

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH**  
*Petitioners*

**v.**

**Maquet Cardiovascular, LLC**  
*Patent Owner*

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**Case IPR2017-02151**  
**U.S. Patent No. 9,327,068**

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**PATENT OWNER'S EXHIBIT 2010**

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**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

ABIOMED INC.,

Plaintiff and Counter-Defendant,

v.

MAQUET CARDIOVASCULAR LLC,

Defendant and Counter-Claimant,

v.

ABIOMED R&D, INC. and ABIOMED  
EUROPE GMBH,

Third-Party Defendants.

No. 1:16-cv-10914-FDS

**ABIOMED'S OPENING CLAIM CONSTRUCTION BRIEF**

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<b>Exhibit 2</b>	Aboul-Hosn et al., U.S. Patent No. 8,888,728 (“728”)
<b>Exhibit 3</b>	Aboul-Hosn et al., U.S. Patent No. 9,327,068 (“068”)
<b>Exhibit 4</b>	Aboul-Hosn et al., U.S. Patent No. 9,545,468 (“468”)
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<sup>1</sup> Refers to the Exhibits attached as part of the Declaration of John P. Padro in Support of Defendant Abiomed’s Opening Claim Construction Brief, dated December 15, 2017 (“Padro Decl.”).



<b>Exhibit<sup>1</sup></b>	<b>Description</b>
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<b>Exhibit 26</b>	Masch, U.S. Patent No. 4,728,319 (Issued Mar. 1, 1988) ("Masch")

<b>Exhibit<sup>1</sup></b>	<b>Description</b>
<b>Exhibit 27</b>	Sammler et al., U.S. Patent No. 6,544,216 (Issued Apr. 8, 2003) (“Sammler”)
<b>Exhibit 28</b>	Voelker, U.S. Patent No. 6,248,091 (Issued, Jun. 19, 2001) (“Voelker”)
<b>Exhibit 29</b>	Radial, Dictionary.com (2017), <i>available at</i> <a href="http://www.dictionary.com/browse/radial">http://www.dictionary.com/browse/radial</a>
<b>Exhibit 30</b>	Comparison of independent claims of the ’728 and ’068 patents

## I. INTRODUCTION

The standard for construing patent claims is well-established. Courts construe claim terms as they would be understood by a person of ordinary skill in the relevant art, considering the patent's specification and its prosecution history. In this brief, Abiomed provides its proposed constructions of the claim terms in dispute. A complete reading of the patent specifications and their long and convoluted prosecution history is revealing. It shows that the claim terms do not cover every conceivable "intravascular blood pump" but instead require one of three integrated guide mechanisms and other features that are narrow and limited in scope. In contrast, Maquet insists that no claim construction is required—that the plain meaning is sufficient and the Court need look no further. The record shows otherwise, and Maquet's position is deeply at odds with the law.

Maquet's patents all spawned from the same provisional application filed in 1999.<sup>2</sup> They recycle the same ideas, minor details of well-known blood pump technology developed a decade earlier. Maquet drew the patent proceedings out over a period now approaching twenty years. Along the way, it repeatedly narrowed, limited, and qualified the claim language to steer around prior art and to gain allowance. Especially in recent years, it stretched terms, not to cover its own products—since it doesn't practice these patents—but to target Abiomed's.

Maquet's limiting, qualifying, and characterizing of its claims before the U.S. Patent and Trademark Office, while not impermissible, nevertheless has consequences: Maquet's positions narrow the language of the claims, rather than expand them. For that reason, it is crucial to understand the full record, including all admissions and positions taken by Maquet.

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<sup>2</sup> The patents at issue are U.S. Patent Nos. 7,022,100 (the "'100 patent"); 8,888,728 (the "'728 patent"); 9,327,068 (the "'068 patent"); 9,545,468 (the "'468 patent"); 9,561,314 (the "'314 patent"); and 9,397,437 (the "'437 patent").

Maquet now hopes the Court will overlook the voluminous record it is bound to apply when construing the claims. In pre-briefing exchanges, including its response to Abiomed's proposed constructions, Maquet whitewashes its nearly two decade prosecution history, deeming the construction of *every* term in dispute, in *every* asserted claim, to be merely its unexplained "plain meaning." Maquet offers no attempt to state these purported "plain meanings." The entire prosecution history, and even the patent specification itself, are simply assumed to have no impact on construction. Maquet does not even acknowledge them.

At the same time, Maquet points to the entirety of the intrinsic record as "support" for its non-constructions. Maquet dismisses the impact of the intrinsic record through its "plain meaning" assertions, while at the same time reserving for itself the benefit of that record for use at some future time—when needed—without investing any effort to explain to the Court or Abiomed what its theories may be. This leaves Abiomed and the Court with no alternative but to recognize Maquet's position as follows: that no statement in the intrinsic record, neither the patent nor the prosecution history, has a bearing on the scope and understanding of the claims.

Maquet invites serious legal error in suggesting that the Court may ignore the intrinsic record. The public has a right to rely on the full record, including the prosecution history. The Court should resist Maquet's attempt now to rid itself of its claim-limiting characterizations and adopt Abiomed's constructions, which align with the patents' specification and prosecution.

## **II. THE PATENTS**

The patents are nearly identical, sharing a common written description and figures, and differing only in their claims and, even there, only slightly.<sup>3</sup> Although the claims are framed in terms of "intravascular blood pumps," the applicants did *not* invent intravascular blood pumps.

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<sup>3</sup> For simplicity, all cites to the patents are to the '437 patent which incorporates the added subject matter. *See* '437 at 20:24-44 (referencing the subject matter added at 21:4 –33:38).

Nor were they first to create a **guidable** intravascular blood pump, as the patents are titled, that positioned the pump using a guide wire. The patents themselves acknowledge as much.

**A. The “Intravascular Blood Pump” of the Patents**

As each claim requires an “intravascular blood pump,” an understanding of that pump is critical. The patents describe the pump as one driven by a cable that is rotated by a motor located outside the patient’s body (*i.e.*, a cable-driven pump). A cable is necessary to connect, and transmit rotational energy from, the external motor to the rotor inside the patient’s heart.

The patents begin by describing such cable-driven pumps as being part of the prior art:

One type of intravascular pump is an axial flow **blood pump comprising a cable-mounted rotor surrounded by a protective shroud** . . . [wherein a] catheter device encloses a **rotating drive cable** which is coupled to the impeller blade at one end, . . . [where the other end] is mechanically rotated, using a device located outside the patient’s body, [so that the cable] conveys **rotational force** through the length of the catheter, causing the impeller to spin at high speed near the heart.

’437 at 2:1-17 (emphasis added). The patents continue by describing that “[a] significant drawback is that prior art intravascular blood pumps are difficult to guide into the appropriate position within the circulatory system of a patient” (*id.* at 2:23-26) and explaining that “[t]he present invention is directed at eliminating and/or reducing the effects of the foregoing drawbacks of **prior art intravascular blood pumps**.” *Id.* at 2:57-59 (emphasis added). Not surprisingly, the figures of the patents, when they depict the claimed “invention,” consistently show a motor located outside the patient’s body that is connected to the pump inside the heart by a drive cable. *See id.* at Figs. 1, 6, and 10. The patents describe no other blood pump design.

Notably, these types of pumps were a dangerous proposition given that the cable rotated at very high speeds in order to move human blood in adequate quantities. In contrast, the accused Impella® products, after years of painstaking research by their inventor, Dr. Thorsten

Siess, included the first use of an electric motor located inside the patient's heart with the pump. This was a revolutionary departure from the pumps of the asserted patents.

**B. The Patents' Characterization of the "Invention"**

Not only were cable-mounted pumps well known but, as the patents acknowledge, so were "guide mechanisms" for inserting the pumps, such as a guide catheter. *Id.* at 2:36-56; *see id.* at 2:3-13, 2:21-35. The patents refer to three integrated guide mechanisms as the three "broad aspect[s] of the present invention": the over-the-wire, the side rigger, and the guide catheter. '437 at 3:5-19 (the "over-the-wire" type is "a first broad aspect of the present invention"); *id.* at 3:20-34 (the "side rigger" type is "a second broad aspect of the present invention"); *id.* at 3:35-59 (the "guide catheter" type is "a third broad aspect of the present invention").

Maquet was not the first to invent these guide features. They were common, having been used for years by cardiologists to insert catheters for various applications. *See* Ex. 28 (Voelker (its international equivalent Völker was cited during prosecution)) at 3:56-65, Fig. 3 (discussing an "over-the-wire" design); Ex. 24 (Gordon) (also cited during prosecution) at 6:39-45 (discussing a "rapid-exchange" design). During prosecution, Maquet acknowledged that guide wires were known and used in the prior art for inserting and positioning intravascular blood pumps. *See, e.g.,* Ex. 8-A ('068 PH, Nov. 17, 2014 IDS) at MAQ\_00005083-94 (listing prior art references Siess, Völker, and Aboul-Hosn, which all describe the use of guide wires).

Aware of this prior art, the inventors sought to claim something very specific—*integration* of three distinct kinds of guide mechanisms with *known* intravascular blood pumps:

***The present invention*** overcomes the drawbacks of the prior art ***by providing an improved intravascular blood pump equipped with integrated features for selectively guiding*** the intravascular blood pump to a predetermined location in the patient's circulatory system, *i.e.* heart and/or vasculature. In so doing, ***the intravascular blood pump of the present invention eliminates the need for supplemental guiding mechanisms***, such as a separate, large diameter guide catheter ***as used in the prior art.***

'437 at 2:63-3:4 (summary of the invention) (emphasis added); *see also id.* at 8:53-56 (“the **present invention** overcomes the drawbacks of the prior art by providing a guide mechanism as part of the intravascular blood pump.”) (emphasis added), *id.* at 2:57-59 (accord). These guide mechanisms are “integrated;” meaning they do not include temporary guide mechanisms such as a guide wire that is removed before turning on the blood pump. *See, e.g.,* Ex. 7-K, ('728 PH, July 21, 2014 Notice of Allowance) at MAQ\_00004994 (The Examiner explained how the guide wire of Völker (or Voelker), which is removed prior to turning on the rotor, does not meet the claimed requirements); Ex. 12 ('728 POPR, IPR2017-01027) at 63 (Maquet endorsed the Examiner’s interpretation of Völker); *see also, infra* § IV.A.

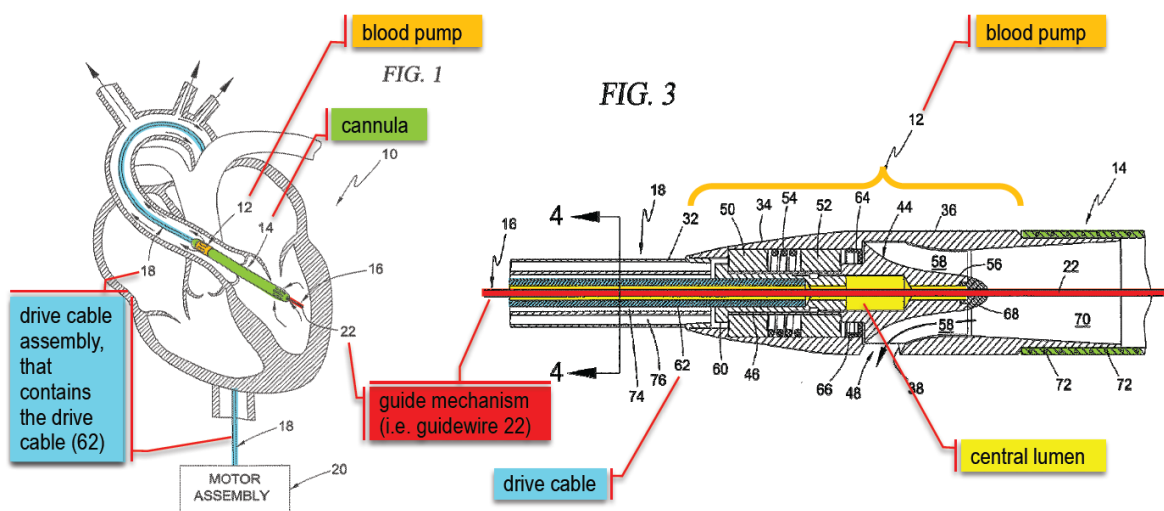
### C. The Integrated Guidance Mechanisms Required by the Asserted Claims

Each asserted claim requires one of the three separate integrated guide mechanisms, each of which has specific arrangements for either (1) a guide wire with a lumen or (2) a guide catheter. Given that the patent alleges that each configuration is a distinct “aspect of the invention,” ('437 at 3:5-59; 9:13-16; 13:62-14:25; 15:5-40), each claims only a **single** one of the three guide mechanisms. Maquet was forced to acknowledge this, conceding during *inter partes* review (IPR) proceedings that the over-the-wire and side-rigger guide mechanisms “are distinct designs [and it] would be nonsensical for a system to include both of these alternative guide mechanisms” (*see, e.g.,* Ex. 15 ('468 POPR, IPR2017-01201) at 42; *see also* '437 at 3:5-59; 9:13-32; 13:62-14:25; 15:5-40 (separately describing each distinct “aspect of the invention”).

