evidence supports the evidence of Dr Dekker and Dr Reitan. Thus Dr Sieß gave evidence that Jomed was “aggressive in its marketing” of the RCP, including making flyers available, although he said that the information they made public was “focussed on the pump head as opposed to any of the inner workings of the device and its drive system”. Dr Sieß also gave evidence that Dr Reitan attended conferences prior to 2000, attempting to attract interest in the RCP. This involved Dr Reitan or a representative giving a short talk during a conference session and showing the device at a booth. Dr Sieß recalled that Dr Reitan claimed that the RCP performed better than

the IABP. He had been informed that Dr Reitan would demonstrate his device in a tank of water, but he had not seen this himself. Similarly, Dr Ferrari gave evidence that Dr Reitan was an enthusiast for his device and went around trying to interest anyone who would listen.

174. Finally, there is the circumstantial evidence provided by a number of documents in evidence. This can also be divided into four categories. First, it appears from a review of the patent literature that is in evidence that Dr Reitan obtained US Patent No. 5,749,855 in respect of the pump head of the RCP, which was granted in 1998. This supports Dr Reitan's evidence quoted above that he had already patented anything he thought worth patenting prior to 2001.
175. Secondly, there are a number of academic papers concerning the RCP which were published both before and after Dekker. These include: Ö. Reitan *et al.*, "Initial Tests with a New Cardiac Device", 1999, *ASAIO J*, 317-32, which includes photographs of the pump head and of the assembled pump-catheter-motor system (albeit that this does not show the magnets); Reitan 2000; Ö. Reitan *et al.* "First Human Use of the Reitan Catheter Pump", *ASAIO Cardiopulmonary Abstracts*, 2001, 124 ("Reitan 2001"); Ö. Reitan *et al.* "Hemodynamic Effects of a New Percutaneous Circulatory Support Device in a Left Ventricular Failure Model", *ASAIO J*, 2003, 731-736 ("Reitan 2003") which states that it was presented at the annual ASAIO conference in New York in 2000 and includes a photograph of the pump head in both states and of what is described as the "catheter with the drive coupling" (albeit that this does not show the magnets); and E.J. Smith *et al.*, "A First-in-Man Study of the Reitan Catheter Pump for Circulatory Support in Patients Undergoing High-Risk Percutaneous Coronary Intervention", *Catheterization and Cardiovascular Interventions*, 2009, 859-865 ("Smith"), which reports on a study on 10 patients between March and August 2007.
176. Thirdly, there is a presentation about the RCP given by Professor Martin Rothman of the London Chest Hospital, a leading interventional cardiologist, at the Transcatheter Cardiovascular Therapeutics Congress in Washington DC, USA in October 2006, which includes photographs of the pump head and catheter unit and of the "drive unit coupling the catheter to the console" (albeit not the magnets) as well as reviewing some of the literature and looking forward to the study published in Smith.
177. Fourthly, there are a number of documents published by Jomed. These include: Jomed's Annual Report 2000 (reference 5 in Dekker), which includes a photograph of the pump head; a flyer published at the European Association for Cardio-Thoracic Surgery conference in Lisbon in September 2001 inviting readers to come and visit Jomed's booth, which refers to the device being "on display" and which includes a photograph of the pump head; and two brochures for the RCP which, although undated, must date from before the end of 2003, which explicitly state that the catheter is connected to the drive unit by means of "a magnetic coupling" and which include photographs of the pump head and drive unit (albeit not the magnets).
178. In my judgment, considered as a whole, the evidence firmly rebuts any presumption that the supply of the RCP by Jomed to Dr Dekker and his colleagues was subject to an implied obligation of confidentiality. In particular, I am satisfied that the arrangement of the magnetic coupling was not confidential.

*Sieß*

179. As noted above, this is Dr Siëß's PhD thesis, which dates from 1999. It is entitled "System Analysis and Development of Intravascular Rotation Pumps for Cardiac Assist". The thesis has 14 chapters, but Thoratec only relies on Chapters 1 – 3, which contain (1) an introduction, (2) a review of the Hemopump system and (3) an analysis of possible designs for a new device.
180. Chapter 1 introduces the project as follows:

"Only since the 'Hemopump' catheter pump introduced by Richard Wampler in 1989, which works based on the rotation pump principle, an intravascular blood pump is clinically available which can substantively relieve the left heart. With the Hemopump, for the first time, it was proven that a fast-spinning rotation pump damages blood only within physiologically reasonable limits, despite the high pump-specific shear rate. The prevailing doctrine – that only slowly running radial pumps with comparably large impellers are suitable for blood transport – had to be revised after that.

