UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ABIOMED, INC., **Plaintiff/Counter-Defendant,** **v.** **MAQUET CARDIOVASCULAR LLC,** **Defendant/Third-Party Plaintiff/Counter-Defendant/ Counter-Claimant,** **v.** **ABIOMED EUROPE GMBH,** **Third-Party Defendant,** **v.** **ABIOMED R&D, INC.,** **Third-Party Defendant/ Counter-Claimant.**	**Civil Action No. 16-10914-FDS**

MEMORANDUM AND ORDER ON ABIOMED'S MOTION FOR PARTIAL SUMMARY JUDGMENT AS TO INVALIDITY

SAYLOR, C.J.

This is an action for patent infringement. Defendant and counterclaim-plaintiff Maquet Cardiovascular LLC owns six patents directed to guidable intravascular blood pumps and related methods. Plaintiff and counterclaim-defendants Abiomed, Inc.; Abiomed R&D, Inc.; and Abiomed Europe GmbH (collectively, "Abiomed") manufacture the "Impella" line of intravascular blood pumps. Abiomed filed this action seeking a declaratory judgment that its

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Impella products do not infringe Maquet's patents and that they are invalid. Maquet has filed a counterclaim seeking a declaratory judgment and damages for infringement. The scope of the case has been narrowed to Claims 16 and 17 of Maquet's Patent No. 7,022,100 ("the '100 patent").[1]

Abiomed has moved for summary judgment on the issue of invalidity. (Docket No. 732). In substance, it contends that the claims are invalid because they fail to satisfy the written description requirement of 35 U.S.C. § 112(a) and are obvious under 35 U.S.C. § 103.

For the following reasons, the motion for summary judgment on the issue of invalidity will be denied.

I. Background

A. Factual Background

The following facts are undisputed except as otherwise noted.[2]

1. Parties

Abiomed is a manufacturer of the "Impella" line of intravascular blood pumps, which it has been marketing in the United States since June 2008. (Am. Compl. ¶¶ 4, 8). Maquet is the owner of several patents directed to intravascular blood pumps, including the '100 patent. ('100 patent).

2. The Underlying Technology

The '100 patent involves guidance systems for intravascular blood pumps—essentially, miniature pumps that are inserted through a patient's vasculature, typically into the heart, for medical purposes. (*See* '100 patent, col. 1 ll. 48-51; *id.*, col. 17 ll. 52-59). Intravascular blood

[1] This case originally concerned infringement of six patents owned by Maquet: U.S. Patent Nos. 7,022,100; 8,888,728; 9,327,068; 9,545,468; 9,561,314; and 9,597,437.

[2] Many of these facts are drawn directly from the Court's claim-construction order.

pumps are used "(1) for acute support during cardio-pulmonary operations; (2) for short-term support while awaiting recovery of the heart from surgery; or (3) as a bridge to keep a patient alive while awaiting heart transplantation." (*Id.*, col. 1 ll. 22-27).

Among the challenges in developing such pumps are miniaturization (that is, designing a pump that will work effectively but be small enough to be inserted); preventing the pump from damaging the heart or the blood (blood cells are delicate); and providing a method for guiding the device to the heart (such pumps are commonly inserted through the femoral artery in the thigh and guided through the body to the heart). (*See id.*, col 1 l. 33-col. 2 l. 18). The '100 patent principally addresses the third issue: safely and effectively guiding the pump into the heart.

In the 1980s and 1990s, before the subject matter of the '100 patent was developed, that issue had not yet been solved. The only methods then available to provide cardiac assistance to a patient in cardiogenic shock were a pump system with a connection to the vascular system that involved major surgery, or a balloon catheter inserted into an appropriate artery. (Docket No. 853 ("Perrin Aff."), Ex. 10 ("Leschinsky Op. R.") ¶ 143 (quoting U.S. Patent 4,625,712 filed in 1983); *id.* (discussing a similar statement from 1991)). Major surgery had the disadvantage of delay and risk for a patient, and balloon catheters did not provide sufficient improvement in cardiac output. (*Id.*).

Thus, at that time, there was a need for a method of inserting a device into a patient's heart that would sufficiently improve cardiac output—that is, a left ventricle assistance device—that did not require major surgery. (Leschinsky Op. R. ¶¶ 141-143). The only commercially developed blood pump that could potentially provide such improvement was the Hemopump. (Leschinsky Op. R. ¶ 142; Maquet SMF ¶ 72; Docket No. 187 ("Maquet Markman Brief") at 7).

But as one inventor of the '100 patent explained, "[o]ne of the shortcomings of the [H]emopump was that there was never . . . a lot of thought put into how [] [to] get it in there." (Perrin Aff., Ex. 3 ("Baker Dep.") at 31). "Clinical stud[ies] show[ed] that [] [doctors] had a hard time placing it," and that guiding it was a "big functional issue." (*Id.* at 222).

3. The '100 Patent

The '100 patent purports to teach a solution to that problem. Broadly speaking, the patent is directed to "[a]n improved intravascular blood pump system . . . and related methods involving the broad inventive concept of equipping the intravascular blood pump . . . with guiding features such that the intravascular blood pump can be selectively positioned at a predetermined location within the circulatory system of a patient." ('100 patent, Abstract). It explains that a "significant drawback" of prior-art intravascular blood pumps is that they were "difficult to guide into the appropriate position within the circulatory system of a patient" because "the elongated catheter is incapable of providing the degree of control necessary to easily negotiate the pump through the tortuous pathways leading up to and into the heart." (*Id.*, col. 2 ll. 6-12). The supplemental guide mechanisms then available had the disadvantage of taking up valuable extra space in the blood vessel and requiring a larger access wound than would otherwise be necessary. (*Id.*, col. 2 ll. 19-39).[3] The patent purports to improve the prior art by equipping the pump with integrated guide mechanisms. ('100 patent, col. 2 ll. 47-55).

The '100 patent issued from U.S. Patent Application No. 10/070,178 (the "'178 Application"), which was filed on September 1, 2000, and claims priority to U.S. Provisional

[3] According to Maquet's expert, Dr. Boris Leschinsky, the invention "disprov[ed] the conventional wisdom at the time [] that intravascular blood pumps systems adapted to be guided within the circulatory system of a patient should be as simple as possible in their design" because the '100 patent "add[ed] . . . elements" to the guidance mechanisms, which allowed the pumps to be inserted successfully "time and again." (Leschinsky Op. R. ¶¶ 155, 156).

Application No. 60/152,249 (the "'249 Provisional"), which was filed on September 3, 1999. (*Id.*, Cover Page; *id.*, col. 1 ll. 6-8).[4]

Again, as the litigation has progressed, the claims have narrowed to encompass only Claim Limitations 16 and 17 of the '100 patent. Those claims recite:

> 16. An intravascular blood pump system comprising: an intravascular blood pump having a cannula coupled thereto, a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient, and a blood pressure detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.
>
> 17. The intravascular blood pump system of claim 16 and further, wherein said blood pressure detection mechanism comprises at least one of fluid filled column disposed within at least a portion of said cannula, a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, and a strain gauge coupled to at least one of the intravascular blood pump and cannula.

('100 patent).

The Court's *Markman* order construed the terms "intravascular blood pump" and "blood pressure detection mechanism" according to their ordinary meaning. (Mem. and Order on Claim Constr. at 20, 48-50). It construed "guide mechanism" as a means-plus-function term with three claimed structures, where the function is "guiding said intravascular blood pump and cannula to a predetermined location within the circulatory system of the patient." (*Id.* at 47). Those claimed structures are:

> (a) a guide wire passing slideably through a central lumen extending through a drive cable assembly, blood pump, and cannula; (b) a guide wire passing slideably through a lumen extending through a guide carriage integrally formed along at least a portion of the cannula sidewall; or (c) a conduit assembly, including guide catheter, a rotor shroud, and a cannula, which is capable of docking to a separate pump assembly.

[4] The September 3, 1999, priority date is disputed and is also the subject of a motion to strike. That motion contends that that priority date was introduced for the first time on March 12, 2020, in a rebuttal report. (Docket No. 740). On May 22, 2018, Maquet had served interrogatory responses that stated that the '100 patent had a priority date of November 11, 1999. (Docket No. 744, Ex. 3 at 3).

(*Id.* at 44-47).

Structure A is colloquially known as an "over-the-wire" guide mechanism, Structure B is known as a "side-rigger" or "rapid exchange" guide mechanism, and Structure C is known as a "guide catheter" guide mechanism. (*Id.* at 4). Maquet alleges that the Impella infringes on Structure B, the "side-rigger" or "rapid exchange" guide mechanism.

B. Procedural Background

On May 19, 2016, Abiomed filed a complaint seeking a declaratory judgment that four of its Impella products do not infringe Maquet's patents: the Impella 2.5, Impella 5.0, Impella CP, and Impella RP. After amendments to the pleadings to add three newly granted patents, on November 20, 2017, Maquet filed an answer and amended counterclaim asserting that those four products infringe its patents. As the litigation has progressed, the claims have narrowed to encompass only claims 16 and 17 of the '100 patent.

On September 7, 2018, the Court issued a memorandum and order on claim construction. On July 9, 2020, the Court permitted Maquet to supplement its infringement contentions to add an Impella product released in May 2019, the Impella CP with SmartAssist, which it alleges infringes upon Claim 16 of the '100 patent.

On September 30, 2021, the Court granted Abiomed's motion for summary judgment on non-infringement.

Abiomed has moved for summary judgment of invalidity for obviousness under 35 U.S.C. § 103 and failure to satisfy the written description requirement of 35 U.S.C. § 112(a).