The three integrated guidance mechanisms are briefly described here. In the “over-the-wire” design, “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 . . . .” '437 at 3:12-15. Figures 1-5 show a guide mechanism **16** configured as a guidewire **22**

“dimensioned to pass slideably through a central lumen extending through the drive cable [assembly] **18**, blood pump **12**, and cannula **14**.” *Id.* at 9:22-24; Fig. 1; *see also* Fig. 3 & *id.* at 12:47-13:2 (providing a cross section of the blood pump **12**, cannula **14**, and drive cable **22** (and the assembly or catheter **18** that houses it) to show how the guide mechanism **16** runs through a central lumen passing through all such components).

### “Over the Wire” Design



'437 Patent, Figs. 1, 3 (annotated)

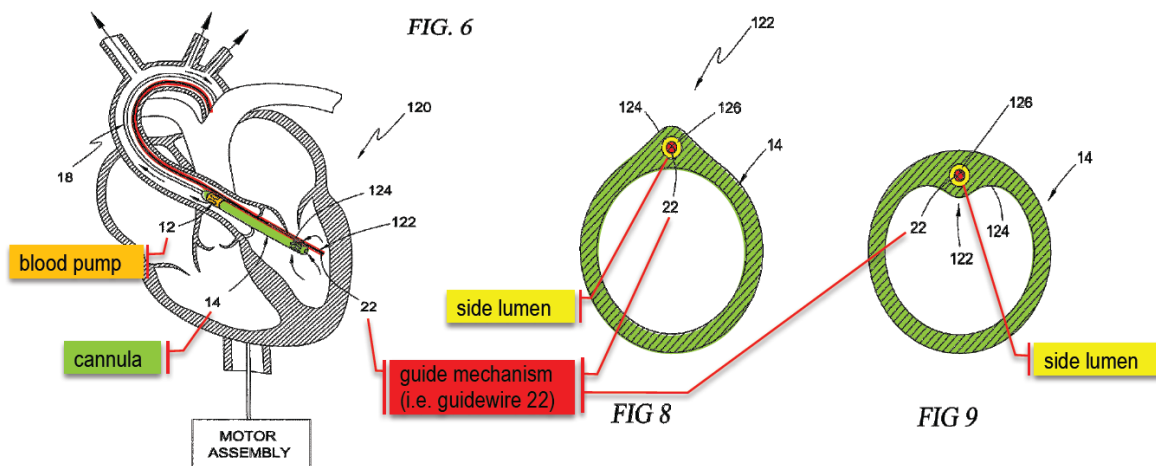
This configuration is known as “over-the-wire” because the entire intravascular device passes over the wire, *i.e.* the wire passes centrally through the entire device, including the catheter and the pump. *See e.g., id.* at 10:47-51.

In contrast to the “over the wire” design, the “side-rigger” or “rapid exchange” design uses “a side lumen [] formed along a length of at least one of the intravascular blood pump and the cannula. A guide element, such as a guide wire, may be advanced [through the lumen].” *Id.* at 3:26-29. The patent explains that “[i]n an important aspect of the present invention, the ‘rapid exchange’ or ‘side rigger’ guide mechanism **122** includes a guide carriage **124** formed along at least a portion of the cannula **14**, and a suitable guide element (such as guide wire **22**)



dimensioned to pass slidably through a lumen (not shown) extending through the guide carriage 124.” *Id.* at 14:15-21, Fig. 7. The patent includes cross-sectional views to show how the lumen for the guide wire is present in the guide carriage formed along the exterior or interior surface of the cannula. It is a lumen formed within the guide carriage. *Id.* at 14:39-44, Figs. 8 & 9.

### “Side Rigger” Design



'437 Patent, Figs. 6, 8, 9 (annotated)

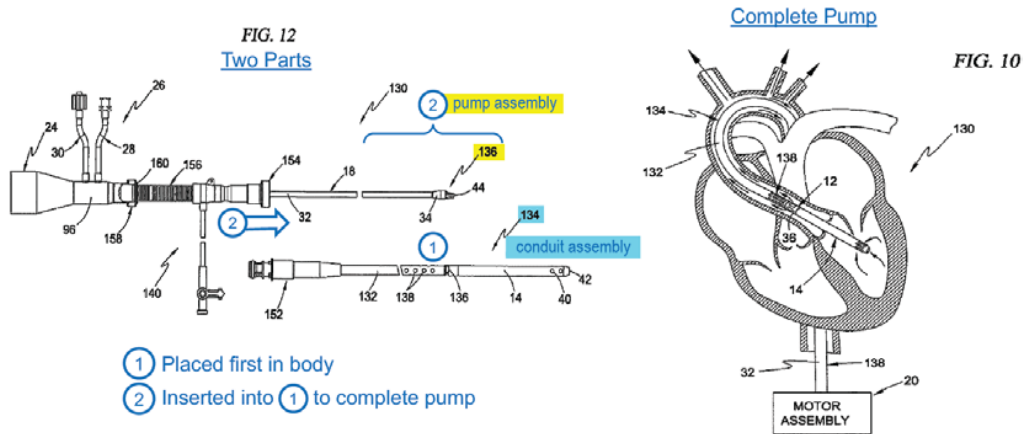
Because the guide mechanism runs along the side of the device, it is called a “side rigger.” Alternatively, it is called a “rapid exchange” system because the guide wire can be inserted and removed from the lumen much faster since the guide wire lumen is far shorter than the “over-the-wire” lumen, which must extend all the way from the heart out of the body.

In contrast to both the side rigger and the over-the-wire designs, the “guide catheter” design is a two-piece device, inserted in two steps, where the blood pump is positioned by first positioning a guide catheter, and then docking the pump into the guide catheter.<sup>4</sup> '437 at 15:5-

<sup>4</sup> Maquet makes no allegation that the accused Impella® devices are a two-piece design, and they are not, so this brief focuses on the “over-the-wire” and “side rigger” designs.

55, Figs. 10-18. Fig. 12 depicts the two separate components: the conduit assembly **134**, which is placed first and contains the cannula **14**, rotor shroud **36**, and guide catheter **132**, and the separate pump assembly **136**, which contains the pump body **34** and rotor **44**, and is placed into the already-positioned conduit assembly **134**. *Id* at Fig. 12, 15:22-55.

### “Guide and Catheter” Design



'437 Patent, Figs. 10, 12 (annotated)

#### D. Certain Asserted Claims Additionally Require Specific Well-Known Features

In addition to requiring an integrated guide mechanism, the claims require various other well-known blood pump features, including, *e.g.*, a cannula, a rotor, and a connective housing that houses components for blood pressure detection or passing purge fluid. The patents do not suggest that the named inventors were the first to develop or apply these known components to intravascular blood pumps, and they were not the first to do so. When the claims require blood pump features, they refer to very specific types of these features, as described below.

### III. THE STANDARD FOR CLAIM CONSTRUCTION

Claim terms should be construed as they would be understood by one of ordinary skill in the relevant art at the time the application was filed, in view of the specification and the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc).

The specification “is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.” *Id.* at 1315 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). When construing claims, courts “strive to capture the scope of the actual invention, rather than . . . allow the claim language to become divorced from what the specification conveys is the invention.” *Retractable Techs., Inc. v. Becton*, 653 F.3d 1296, 1305 (Fed. Cir. 2011). “The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Phillips*, 415 F.3d at 1316 (quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)). Through the specification, applicants may give a specialized definition to claim terms, identify certain terms or features as being essential to the invention, or may disclaim or disavow subject matter that would otherwise fall within the scope of the claim. *Phillips*, 415 F.3d at 1316. When the specification makes definitional statements about the scope of the invention, for example by identifying certain features as the “present invention” or as being “important” to the invention, the claims are necessarily limited to the described invention. *See, e.g., Pacing Techs., LLC v. Garmin Int’l, Inc.*, 778 F.3d 1021, 1024-25 (Fed. Cir. 2015).

In addition to consulting the specification, a court “should also consider the patent’s prosecution history . . .” *Phillips*, 415 F.3d at 1317; *see also Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1094 (Fed. Cir. 2013) (A “term’s ordinary meaning ***must be*** considered in the context of all the intrinsic evidence, including the claims, specification, and prosecution history.”) (emphasis added). Claims cannot “cover subject matter broader than that which ***the patentee itself regarded as comprising its inventions and represented to the PTO.***” *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004) (emphasis added).

Arguments and amendments made during prosecution “to overcome prior art can lead to narrow claim interpretations because ‘the public has a right to rely on such definitive statements.’” *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319, 1325 (Fed. Cir. 2002) (citations omitted). “[T]he specification particularly, but also the prosecution history, informs the determination of claim meaning in context, including by resolving ambiguities; and *even if the meaning is plain on the face of the claim language, the patentee can*, by acting with sufficient clarity, *disclaim such a plain meaning or prescribe a special definition.*” *World Class Tech. Corp. v. Ormco Corp.*, 769 F.3d 1120, 1123 (Fed. Cir. 2014) (emphasis added). Moreover, the original claim scope is also surrendered if claims presented during examination are rejected and the rejected claims are thereafter withdrawn or narrowed. *See, e.g., UCB, Inc. v. Yeda Research & Dev. Co.*, 837 F.3d 1256, 1261 (Fed. Cir. 2016) (“[T]he general rule is that a patent applicant cannot later obtain scope that was requested during prosecution, rejected by the Examiner, and then withdrawn by the applicant.”); *Rheox*, 276 F.3d at 1326 (the deletion of named fertilizer from claims, in response to rejection, disclaims that fertilizer regardless of the applicant’s accompanying arguments).

The law applies not only to statements made to gain allowance in the first instance, but also equally to representations made during *inter partes* review proceedings. *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1363, 1359-61 (Fed. Cir. 2017).

“[W]here multiple patents ‘derive from the same parent application and share many common terms, [the Court] must interpret the claims consistently across all asserted patents.’” *Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1369 (Fed. Cir. 2016). “A statement made during prosecution of related patents may be properly considered in construing a term common to those patents, regardless of whether the statement pre- or post-dates the issuance of

the particular patent at issue.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1343 (Fed. Cir. 2015).

A party’s reliance on a position of “no construction” or “plain and ordinary meaning” is inadequate, particularly when reliance on a term’s so-called “ordinary” meaning does not resolve the parties’ dispute or if the term has more than one “ordinary meaning.” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008). Courts have found constructions “deficient” when a party seeks a “plain and ordinary meaning” construction without explanation. *See, e.g., Baxter Healthcare Corp. v. Mylan Labs. Ltd.*, No. 14-7094 (JBS/JS), 2016 U.S. Dist. LEXIS 45670, at \*15-16 (D.N.J. Apr. 5, 2016).