In 1994, the Hemopump microaxial pump system, which is extensively suitable for left ventricular assist, completed its first clinical trial phase. The interim euphoria of having discovered a universal pump concept for cardiac assist has meanwhile given way to a more realistic evaluation of the capabilities and system-specific restrictions. In particular, the powering of the pump head via a flexible and breakable shaft as well as the flow rate, which at approximately 2.5l/min is too low at this point in time, and the diameter of the pump head, which at 7.4mm is too large for the placement of the pump through peripheral vessels, together with the long time required for putting it into action have prevented a wide acceptance of the pump in clinical routine.

Based on these system-specific disadvantages and limitations of the Hemopump system described in the literature, an improved concept of intravascular microaxial blood pumps for temporary cardiac assist is pursued at the Helmholtz Institute for Biomedical Engineering in Aachen."

181. It goes on to describe how the improved concept under consideration by the author differs from the Hemopump, in particular by the use of a drive unit connected directly to the pump unit, thus eliminating the need for a flexible drive cable.
182. In Chapter 2, Siëß describes the Hemopump, including the Hp21, Hp31 and Hp14 models, and sets out a thorough analysis of its advantages and disadvantages. At the end of Chapter 2, in section 2.4, Siëß summarises the requirements for an improved percutaneously-insertable system, beginning as follows (at page 9):

“A pump insertable via the periphery may not significantly exceed a diameter of 6mm. In addition, the length of the rigid pump part has to be restricted to approx. 30mm, in order to enable an insertion of the pump via bent peripheral vessels. To avoid the disadvantages resulting from the flexible shaft, the drive unit is to be integrated directly into the pump.”

183. Chapter 3 describes and analyses a number of possible designs for an improved device. The first part describes the manner of transmitting torque to the impeller via an integrated motor. It is explained (on page 12) that the motor is situated “behind” the pump for better heat dissipation i.e. the motor is at the proximal end of the assembly, and the pump is at the distal end. Sieß emphasises the importance of preventing blood from entering the mechanical components of the pump and identifies two approaches to address this requirement, schematically illustrated in Figure 3.1.
184. These two approaches are described as “magnetostatic” and “form locking”. The latter refers to the use of a shaft that directly connects the motor to the impeller. This approach requires a seal to separate the wet and dry sides of the system. This is contrasted with the magnetostatic approach, in which there is a physical divide between the “driving” side and the “rear” side. Torque is transmitted by magnetic force between juxtaposed magnets positioned on the end of the motor and the rotor. In the figure, it is clear that these magnets form an axial gap. The assemblage of the two magnets is described as a “magnetic coupling”.
185. Section 3.1 of Chapter 3 provides a more detailed analysis of the magnetic coupling. Two arrangements of the two sets of magnets in the coupling are described, namely a face-to-face “disk” configuration and a concentric “ring” configuration. These are depicted schematically in Figure 3.2 (see paragraph 87 above). Sieß identifies the advantages and disadvantages of each type of coupling. The face-to-face disk type is said to be relatively simple to construct, but it generates an axial thrust which has to be absorbed by the bearings. The concentric ring type is said to be practically free of such axial force. Devices having both types of magnetic coupling are illustrated in Fig 3.6 of Sieß.
186. The remainder of Chapter 3 describes four concepts, labelled Concepts I to IV. Concepts I-III employ magnetic couplings, whereas Concept IV employs a direct connection from the shaft to the motor. Having described each concept, the chapter sets out a tabular comparison of their characteristics. It can be seen that each has advantages and disadvantages. Sieß concludes:

“For short term use, concept IV is most suitable, since based on its structure it is the shortest system with the highest hydraulic output at the lowest complexity (lip seal).”