II. Legal Standard

The role of summary judgment is to "pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Mesnick v. Gen. Elec. Co.*, 950 F.2d 816, 822

(1st Cir. 1991) (internal quotation marks omitted). Summary judgment is appropriate when the moving party shows that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Essentially, Rule 56[] mandates the entry of summary judgment 'against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.'" *Coll v. PB Diagnostic Sys., Inc.*, 50 F.3d 1115, 1121 (1st Cir. 1995) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). In making that determination, the court must "view the record in the light most favorable to the nonmovant, drawing reasonable inferences in his favor." *Noonan v. Staples, Inc.*, 556 F.3d 20, 25 (1st Cir. 2009). When "a properly supported motion for summary judgment is made, the adverse party must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (internal quotation marks and footnotes omitted). The non-moving party may not simply "rest upon mere allegation or denials of his pleading," but instead must "present affirmative evidence." *Id.* at 256–57.

Because "[a] patent shall be presumed valid," 35 U.S.C. § 282, a defendant arguing invalidity must prove that defense by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100 (2011). That heightened burden applies even at the summary judgment stage. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986) ("[I]n ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burden.").

III. Analysis

A. Invalidity Under 35 U.S.C. § 112

Abiomed contends that the asserted claims are invalid under the written-description

requirement of 35 U.S.C. § 112(a) because the specification fails to disclose a species representative of guidance systems for internally-driven pumps.

1. Background

As noted, the Court's *Markman* order construed the term "intravascular blood pump" according to its ordinary meaning. The '100 patent describes them as "miniaturized blood pumps capable of being percutaneously or surgically introduced into the vascular system of a patient, typically to provide left and/or right heart support . . . ." ('100 patent at col. 1 ll. 48-51, col. 2 ll. 4-6).

A section of the patent titled "Description of Related Art" describes one type of those pumps:

> [o]ne type . . . is an axial flow blood pump comprising a cable-mounted rotor surrounded by a protective shroud. The pump, along with the rotor and shroud, are mounted at the end of an *elongated flexible catheter*. The *catheter* is inserted into the aorta from a remote entry point, such as an incision below the groin that provides access into a femoral artery. The catheter then passes through the descending aorta until it reaches the ascending aorta, near the heart. The *catheter device encloses a rotating drive cable* which is coupled to the impeller blade at one end, and which emerges from the exposed end of the catheter, near the patient's groin, at the other end. When the exposed end of the drive cable is mechanically rotated, using a device located outside the patient's body, it conveys the rotational force through the length of the catheter, causing the impeller to spin at high speed near the heart.

('100 patent, col. 1 ll. 51-67).

The next paragraph of that section explains some of the drawbacks that the invention is "directed at eliminating and/or reducing" (*id.*, col. 2 ll. 40-42):

> While generally effective in providing ventricular assisting functions, prior art intravascular blood pumps nonetheless suffer various drawbacks. [P]rior art intravascular blood pumps are difficult to guide into the appropriate position within the circulatory system of a patient. This is due largely to the fact that the *elongated catheter* is incapable of providing the degree of control necessary to easily negotiate the pump through the tortuous pathways leading up to and into the heart. When attempting to place the blood pump in a trans-valvular

> configuration (with the inlet in the left ventricle and the pump outlet in the ascending aorta), the natural tendency of the *catheter* to stay straight may cause the pump to be inadvertently placed in the carotid ostia, which can be dangerous if the pump is operated to withdraw blood from the brain.

(*Id.*, col. 1 ll. 52-57).

The figures in the patent depicting the three claimed structures only illustrate the cable-driven pump described above—that is, an intravascular blood pump that is cable-driven using an external motor outside the patient's body. (*Id.*, figs. 1, 6, 10, 15). For example, figures 1, 6, and 10 below illustrate human hearts with the intravascular blood pump system using the "over-the-wire," "side-rigger," and "guide catheter" mechanisms, respectively. (*Id.*, figs. 1, 6, 10; *id.*, col. 5 ll. 7-12 (over-the wire); *id.*, col. 5 ll. 30-35; *id.*, col. 11 ll. 60-65; *id.*, col. 12 ll. 9-15, 57-66 (side-rigger); *id.*, col. 5 ll. 48-54; *id.*, col. 10 ll. 3-25; *id.*, col. 6 ll. 10-15; *id.*, fig. 15 (guide catheter)).

FIG. 1

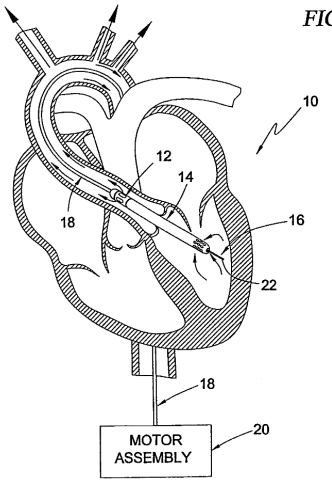


FIG. 6

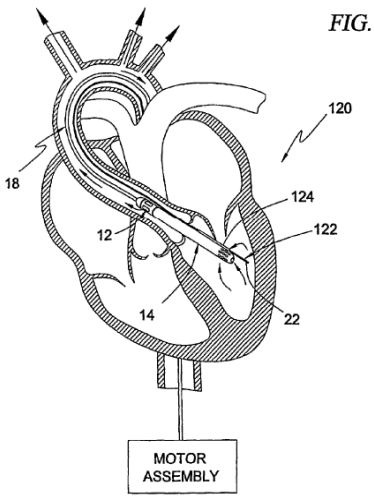
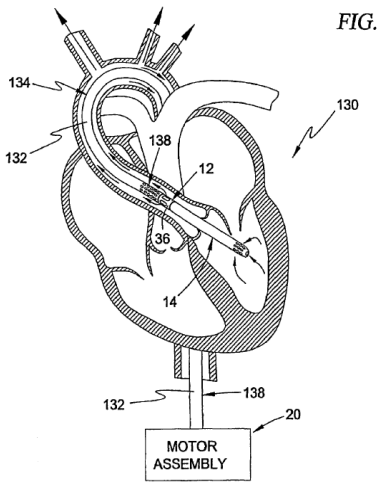


FIG. 10

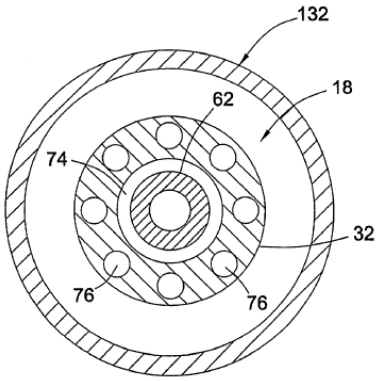


('100 patent, figs. 1, 6, 10).

All of them illustrate an external motor assembly. Figures 1 and 6 also show a drive cable assembly, indicated by number 18, to drive the blood pump, indicated by number 12. While figure 10 does not show a drive cable assembly, it shows a guide catheter—indicated by

number 132, and figure 15 shows that the guide catheter contains the drive cable assembly. (*Id.*, col. 7 ll. 10-17; *id.*, col. 11 ll. 60-67; *id.*, col. 12 l. 1; *id.*, col. 13 ll. 3-10; *id.*, col. 13 ll. 20-25).

FIG. 15



(*Id.*, fig. 15).

As to the "over-the-wire" technique illustrated by figure 1 and indicated by number 10, the specification states:

> The system 10 includes an intravascular blood pump 12, a cannula 14, and an 'over-the-wire' type guide mechanism 16. A *drive cable assembly* 18 and *a motor assembly* 20 are provided to drive the intravascular blood pump 12. The 'over-the-wire' guide mechanism 16 comprises a suitable guide element dimensioned to pass slideably through a central lumen extending through the *drive cable 18*, blood pump 12, and cannula 14.

(*Id.*, col. 7 ll. 13-21) (emphasis added).

As to the side-rigger technique illustrated by figure 6 and indicated by 122, the specification states it is "constructed in virtually the same manner" as the over-the-wire embodiment except "there is no need to form a central lumen extending through the blood pump 12, *drive cable assembly* 18" and other structures. (*Id.*, col. 12 ll. 57-66) (emphasis added). And as to the guide catheter in figure 15, a section titled "Brief Description of the Drawings" states that figure 15 shows an "exemplary construction of the *drive cable assembly* and guide catheter according to the third broad aspect of the present invention." (*Id.*, col. 6 ll. 7-10) (emphasis added).

Other parts of the specification also discuss how to use a cable-driven pump with the guide mechanisms. (*See, e.g.*, *id.*, col. 8 ll. 10-15 ("[T]he length of the drive cable assembly 18 must be enough to reach between the motor coupler 24 and purge fluid delivery system 26, located outside the patient, and the desired location within the patient's circulatory system where the blood pump 12 is to be positioned"); *id.*, figs 2–5, 7, 11–12, 14–18, 19 (indicating a drive cable, 62, or drive cable assembly 18)).

The specification states several times that the figures are "exemplary" only. (*See, e.g.*, *id.*, figs. 2-5; *id.*, col. 7 ll. 10-13, 55-57; *id.*, figs. 12-17; *id.*, col. 14 ll. 35-37). And again, it states that the cable-driven pumps are "one type" of intravascular blood pump. (*Id.*, col. 1 ll. 52-57). Furthermore, after discussing figures 1-17, it states:

> The foregoing discussion details a host of inventive aspects forming part of the present invention. It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concepts thereof. The following evidences, by way of example only, various additional aspects forming part of the present invention.

(*Id.*, col. 15 ll. 49-55).