#### IV. GUIDE MECHANISM TERMS

Maquet purports to have invented the use of integrated guide mechanisms, but Maquet was not the first to conceive of such a solution. To obtain the patents, Maquet repeatedly distinguished its claims from the prior art on the grounds that the guide mechanisms of the patents differed from the prior art. Maquet’s statements about these differences are binding; they define and limit the claims and resolve ambiguities about the claim scope.

##### A. Every Independent Claim Requires a Guide Wire and a Lumen that Do Not Pass Through the Free Space between the Rotor Blades

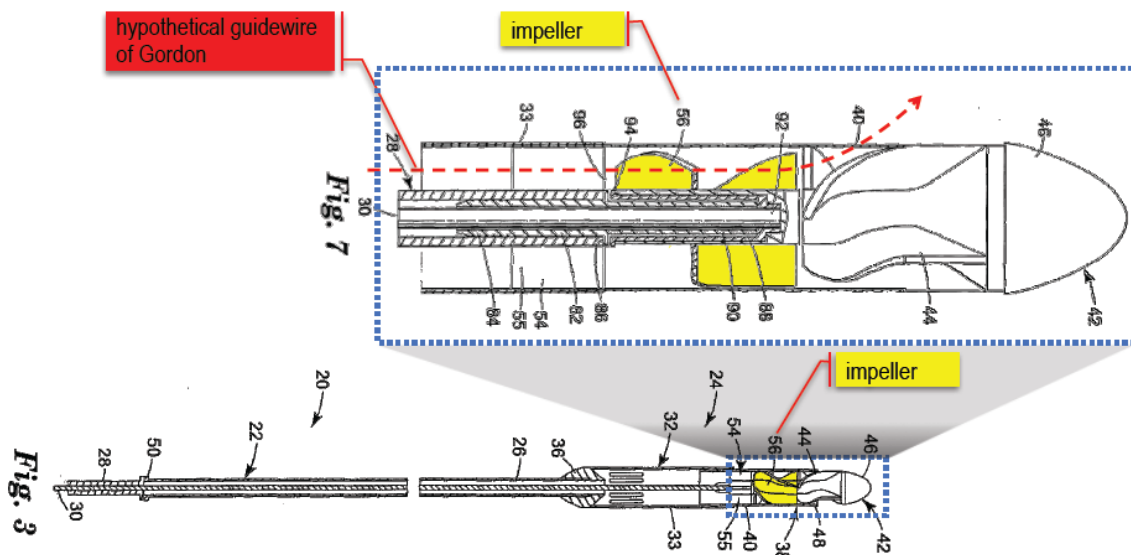
Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“guide mechanism” (100: 16) “elongate lumen sized to slideably receive a guide wire” (468: 1, 22; 437: 1, 28; 314: 1, 20, 27) “guide mechanism is configured as a second lumen... wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong” (728: 1; 068: 1) “a guide mechanism configured as an elongate lumen ... a guide wire arranged to be advanced along the lumen” (728:10)	100: 9, 16 728: 1, 10 068: 1, 10, 20 468: 1, 22 314: 1, 20, 27 437: 1, 28	“lumen and guide wire not extending through the free space between the rotor blades”	Plain meaning

“guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump ... the method comprising: ... advancing the blood pump system along the guide wire” (068: 10)  “elongate lumen having a luminal interior... sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong ... advancing the blood pump along the guide wire to the predetermined location” (068: 20)			
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	--	--

A significant part of this case turns on a clear concession by Maquet during prosecution<sup>5</sup>: Maquet repeatedly sought to distinguish the patents by representing—and emphasizing—that the guide wire and its lumen do not pass through the “free space” between the rotor blades of the pump. As Maquet was forced to admit, such a design would be “inoperable” because the guide wire and its lumen would be threaded between the blades of the impeller and prevent the impeller from rotating. Maquet’s statements, quoted in detail below, constitute prosecution disclaimer. The proper construction of the claim terms must incorporate these representations by Maquet.

Maquet first advanced its position in an interview and follow-on exchange with the Examiner during prosecution of the ’728 patent. In the interview, Maquet explained that the very nature of its alleged invention excluded insertion of an impediment in the rotor blade free space: “Applicant clarified the nature of the invention, noting that the rotors require a space to rotate within the shroud while pumping blood . . . .” Ex. 7-H (’728 PH, Feb. 24, 2014 Examiner Interview) at MAQ\_00004714. Maquet contrasted the claims from the prior art reference Bedingham, arguing that if “Bedingham were modified with guidewire lumen 46 of Gordon, it would occupy space within the shroud and obstruct impeller 56 of Bedingham.” *Id.*

<sup>5</sup> “Prosecution” refers to both the original prosecution history and the IPR proceedings.



Bedingham, Figs. 3, 7 (annotated)

This concession is critical and, as discussed below, applies not only to the claims of the '728 patent but to all related patents. An applicant's statements about the "invention" "unambiguously" reflect the applicant's "own understanding of its inventions" and they constitute a clear disavowal of such a configuration. *Microsoft Corp. v. Multi-Tech Sys.*, 357 F.3d 1340, 1349-50 (Fed. Cir. 2004); *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1376 (Fed. Cir. 2008) (holding prosecution statements regarding "the Applicants' invention" constituted clear and unambiguous disavowal).

Maquet followed this Interview with a further representation and admission about how the distinction applies to the claim language "*guide mechanism configured as a second lumen*"<sup>6</sup> (found in claim 1 of the '728 patent and claim 1 of the '068 patent) and the claim language "*guide mechanism configured as an elongate lumen*" (found in claim 10 of the '728 patent and claim 10 of the '068 patent). Ex. 7-I ('728 PH, Mar. 28, 2014 Amendment and Response) at

<sup>6</sup> For clarity, proposed and issued claim language is italicized throughout the brief.

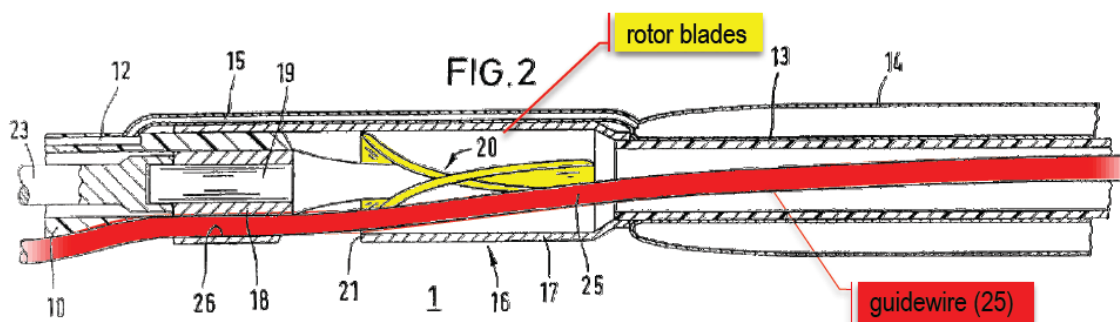
MAQ\_00004724. In particular, Maquet admitted that these terms require a lumen designed for a guide wire, and that the guide wire cannot merely run through the pump housing itself without the aid of this lumen. *Id.* (“Instead of a guide wire mechanism configured as a lumen [such as in the claim terms], Bedingham only suggests inserting a guide wire into the existing structure of the pump housing ... so that the guide wire passes between the vanes of the outlet flow straightener, the impeller and inlet flow straightener.”) (internal citations omitted); *id.* at MAQ\_00004728 (same). Maquet then reemphasized its Interview statement that modifying Bedingham to add a dedicated guide wire lumen “would render the resulting modified device *inoperable*,” because it “would thus result in the lumen 46 and its sidewall being located in the open space between the blades of the blood pump of Bedingham. If such a lumen were so arranged, the blades of the motor would hit the wall of the lumen and be unable to rotate, thereby preventing the blood pump from operating.” *Id.* at MAQ\_00004726 (emphasis added); *see also id.* MAQ\_00004729. Consequently, Maquet made clear that the claims exclude designs that pass the guide wire and dedicated guide wire lumen and the guide wire itself through the free space between the rotor blades.

The Examiner relied on this distinguishing feature as the reason for allowing the ’728 claims over *two* prior art references. *See* Ex. 7-J (’728 PH, Apr. 7, 2014 Notice of Allowance) at MAQ\_00004746 (the Examiner explained that “[m]odifying Bedingham and Nix with Gordon *would not provide an operable device* since Bedingham requires free space for impeller 56 to rotate.”) (emphasis added); *id.* at MAQ\_00004748 (“Masch provides no teaching for how to modify ... impeller 56 ... in order to pass a guidewire.”). The Examiner’s understanding of prosecution arguments was decisive in his allowance of the claims and reflects how a person of ordinary skill would understand those arguments. *See Salazar v. Procter & Gamble Co.*, 414



F.3d 1342, 1347 (Fed. Cir. 2005) (“Statements about a claim term made by an examiner during prosecution of an application may be evidence of how one of skill in the art understood the term at the time the application was filed.”); *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1332 (Fed. Cir. 2013) (explaining that “examiner’s statement during reexamination was . . . representative of how one of skill in the art would understand the term.”).

After considering additional art, the Examiner again allowed the ’728 claims for the same reason, specifically distinguishing prior art that ran the guide wire through the rotor blade free space. *See* Ex. 7-K (’728 PH, July 21, 2014 Notice of Allowance) at MAQ\_00004994. In particular, the Examiner explained that “Völker does not provide a separate second lumen for the guide mechanism. Instead, *Völker threads guidewire 25 through the pump housing, which temporarily prevents the rotor from turning* (p. 14, ¶4, while the guide wire 25 is located in the pump housing, no Rotation (sic) of the impeller). Therefore, Völker fails to teach or suggest the side-rigger or coaxial guide mechanisms of [then-pending] claims 15, 29 or 45 [issued independent claims 1, 10 and 22].” *Id.* (emphasis added). Fig. 2 of Völker shows this concept in practice—guide wire (25) runs within the free space between the rotor blades (20), and would therefore jam the rotor if not removed before the rotor begins to rotate (the non-removable guide wire lumen required by the claims would similarly jam the rotor if it were present).



Völker, Fig. 2 (annotated)

Thus, the claims issued over *three* prior art references because those references pass the guide wire and its lumen through the free space between the rotor blades.

During *inter partes* review, Maquet expressly endorsed the Examiner's reasons for finding the claims patentable over Völker. Ex. 12 ('728 POPR, IPR2017-01027) at 63. ("One reference that the Examiner explicitly considered and found the claims patentable over is Voelker ... As such, Patent Owner submits that the Board should defer to Primary Examiner Kidwell's [sic] considered judgment and deny the Petition."); *see also* Ex. 11 ('728 POPR, IPR2017-01026) at 64. This express endorsement is binding on Maquet and cannot now be ignored. *See, e.g., Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1097 n.6 (Fed. Cir. 2013) (holding "adoption" of examiner's characterization constitutes prosecution disclaimer). The claims of the '728 patent must therefore be construed to exclude guide mechanisms that run the guide wire or the guide lumen through the free space between the rotor blades because they would jam the blades if the pump were actuated with the wire in place.

Maquet's acknowledgement that neither the guide wire nor its lumen can run through the rotor blade free space does not only apply to the independent claims of the '728 patent. Concessions made to gain allowance of a patent apply to its family members that claim similar subject matter. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1343 (Fed. Cir. 2015). That reasoning applies especially here because the same distinction was critical to allowance of claims beyond the '728 patent. For example, in allowing claims with the term "an elongate lumen sized to slideably receive a guide wire"—found in a number of patents (*see* chart above (start of this section))—over Bedingham, the Examiner stated that, "Bedingham also lacks an elongate lumen sized to slidably receive a guide wire. At most, Bedingham calls for a guide wire that does not pass through a separate lumen, but instead passes through existing openings of

the rotor and pump.” *See* Ex. 9-D (’468 PH, Nov. 22, 2016 Notice of Allowance) at MAQ\_00009242 (internal citations omitted). Similarly, in its IPR responses defending the claims of the ’068 patent, Maquet again ratified the Examiner’s understanding of Völker. *See* Ex. 13 (’068 POPR, IPR2017-01028) at 64; Ex. 14 (’068 POPR, IPR2017-01029) at 64.