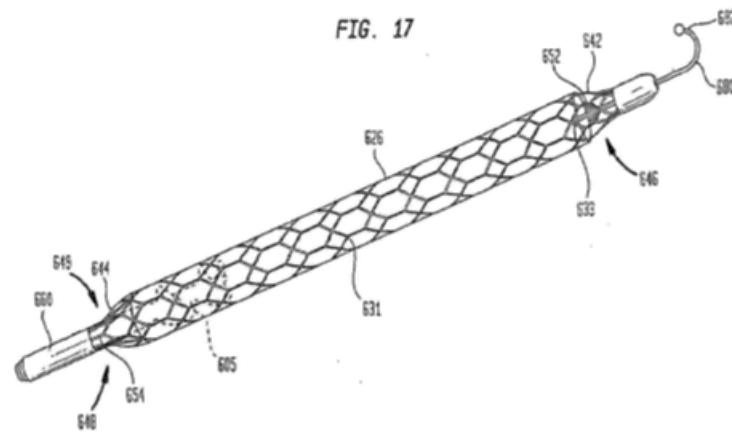
*Johnson & Johnson*

187. This is a document entitled *Compendium of Technical and Scientific Information for the HEMOPUMP Temporary Cardiac Assist System* published by Johnson & Johnson Interventional Systems Inc in 1998. It describes the design, operation and

performance of the Hemopump in a reasonable level of detail, but the description is both less detailed and less up-to-date than that in Sieß.

*McBride*

188. This is International Patent Application No. WO 2007/112033 entitled “Heart assist device with expandable impeller pump” published on 4 October 2007, that is to say, four days before the priority date. It discloses a catheter-based VAD with an expandable impeller inside an expandable cannula comprising a mesh with an elastomeric covering. The cannula is shown schematically in the expanded state in Figure 17 of McBride reproduced below (note that the impeller 605 is indicated by the faint dotted lines).



189. McBride describes the expandable impeller and expandable cannula as follows:

“[0127] In some embodiments, an expandable impeller is used together with a cannula which may or may not have an expandable portion. If the impeller is not stored in an expandable portion, the impeller must be moved axially for expansion to its deployed configuration. If the impeller is stored in an expandable cannula or in an expandable portion of a cannula, the impeller expands into its deployed configuration with the expansion of the cannula.

[0128] For example, a cannula may be provided that has expandable and non-expandable portions, and the impeller may be stored within, or proximate to, the non-expandable portion. The impeller can be urged out of the non-expandable portion of the cannula into an expanded portion of the cannula. The stored potential energy within the flexible blades of the impeller would then induce self-deployment of the impeller, and the cannula may also self-expand through stored potential energy. The expanded cannula then may have the role of a fluid

conduit through which fluid flows when the impeller is rotated. An example of such system is blood pump 600 described below. ....”

190. McBride also specifically discloses such a device being driven by an extracorporeal motor and lubricated with a purge fluid. The connection with the motor is described in very general terms at [0153] as follows:

“A rotatable drive shaft 630 provides rotational coupling between a motor (not shown), located outside of the patient, and the impeller 605. Drive shaft 630 may have a substantially rigid portion 632 at its distal end which is connected to impeller 605, and a substantially flexible portion 634. The flexible portion 634 of the drive shaft may be housed within a flexible tube 638 which supports the flexible portion and maintains its shape as it is driven rotationally. The proximal end of drive shaft 630 may be connected to the motor for rotating the drive shaft and with it impeller 605. Alternatively, drive shaft 630 may be omitted, and the electric power may be provided through a proximal portion of the assembly to operate a pump motor and impeller 605.”

#### Novelty of claims 1 and 5

##### *Dekker*

191. Thoratec contends that claims 1 and 5 lack novelty over Dekker. AIS disputes this. The issue is whether Dekker discloses that the PP has a magnetic clutch with proximal and distal magnet units physically separated by a wall. All that Dekker says about the connection between the driveshaft and the drive unit is the following:

“The other end of the driveshaft is a permanent, disk-shaped magnet, which is placed in the driving unit. The driving unit consists of a rotating magnet ...”