The Hemopump, which was the only intravascular pump system to have been developed at the time of the invention, is a cable-driven rotor pump. (Maquet SMF ¶ 72; Maquet Markman Brief at 7). However, at least two patents that were filed and published before the invention of the '100 patent, U.S. Patent No. 5,921,913 ("Siess '913") and PCT WO 97/7696 ("Rau"), described intravascular blood pumps with internal motors, also known as "on-board" motors. (Hummel Aff., Ex. 21 (Siess '913) (filed June 24, 1997, and dated July 13, 1999), col. 3 ll. 4-6 (The "present invention employs an electric micro motor contained in the drive unit that rotates an impeller disposed in the attached pumping segment."); *id.*, col. 1 ll. 44-48 ("[Other] intravascular heart pumps are known, in which the pumping segment is driven by a remotely

disposed drive unit."); Perrin Aff., Ex. 4 (Rau) (Abiomed's translation) (published October 16, 1997) at 9 (the design is based on a blood pump "compris[ing] a motor housing containing an electric motor and connected on the rear end to a catheter. In the motor housing, the motor shaft is mounted at two ends.")).[5]

Abiomed's expert, Dr. James Antaki, testified as follows:

Q. So you mentioned that the Hemopump was driven by a cable, right?

A. Yes.

Q. And then a couple of the prior art references – the Siess prior art references describe a direct-drive design. Is that right? Where the motor is attached to the pump directly?

A. Yes. That is correct.

Q. So is it your opinion that back in 1999 or 2000, a person of ordinary skill in the art would understand those were the two options for providing rotation to a pump?
. . .
A. So I would agree those were the two prevailing solutions in existence. So I believe that the answer would be yes.
. . .
Q. But back in 1999, the two options for driving the rotation of a blood pump were either a directly coupled motor or a motor coupled through drive cable. Right?

A. I believe that's what I said, and I believe so.

Q. So when a person of ordinary skill in the art sees that a blood pump includes a rotor and a housing, they would know that it could be driven by a cable-attached motor or a directly attached motor. Right?
. . .
A. Yes, I think that's accurate. And I – I think the same conclusion can be drawn from Siess's thesis, whereby he evaluates the taxonomy of intravascular blood pumps.

[5] Neither patent is cited as prior-art references by the '100 patent.

(Perrin Aff., Ex. 1 ("Antaki Dep.") at 74-76).[6]

Dr. Boris Leschinsky, Maquet's expert, testified that "both internal and external motors were known [at the time of the invention] to be used to drive a rotor of the blood pump, and a person with ordinary skill in the art would understand that showing an external motor would be an exemplary discussion, but [that] it is not critical for the purposes of the claims as to which motor and which way the rotor is being driven, which one is used." (Perrin Aff., Ex. 5 ("Leschinsky Apr. 2020 Dep.") at 166; *see also* Perrin Aff., Ex. 6 ("Leschinsky Rebuttal R."), at ¶¶ 394-96). He further testified that while "he did not see any [figure] of an onboard motor [in the '100 patent]," it "would be implied in the term [an intravascular blood pump] that it can be driven with an external motor or with an onboard motor." (Leschinsky Apr. 2020 Dep. at 165, 171; *see also id.* at 167 ("[A] person with ordinary skill in the art would read the intravascular blood pump and understand that it can be driven either by onboard motor or external motor[.]")).

Dr. Aboul-Hosn, one of the inventors of the '100 patent, testified that "[he] did [not] consider any alternatives to a cable-driven system for [the '100 patent's] pump" because "the technical difficulty in miniaturizing an electric model to the size required to pass through a vessel, back at that time [] was perceived as almost impossible." (Hummel Aff., Ex. 15 ("Aboul-Hosn Dep.") at 23-24); ('100 patent at 1). He also testified as to his interactions with Dr. Thorsten Siess, the inventor of Siess '913, which described an internal motor:

> Q. During your period at A-Med, you had mentioned you met Dr. Siess in the mid 90s. Did you have any interaction with him while [Abiomed] was up and running?
>
> A. Yes, we did.
>
> Q. And were you aware of any work he was doing on board, sort of pump

[6] However, in his expert report, Dr. Antaki stated that "[t]here is no disclosure [in the '100 patent] to demonstrate that the inventors were in possession of or even considered a system where the motor is located inside the body connecting directly to the impeller." (Perrin Aff., Ex. 22 ("Antaki R.") at ¶ 181).

designs that include a motor on board?
. . .
A. Yes, I did.

. . .
Q. And what did you think of his efforts in that regard?

A. [That] [h]e is crazy.

(*Id.* at 24-25).

As to Siess '913, Dr. Aboul-Hosn testified:

Q. [Siess '913] is a patent that is related to an intravascular heart pump; is that right?

A. That is correct.

Q. And in this patent, there is a miniaturized electric motor that is used in connection with that pump; right?

A. That is correct.

Q. It is not using a drive cable?

A. It is not using a drive cable.

Q. So, at least as of June 24, 1997, it was known by people in the art that you could use a miniaturized electric motor with an intravascular heart pump?

A. Yes.

. . .
Q. [So] [A]t some point you learned that it could be done; right?

Q. And you probably knew as of [that] time, around 1997, 1998, 1999, that that could be done; right?
. . .
A. That is correct, yes. Can I restate my last answer just for correctness?
. . .
A. I didn't know that it could be done, I knew somebody was thinking about it. I thought it can't be done. That was my assumption.

Q. But you knew people were discussing it?

A. Yes. Clearly, I knew people were discussing it, but I thought it is not possible technologically.

(Aboul-Hosn Dep. at 207-10).

Dr. Bruce Baker, another inventor of the '100 patent, testified that "[he] knew [internal electric motors] existed by the time we were working on the [Abiomed] product[, but] [he] didn't see any motors that would be suitable for what [he thought] [they] needed, and [they] kind of just said, well, that's one way. Here's our way." (Perrin Aff., Ex. 3 ("Baker Dep.") at 211-12; '100 patent at 1).

2. The Written-Description Requirement Generally

To satisfy the written-description requirement, the disclosures in a patent specification must "clearly allow [a person] of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (internal quotation marks and alterations omitted). In other words, the written description "must convey with reasonable clarity . . . that, as of the filing date sought, [the patentee] was in possession of the invention . . . ." *Carnegie Mellon Univ. v. Hoffmann–La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (internal quotation marks omitted). Making that determination requires an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351. "Given this perspective, in some instances, a patentee can rely on information that is 'well-known in the art' to satisfy written description." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285, 1287 (Fed. Cir. 2012) ("The district court properly concluded that one skilled in the art would have recognized that the claimed integrated controls could be made using either true reticulocytes or reticulocyte analogs . . . . [g]iven the language in the patents-in-suit, coupled with the well-known use of true reticulocytes in the prior art . . . ."); *see also Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998) ("Missing subject matter in a description [can be] shown to be part of the

prior art that would be understood as part of the description of the subject matter of the count.").

When the patent claims an entire class (genus) of systems but only discloses a few embodiments (species), the specification must describe the invention in a way that makes clear that the genus has been invented, and not just one or more species. *Carnegie Mellon*, 541 F.3d at 1124. As the Federal Circuit has explained, written-description problems are "especially acute with genus claims that use functional language" because such claims run the risk of "simply claim[ing] a desired result . . . without describing species that achieve that result." *Ariad*, 598 F.3d at 1349. The specification must therefore disclose, as relevant here, a "representative number of species falling within the scope of the genus." *Id.* at 1350.

A patent's failure to comply with the written-description requirement may generally be determined as a matter of law. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004). However, summary judgment is not appropriate if a fact-intensive inquiry is necessary to determine how many species are needed to represent a particular genus. *See Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005) (noting that the distinction between "generic inventions that are adequately supported, those that are merely a 'wish' or 'plan' . . . , and those in between" is dependent on the "facts of the specific case").

3. Analysis of the Written Description

Here, the patent claims guidance systems for an intravascular blood pump. Maquet contends that the invention "[does] not recite any limitation regarding what mechanism drives the blood pump" and is "not directed at pump propulsion," and thus, the specification need not adequately describe mechanisms driving the blood pumps at all. (Maquet Opp. at 5, 7).

The written-description requirement does not require "a patent [to] describe the *unclaimed* features of the infringing product." *Hologic, Inc. v. Minerva Surgical, Inc.*, 325 F.

Supp. 3d 507, 526 (D. Del. 2018) (emphasis added); *see also Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1333 (Fed. Cir. 2003).[7] Here, the claims are not directed to pump propulsion or to the mechanism driving the pump, but to a means of safely and effectively guiding such pumps into the heart. Nonetheless, the specification must adequately describe a device that achieves that result, which requires adequately describing an intravascular blood pump equipped with the guide mechanisms. The issue is thus whether disclosure of a system that has a cable-driven pump equipped with the guide mechanism is sufficient to encompass an internally driven pump equipped with the guide mechanism.

No "bright-line rules" exist as to the number of representative species required to support a genus claim, because "this number necessarily changes with each invention, and it changes with progress in a field." *Ariad*, 598 F.3d at 1351. Rather, it is a case-by-case question of whether "the species [that] are adequately described are representative of the entire genus." *Carnegie Mellon*, 541 F.3d at 1124 (emphasis omitted). "If the difference between members of [a species] is such that [a] person skilled in the art would not readily discern that other [species] of the genus would perform similarly to the disclosed members, i.e., if the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus." *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125 (Fed. Cir. 2004).