Even though the claim language differs slightly in each asserted claim, as reflected in the chart above, the concept that the guidewire and its dedicated lumen cannot pass through the rotor blades remains the same throughout. *See, e.g., Advanced Cardiovascular Sys. v. Medtronic Vascular, Inc.*, 182 F. App’x 994, 997 (Fed. Cir. 2006) (holding “circular member,” “stent member,” “ring,” and “endovascular support member,” found in later patents, to have the same construction as “stent,” found in the parent patent, when the terms from the later patents were used “in a manner analogous to and interchangeable with the term ‘stent’” in the claims).

The specification of the patents is consistent with the clear disavowals made by Maquet during prosecution—the specification provides no teaching or example where the guide wire, or its dedicated lumen, passes through the free space between the rotor blades. The “over-the-wire” approach requires that “a central lumen is formed through at least a portion of the intravascular blood pump system” (’437 at 3:11-14) and this central lumen runs through the central hub of the rotor, not the free space for the rotor blades (*id.* at 9:12:47-55). *See also* Fig. 3 (showing the guide wire lumen passing through the rotor hub). Similarly, the “side rigger” type requires that “a side lumen is formed along a length of at least one of the intravascular blood pump and the cannula” and therefore does not pass through the free space for rotor blades either. ’437 at 3:26-29; *see also* Fig. 7 (showing the guidewire running outside of the rotor blades). The “guide catheter” does not use a guide wire to insert the pump rotor into the housing and therefore is not relevant to the asserted claims.

None of the patents' embodiments runs the guide wire through the rotor blade free space; nor does the patent specification offer any suggestion of how this could be achieved by modifying any of the described embodiments. This is not surprising, because the patents contemplate that the guide wire may remain in place while the rotor turns. *See* '437 at 12:59-13:2 (discussing that, in the over-the-wire design, the central lumen should be sized to avoid "inadvertent rotation of the guide wire during pump operation" and removal of the guide wire is optional); 14:48-53 (discussing that removal of the guide wire is optional in the side-rigger).

Abiomed's construction, set forth in the table above, is thus consistent with the specification and is required by the prosecution history and IPR positions Maquet has taken. Due to the clear and unambiguous disavowal during prosecution of systems that extend the guide wire and the guide wire lumen through the free space between the rotor blades, and the Examiner's clear understanding and reliance upon the criticality of this distinction in allowing the claims to issue, each of these claim terms should be construed to require that the "lumen and guide wire not extend[ ] through the free space between the rotor blades."

This construction applies equally to claim 16 of the '100 patent, even though it pre-dates the cited prosecution statements and does not expressly recite a guidewire or guidewire lumen. Claim 16 contains claim language "*guide mechanism adapted to guide said intravascular blood pump*"—the same found in other claims that are subject to the above-described prosecution disclaimer (*see, e.g.*, '068 at claim 10). Because Maquet's disclaimer was not limited to a specific claim or guide mechanism type, but concerned the overall inventions disclosed in the patents, claim 16 must be construed consistently with Maquet's later patents given the common claim language. *See, e.g., Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1369 (Fed. Cir. 2016) ("where multiple patents derive from the same parent application and share many

common terms, we must interpret the claims consistently across all asserted patents.”); *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1343 (Fed. Cir. 2015) (“statement made during prosecution of related patents may be properly considered in construing a term common to those patents, regardless of whether the statement pre- or post-dates the issuance of the particular patent at issue.”). Further, as described below, Claim 16 is a means-plus-function term and thus limited to the three guide mechanisms disclosed in the specification, none of which suggest a guide wire running through the free space between the rotor blades. *See* § VIII.B.1.

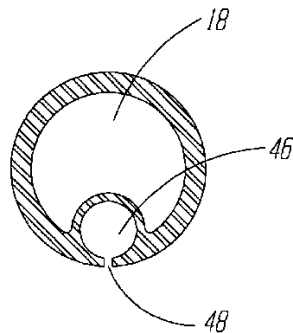
**B. The “Over-the-Wire” Claims Require the Lumen to Extend Through the Cannula and the Catheter**

Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“wherein the lumen is arranged coaxially with [at least one of a distal end or a proximal end] / [a portion] of the cannula”	728: 10 068: 10, 20 314: 1, 20	“A guide lumen that passes coaxially through [at least one of a distal end or a proximal end] / [a portion of] the cannula and extends through the catheter”	Plain meaning

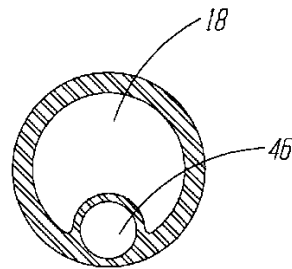
This dispute is whether the guide wire lumen in the above “over-the-wire” claims must not only extend through the cannula, but also through the catheter that extends out of the body. During prosecution, Maquet conceded that the lumen must extend through both structures, and this design is reflected in the specification and in Abiomed’s construction.

On its face, the claim term describes an “over-the-wire” configuration because it requires that the lumen is coaxial with (*i.e.*, shares a common axis with) one end of the cannula. *See* § II.C (background). The only lumen that meets this description is the lumen of the “over-the-wire” configuration demonstrated in Figs. 1-5. ’437 at Figs. 1-5, 12:47-63; *see also id.* at 9:13-32; 10:47-57. Consistent with this understanding, when Maquet added the above claim limitation during prosecution, Maquet cited the “over-the-wire” design of Figs. 1-3 as support. *See* Ex. 7-F (’728 PH, Nov. 8, 2013 Amendment and Response) at MAQ\_00004663 (claim 29),

MAQ\_000004667. In that amendment, Maquet cited this same support and the “coaxial” claim language to distinguish the prior art Gordon (*id.* at MAQ\_00004670). Specifically, Maquet argued that in “Figures 5(b) and 5(c) . . . the lumen (46) of Gordon is not coaxial with either the distal or proximal ends of the catheter.” *Id.*



*FIG. 5(b)*



*FIG. 5(c)*

The Examiner understood Maquet’s distinction in the way any person of ordinary skill would, stating that the claim language in then-pending claim 29, “a *guide mechanism having a lumen arranged coaxially with the cannula*,” “describes the . . . ‘over-the wire’ guide mechanism.” Ex. 7-G (’728 PH, Nov. 25, 2013 Final Rejection) at MAQ\_00004679.

The Examiner’s November 25, 2014 Office Action is important for a second reason. The Examiner was responding to Maquet’s attempt to add dependent claim 30 (which depended from claim 29, which is quoted in the paragraph above). Claim 30 included the phrase “*the guide wire passing through the elongate lumen in the cannula but not extending through the catheter.*” *Id.* (emphasis added).

The Examiner rejected the proposed language of dependent claim 30 because it was not “enabled” under 35 U.S.C. § 112, ¶ 1. The Examiner explained that “no single embodiment or combination of embodiments discloses a coaxial guide lumen that passes through an elongate lumen in the cannula and does not extend through the catheter.” *Id.* at MAQ\_00004680. In

other words, the Examiner rejected the claim language for inappropriately combining the “side rigger” concept, where the guide wire and its lumen pass outside the catheter (*i.e.*, do not extend through the catheter) with the “over-the-wire” concept, where the guide wire and its lumen extend through the catheter. These differences are illustrated, for example in the Background above (§ II.C) where Figure 6 of the patents shows guide wire 22 running next to the catheter in the “side rigger” design,” while Figures 1 and 3 of the patents show guide wire 22 running through the center of the pump to the catheter in the “over-the-wire” design.

Maquet did not dispute the Examiner’s characterization but simply canceled the rejected claim 30 and its language, “*the guide wire passing through the elongate lumen in the cannula but not extending through the catheter.*” Ex. 7-I (’728 PH, Mar. 28, 2014 Amendment and Response) at MAQ\_00004723. The consequence of Maquet’s cancellation of dependent claim 30 is that the claim on which it depended, then-pending claim 29 (now claim 10 of the ’728) and its language, “*a guide mechanism having a lumen arranged coaxially with the cannula,*” is properly understood to require that the guide wire **must** extend through the catheter. *See, e.g., UCB, Inc. v. Yeda Research & Dev. Co.*, 837 F.3d 1256, 1259-61 (Fed. Cir. 2016) (holding that cancelling dependent claims during prosecution following an examiner’s rejection constitutes surrender of the dependent claims’ scope from within any allowed independent claims); *Rheox*, 276 F.3d 1319 at 1326.

Moreover, the Examiner correctly determined that the “over-the-wire” claims require the guide wire lumen to extend through the catheter. The “over-the-wire” disclosures in the specification, Figs. 1-5, all depict a guide wire **22** passing through the central lumen of the entire device, including the central lumen of the drive cable assembly **18** (*i.e.* the catheter) and the central lumen of the pump and cannula. *See supra* § II.C; *see also* ’437 at Figs. 1-5; 12:47-63;

*see also id.* at 9:13-32; 10:47-57. Modifying the configuration, as Maquet sought to do with dependent claim 30, would require deviating substantially from the consistently disclosed design. Specifically, it would have required the undisclosed combination of the “over-the-wire” and “side rigger” designs, which Maquet admitted was not practical. During *inter partes* review, Maquet further embraced the Examiner’s distinction that it was inappropriate to combine these embodiments, arguing that “both ***the challenged patent*** and the Petition ***agree*** that an over-the-wire guide feature and a rapid exchange guide system ***are distinct designs. It would be nonsensical for a system to include both of these alternative guide mechanisms . . .***” Ex. 15 (’468 POPR, IPR2017-01201) at 42 (internal citations omitted) (emphasis added). Accordingly, the claim must reflect what the specification says is the “scope of the ***actual*** invention.” *See e.g., Retractable Techs., Inc. v. Becton*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) (emphasis added); *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1355 (Fed. Cir. 2006) (Claims do not “enlarge what is patented beyond what the inventor has described as the invention.”).

Abiomed’s proposed construction applies what is plain from the prosecution and the patents themselves—the guide wire lumen of the “over-the-wire” claims must extend “coaxially through” the cannula and through the catheter as well.

### C. The “Side Rigger” Claims

Although the prose styles of the claim terms presented below differ (as does their scope, though only slightly), the meanings of these terms were formed through their extensive prosecution history as Maquet sought to capture a “side-rigger” concept while navigating a crowded field of prior art. While both terms describe a permanent lumen that runs along the cannula, the “delimited by the outer cannula surface” term is narrower given its explicit reference to being within the cannula surface.



**1. Certain “Side Rigger” Claims Require a Permanent Guide Wire Lumen Formed Along the Side of the Cannula**

<b>Claim Term</b>	<b>Claims</b>	<b>Abiomed’s Proposal</b>	<b>Maquet’s Proposal</b>
“an elongate lumen associated with the cannula”	468: 1, 22 314: 27 437: 1, 28	“a permanent lumen formed along the side of the cannula”	Plain meaning

The claim term “an elongate lumen associated with the cannula” refers to a guide wire lumen of the side-rigger type. The term is properly construed as calling for “a permanent lumen formed along the side of the cannula.” This construction follows from the claim language and specification, and is required by two critical narrowing limitations Maquet made during prosecution: (1) each claim that requires “an elongate lumen associated with the cannula” claims a “side-rigger” design due to other language in the claim; and (2) the elongate lumen claimed in those side rigger claims is a permanent side lumen of the cannula, rather than a separate, removable lumen.

The claim language in the specification sheds light on the claim term. Claim 1 of the ’468 patent is representative, as each claim above requires:

*An intravascular blood pump system, comprising: . . .*

*a cannula coupled to a distal end of the intravascular blood pump, . . . ;*

*an elongate lumen associated with the cannula and sized to slidably receive the guide wire . . . both the elongate lumen and the cannula lumen not extending through the rotor hub, . . . the guide wire not passing through the rotor hub or the catheter; . . .*

’468 at 33:58-34:42 (claim 1). Importantly, the claims require that the elongate lumen “*slidably receive the guide wire*,” meaning the elongate lumen is designed for the guide wire. They also require that the elongate lumen “*not extend through the rotor hub*,” a marked distinction from the over-the-wire design where the lumen passes through the rotor hub. *See supra* §§ II.C & IV.B.