192. Prof Antaki’s evidence was that the skilled person would interpret this in the light of his common general knowledge, and in particular his knowledge of devices such as the BioPump, as describing a magnetic clutch. Dr Gaddum’s evidence was that the skilled person would find this description unclear. Taking the expressions “a permanent, disk-shaped magnet” and “a rotating magnet” literally, however, Dr Gaddum concluded that the skilled person would interpret it as disclosing a direct, friction coupling between the two magnets. He accepted that this was not an arrangement that the skilled person would have encountered in the field of VADs before. The essential difference between the two witnesses was that Prof Antaki did not think that the skilled person would interpret the expressions “a permanent, disk-shaped magnet” and “a rotating magnet” literally as meaning a single magnet with axially-aligned poles in each case, but rather would interpret them as referring to a magnet or magnet unit with radially-segmented poles.
193. In order to anticipate claims 1 and 5, Dekker must clearly and unmistakably disclose a magnetic clutch. In my judgment, it does not. Although the skilled reader would

consider it more likely that the arrangement being described was a magnetic clutch rather than a friction coupling, he would not be sure. Counsel for Thoratec ingeniously argued that, if the disclosure was ambiguous, it disclosed both possibilities, but I do not accept this argument.

#### *The prior use*

194. It is common ground that, if, as I have concluded, it was not confidential, the prior use of the RCP deprives claims 1 and 5 of novelty.

#### Obviousness of claim 1

195. I shall consider the obviousness of claim 1 on the assumptions that, as I have concluded, claim 1 is novel over Dekker and that, contrary to my conclusion, the prior use was confidential and thus not available as prior art.

#### *General considerations*

196. As always, the question of obviousness must be considered from the perspective of the skilled person and without hindsight. The skilled person reads the cited prior art in the light of the common general knowledge. It is important to identify the context in which the skilled person is deemed to read the prior art. In the present case, this has two main aspects to it. The first consists of the attitudes and perceptions of the skilled person. The second consists of the skilled person's approach to the design of a VAD.

197. *The attitudes and perceptions of the skilled person.* AIS relies heavily on three points with respect to the attitudes and perceptions of the skilled person which I would summarise as follows. First, the skilled person would know that the vast majority of VADs were extracorporeal or implantable devices. Secondly, the skilled person would only be familiar with two catheter-based devices from his common general knowledge, namely the Hemopump and the Impella. Thirdly, the skilled person would be aware of the successive generations of VADs, and thus would consider that the "direction of travel" in the art was towards devices incorporating brushless motors, and in particular maglev devices.

198. I did not understand counsel for Thoratec to take issue with the first two points, and in any event they follow from my findings as to the common general knowledge. Counsel for Thoratec did, however, take issue with the third point, at least if pressed too far. He did not dispute that the skilled person would be aware of the different generations, that many second and third generation devices incorporated brushless motors and that the third generation devices were maglev ones. As he submitted, however, it does not follow that the skilled person would have no interest in catheter-based devices.

199. In fact, as counsel for Thoratec submitted, the evidence shows that at least seven groups were working on catheter-based VADs, most of which were extracorporeally-driven, in the years before the priority date:

- i) Dr Sieß and his collaborators, who were working on the Impella.
- ii) Dr Reitan and his collaborators, who were working on the RCP.

- iii) McBride and his collaborators, some of whom were based at Penn State Research University.
  - iv) A-Med Inc, which developed a device similar in many respects to the Hemopump. The successful first use of the A-Med device in man was reported in M. Ferrari *et al*, “Successful High-Risk Coronary Angioplasty in a Patient with Cardiogenic Shock Under Circulatory Assist with a 16F Axial Flow Pump”, *Catheterization and Cardiovascular Interventions*, 2005, 557-561, although it did not achieve clinical acceptance in the longer term. Dr Ferrari agreed that his paper showed that there was considerable interest in devices of this kind in the mid 2000s.
  - v) Amy Throckmorton and her collaborators, who were based variously at Virginia Commonwealth University, Indiana University School of Medicine, University of Louisville and Purdue University. They developed a device with some similarities to the Hemopump, but with a foldable propeller with some similarities to that of the RCP, in order to treat patients with single functional ventricles: see A.L. Throckmorton *et al*, “Mechanical Cavopulmonary Assist for the Univentricular Fontan Circulation Using a Novel Folding Propeller Blood Pump”, *ASAIO J*, 2007, 734-741.
  - vi) Terumo Cardiovascular Systems Corp patented a catheter-based pump and stated that it could suitably be driven by a maglev drive: see US Patent No 6,245,007 (2001), in particular at column 8.
  - vii) Khaw and Li patented a similar device: see US Patent No. 6,981,942 (2006).
200. Furthermore, Dr Gaddum accepted that a catheter-based, extracorporeally driven device was something that the skilled person would have thought worth pursuing.
201. *The skilled person’s approach.* Turning to the second question in paragraph 196 above, Thoratec posits a skilled person who is interested in developing a catheter-based, externally-driven VAD. For the reasons outlined above, I agree with Thoratec that this is not merely a permissible, but also a realistic, starting point for consideration of the prior art. In any event, counsel for AIS was constrained to accept in his closing submissions that the development of such a VAD would be obvious. There is no dispute that such a device would be likely to have a purge system.
202. Counsel for AIS argued that, even on that hypothesis, the skilled person would simply develop the Hemopump, and in particular would not change the brushless motor arrangement, which the experts agreed would be perceived as an elegant solution. There is no reason why the skilled person would feel constrained to use a brushless motor, however, particularly given that the skilled person would also be familiar with the Impella. On the contrary, it is clear from the evidence of both Prof Antaki and Dr Gaddum that the skilled person would appreciate from his common general knowledge that another obvious option would be to use a conventional DC motor and a magnetic coupling of the kind employed in the BioPump, which would also enable the “wet” side of the device to be hermetically sealed from the “dry” side. Counsel for AIS submitted that that would be perceived as old-fashioned technology, but this simply confirms that its use would not require invention. I shall return to this point below.