Abiomed contends that the patent covers a genus of blood-pump systems, of which there are two different species: cable-driven pumps and internal motor pumps. It thus contends that

[7] The principle of "unclaimed features" often arises when an alleged infringer contends that a patent must disclose a method for making a product, when in fact the claims are product claims, not method claims. *See, e.g.*, *Amgen*, 314 F.3d at 1333-34; *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1383 (Fed. Cir. 2011). For example, in *Crown Packaging*, the court found that the product claim in question did not have to describe an unclaimed method of making the product, but specifically distinguished method claims that "claim[] to a functionally defined genus," and noted that their specifications "[would] not satisfy the written description requirement without a disclosure showing that the applicant had invented species sufficient to support the claim." *Id.* at 1378, 1381, 1382-83.

"[t]he specification describes three species (the three embodiments) of only one class (cable-driven pumps) but provides no examples of the second class (internally driven pumps)," and contends that genus claims "covering two broad non-overlapping classes" are routinely invalidated. (Abiomed R. at 5-6). It relies on *Synthes USA, LLC v. Spinal Kinetics, Inc.*, 734 F.3d 1332 (Fed. Cir. 2013) and *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, 558 F.3d 1368 (Fed. Cir. 2009) in support of that argument.[8]

In *Synthes*, the court affirmed a jury verdict of invalidity for lack of an adequate written description where the specification in question was for a prosthetic device designed to replace a disc located between adjacent vertebrae of the human spine. *Synthes*, 734 F.3d at 1334-35, 1336. At issue was a part of a claim requiring "a third plate operatively coupled to the first bone contacting plate, the third plate including a plurality of openings," which the court construed to mean "the third plate including two or more openings to allow the fiber system to be joined or anchored to that plate." *Id.* at 1336, 1338-39. The written description disclosed one member of the species—grooves—but no other members of the species, such as internal slots. *Id.* at 1341-42. The court noted that the jury was free to conclude, "based on [the trial testimony]" that "there would be *significant biomechanical differences* between using peripheral grooves and internal slots" and "that the use of internal slots for these devices was *not predictable*." *Id.* at

[8] Written description is judged based on the state of the art as of the priority date of the patent, although "post-priority-date evidence of a particular species" can bear on whether the disclosure is representative. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1374 (2017). Here, the Hemopump, a cable-driven rotor pump, was the only commercial intravascular pump system to have been developed at the time of the invention. (Maquet SMF ¶ 72; Docket No. 187). However, at least two patents that were filed and published before the invention of the '100 patent—Siess '913 and Rau—described intravascular blood pumps with internal motors.

Abiomed also contends that there could be a third "broad non-overlapping class" of "other pumps" covered in the genus. It gave the example of "if someone . . . [came] up with a way to drive a pump that was implanted in the heart through some sort of magnets outside the body." (Docket No. 942 at 10). However, because such a device has not yet been invented—at least, not filed in a patent or commercialized—the Court will not consider that purported species in its analysis.

1344 (emphasis added).

In *ICU Medical*, the patent was directed to medical valves used in the transmission of fluids to or from a medical patient such as when using an intravenous setup. *ICU Med.*, 558 F.3d at 1371. The valves disclosed in the specification used a spike to "pierc[e] a seal inside the valve" to effectuate the fluid pathway, but the claim also covered valves operating without a spike. *Id.* at 1374-75, 1377. The court rejected the argument "that the figures and descriptions that include spikes somehow demonstrate that the inventor possessed a medical valve that operated without a spike," and noted that "it is not enough that it would have been obvious to a person of ordinary skill that a preslit trampoline seal could be used without a spike." *Id.* at 1377, 1379. Specifically, the court appears to have affirmed the grant of summary judgment because the spike was "critical to the inventor's contribution," and "having a spike within the medical valve was necessary to [the] use of the claimed invention." *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 483 (D. Del. 2019) (discussing *ICU Medical*); *Crown Packaging*, 635 F.3d at 1382 (discussing *ICU Medical*).

It is undisputed that the embodiments in this case only illustrate a guidance mechanism for a cable-driven intravascular blood pump. Abiomed thus contends that this case presents "the exact same fact pattern" as *ICU Medical*—that is, like the spike in *ICU Medical*, the drive mechanism here is "critical to the inventor's contribution," and internally-driven intravascular blood pumps with onboard motors are not disclosed. (Abiomed R. at 7). According to Abiomed, the drive mechanism is critical because the claims are directed to reducing the difficulties guiding pumps into the appropriate position, and the specification states that such difficulties are "due *largely* to the fact that *the elongated catheter* is incapable of providing the degree of control necessary to easily negotiate the pump through the tortuous pathways leading up to and into the

heart." ('100 patent, col. 1 at 52-57; *id.*, col. 2 at 40-42). It essentially contends that the term "elongated catheter" necessarily refers to is the "elongated flexible catheter" that "encloses [the] rotating drive cable," and cannot refer to any other form of catheter, such as one enclosing a pair of wires. (Abiomed R. at 4-5). That argument, however, fails for a variety of reasons.

First, Abiomed has framed the issue incorrectly. The relevant genus is not "blood-pump systems." The claimed function is guiding an intravascular blood pump and cannula into the circulatory system, and the claimed means are the three structures disclosed in the specifications.

Second, Abiomed has offered no evidence, expert or otherwise, that the term "elongated flexible catheter" would be understood by a person of skill in the art to mean a catheter enclosing a rotating drive cable.

Third, Abiomed has offered no evidence, expert or otherwise, that a catheter containing a rotating drive cable, rather than (for example) a pair of wires, is "critical to the inventor's contribution." Put another way, Abiomed has not shown that the inventor's claimed contributions—effective guidance mechanisms—would not also contribute to the guidance of internally driven pumps. And, in any event, Maquet has offered unrebutted expert testimony to the contrary. Dr. Leschinsky testified expressly that "it is not critical for the *purposes of the claims* as to which motor and which way the rotor is being driven, which one is used." (Leschinsky Apr. 2020 Dep. at 166 (emphasis added)).

Fourth, Abiomed has not shown that the use of internally driven pumps in the invention was not predictable, or that a person of ordinary skill in the art would not have recognized that one could use the guidance system for internally driven pumps based on the description of cable-driven pumps. It contends that the "inventors did not contemplate using internal motors" because "they testified that *they* [] thought such pumps were not feasible *in their invention* as of

the priority date." (Abiomed R. at 3 (emphasis in original)). But the inventors appear to have been simply suggesting that they were not certain that internally driven pumps would function at all, or provide the same functionality as cable-driven pumps. That is quite different than saying that if they *did* provide the same functionality, they would not work in the invention.

Finally, the inquiry is an objective one: whether persons with ordinary skill in the art reading the specification would recognize from it that one could use it to guide internally driven pumps. It is not whether the inventors actually reduced the invention to practice using an internally driven pump. *See Streck*, 665 F.3d at 1286 ("[T]he mere fact that [the inventor] chose to reduce his invention to practice using a reticulocyte analog rather than a true reticulocyte is not relevant to the written description inquiry. Although [the alleged infringer] contends that [the patentee] 'did not posses [sic] true reticulocyte integrated controls,' [the patentee] is not required to prove an actual reduction to practice as to all disclosures.").

Here, Dr. Leschinsky testified that "both internal and external motors were known to be used to drive a rotor of the blood pump, and a person with ordinary skill in the art would understand that showing an external motor would be an exemplary discussion." (Leschinsky Apr. 2020 Dep. at 166). Dr. Antaki further testified that he "[thought] it was accurate" that "when a person of ordinary skill in the art [saw] [] a blood pump includ[ing] a rotor and a housing, they would know that it could be driven by a cable-attached motor or a directly attached motor" and that he "[thought] the same conclusion [could] be drawn from Siess's thesis, whereby he evaluates the taxonomy of intravascular blood pumps." (Antaki Dep. at 74-76). At the very least, Maquet has established that there is a genuine dispute of fact as to what a person of ordinary skill would recognize from the specification.

In summary, at a minimum, there is a genuine dispute of fact as to whether the disclosure

of a guidance system using cable-driven motors is sufficient to satisfy the written-description requirement for a guidance mechanism using internally driven pumps. Therefore, summary judgment for failure to satisfy the written-description requirement is not warranted.

B. Invalidity Under 35 U.S.C. § 103(a)

Abiomed further contends that the claims are invalid because they are obvious under 35 U.S.C. § 103 in light of the combination of prior art references U.S. Patent No. 6,248,091 ("Voelker") and U.S. Patent No. 5,964,714 ("Lafontaine"), and Voelker and Canadian Patent No. 2,295,951 ("Sammler Canada").

For the reasons set forth in the Court's Memorandum and Order on Maquet's Motion for Partial Summary Judgement, Abiomed did not disclose Sammler Canada as prior art during discovery, and accordingly it will be barred from relying upon the reference. The Court will not, therefore, consider the issue of the combination of Voelker and Sammler Canada.

1. The Prior Art

a. Voelker

Voelker was published on June 19, 2001, and claims priority to German Patent 196 22 335, which was filed on June 4, 1996. (Voelker, Cover Page).[9] According to Abiomed, Voelker

[9] Whether a U.S. patent claiming the benefit of a filing date of a PCT international application earlier than November 29, 2000, qualifies as a reference under 35 U.S.C. § 102(e) is based on the version of that statute in force on November 28, 2000. The relevant version of the statute provides:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in—(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e) (Pre-AIA).

> Pursuant to section 122(b), patents are generally published promptly after the expiration of a period of 18

discloses the intravascular blood pump and the "over-the-wire" guide mechanism components of the asserted claims.