The claim term “*guide wire not passing through the catheter*” provides particularly important context as Maquet admitted during prosecution of the related ’728 patent that this phrase refers to a “side rigger” design. *See supra* § II.C. As described above, the Examiner rejected Maquet’s attempt to combine the phrase “*guide wire not passing through the catheter*” with a claim directed to the over-the-wire guide mechanism, on the grounds that “no single embodiment or combination of embodiments discloses a coaxial guide lumen that passes through an elongate lumen in the cannula and does not extend through the catheter.” Ex. 7-G (’728 PH, November 25, 2013 Final Rejection) at MAQ\_00004680. Maquet did not challenge the Examiner’s characterization and instead cancelled the dependent claim containing the “*guide wire not passing through the catheter*” limitation, leaving only the “over-the-wire” claim. Later, Maquet echoed the Examiner’s understanding of its claimed invention during *inter partes* review: “It would be nonsensical for a system to include both of these alternative guide mechanisms [over-the-wire and side rigger].” Ex. 15 (’468 POPR, IPR2017-1201) at 42.

The public is entitled to rely on Maquet’s acquiescence in the Examiner’s interpretation that the claim term “guide wire not passing through the catheter” refers to the “side-rigger” design. *See supra* § II.C (background); *Biogen*, 713 F.3d at 1095-97. Because the claims are side-rigger claims, at least due to inclusion of the “guide wire not passing through the catheter” claim language, the claim term “elongate lumen associated with the cannula,” refers to a side-rigger guide wire lumen.

During *inter partes* review, Maquet repeatedly emphasized that the elongate lumen of the above side rigger claims must be a permanent lumen. Regarding the “*elongate lumen*” limitations of the ’468 patent, Maquet distinguished the Jegaden prior art because “Jegaden ***does not teach or suggest a permanent lumen*** at the distal end of the cannula. Thus, Jegaden fails [to

disclose the alleged invention] for this and several additional reasons.” Ex. 15 (’468 POPR, IPR2017-01201) at 48. Therefore, Maquet concluded that Jegaden lacked “*an elongate lumen.*” *Id.* Maquet likewise repeated this distinction with the “*elongate lumen*” limitations of the ’314 patent: “Jegaden provides a separate device—a catheter with a guide wire—to guide an unmodified device into a patient. If anything, this teaches away from Petitioners’ proposed modification, as Jegaden teaches using a separate catheter *instead of modifying the cannula to accommodate a side lumen.*” Ex. 19 (’314 POPR, IPR2017-01205) at 46-47 (emphasis added). Maquet sought to differentiate its claimed “elongate lumen” from Jegaden’s removable guide catheter on the grounds that the claimed lumen is a permanent side lumen of the cannula. The public is entitled to rely on these statements, and Maquet cannot now deny them. *Biogen Idec*, 713 F.3d at 1095.

Abiomed’s construction that the guide lumen is “a permanent lumen formed along the side of the cannula” is consistent with the definitional statements made in specification. In the Summary of the Invention, the patents state: “To accomplish [the side-rigger design], a side lumen is *formed along a length of* at least one of the intravascular blood pump and the cannula.” ’437 at 3:26-29 (emphasis added). Such a statement in the Summary of the Invention Section” constitutes a “clear and unmistakable statement of disavowal or disclaimer” when it described the “present invention;” here, the statement defines the side rigger invention. *See, e.g., Pacing Techs., LLC v. Garmin Int’l, Inc.*, 778 F.3d 1021, 1024-25 (Fed. Cir. 2015); *C.R. Bard, Inc. v. United States Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004) (“the location [in the Summary of the Invention] can signal the likelihood that the statement will support a limiting definition.”).

In the Detailed Description, the patents continue to define the side-rigger design consistent with Abiomed’s construction: “In *an important aspect of the present invention*, the

“rapid exchange” or “side-rigger” guide mechanism 122 includes a guide carriage 124 formed *along at least a portion of the cannula 14 . . .*” ’437 at 14:15-21 (emphasis added). The figures consistently depict a permanent lumen along the side of the cannula. *See, e.g., id.* at Figs. 6-11 and 21, 23, 25-26, 31; *see also supra* § II.C. The patent explains that “FIGS. 7 and 8 . . . illustrat[e] the guide carriage 124 *formed along the exterior surface of the cannula 14*. FIG. 9 illustrates an alternate embodiment wherein the guide carriage 124 may be *formed along the interior surface of the cannula 14*.” *Id.* at 14:39-44. The patents explain the benefits of a side-rigger design that has a permanent guide lumen along the side of the cannula: “because the guide mechanism 122 is *disposed along the side of the cannula 14*, there is no need to form a central lumen extending through the blood pump 12 . . . . [Consequently,] components need not be specially machined or molded to include such central lumens as was required [by the over-the-wire design].” *Id.* at 14:63-15:4. Such repeated and consistent characterizations of the invention define the scope of the claim. *See Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d at 1347-48 (Fed. Cir. 2004) (limiting claim terms to an embodiment that was “repeatedly and consistently describe[d]”). Notably, a non-permanent lumen is not mentioned.

For all of these reasons the term “elongate lumen associated with the cannula” refers to a side rigger configuration, and should therefore be construed to mean “a permanent lumen formed along the side of the cannula,” consistent with the patent and the prosecution history.

**2. Certain “Side Rigger” Claims Require the Guide Wire Lumen to be Integrally Formed within the Cannula Surface**

Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface”	728: 1 068: 1	“guide lumen integrally formed within the surface of the cannula”	Plain meaning

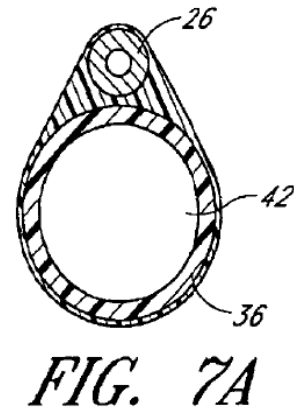
Like § V.A above, the above claims require a side-rigger guide wire mechanism. The claims, however, are even narrower, describing a side-rigger configuration where the axis of the guide mechanism “*extends through a region delimited by the outer cannula surface.*” While obscurely worded, the prosecution history and specification demonstrate that this term refers to a guide lumen integrally formed within the cannula surface, as particularly illustrated in Figs. 8-9.

Claim 1 of the ’728 patent and claim 1 of the ’068 patent require a portion of the guide mechanism to have an “axis coaxial with and extending through . . . a region delimited by the outer cannula surface.” On its face, this claim term is contrived, confusing, and ambiguous. What little can be gleaned from the words alone is that the axis of the guide mechanism passes within the cannula structure itself (*i.e.*, the region delimited by the cannula’s outer surface).

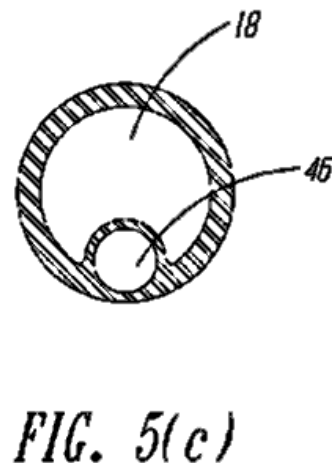
The surrounding claim language provides some additional explanation. In particular, because each claim requires three separate lumens—the “*cannula*” (a lumen “transporting fluid into the blood pump” (’437 at 15:56-62)), a “first lumen . . . operatively arranged to deliver purge fluid,” and “a guide mechanism configured as a second lumen”—thus, the guide mechanism lumen cannot merely be the cannula itself. *See, e.g.*, ’728, claim 1.

The lack of clarity in the claims is the direct result of their tortured prosecution. No fewer than eight (8) office actions and responses implicated the term, over the course of which Maquet amended the term twice to avoid prior art. Throughout this process, the common understanding guiding both Maquet and the U.S. Patent and Trademark Office (“USPTO”) was that Maquet sought claim language to cover a side-rigger design where the guide lumen is within the surface of the cannula.

Then-pending claim 15 of the '728 patent (now issued claim 1) initially required that the “guide mechanism is configured to accept a guide wire for passage through a *side lumen formed in* said distal portion of said intravascular blood pump system.” Ex. 7-A ('728 PH, June 16, 2011 Preliminary Amendment) at MAQ\_00004467-68 (emphasis added). To overcome the prior art Bagaoisan patent (U.S. Pat. 6,849,068), which disclosed a side lumen (guide wire **26** is placed in it) in the cannula **42** (Fig. 7a), Maquet narrowed the claim language by requiring that the “*guide mechanism is positioned along a length of the cannula and interior to a region delimited by the outer cannula surface.*” Ex. 7-B ('728 PH, July 17, 2012 Amendment and Response) at MAQ\_00004564 (emphasis added). Maquet emphasized the bolded language as one of the features Bagaoisan lacked. *See id.* at MAQ\_00004568.



Nonetheless, the Examiner again rejected the claims, concluding that Gordon (U.S. Pat. 5,938,645) disclosed a guide lumen interior **46** to the cannula surface (Fig. 5c) that could be combined with blood pumps disclosed by other prior art. Ex. 7-C ('728 PH, Aug. 28, 2012 Final Rejection) at MAQ-00004584. In response, Maquet amended the term again, replacing it with the current “wherein” language. *See* Ex. 7-D ('728 PH, Feb. 28, 2013 Amendment and Response) at MAQ\_00004616. Maquet made no argument to distinguish Gordon in relation to the guide lumen, focusing instead on other claim amendments. *Id.* at MAQ\_00004625-26.



When the “wherein” language was added, the Examiner stated his understanding that the claim had “been amended to describe the ‘side rigger’ or ‘rapid-exchange’ guide mechanism described in the specification” and cited Fig. 9 and its description as support. Ex. 7-E (’728 PH, May 8, 2013 Non-Final Rejection) at MAQ\_00004633 (emphasis added) (“¶ [0074], Fig. 9, guide carriage 124 *formed along the interior surface of the cannula 14*”). The Examiner had previously cited the same Fig. 9 disclosure as support for the earlier version of the claim language—“wherein said guide mechanism is positioned along a length of the cannula and interior to a region delimited by the outer cannula surface.” Ex. 7-C (’728 PH, Aug. 28, 2012 Final Rejection) at MAQ\_00004584. The Examiner understood that the original and revised claim language reflected the same core concept described by Fig. 9; one of skill in the art would understand the term the same way. *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1332 (Fed. Cir. 2013).

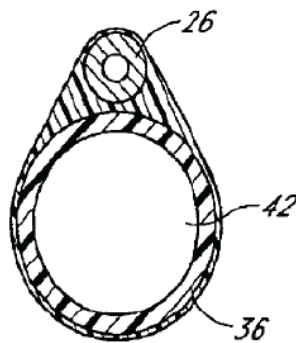
Importantly, the Examiner cited Fig. 9 and its related disclosure in rejecting Maquet’s priority claim because the “side-rigger” element was not “supported” in the September 1, 1999 provisional application, which lacked Fig. 9. Ex. 7-E (’728 PH, May 8, 2013 Non-Final Rejection) at MAQ\_00004633. Despite having every reason to dispute that finding, due to the importance of priority dates, Maquet did not dispute the Examiner’s characterization or contested the priority date rejection. *See, e.g., Evonik Degussa GmbH v. Materia Inc.*, 53 F. Supp. 3d 778, 785 n.5 (D. Del. 2014) (“Under U.S. patent law, the priority date is a crucial element in determining patent validity because it delineates the cutoff for prior art.”) (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1372 (Fed. Cir. 2011)). Remaining silent and accepting a rejection for claimed priority is no different than cancelling a claim after a rejection—it constitutes a binding acquiescence as to the validity of the examiner’s rejection.

*Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1096-97, n. 6 (Fed. Cir. 2013)

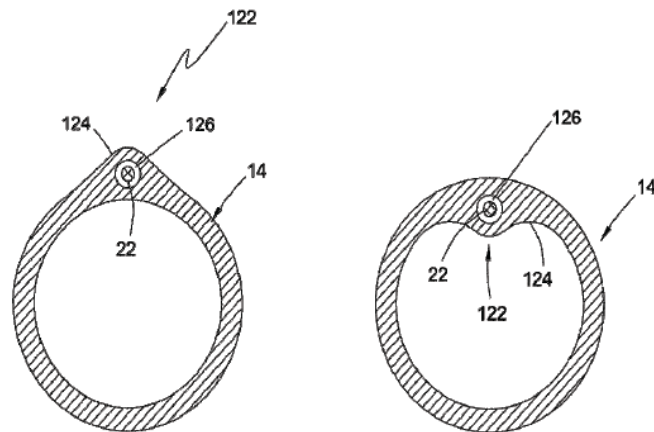
(prosecution history disclaimer applies when applicant adopts examiner’s characterization).

Maquet’s acquiescence is binding, and the claim term should be construed accordingly.

The extensive prosecution history reveals that Maquet consistently sought claim coverage for a guide wire lumen integrally formed within the surface of the cannula, and Maquet maintained this concept from its initial language through its amendments to distinguish guide lumens attached to the outside of the cannula, like Fig. 7(a) of Bagaosian. As the Examiner understood, Figs. 8 and 9 of the patents illustrate this concept and, as shown below, are different from Bagaosian in that the lumen is formed as part of the cannula wall (as opposed to being attached to it).



Bagaosian Fig. 7A



'437 Patent, Figs. 8, 9

In particular, Figs. 8 and 9 depict lumens with diameters larger than the thickness of the cannula surface so that the lumen protrudes outside the cannula (Fig. 8 at **124**) or into the interior of the cannula (Fig. 9 at **122**). However, in both embodiments, unlike Bagaosian Fig. 7(a), the lumen of the guide mechanism is integrally formed within the surface of the cannula wall. This concept is emphasized by the patents: “In *an important aspect of the present invention*, the ‘rapid exchange’ or ‘side-rigger’ guide mechanism 122 includes a guide carriage 124 formed *along at*



*least a portion of the cannula 14 . . .*” ’437 at 14:15-21 (emphasis added); *see also supra* §§ IV.A & IV.C.1 (quoting ’437 at 3:26-29, 14:15-21, 14:39-44, 14:63-15:4, Figs. 6-11 and 21, 23, 25-26, 31). Nothing in the specification, other than the side-rigger embodiments of Figs. 8-9, identifies a guide lumen that “*extends through a region delimited by the outer cannula surface.*”

## V. “INTRAVASCULAR BLOOD PUMP”

Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“intravascular blood pump”	All asserted claims	“a drive cable-mounted rotor and rotor housing ( <i>i.e.</i> , body and shroud), which collectively are capable of insertion into a patient’s circulatory system”	Plain meaning

The specification repeatedly defines the intravascular blood pump to require a drive cable-mounted rotor driven by a motor external to the patient’s body. That is not surprising because the pump will not work otherwise—without the drive cable, the motor, which is located outside the body, cannot deliver the torque needed to turn the pump’s rotor and cause it to pump blood. The patents do not describe any blood pump that lacks the drive cable-mounted rotor and external motor, nor do they hint at how to configure and operate a blood pump without a rotating drive cable. Therefore, the drive mechanism (*i.e.*, the drive cable-mounted rotor) is essential to any claimed blood pump in the patents. Any broader construction lacks written description and enablement. Moreover, the prosecution history and IPR proceedings reinforce that both Maquet and the USPTO understood that the drive cable was a central aspect of the claimed invention.

### A. The Specification Defines the Claimed “Intravascular Blood Pumps” to Require Drive-Cable Mounted Rotors

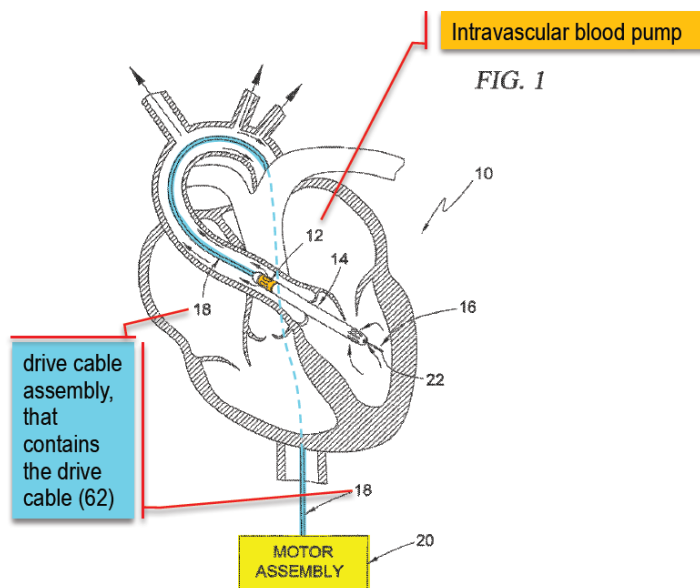
The “Description of Related Art” opens by describing the “intravascular blood pumps” that are purportedly improved by the integrated guide mechanisms of the patents:

an axial flow ***blood pump comprising a cable-mounted rotor surrounded by a protective shroud*** . . . [wherein a] catheter device encloses a ***rotating drive cable*** which is coupled to the impeller blade at one end, and which merged from the unexposed of the catheter, .

... on the other end [, where that end] is mechanically rotated, using a device located outside the patient's body, [so that the drive cable] conveys **rotational force** through the length of the catheter, causing the impeller to spin at high speed near the heart.

*Id.* at 2:1-20 (emphasis added). From that common understanding, the specification describes limitations associated with existing designs to place these pumps in the body. *Id.* at 2:21-35. The patents then *define* “the present invention” as solutions to the drawbacks associated with pumps possessing cable-mounted rotors. *Id.* at 2:36-59; *see also id.* at 2:63-67 (emphasis added) (“The **present invention** overcomes the drawbacks of the prior art by providing an improved intravascular blood pump equipped with integrated features for selectively guiding [the pump] to a predetermined location in the patient's circulatory system.”).

The specification confirms that each of the three self-described “broad aspects of the present invention” (*i.e.* the guide mechanisms) are integrated with, and designed for, a pump connected to a drive cable and external motor that mechanically turn the pump rotor:



'437 Patent, Fig. 1 (annotated)

Referring to FIG. 1, **shown is a guidable intra-vascular blood pump system 10 according to a first broad aspect of the present invention** shown, by way of example only, in a left-heart assist configuration within a human heart. 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.** . . . According to the present invention, the ‘over-the-wire’ guide mechanism **16** provides the ability to selectively guide the blood pump **12** and cannula **14** to a predetermined position in the circulatory system of a patient . . .

*Id.* at 9:13-31 (emphasis added); 13:63-14:14 (describing the “second broad aspect of the present invention” as having the same pump structure but a different guidance mechanism); 15:5-21 (accord for the “third aspect of the present invention”); *see also* Figs. 6, 10. Like here, the specification’s “repeated use of the phrase ‘the present invention’ describes the invention as a whole.” *Netcraft Corp. v. eBay, Inc.*, 549 F.3d 1394, 1398-1400 (Fed. Cir. 2008); *Trading Techs. Int’l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1352-53 (Fed. Cir. 2010) (construing claim term consistent with specification’s description of the “present invention”).

The guide mechanisms are also specifically designed to integrate with a cable-driven pump.<sup>7</sup> *See, e.g.*, ’437 at 9:20-24 (the guide or central lumen in the “over-the-wire” design “extends through the drive cable”), 12:59-63 (central lumen is sized so that the guide wire does not rotate itself or prevents the drive cable from rotating), 14:59-15:4 (describing the benefit of the “side rigger” design as negating the need for a lumen in the drive cable), 12:40-46 (describing how the purge system “bathes the components of the pump 12 and/or drive cable 62 and thereby reduces frictional heating within the pump 12 and/or the central lumen of the sheath 32 during pump operation.”). The patents’ repeated statements, and specific design considerations, indicate that the “inventions” are guide mechanisms designed to integrate with a very specific type of pump system, an “intravascular blood pump system” based on a drive cable that connects the pump rotor to the external motor.

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<sup>7</sup> The drive cable is a mechanical cable that drives the blood pump motor. The specification states that there is a “mechanical connection between a motor [] and drive cable [] for providing motive force to the blood pump 12 for operation” and that connection is located outside of the body, i.e. with the external motor. *Id.* at 10:2-17. The specification discloses an additional feature where the rotating drive cable is bathed in purge fluid “to reduce frictional heating . . . during pump operation.” *Id.* at 12:40-46; 18:8-15. These statements reinforce that a drive cable-based pump is the “intravascular blood pump” in the claims.

The “intravascular blood pump” of the patents comprises an impeller (*i.e.*, a rotor) and a protective covering/shroud for that impeller. *Id.* at 10:20-24 (“The blood pump 12 includes pump body 34, a rotor shroud 36 . . . and internally disposed rotor (not shown) having a shaft rotatably disposed with the pump body 34 and an impeller rotatably disposed within the rotor shroud 36.”). Throughout the specification, the rotor is consistently described as driven by a mechanical drive cable. *Id.* at 11:21-32; 12:14-16; *see also* 2:1-17 (discussing “related art”).

In fact, no other types of pumps or rotors are disclosed or even contemplated by the patents. There are no embodiments or disclosures of a non-drive cable pump system. *See id.* Nor are there any embodiments or disclosures concerning a blood pump with a motor positioned inside the body (rather than having it located outside the body as repeatedly disclosed in the patents), like the accused Impella® products. *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009) (limiting “graft” to “intraluminal graft” when the specification used the terms interchangeably and did not disclose any other types of grafts).

A pump design with an integrated motor inside the body presents a substantial technical challenge and is very different from the drive cable approach. This concept was not invented by the named inventors of the patents. Rather, only after decades of work *by Abiomed* through the development of the Impella® products was a viable intravascular blood pump developed that put the motor within the heart and avoided the use of a mechanical drive cable. Put simply, any construction broader than what Abiomed has proposed would grant Maquet patent protection for contributions it did not make and did not disclose to the public in exchange for a patent. The specification describes what the named inventors of the patent possessed, and any interpretation broader than what is described is impermissible because such claims would lack sufficient written description or enablement. *See Retractable Techs., Inc. v. Becton*, 653 F.3d 1296, 1311

(Fed. Cir. 2011) (“[T]he basic mandate is for claims to be interpreted in light of the specification of which they are a part because the specification describes what the inventors invented. The specification is the heart of the patent. In colloquial terms, ‘you should get what you disclose.’”) (Plager, J., concurring) (quoting *Arlington Indus. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1252 (Fed. Cir. 2011)).

**A. During Prosecution and Related IPR Proceedings Maquet Required a Drive Cable-Mounted Rotor Design**

The need for a drive cable and external motor was also a critical part of prosecution and the IPR proceedings. During prosecution, the Examiner considered the prior art patent Sammler (U.S. Pat. No. 6,544,216) which describes Abiomed’s early attempts to eliminate the drive cable in what would become the accused Impella® products. Sammler describes a pump integrated with a motor that are together placed inside the heart. The Sammler pump is fundamentally different from the claimed pumps because *it locates the motor inside the heart* (instead of outside the body). This design distinction was critical to the Examiner’s decision to allow the claims over Sammler: “Sammler lacks several critical feature of the invention . . . . Significantly, Sammler relies on the motor-driven pump of Siess to move blood through vessels (Siess, Figs. 2, 3). *Since the motor of Siess occupies the entire cross-section of the lumen*, no space remains for a lumen to pass a guide wire or purge fluid.” Ex. 8-B (’068 PH, Oct. 5, 2015 Notice of Allowance) at MAQ\_00005189 (emphasis added). A person of ordinary skill would have the same understanding of the claimed design. *See, e.g., Salazar*, 414 F.3d at 1347. Maquet never challenged the Examiner’s assessment, instead choosing to assert the very claims allowed over this distinction against Abiomed.