203. *Unpleaded case based on common general knowledge alone?* Counsel for AIS submitted that Thoratec's case on obviousness as presented at trial amounted to an unpleaded case of obviousness based on common general knowledge alone. Although he did not go so far as to submit that the case was not open to Thoratec, he did remind me of the considerable caution which needs to be exercised before accepting a case advanced on that basis. Counsel for Thoratec disputed that he was advancing a case of obviousness over common general alone, although he accepted that some of the cited prior art amounted to specific instances of the application of the common general knowledge regarding magnetic couplings. I accept that characterisation of Thoratec's case.
204. *Long-felt want?* A separate general matter which is convenient to consider here is that counsel for AIS submitted that the claimed invention had satisfied a long-felt want in the art and that this was secondary evidence of inventiveness, particularly given the age of the prior art relied upon. As counsel for Thoratec pointed out, however, AIS accepts that the RCP fell within claims 1 and 5 several years before the priority date, even though AIS contends that the prior use relied upon by Thoratec was confidential. Moreover, Dr Reitan's evidence indicates that he did not consider that the magnetic clutch was inventive. Thus the secondary evidence is supportive of a conclusion of obviousness, not inventiveness. I would add that, although the evidence shows that there was a long-standing demand for VADs of all kinds, including for acute, short-term use, it does not show the demand was satisfied by a device in accordance with the claimed inventions. Indeed, for reasons that will appear, it is implicit in AIS's case on Dekker and the prior use that it was not satisfied by the RCP.

*Dekker*

205. Thoratec's case on the obviousness of claim 1 over Dekker goes back to the question of what Dekker discloses to the skilled reader. I have concluded that the skilled person would consider it more likely that the arrangement being described was a magnetic clutch than that it was a friction coupling, but would not be sure. On that basis, Thoratec contends that an obvious way to interpret the disclosure, and an obvious way to implement it if so desired, would be as teaching the use of a magnetic clutch. Counsel for AIS had no real answer to this argument, and I accept it. Accordingly, I conclude that claim 1 is obvious over Dekker.

*Sieß*

206. Thoratec's case of obviousness of claim 1 over Siëß starts with a skilled person who is interested in developing a catheter-based, externally-driven VAD with a purge system, but who has not yet decided how to couple the drive shaft to the motor. Thoratec contends that, although the skilled person would be aware of the possibility of using a magnetic coupling from the common general knowledge, Siëß sets out very clearly the advantages (and disadvantages) of a magnetic coupling and the two main possible arrangements of the magnets in such a coupling. Furthermore, the skilled reader of Siëß would appreciate that one of the advantages of using a magnetic coupling was that it would enable him to use a conventional, simple, inexpensive, off-the-shelf DC motor rather than the more expensive and intricate brushless motor arrangement of the Hemopump. Once the skilled person decided to adopt that approach, they would rapidly arrive at claim 1.