The Voelker specification states that the invention is directed to "a balloon catheter adapted for insertion into a blood vessel to, for example, expand obstructions in vessels or to temporarily isolate a portion of the blood vessel wall from contact with the blood flow." (Voelker, col. 1 ll. 3-6). It further states that "[f]rom U.S. Pat. No. 4[,]969[,]865, an intravascular blood pump for cardiac support is known. [That] blood pump may be introduced into the heart through a blood vessel." (*Id.*, col. 1 ll. 31-33). The "pump" in Voelker is "[preferably] driven by a flexible shaft connected to a motor provided at the proximal end of the cath[e]ter hose." (*Id.*, col. 2 ll. 26-28). As to its dimensions, the abstract describes it as a "small-diameter pump" and the specification states that "the balloon cath[e]ter 1 . . . comprises an elongate cath[e]ter hose 10 of about 1 m in length and about 1.3 mm in diameter. The flexible cath[e]ter hose 10 has a central hose lumen 11 of about 0.8 mm in diameter . . . . [and] [s]ituated at the cath[e]ter tip is the tubular balloon support 13 having an inner diameter of about 0.8 mm and an outer diameter of about 1.0 mm." (*Id.*, col. 2 ll. 56-59).

The Voelker specification further states that "in order to place [the] balloon cath[e]ter in[to] a blood vessel, a guide wire is usual[l]y inserted over which the cath[e]ter is then pushed. Such placement using a guide wire is also possible with the present balloon cath[e]ter." (Voelker, col. 2 ll. 34-38). The guide wire is illustrated by Figure 3 of the specification, which shows:

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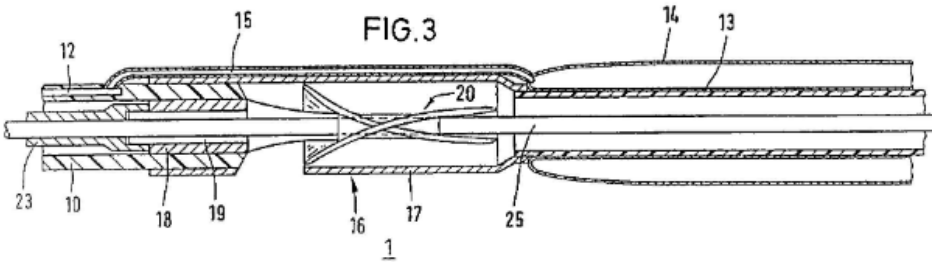
months from the earliest filing date for which a benefit is sought under that title. Section 351(a) defines "treaty" to mean "the Patent Cooperation Treaty" and Article 21(2) refers to the publication of such applications.

Maquet states that "Abiomed provide[d] no support for Voelker's claim of priority [to the German application] and thus [the June 4, 1996 priority date] is not undisputed." (Maquet SMF ¶ 47). However, pursuant to pre-AIA § 102(e), Voelker is prior art regardless of whether it is entitled to claim the priority date of German Patent 196 22 335, filed on June 4, 1996, because Voelker's cover page shows that a PCT Application was filed on June 3, 1997, published on December 11, 1997, and has a § 102(e) date of December 2, 1998. (Voelker, Cover Page).

> [a] [flexible] guide wire 25 extend[ing] coaxially through the flexible shaft 23, the shaft 19 and the impeller wheel 20. These parts have corresponding axial channels to be slipped over the guide wire (over-the-wire technique). When the pump [16] is operated, the guide wire may be withdrawn to improve the throughflow through the balloon support 13. After the guide wire has been withdrawn, it may be advanced again, if the position of the cath[e]ter is to be changed. However, this is not essential for the operation of the pump.

(*Id.* col. 3 ll. 56-65; col. 3 l. 37).[10]

Figure 3 of Voelker



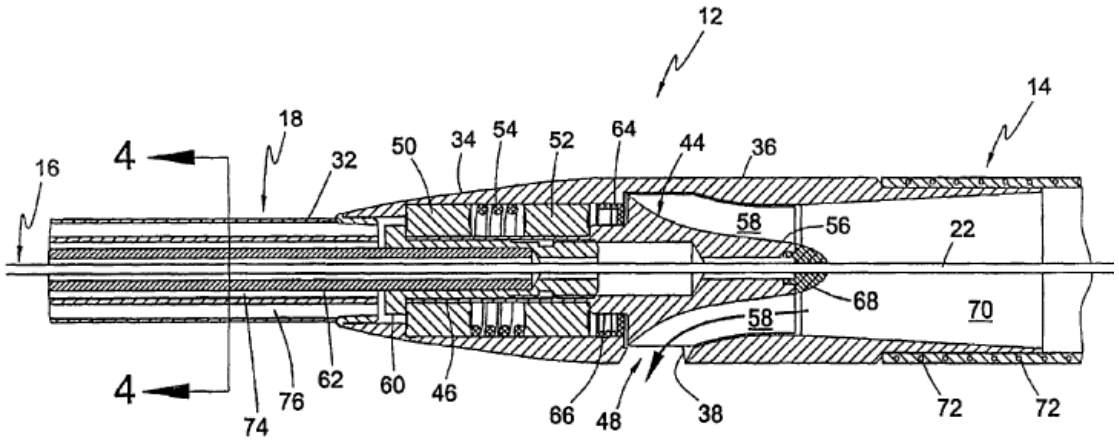
In the '100 patent's "over-the-wire" guide mechanism, "a central lumen is formed through at least a portion of the intravascular blood pump system such that a guide element, such as a guide wire, may be progressed therethrough and advanced to the predetermined location in the circulatory system of the patient." ('100 patent, col. 2 ll. 56-66). In the context of that patent, a "lumen" is the central cavity of a tubular structure. Thus, in the "over-the-wire" system of the '100 patent, there is in effect a tube within a tube; the innermost tube contains a space (the lumen) through which the guide wire is inserted. The intravascular blood pump is then advanced along the guide element. (*Id.*, col. 2 l. 66-col. 3 l. 2).

Figure 3 of the '100 patent illustrates the intravascular blood-pump system with the over-the-wire guide mechanism. (*Id.*, col. 5 ll. 22-25). The specification states that the figure shows the "over-the-wire guide mechanism 16, [which] includes a central lumen through which the

[10] The pump (16) is located between the catheter hose (10) and the balloon support (13). (*Id.*, col. 3 ll. 3-5). The balloon support (13) is enclosed by at least one balloon (14). (*Id.*, col. 2 ll. 64-65).

guide wire 22 may extend for the purpose of slidably advancing the blood pump 12 and cannula 14 into a desired position . . . ." (*Id.*, col. 10 ll. 45-49). It further states that "the central lumen is established by forming and co-aligning the individual central lumens within each of the drive cable 62, the cable adapter 60, the shaft 46 and hub 56 of the rotor 44, and the cannula 14." (*Id.*, col. 10 ll. 49-53).

Figure 3 of the '100 Patent



(*Id.*, fig 3).

b. Lafontaine

Lafontaine was published on October 12, 1999, and was filed on March 7, 1996. (Hummel Aff., Ex. 11 ("Lafontaine"), Cover Page). Abiomed contends that Lafontaine discloses the "blood pressure mechanism" of the '100 patent. (Abiomed Supp. Mem. at 18).

Leschinsky testified that "measuring blood pressure with patients [who have] some sort of [] internal or external blood pump operating . . . [was] a common thing" in "literature" and "in the prior art generally." (Leschinsky Apr. 2020 Dep. at 104-05, 106).[11] As Lafontaine explains, "it is [] highly desirable to know the pressure wave form for places within the heart and various

[11] However, he also testified that speaking more "specifically," in the "narrow" sense of the '100 patent, the "blood pressure detection mechanism to detect the pressure of blood proximate at least one of the intravascular blood pump and cannula" was not known prior to the invention. (Leschinsky Apr. 2020 Dep. at 106-07).

vessels [] [because] [s]tandard pressure wave forms [and non-standard wave forms] have been documented for [] healthy vasculature. . . . [and for] particular maladies. Therefor[e], a device which was responsive enough to measure wave forms within the heart chambers would [] be useful." (Lafontaine, col. 2 ll. 59-65).

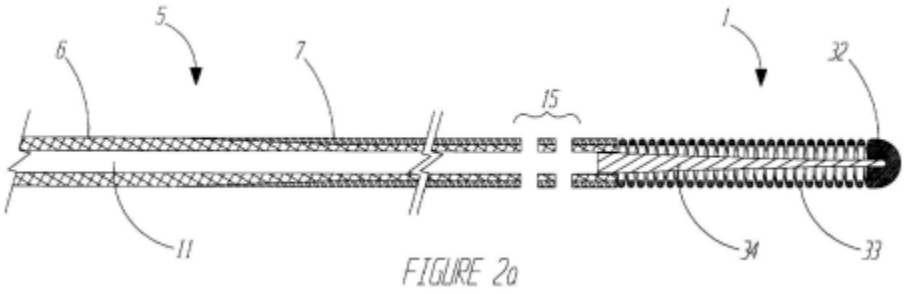
Lafontaine's invention is directed to "a pressure sensor, and more particularly, a wire capable of functioning as a guidewire and measuring fluid pressure at various places within the human vasculature," which the specification explains "[can] be used in all [] procedures that typically use a guidewire." (Lafontaine, col. 1 ll. 4-8; *id.*, col. 4 ll. 5-7). According to that specification, that guide wire can be used to measure fluid pressure in, among other locations, "specific locations in and around the heart, including the chambers of the heart for cardiac assessment, and across the heart valves for pressure gradients," and has an outer diameter of 0.014" or 0.3556 mm. (*Id.*, col. 4 ll. 5-14; *id.*, col. 6 ll. 49-54; *see also id.*, col. 7 ll. 7-9 ("The distal end of core member 6 fits within hypotube 8 which has an outer diameter of 0.014 . . . .").