Similarly, in opposition to a number of Abiomed’s petitions for *inter partes* review, Maquet explained its invention to the PTO as follows: “the intravascular blood pump, catheter,

cannula, and guide mechanism [are] *located within the circulatory system* ... [and the catheter] *allows for communication between pump features and devices located outside the body.*” See, e.g., Ex. 16 (’468 POPR, IPR2017-01202) at 12-13; Ex. 18 (’314 POPR, IPR 2017-01204) at 12-13; Ex. 21 (’437 POPR, IPR2017-01208) at 12-13; Ex. 22 (’437 POPR, IPR2017-01209) at 12-13. As support for its statement about “devices located outside the body,” Maquet referred to the PTO to the portion of the patent specification that describes the external motor and the drive cable. *Id.* (citing ’437 at 10:2-17). Thus, Maquet emphasized that the drive cable is an essential aspect of its claimed invention.

Read together, the specification and the prosecution history make clear that the drive cable-mounted rotor is essential to the claimed “intravascular blood pump” purported to have been invented. Accordingly, Abiomed’s proposed construction should be adopted.

## VI. PUMP FEATURES

### A. “Blade Extending radially (outward) from the rotor hub”

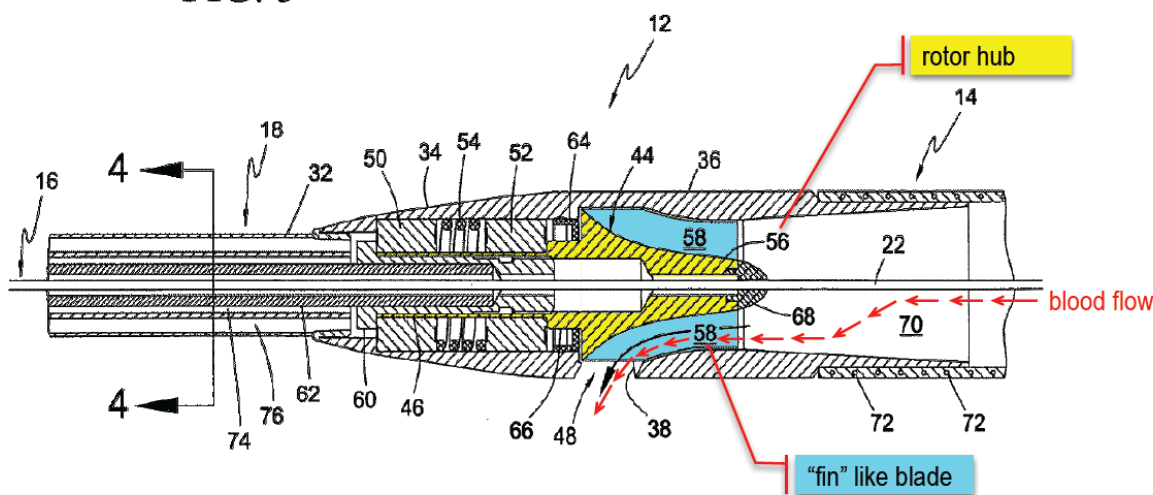
Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“blade extending radially outward from the rotor hub” “blade[s] extending radially from the rotor hub”	728: 1, 10 068: 1, 10, 20 468: 1, 2, 22 314: 1, 2, 20, 27 437: 1, 28	“blade[s] shaped as an extension of a radius of the rotor hub, not including helical, corkscrew or screw-shaped”	Plain meaning

All of the asserted claims except for those in the ’100 patent require that the claimed pump have a rotor with “blade[s] extending radially [outward] from the rotor hub.” The plain meaning of “extending radially,” and the limited description in the specification about the shape of the blades, is consistent with the understanding that the claimed blades are an extension of a radius of the rotor hub (*i.e.* a straight line). During prosecution, Maquet repeatedly distinguished

prior art that described “helical, corkscrew or screw-shaped” blades on the grounds that such blades do not “extend radially.” The Court should construe the claim terms as “blade[s] shaped as an extension of a radius of the rotor hub, not including helical, corkscrew or screw-shaped.”

Abiomed’s construction is consistent with the plain meaning of “extending radially from.” The common definition of “radial” and “radially” is “arranged like radii or rays.” Ex. 29 (Definitional of “Radial,” Dictionary.com (2017), *available at* <http://www.dictionary.com/browse/radial>). A radius is a straight line, extending in a single direction from a center point. Therefore, in this case, the term “extending radially from” indicates that the blade extends like a radius, *i.e.*, in a straight line in a single direction from the rotor hub where it originates. To read the claims to include non-radial blades, such as curved blades, for example, would read the modifier “radially” out of the claim. *See Convolve, Inc. v. Compaq Comput. Corp.*, 812 F.3d 1313, 1318 (Fed. Cir. 2016) (affirming construction of “user interface” that excludes programming interfaces such as APIs to preserve the meaning of the modifier “user,” noting “[t]he claim term is ‘user interface,’ not just ‘interface.’”).

**FIG. 3**



'437 Patent, Fig. 3 (annotated)

Abiomed's construction is also consistent with the specification. The specification does not use the claim language anywhere, nor does it use any other language to describe the shape of the rotor blades. *See generally* '437 Specification. Therefore, the only information in the patents for a person of skill to consider is the blades depicted in the figures. Fig. 3 (reproduced above), which the patents state depicts the claimed blades ('437 at Fig. 3; 11:33-59), shows a cross-sectional view of the blood pump with straight "fin" like blades (58) that extend from the rotor hub (56) in a single direction (*i.e.*, the blades "extend radially"). Blade 58 has no shading or other indication to show that it is curved or bent. The same straight blade configuration is demonstrated in all of the blades depicted in the figures of the patents. '437 at Fig. 14, 18.

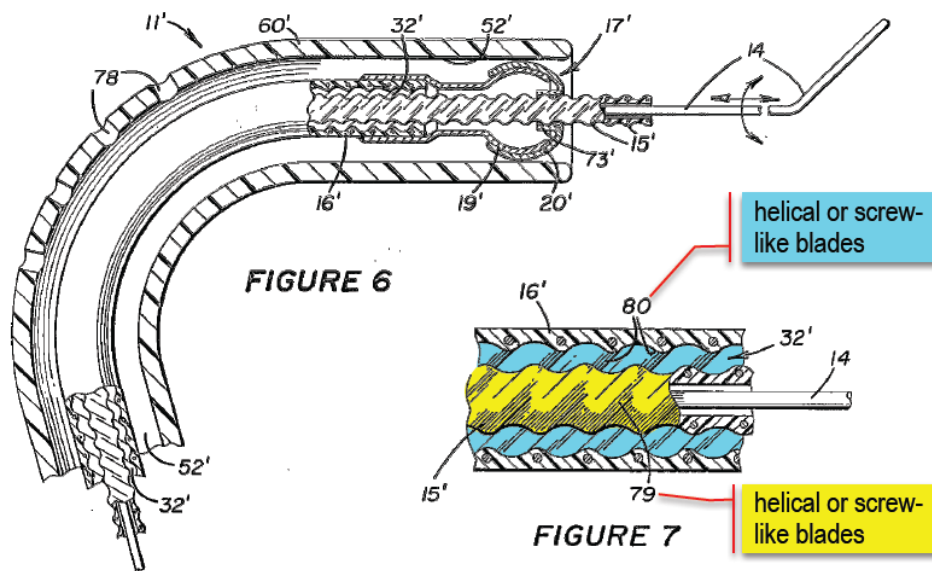
The combination of blades and the flow passage create axial and radial outflow of blood from the pump, *i.e.*, a "mixed flow." *See e.g.*, '437 at 11:46-53; Fig. 3 (angle of the arrow representing the trajectory of the blood flow (formed in a diagonal direction)). Because the blades **58** are located in a cylinder (*i.e.*, the cannula **72**), they impart a circumferential force which accelerates the blood. Then, the rotor hub **56**, which expands as it approaches the flow port **38**, drives blood outward through flow port. The flow port is located within the wall of the shroud and steers the blood away from the pump in an axial and radial component or vector.

Abiomed's construction is also consistent with the prosecution history, where Maquet disclaimed helical, corkscrew, or screw-shaped blades to distinguish prior art. The claim language "blade extending radially outward from the rotor hub" was first-added during prosecution of the '728 patent to overcome an obviousness rejection based on Masch, Summers, and additional references. *See* Ex. 7-D ('728 PH, Feb. 28, 2013 Amendment and Response) at MAQ\_00004616-4621; Ex. 7-C ('728 PH, Aug. 28, 2012 Final Rejection) at MAQ\_00004582-



4593. Before this amendment, the claims lacked any blade limitations and instead claimed a rotor generically. *Id.*

In explaining the amendment, Maquet disclaimed the helical, corkscrew, or screw-shaped blades disclosed in Masch and Summers. Masch, Fig. 7 is reproduced below to show the helical or screw-like blades (79 and 80) cited by the Examiner. Ex. 26, Masch at 8:8-23, and Fig. 7 (elements 79, 80); Ex. 7-C ('728 PH, Aug. 28, 2012 Final Rejection) at MAQ\_00004593. In response, Maquet argued, “nor is the [claimed] structure of a ‘blade’ taught or suggested in Siess, **Masch**, or Gordon.” See Ex. 7-D ('728 PH, Feb. 28, 2013 Amendment and Response) at MAQ\_00004628.



Masch Patent, Figs. 6, 7 (annotated)

Maquet also explained that the added limitations distinguished the rotor in Summers (U.S. Pat. No. 5,112,349), which had “a shape resembling a cork-screw” and was “formed in a helical shape.” Ex. 7-D ('728 PH, Feb. 28, 2013 Amendment and Response) at MAQ\_00004625. Maquet explained that “this cork-screw rotor does not extend radially from a

rotor hub and therefore cannot be construed as a blade of the claimed invention.” *Id.*; *see also id.* at MAQ\_00004627-4628.

For these reasons, Abiomed’s proposed construction should be adopted so that the claims are construed consistent with the specification and Maquet’s statements during prosecution.

**B. “A Rotor Having a Rotor Hub Tapering in the Distal Direction”**

Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“a rotor having a rotor hub tapering in the distal direction”	728: 1, 10 068: 1, 10, 20 468: 1, 2, 22 314: 1, 2, 20, 27 437: 1, 28	Plain meaning, where patentee disclaimed a hub where any portion tapers in the proximal direction	Plain meaning

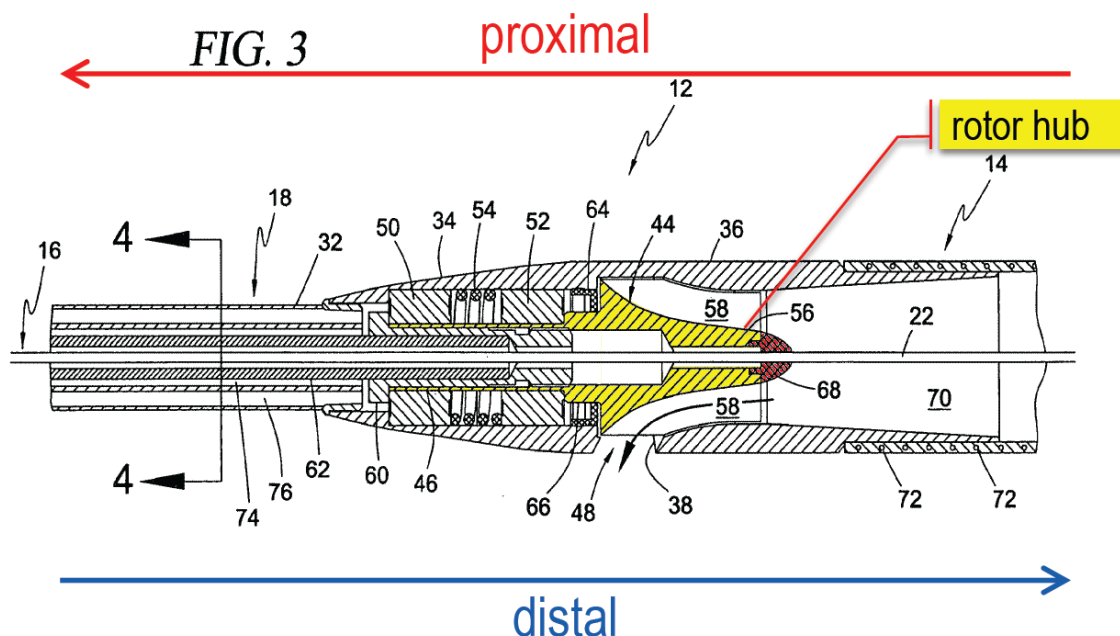
The dispute over this term is whether Maquet disclaimed pump rotors where any portion of the rotor hub tapers in the proximal direction (*i.e.*, toward the insertion site of the device into the body). Put another way, the question is whether Maquet’s prosecution statements require the entirety of the rotor hub to taper in the distal direction (*i.e.*, away from the insertion point of the device into the body). Abiomed’s construction affirms that the plain meaning of the terms is consistent with Maquet’s disclaimers and the specification.