207. AIS's main answer to this case (apart from its reliance upon the attitudes and perceptions of the skilled person as discussed above) is that Sieß concludes that concept IV is preferable to concepts I-III, and thus teaches away from using a magnetic coupling. As Thoratec points out, however, concept IV involves a miniature intracorporeal motor. Moreover, Sieß teaches the skilled reader that, while concept IV is considered to be most advantageous overall, the other concepts also have certain advantages. I therefore conclude that Sieß would have made it obvious to adopt a magnetic coupling for an extracorporeal motor, and hence to arrive at claim 1, as Thoratec contends.

*Johnson & Johnson*

208. Given that Sieß both contains a better description of the Hemopump and describes a magnetic coupling in more detail, Johnson & Johnson adds nothing to Thoratec's case over Sieß which I have accepted. If it were to be accepted that Sieß taught away from using a magnetic coupling as AIS argues, however, then in my judgment claim 1 would remain obvious over Johnson & Johnson. Although the Hemopump and magnetic coupling are described in less detail, the essence of the arrangement is disclosed.

*McBride*

209. Thoratec puts its case of obviousness over McBride in two different ways. At this stage I will consider the first of these.
210. As is common ground, McBride discloses a catheter-based VAD driven by an extracorporeal motor and a purge system, but it does not specify how the drive shaft is connected to the motor. Thus it does not disclose the magnetic clutch of claim 1.
211. Thoratec contends that an obvious option for the skilled person who was interested in developing McBride's design of pump for use in a catheter-based, extracorporeally-driven VAD would be to use a magnetic coupling, which again would lead him to claim 1. This is supported by the evidence of both Prof Antaki and Dr Gaddum. AIS's only answer to this case is to argue that the skilled person would consider that McBride was envisaging a direct coupling. Thoratec accepts that that would be another obvious option, but contends that it does not detract from the obviousness of a magnetic coupling. I agree with this. Accordingly, I conclude that claim 1 is obvious over McBride.

Obviousness of the subsidiary claims

*Dekker*

212. It is common ground that claim 5 stands or falls with claim 1 over Dekker. Since I have concluded that claim 1 is obvious over Dekker, claim 5 is also obvious.
213. AIS contends that Dekker does not render any of the other claims obvious, however, since the skilled person would not regard Dekker as a suitable starting point for development. This is for three reasons. First, the skilled person would not regard the propeller as a suitable type of axial flow pump. Secondly, the skilled person would not consider it sensible to place the device in the descending aorta, because of the risk

that it would reduce flow to the brain and heart. Thirdly, the skilled person would regard the results reported in Dekker as confirming that it was not a good idea, and more generally as showing that the device was inferior to the IABP.

214. Prof Antaki largely accepted each of these points, but nevertheless did not agree that the skilled person would be deterred from treating Dekker as a starting point for development. His main reasons for this were that the placement of the device described in Dekker would eliminate the risk of thrombosis and stroke and that the problem of coronary and carotid perfusion could be solved by slowing the speed of the pump during the diastolic phase of the cardiac cycle. He did not accept the suggestion that the skilled person would think that the risk of embolism was a risk which had already been eliminated by the third generation of VADs, and in any event it was common ground between Prof Antaki and Dr Gaddum that second generation devices (such as the RCP) did present a real risk of stroke. Dr Gaddum supported AIS's case on these points, but nevertheless he volunteered during cross-examination that the device did show promise for the treatment of singular ventricular patients in the manner that Throckmorton *et al* had subsequently done.
215. I do not accept AIS's argument that Dekker would not be considered as a suitable starting point for development for three reasons. First, even if the question is whether the whole device and placement disclosed in Dekker would be regarded as a suitable starting point, as Dr Gaddum's evidence demonstrates, this would depend on what clinical application the skilled person had in mind. For at least one clinical application, it would be regarded as suitable.
216. Secondly, even if one disregards the rather specialised application suggested by Dr Gaddum, the historical record shows that Dekker was not the end of the line for the RCP. On the contrary, as noted above, it continued to be the subject of investigation up to and beyond the priority date. Indeed, the device was favourably presented by Prof Rothman in his 2006 presentation (albeit that he did not mention the findings in Dekker), in which he mentioned that there was to be a Medical and Healthcare Products Regulatory Agency-approved study of the RCP in 10 patients. This is the study that was subsequently reported in Smith. (For the avoidance of doubt, I am not suggesting that the skilled person would have known of, or found, Prof Rothman's presentation, let alone Smith.)
217. Thirdly, in my view, the right question is not whether the whole device and placement disclosed in Dekker would be regarded as a suitable starting point for development, but whether the catheter and its connection to the drive unit would be. Given the propensity to mix and match in this field, I consider that the skilled person would take inspiration from Dekker in that regard even if he did not regard the pump head and its placement in the descending aorta as good ideas.
218. So far as claim 7 is concerned, Prof Antaki's opinion was that there was nothing inventive about using a profiled rod for this purpose, and Dr Gaddum accepted this in cross-examination. Accordingly, I conclude that claim 7 is obvious over Dekker.
219. Turning to claim 8, it will be recalled that I have accepted AIS's broad construction of "sliding bearing". Dr Gaddum accepted that two obvious options for axially supporting a magnet would be to use either a radial bearing or a pivot bearing. Accordingly, I conclude that claim 8 is obvious over Dekker.