As to Figure 2a of Lafontaine, which illustrates one of the embodiments of the invention, the specification explains:

> In order to effectively communicate pressure from holes 15 along lumen 11 to the proximal end of elongate body 5, the entire fluid pathway must be so rigid as to be non-compliant, ie. the flexing of materials in contact with the fluid will not absorb any pressure changes. In addition, lumen 11 must be filled with a non-compliant fluid. Suitable fluids include water, . . . alcohol, or perfluorocarbon. These fluids can be pre-filled when the device is manufactured or injected into the device just prior to use . . . . The resulting structure insures [sic] that a displacing force on the exterior of the distal end of elongate body 5 will cause a force equal to the displacing force to be communicated to the proximal end of elongate body 5 via the fluid in lumen 11.

(Lafontaine, col. 5 ll. 35-43).

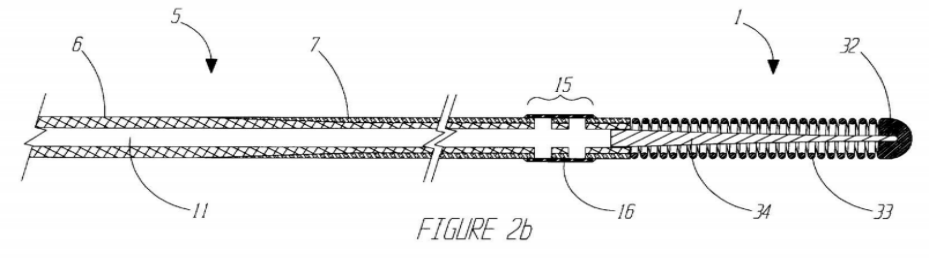
Figure 2a of Lafontaine



(*Id.*, fig. 2a).

The pressure sensing "[h]oles 15 pierce elongate body 5 and make a complete fluid path from the exterior of the distal end 20 of elongate body 5 via lumen 11 to the proximal end of elongate body 5." (*Id.*, col. 5 ll. 19-22). The specification states that it is "preferable" for "each hole 15 [to] allow fluid, including fluid air, to pass only from the interior of elongate body 5 to the exterior while also allowing pressure to be communicated across the valve." (*Id.*, col. 5 ll. 44-48). However, it further states that, "[a]lternatively, a membrane sleeve 16 may made be of an elastomer like urethane, a glass fiber composite, or an acrylic copolymer. Use of any of these materials would allow pressure to be communicated across the sleeve 16 but would not allow fluid to pass through the sleeve 16 . . . . When the pressure on the exterior of elongate body 5 is equal to or greater than that of the interior, the sleeve 16 would seal the hole 15 to any fluid flow." (*Id.*, col. 5 ll. 61-65; *id.*, col. 6, ll. 5-8).

Figure 2b of Lafontaine



(*Id.*, fig. 2b).

2. Obviousness Generally

An invention cannot be patented if the subject matter would have been obvious at the time of the invention. A claim is invalid for obviousness if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Pre-AIA). To challenge a patent as obvious, the challenger must prove, by clear and convincing evidence, that a person of ordinary skill in the art (1) would have been motivated to combine the teachings of the prior art references to achieve the claimed invention and (2) would have had a reasonable expectation of success in doing so. *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009). A reasonable expectation of success does not require absolute predictability. *In re Droge*, 695 F.3d 1334, 1338 (Fed. Cir. 2012).

Obviousness is a question of law based on underlying factual determinations. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406, 427 (2007). Those factual determinations include the so-called *Graham* factors: (1) the scope and content of the prior art; (2) differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) secondary considerations such as "commercial success, long felt but unsolved needs, [and] failure of others." *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). "Where [those determinations] are not in material dispute, and the obviousness of the claim is apparent in light of [them], summary judgment is appropriate." *KSR Int'l Co.*, 550 U.S. at 427 (2007).

3. Whether the Asserted Claims are Obvious

a. Absence of Evidence of Secondary Considerations

Maquet contends that Abiomed has failed to meet its burden because it has not introduced any evidence of the fourth *Graham* factor, secondary considerations. That argument is

foreclosed by the law of the Federal Circuit.

In *ZUP, LLC v. Nash Manufacturing, Inc.*, 896 F.3d 1365 (Fed. Cir. 2018), the court affirmed a grant of summary judgment of invalidity on the ground of obviousness even though the challenger had not introduced any evidence of secondary considerations and the patentee had submitted two affidavits addressing that issue. *Id.* at 1373. The court stated that although the burden of persuasion remains with the challenger because every issued patent is entitled to a presumption of validity, "a patentee bears the burden of production with respect to evidence of secondary considerations of nonobviousness." *Id.* (internal quotation marks and citations omitted). The cases Maquet cites are not in conflict, but rather speak to the proposition that courts must consider evidence of secondary considerations "in every case where [they are] *present*." *See, e.g.*, *Arctic Cat Inc. v. Bombardier Recreational Prods.*, 876 F.3d 1350, 1358 (Fed. Cir. 2017) (emphasis added).

Accordingly, Abiomed's motion will not be denied based on its failure to produce such evidence.

b. Absence of Evidence of Ordinary Skill in the Art

Maquet further contends that Abiomed failed to address the level of ordinary skill in the art. Maquet's expert contends that a person of ordinary skill in the art would have "an undergraduate degree in mechanical engineering or bioengineering or similar subject matter and at least *10 years of experience* designing intravascular heart assist devices; or have an advanced degree in mechanical engineering or bioengineering (either a masters, Ph.D., or equivalent course work) and *at least five years of experience* designing intravascular heart assist devices." (Leschinsky Op. R. ¶ 10 (emphasis added)). Abiomed's expert contended that a person of ordinary skill in the art would have "(i) a Bachelor's degree in mechanical or biomedical engineering, or a similar field, and *two to three years* of work experience with intravascular

cardiac assist devices, (ii) a Master's degree in mechanical or biomedical engineering, or a similar field, and *two to three* years of work experience in medical device or related fields, or (iii) a *Ph.D. in mechanical or biomedical engineering, or a similar field*." (Antaki R. at ¶ 65 (emphasis added)). It is far from clear that there is a material dispute as to that issue. At a minimum, Maquet's hypothetical expert would have greater experience than Abiomed's, and would presumably have a greater ability to grasp what Abiomed contends is an obvious combination of inventions. Accordingly, the motion will not be denied on that basis.

c. Combination of Voelker and Lafontaine

Abiomed contends that the asserted claims are obvious in light of the teachings of Voelker and Lafontaine because (1) together they disclose every element of the asserted claims and (2) a person of ordinary skill in the art would have been motivated to combine them and would have had a reasonable expectation of success in doing so.

i. Voelker Disclosures

(a) "Intravascular Blood Pump"

Abiomed first contends that Voelker discloses the "intravascular blood pump" element of the asserted claims—that is, "an intravascular blood pump having a cannula coupled thereto."

As noted, the specification of Voelker states that the invention is directed to "a balloon catheter adapted for insertion into a blood vessel to, for example, expand obstructions in vessels or to temporarily isolate a portion of the blood vessel wall from contact with the blood flow." (Voelker, col. 1 ll. 3-6). It further states that "in the [] balloon catheter, [the] pump is disposed in the course of the cath[e]ter, in particular at a position proximal of the [sic] balloon support. Through appropriate openings, the pump draws blood laterally from the blood vessel and pumps is [sic] axially through the balloon support. Since the . . . pump is disposed just in front of the balloon support, only a relatively low pump pressure is required." (Voelker, col. 1 ll. 56-62).

The device described in Voelker is undisputedly inserted through a blood vessel, and undisputedly pumps blood. The parties nonetheless dispute whether Voelker discloses an "intravascular blood pump" within the meaning of the '100 patent.

Maquet contends—with substantial justification—that the device in Voelker is a "miniature balloon catheter designed to enter the tiny vessels that feed the heart" that is unlike the intravascular blood pumps illustrated in the embodiments of the '100 patent. (Maquet Opp. at 21). Among other things, Dr. Aboul-Hosn testified that "something [as small as the pump in Voelker] would not be used in the heart," and that "[he] would assume" that the device was intended to pump blood "in[to] the circulatory system" rather than into "the left ventricle." (Aboul-Hosn Dep. at 215-16).[12] Dr. Antaki also testified that it was "unlikely" that the device in Voelker could provide a flow as fast as "2 to 7 liters per minute," as certain devices used in the heart can, and that he was not aware if the Voelker device had ever been used in the heart. (Antaki Dep. at 120, 121 (comparing Voelker to a device described in a thesis by Dr. Siess); *see also* Voelker, col. 2 ll. 1-5). Dr. Antaki further stated that "he was not aware of the Voelker catheter having [] been introduced into a patient's heart" or "commercialized." (Antaki Dep. at 125-26).

Abiomed does not dispute that the device in Voelker is a miniature balloon catheter, unlike the systems contemplated by the '100 patent. Rather, it contends that the ordinary meaning of an "intravascular blood pump" is a "blood pump placed into the body through a blood vessel," and that indeed Maquet contended during claim construction that that is the ordinary meaning of the term. Thus, according to Abiomed, the term necessarily includes both

[12] Baker testified as to balloon catheters generally, "I'm not well versed . . . in the nature of the cycling of an intra-aortic balloon pump. I just know that it only fractionally increases the assistance that's offered to the heart, whereas the [H]emopump with its rotary flow is more of a, you know, continuous . . . [,] substantial amount of assistance for a patient whose own heart is compromised." (Baker Dep. at 24).

miniature balloon catheters such as the device in Voelker and a larger blood pump used in the heart.

The dispute over the meaning of "intravascular blood pump" is potentially significant because a single obvious embodiment of a claim is sufficient to invalidate the entire claim, even if that claim would also cover non-obvious embodiments. *See Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999) ("[W]hen a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim."); *see also Fresenius USA, Inc.*, 582 F.3d at 1298 ("[T]he entire element is disclosed by the prior art if one alternative in the *Markush* group is in the prior art."); *In re Muchmore*, 433 F.2d 824, 826 (C.C.P.A. 1970) (noting that "[w]hile some specific processes within [the claim in question] . . . might be said to yield unexpectedly superior results over [a prior art] process" the totality of processes did not, and thus "because appellant chose to predicate unobviousness on unexpectedly superior elongation properties resulting from his process . . . the claim was too broad in the sense of section 103").

As noted, the Court in its *Markman* order construed the term "intravascular blood pump" according to its ordinary meaning. Ordinary meaning in this context is "the meaning that the term would have [had] to a person of ordinary skill in the art in question at the time of . . . the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). The ordinary meaning of a term is a legal question. While the court does not always need to define the ordinary meaning of a term, "[a] determination that a claim term . . . has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute.'" *NobelBiz, Inc. v. Global Connect, L.L.C.*, 701 Fed. App'x 994, 997 (Fed. Cir. 2017).

The devices described and illustrated in the '100 patent appear to be considerably more sophisticated than the device in Voelker. The Voelker system was not designed for insertion into the heart itself, and the pump would produce only a small fraction of the blood flow of the systems contemplated by the '100 patent. And as Leschinsky noted, "the intravascular blood pump systems of the ['100 Patent], [] would have been used for days or weeks" while the device in Voelker would have been used for only "minutes." (Leschinsky Rebuttal R. at ¶ 308). But again, in its earlier *Markman* brief, Maquet contended that the term "intravascular blood pump" should be construed according to its "ordinary meaning," which it explained as follows:

> the 'intravascular blood pump' term means simply a blood pump placed into the body through a blood vessel—the plain and ordinary meaning of the term. Dictionary definitions confirm that ordinary meaning. Intravascular means 'situated in, occurring in, or administered by entry into a blood vessel.' Ex. 27 (*Webster's Medical Dictionary*) at 339. Likewise, 'blood' is well-known and easily understood by a POSA. Blood is defined as 'the fluid that circulates in the heart, artery, capillaries, and veins of a vertebrate animal carrying nourishment and oxygen to and bringing away waste products from all parts of the body.' *Id.* at 77. Finally, 'pump' means 'any of various machines that force a liquid or a gas into or through, or draw it out of, something, as by suction or pressure.['] Ex. 28 (*Webster's College Dictionary*) at 1162–63.

(Docket No. 187 at 20-21).

Notably, while Maquet now contends that the device in Voelker is "on its face . . . [decidedly] not an intravascular blood pump system," it is not in fact supplying any new definition of that term at this stage of the litigation. In other words, it has not offered evidence of an ordinary meaning of "intravascular blood pump" that is different from or narrower than the meaning for which it previously contended.

In any event, the Court need not resolve the issue at this stage. For present purposes, the Court will assume that the device described in Voelker is in fact an "intravascular blood pump," within the meaning of the '100 patent.

(b) "Guide Mechanism"

Abiomed next contends that Voelker discloses the "guide mechanism" element of the asserted claims—that is, "a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient." (Abiomed Supp. Mem. at 14-15).

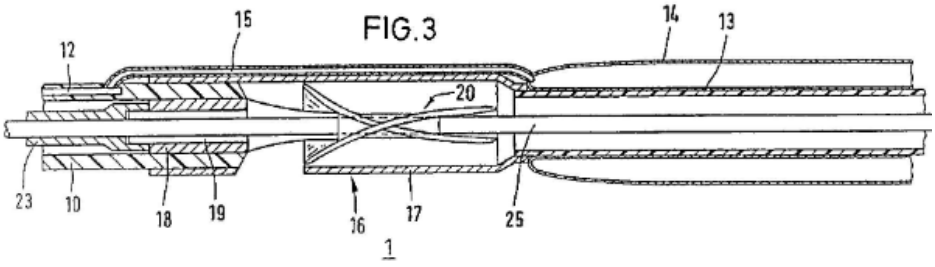
The over-the-wire technique—also known as the "Seldinger" technique—is a technique that was well-known at the time of the invention, and introduces a guide wire into the vascular system of a patient through a suitable access point. ('100 patent, col. 7 ll. 30-33; Aboul-Hosn Dep. at 34-35 (answering "there is a technique called the Seldinger technique . . . called [the] 'over-the-wire' [technique]" when asked "[h]ow were guidewires used for placement in the cardiovasculature?"); *id.* at 34-35 ("[The Seldinger technique] . . . has been used for more than 30 years.")). Similarly, Dr. Leschinsky testified that "[the inventors of the '100 patent] did not invent the concept of advancing something over a guide wire into a patient" but rather invented "a guidance system using a guide wire for delivery of the intravascular blood pump to the vasculature." (Hummel Aff., Ex. 16 ("Leschinsky Feb. 2020 Dep.") at 104-05).

The Court construed the term "guide mechanism" as a means-plus-function term. A term of that nature is obvious if the prior art discloses a function identical to the function at issue, and a structure corresponding to that function or an equivalent thereof. *In re Guess*, 347 Fed. App'x 558, 560 (Fed Cir. 2009); *In re Beigel*, 7 Fed. App'x 959, 962, 963 (Fed. Cir. 2001) ("A proper means-plus-function analysis would compare the structure described in [the patentee] to the structure described in [the prior art reference], to determine if [the prior art reference] discloses identical or equivalent structure.").

The Voelker specification states that "in order to *place* [the] balloon cath[e]ter in[to] a blood vessel, a guide wire is usual[l]y inserted over which the cath[e]ter is then pushed. Such placement using a guide wire is also possible with the present balloon cath[e]ter." (Voelker, col. 2 ll. 34-38) (emphasis added). Maquet does not appear to dispute that Voelker thus discloses an essentially identical function to the function at issue—that is, "guid[ing] an intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient." ('100 Patent, Claim 16). Rather, it disputes that Voelker discloses a structure corresponding to that function.

Abiomed contends that Voelker discloses an over-the-wire structure—that is, a guide wire passing slideably through a central lumen extending through a drive cable assembly, blood pump, and cannula—because the guide wire in Voelker "extends coaxially through the flexible shaft [], the shaft [], and the impeller wheel" and "[such] parts have corresponding axial channels to be slipped over the guide wire (over-the-wire technique)." (Voelker, col. 3 ll. 56-65; *id.*, col. 3 l. 37). It contends that "Voelker's catheter hose (10) around the flexible shaft (23) is the patent's drive cable assembly; Voelker's impeller wheel (20) is the patent's blood pump; and Voelker's balloon support (13) is the patent's cannula." (Abiomed Supp. Mem. at 14-15).

Figure 3 of Voelker



A lumen is, in this context, essentially a tube. Dr. Antaki testified that "the hole through [Impeller 20] [in Voelker] does not extend through the cannula" and thus, "the cannula [in Figure

3] doesn't have some separate lumen somewhere for a guide wire" other than the "*cannula lumen*, the main lumen." (*Id.* at 131-32 (emphasis added); *see also* Baker Dep. at 208 (testifying the Voelker's guide wire emerges "[t]hrough that *central lumen* shown in Figure 1 coming out through the little tip") (emphasis added)).

Abiomed thus contends that the device in Voelker is essentially identical to the device in the '100 patent, which it contends does not have a separate lumen in the cannula. (*See, e.g.*, Docket No. 942 ("Aug. 19, 2020 Tr.") at 39-40) ("[E]verything from the motor to the right in both of these systems is going through the cannula, is going through air. There's not a separate lumen that surrounds it, and the reason for that is because in both of these, in Voelker and in Structure A, the drive cable ends when you get to the rotors.").

That contention finds support in the specification of the '100 patent. That specification states that "the central lumen is established by forming and co-aligning the individual central lumens within each of the drive cable 62, the cable adapter 60, the shaft 46 and hub 56 of the rotor 44, and the cannula 14." ('100 patent, col. 10 ll. 49-53). Moreover, while the specification describes lumens through the drive cable, shaft, and hub of the rotor, there is no description of a separate lumen within the lumen of the cannula or any illustration of such a lumen in the patent's embodiments. (*Id.*, col. 10 ll. 11-16 ("The drive cable sheath 32 includes a central lumen 74 and a plurality of side lumens 76."); *id.*, col. 10 ll. 55-57 ("The central lumens within the cable adapter 60, rotor 44, and gasket 68 may be formed via machining or molding processes.")).

But even assuming that the '100 patent does require "[a tube within a tube] extending through . . . [the] cannula," the Supreme Court has instructed that courts must "remember[] that the 'obviousness' test of § 103 is not one which turns on whether an invention is equivalent to some element in the prior art but rather [turns on] whether the difference between the prior art

and the subject matter in question is a difference sufficient to render the claimed subject matter unobvious to one skilled in the applicable art." *Dann v. Johnston*, 425 U.S. 219, 228 (1976) (internal quotation marks omitted). Neither party has offered any explanation as to whether such a difference is significant or would render the over-the-wire guide mechanism of the '100 patent obvious.

Maquet further contends that there is a genuine dispute as to whether Voelker discloses the over-the-wire structure of the '100 patent because the Voelker structure would not actually function as designed. Dr. Antaki conceded that he was not sure that Figure 3 of Voelker—which illustrates the purported "over-the-wire" structure—could even function. (*See* Antaki Dep. at 128 (testifying that "[he] [was] skeptical [that] Figure 2 [would function]" and "[could] not say whether [Figure 3] would function.")).