220. Thoratec does not contend that claims 21 and 22 are obvious over Dekker.

*The prior use*

221. AIS contends that the skilled person would not regard the RCP as a suitable starting point for development because the skilled person would conduct a literature search and find Dekker, which would put them off. I do not accept this argument for the following reasons. First, there is no evidence that a skilled person who was simply interested in the connection between the catheter and the drive unit in the RCP would conduct a literature search of the kind postulated by AIS, and I do not accept that he would. Secondly, if the skilled person did conduct a literature search, they would not only find Dekker, but also the other articles concerning the RCP such as Reitan 2003. They would conclude from the literature that the RCP was regarded as having potential notwithstanding the results in Dekker. Thirdly, I do not accept that Dekker would put the skilled person off anyway for the reasons given above. The last of those reasons have particular force when one comes to the prior use, because, unlike Dekker, the prior use discloses the arrangement of the magnets.

222. I consider that claims 7 and 8 are obvious over the prior use for the same reasons as I have given in relation to Dekker. Thoratec does not contend that claims 21 and 22 are obvious over the prior use.

*Sieß and Johnson & Johnson*

223. I do not understand there to be any real dispute that, if claim 1 is obvious over Siëß or Johnson & Johnson, then so too is claim 5. I consider that claims 7 and 8 are also obvious for the same reasons as I have given in relation to Dekker. Thoratec does not contend that claims 21 and 22 are obvious over Siëß or Johnson & Johnson.

*McBride*

224. It is common ground that claim 5 stands or falls with claim 1 over McBride, and so claim 5 is also obvious over McBride. I consider that claims 7 and 8 are obvious for the same reasons as in relation to Dekker. It is also common ground that McBride discloses the features of claims 21 and 22. Accordingly, claims 21 and 22 are obvious over McBride.

225. If, as I have concluded, the inventions of claims 21 and 22 are separate inventions to the inventions of claims 1, 5, 7 and 8, it follows that Thoratec is entitled to attack each set of inventions from separate starting points, namely Dekker/the prior use/Sieß/Johnson & Johnson in the case of claims 1, 5, 7 and 8 and McBride in the case of claims 21 and 22. This is the second way in which Thoratec puts its case of obviousness over McBride. I agree with Thoratec that claims 21 and 22 are also obvious over McBride on this basis.

Insufficiency

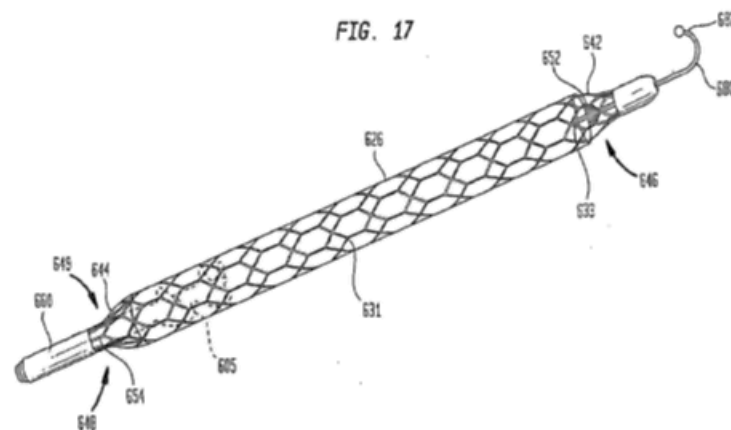
226. Thoratec argues that, if the claims are construed as AIS contends, then they are insufficient. I disagree with this for the reasons given by counsel for AIS. It is unnecessary to lengthen this judgment further by elaborating.