An individual prior-art reference "need not be enabled[,] [and] qualifies as a prior art, regardless, for whatever is disclosed therein.'" *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1289, 1297 (Fed. Cir. 2010), *vacated for en banc rehearing on inequitable conduct*, 374 Fed. App'x 35 (Fed. Cir. Apr. 26, 2010). Thus, "[e]ven if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). However, in order to render a claimed apparatus or method obvious, the cited prior art as a *whole* must enable one skilled in the art to make and use the apparatus or method. *Therasense, Inc.*, 593 F.3d at 1297.

The issue with Figure 3 of Voelker appears to stem from the fact that the figure shows the guide wire passing through the impeller blades. Dr. Antaki testified that "[the figures] have interpenetrating impeller blades" and was especially concerned about Figure 2 because it

"doesn't even have [a] hub" like Figure 3 does. (Antaki Dep. at 127-28).[13] However, he testified only that Figure 3 might not function "*as drawn*," and that a person of ordinary skill would nevertheless be able to make the device in Figure 3 work. (Antaki Dep. at 128 (emphasis added); *id.* at 130 ("I believe a person of ordinary skill could figure out how to make [Figure 3] work.")).[14]

Dr. Baker appeared to share Dr. Antaki's concerns, although he was never asked specifically nor testified to whether the figure could function as drawn. He testified that "he [didn't] see how a guidewire [could] go through [the] part of the pump [where the rotor is rotating] and not be interfering with the function of rotation of the pump" but that they must be using it "to get it in there, they withdraw it, and then they turn on the pump." (Baker Dep. at 196). He then noted the portion of the specification that states that "[w]hile the guide wire 25 is in the pump housing, the impeller wheel is not rotated," and testified in light of that, "[s]o it's as I figured it was." (*Id.* at 197).

The guide mechanisms are a core feature of the invention of the '100 patent, and there is evidence in the record that, generally speaking, such mechanisms were new and distinguishable from prior-art guide mechanisms. (*See* Baker Dep. at 31, 222 ("[O]ne of the shortcomings of the [H]emopump was that there was never . . . a lot of thought put into how [] [to] get it in there."); *id.* at 222 ("Clinical stud[ies] show[ed] that [] [doctors] had a hard time placing it," and that

[13] He clarified that by "hub" he meant the "wine-glass-shaped" structure that extends from 18 (the bearing in which the shaft 19 of the impeller wheel 20 is supported) and connects to 20 (the impeller wheel) but is not called out specifically. (Antaki Dep. at 128-29; Voelker, col. 3 ll. 8-10).

[14] It is difficult to determine whether Dr. Antaki's opinion that he could make Voelker's guide mechanism work is based on hindsight, which would be impermissible, or based on a determination that the cited prior art as a *whole*, including the teachings of Voelker and the well-known Seldinger technique, would have enabled one skilled in the art to make and use the apparatus. *See Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) ("The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art.").

guiding it was a "big functional issue"); *see also* Leschinsky Op. R. ¶¶ 155, 156 (noting that the invention "disprov[ed] the conventional wisdom at the time [] that intravascular blood pumps systems adapted to be guided within the circulatory system of a patient should be as simple as possible in their design" because the '100 patent "add[ed] . . . elements" to the guidance mechanisms, which allowed the pumps to be inserted successfully "time and again.")).

If the guide mechanism of the '100 patent is "[a] mere carrying forward or new or more extended application of the original thought, [such as] a change only in form, proportions, or degree, the substitution of equivalents, doing substantially the same thing in the same way by substantially the same means with better results, [it] is not such an invention as will sustain a patent." *Smith v. Nichols*, 88 U.S. 112, 119 (1874). On the other hand, if the guide mechanism of the '100 patent is "[a] new idea [] ingrafted upon an old invention," it is patentable as long as it is "distinct from the conception which preceded it, and [] an improvement." *Id.* at 118-19; *see also Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1302–03 (Fed. Cir. 2010) ("The district court correctly concluded as a matter of law that the differences between the prior art and the claimed improvement were minimal.").

Under the circumstances, and drawing all reasonable inferences in favor of Maquet, the Court concludes that there is a genuine factual dispute as to whether Voelker discloses the "guide mechanism" element of the asserted claims.

ii. Lafontaine Disclosures

Abiomed further contends that Lafontaine discloses the "blood pressure detection mechanism" element of the asserted claims—that is, "a blood pressure detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula."

Claim 17 is a *Markush* claim that lists three claimed blood pressure detection

mechanisms:

> The intravascular blood pump system of claim 16 and further, wherein said blood pressure detection mechanism comprises at least one of [1] fluid filled column disposed within at least a portion of said cannula, [2] a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, and [3] a strain gauge coupled to at least one of the intravascular blood pump and cannula.

('100 Patent). *See Ex Parte Markush*, 1925 Dec. Comm'r Pat. 126, 127 (1924); *Abbott Lab'ys. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1280-81 (Fed. Cir. 2003). "[T]he entire element [of a *Markush* group] is disclosed by the prior art if one alternative in th[at] [] group is in the prior art." *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1298 (Fed. Cir. 2009).

Maquet does not appear to dispute that Lafontaine discloses "a fluid filled column disposed within at least a portion of said cannula." Lafontaine's specification teaches that its column measures "fluid pressure at various places within the human vasculature" including "in specific locations in and around the heart" and does so in part by "fill[ing] [a lumen] with a non-compliant fluid." (Lafontaine, col. 5 l. 31; *id.*, col. 1, ll. 7-8; *id.*, col. 4 l. 11-12). It thus discloses "a fluid filled column disposed within at least a portion of said cannula."

iii. Motivation to Combine and Reasonable Expectation of Success

Even assuming that Voelker in fact disclosed every element of the asserted claims, there is a material dispute as to whether a person of skill in the art would have been motivated to combine Voelker and Lafontaine and would have had a reasonable expectation of success in doing so.

Abiomed contends that there would have been a motivation to combine Voelker and Lafontaine because of the importance of measuring a patient's blood pressure proximate to an

intravascular blood pump system.[15] Thus, it contends that a skilled person would have been motivated to combine Voelker's guide wire with a guide wire, like Lafontaine's, that could sense pressure.

There is no dispute that measuring blood pressure in or near the heart is important to the placement of the pump and its safe operation. A motivation to combine is also implicit in Lafontaine's specification, which discloses "a wire capable of functioning as a guidewire and measuring fluid pressure at various places within the human vasculature" and teaches that it "may be used in *all* [] *procedures* that typically use a guidewire." (Lafontaine, col 1 ll. 6-7; *id.*, col. 4 ll. 5-7 (emphasis added)). Whether, however, a person of ordinary skill would have such a motivation is an issue of fact that is not appropriate for resolution on summary judgment.

Abiomed further contends that a person of ordinary skill would have had a reasonable expectation of success in combining Voelker and Lafontaine "because the guide wire in Voelker and the pressure sensing guide wire in Lafontaine were both designed to place a balloon catheter (and in Voelker, also a blood pump) in[to] a blood vessel." (Abiomed Supp. Mem. at 20). Specifically, Lafontaine explains that "[t]he most widely used form of angioplasty makes use of a dilation catheter which is threaded over a guidewire and has an inflatable balloon at its distal end." (Lafontaine, col. 1 ll. 17-19).

Maquet makes essentially four contentions as to why there is not a reasonable expectation of success. It contends (1) that Lafontaine's guide wire is too stiff to be used with Voelker; (2)

[15] Measuring blood pressure in a patient with an intravascular blood pump is useful because it indicates whether the blood pump is in the correct position in the heart, and different levels of blood pressure are associated with healthy vasculature and with certain maladies. (Lafontaine, col. 2 ll. 59-65; Hummel Aff., Ex. 18, U.S. Patent No. 6,176,822, col. 6 ll. 25-27; *see also* Hummel Aff., Ex. 14 at 28 (discussing using a catheter to measure aortic, central venous, and pulmonary artery pressure during and after insertion of the Hemopump)). Thus, according to Leschinsky, at the time of the invention, measuring the blood pressure of patients who used an internal or external blood pump was "a commonly known thing." (Leschinsky Apr. 2020 Dep. at 104-05, 106 ("[I]n a broad sense . . . it is well known to use – to detect blood pressure whether these pumps are operating or not.")).

that the Lafontaine device is too large to be combined with the Voelker device; (3) that the pressure-sensing capabilities of Lafontaine would be impaired, if not completely crippled, by combining its guide wire with Voelker's; and (4) that Lafontaine requires an impermissibly lengthy set-up and calibration procedure precluding its use in connection with Voelker. (Maquet Opp. at 28-30).

As to each of those issues, the parties have asserted various contentions as to the degree of difficulty involved in adapting the devices and how that might affect how a person of ordinary skill in the art would have a reasonable expectation of success. For present purposes, it is sufficient to note that there are multiple disputed issues of material fact as to those contentions, both individually and when taken as a whole, and that summary judgment in favor of Abiomed is therefore not appropriate.

In summary, there are material disputes of fact as to whether a person of skill in the art would have been motivated to combine Voelker and Lafontaine and would have a reasonable expectation of success in doing so, precluding summary judgment on that basis.

IV. Conclusion

For the foregoing reasons, the motion of Abiomed for summary judgment on the issue of invalidity for failure to satisfy the written description requirement of 35 U.S.C. § 112(a) and for obviousness under 35 U.S.C. § 103 is DENIED.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court

Dated: June 15, 2023