### Amendment of 658

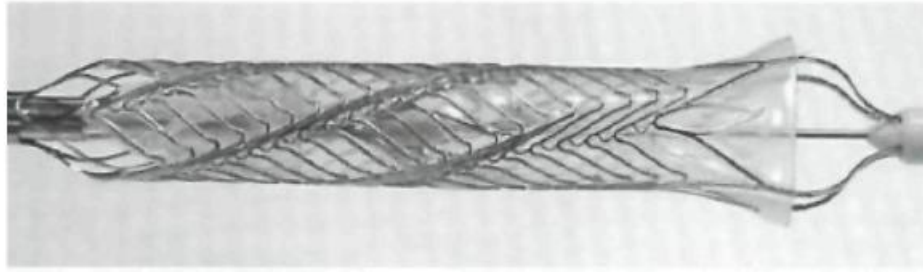
227. Since the proposed amendments would not save the validity of 658, it is unnecessary to consider AIS's amendment application. I will say, however, that I disagree with Thoratec's contentions that the amendments to claim 1 would add matter or result in the claim being insufficient for the reasons given by counsel for AIS. I agree with Thoratec that it would not be permissible to introduce new claim 2 as a new dependent claim, but it would be open to AIS to introduce the features of that claim into claim 1 if needed.

### Infringement

228. As explained above, Thoratec claims a declaration of non-infringement in respect of the HeartMate PHP. This is described in Thoratec's Product Description which has been amplified by further information provided by Thoratec in responses to requests from AIS. It is not necessary for present purposes to describe the HeartMate PHP in detail. It suffices to note the following. In general terms, it is a catheter-based device with an extracorporeal motor. The pump consists of an expandable impeller in a stent-like cannula. The pump is driven by a drive cable which is magnetically coupled to the motor.
229. The magnetic coupling comprises concentric driver and follower magnet units separated by a cylindrical surface as shown (disassembled) in Figure 6B of the Product Description reproduced below.



230. The follower magnet is mounted on a stainless steel core. The stainless steel core is welded to an adapter shaft which is mounted on two journal bearings so that it can rotate.
231. The cannula consists of a nitinol support coated in Thoralon polymer. It is depicted in expanded form in Figure 3 of the Product Description reproduced below.



232. *Claim 1.* The only issue is whether the HeartMate PHP has “proximal” and “distal” magnet units. As I have construed the claim, it does.
233. *Claim 5.* I do not understand it to be in dispute that, if claim 1 is infringed, then so too is claim 5.
234. *Claim 8.* The issue is whether the HeartMate PHP has a “sliding bearing”. As I have construed that expression, it has two, namely the two journal bearings.
235. *Claim 21.* The issue is whether the HeartMate PHP has a pump housing formed by a “mesh”. As I have construed that expression, it does.
236. *Claim 22.* There is no dispute that, if claim 21 is infringed, then so too is claim 22.

#### Summary of principal conclusions

237. For the reasons given above, I conclude that:
- i) none of the claims lacks novelty over Dekker;
  - ii) claims 1 and 5 of 872 (claims 1 and 4 of 658) lack novelty over the prior use;
  - iii) claims 1, 5, 7 and 8 of 872 (claims 1, 4, 6 and 7 of 658) are obvious over Dekker;
  - iv) claims 7 and 8 of 782 (claims 6 and 7 of 658) are obvious over the prior use;
  - v) claims 1, 5, 7 and 8 of 872 (claims 1, 4, 6 and 7 of 658) are obvious over Sieß and Johnson & Johnson;
  - vi) claims 1, 5, 7, 8, 21 and 22 of 872 (claims 1, 4, 6 and 7 of 658) are obvious over McBride; and
  - vii) claims 1, 5, 8, 21 and 22 of 872 (claims 1, 4 and 7 of 658) would be infringed by the HeartMate PHP if they were valid.