The rotor hub is an essential component of any blood pump. Its shape is critical to ensuring that blood flows through the blood pump (*i.e.*, it provides “axial flow”). *See, e.g.*, ’437 at 11:33-59; *see supra* § VI.A (describing how the flow of the claimed pump is created).

The plain meaning of the term is clear: the rotor hub tapers in the distal direction. The term does not allow for distal tapering of just a portion of the rotor hub, but references the entirety of the hub (“having a rotor hub tapering...”). To capture a rotor hub that tapers in both the proximal and distal directions, the claim terms would need something more.

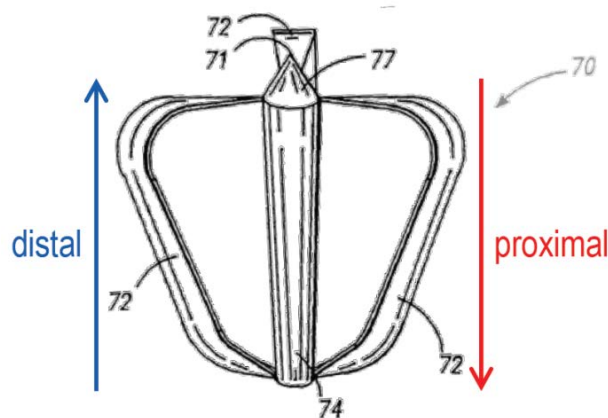
The plain meaning is consistent with the specification. The rotor hubs disclosed all taper in a single direction—the distal direction. *See, e.g.*, '437 at Figs. 3, 14 and 18. For example, in Fig. 3 (below), rotor hub **56** tapers, *in its entirety*, from left to right (*i.e.*, the distal direction).

## Cross-Section of Pump



'437 Patent, Fig. 3 (annotated)

Moreover, Maquet confirmed this interpretation in its opposition to numerous IPR petitions. Maquet sought to distinguish “Aboul-Hosn” (Pub. PCT App. WO 99/02204), an earlier application filed by one of the named inventors of the patents. As shown to the right, part of the hub of Aboul-Hosn Fig. 7b tapers proximally, while the tip



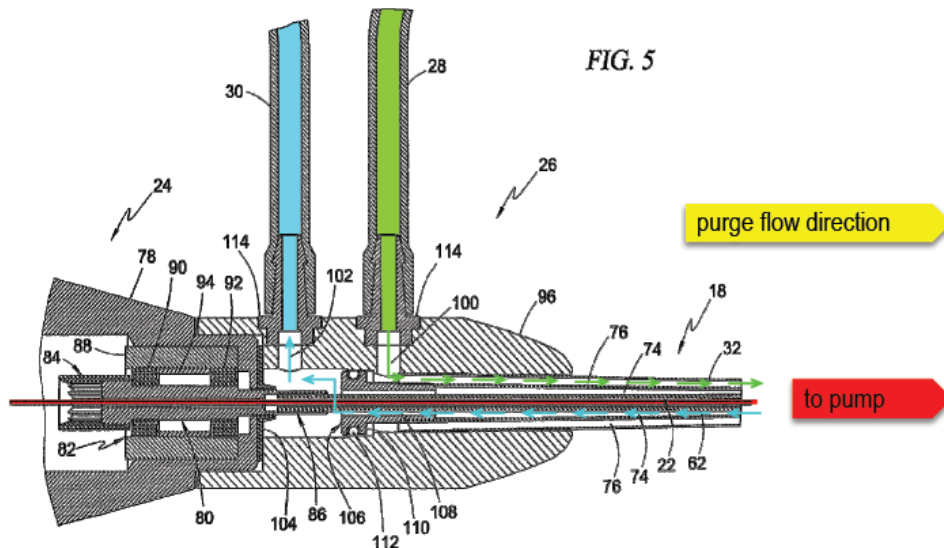
Aboul-Hosn Patent, Fig. 7B (annotated)

of the rotor hub 77 tapers distally. Maquet distinguished the claim term by arguing that the Aboul-Hosn rotor hub, in part, “tapers *in the opposite direction, i.e., it tapers in the proximal direction.*” Ex. 12 at 47 (emphasis added); Ex. 14 at 47; Ex. 18 at 40; Ex. 19 at 36; Ex. 20 (’437 POPR, IPR2017-01207) at 34; Ex. 21 at 37; Ex. 22 at 38; Ex. 23 (’437 POPR, IPR2017-01253) at 37; Ex. 15 at 38; Ex. 16 at 38; Ex. 17 (’468 POPR, IPR2017-01203) at 37; Ex. 11 at 46. Such two-way tapering does not satisfy the “tapering” limitation, thus precluding any such design from Maquet’s claims.

## **VII. PURGE FLUID FEATURES**

Purge fluid is a pressurized lubricating fluid used to maintain the proper operation of an intravascular blood pump. *See, e.g., id.* at 13:56-61. As seen in Fig. 5 below, the intravascular blood pumps of the patents have a two-way purge-system where fluid is passed to the pump through the “inflow conduit” **28** and then returned out of the body through the “outflow conduit” **30**. *See* ’437 at 9:60-10:2, 13:39-56. This two-way purge system is particularly important to the pumps in the patents because the entering purge fluid is used to “prevent the ingress of blood into the pump body during pump operation” to avoid “clotting and/or pump damage” (’437 at 12:31-40) and the return purge line “bathes the components of the pump and/or drive cable and thereby reduces frictional heating within the pump and/or the central lumen of the sheath during pump operation.” ’437 at 12:40-46. The return purge system is particularly important because the blood pumps of the patents use a drive cable under extensive torque and force that requires purge fluid for cooling and lubrication. *Id.* at 13:56-61, 12:42-46.

## Two-Way Purge Systems



'437 Patent, Fig. 5 (annotated)

### A. The Claimed “First Conduit” and “Second Conduit” Must Comprise a Two-Way Purge Fluid System

Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“first conduit . . . second conduit”	728: 8 068: 9 468: 1, 22 314: 1, 20, 27 437: 10, 29	“a pair of conduits for introducing and returning purge fluid”	Plain meaning

In every instance where a “first conduit” and “second conduit” are claimed, the claims expressly require that at least one of the conduits be connected to the purge fluid system so that purge fluid may pass through it. *See* ’468 at 34:40-42 (claim 1) (“*at least one of the first conduit and second conduit in fluid communication with the purge lumen,*” which is “*operatively arranged to deliver purge fluid to the intravascular blood pump*”); ’728 at 19:18-24 (claim 8

(“... *in fluid communication with the first lumen*,” and the first lumen is defined in claim 1 to be “*operatively arranged to deliver purge fluid to the intravascular blood pump*”)); ’068 at 19:31-37 (claim 9); ’314 at 25-37; 36:18-20; 38:12-14 (claims 1, 10, 27); ’468 at 34:40-42, 36:53-54 (claims 1, 22) (accord). The dispute is whether the other claimed conduit must also be part of the purge fluid system. The claims, specification, and prosecution history show that it must: these terms refer to a purge fluid system comprising two conduits—one to introduce purge fluid into the body and the other to return purge fluid out of the body. The claims should be construed accordingly.

As described above, the specification repeatedly describes that the purge fluid system has first and second conduits to facilitate introducing and returning purge fluid. *See, e.g.*, ’437 at 9:64-10:2; 12:21-29; 13:43-46 (discussing “inflow” and “outflow” conduits); Figs. 2, 5, 7, 12, 13, 16. The claims describe no purpose for the “*conduits*” other than that at least one is connected to the purge system (*see, e.g.*, ’468 at claim 1). To construe the claim in any way other than to conclude that both conduits are related to the purge fluid system is nonsensical in that it would render the other conduit superfluous. *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”).

Moreover, the claimed pump would be inoperative if only the outflow conduit (second port) was connected, as no purge fluid would enter into the pump. Such a construction would also be inconsistent with the only disclosure in the specification. *See ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1374-76 (Fed. Cir. 2009) (limiting construction of “spike” to disclosed shapes, instructing terms should be construed “not only in the context of the particular claim in

which the disputed term appears, but in the context of the entire patent, including the specification”) (quoting *Phillips*, 415 F.3d at 1315).

The prosecution history confirms that both conduits must relate to the purge system. In allowing the claims of the ’468 patent, all of which require “*first*” and “*second conduits*,” the Examiner found the claims patentable over the prior art reference Bedingham because the claimed system made use of two conduits to deliver and return purge fluid. *See* Ex. 9-D (’468 PH, Nov. 22, 2016 Notice of Allowance) at MAQ\_00009242 (the examiner explained that “[t]he claimed invention includes a pair of conduit [sic] for introducing and returning purge fluid ([¶]0061), fluid inlet conduit 28 for introducing pressurized purge fluid, and a fluid outlet conduit 30 to withdraw a return flow of purge fluid.)” In contrast, according to the Examiner, Bedingham disclosed “only a single channel for supplying purge fluid which is not returned through a second lumen ***but instead mixes with blood.***” *Id.* (emphasis added). The Examiner’s understanding of the claim terms is reflective of the understanding of a person of ordinary skill. *See Salazar*, 414 F.3d at 1347.

To the extent Maquet contends that “*first conduit*” and “*second conduit*” in the claims do not require a two-way purge system, Maquet’s comments during *inter partes* review in relation to other claims should be considered. There, Maquet stated as follows: “A POSITA would recognize that injecting floating particles from [pump] bearings into a patient’s blood stream ***is a bad idea.*** In short, the design disclosed . . . ***is not, and would never be compatible with,*** a purge fluid line.” *See* Ex. 11 (’728 POPR, IPR2017-01026) at 53 (emphasis added). Thus, by Maquet’s own admission, a “purge fluid line,” such as the above claims require, must be a two-way line so it does not mix the purge fluid with the blood. Maquet should not be allowed to reclaim this “bad idea” now by reading one of the two required conduits out of the claims.

**B. Maquet Disclaimed Delivering Purge Fluid Through a One-Way Purge Fluid System**

Claim Term	Claims	Abiomed's Proposal	Maquet's Proposal
"[first lumen / purge lumen] ... operatively arranged to deliver purge fluid [to / towards] the intravascular blood pump"	728: 1 068: 1 468: 1, 22 314: 1, 20, 27	"arranged to operate such that purge fluid is delivered to the blood pump where the purge fluid does not go through the rotor bearings and into the bloodstream"	Plain meaning
"passing purge fluid through the purge lumen to the intravascular blood pump"  "passing purge fluid through one of the first and second conduits, through the housing and purge lumen to the intravascular blood pump"	437: 1  437:22	"passing purge fluid to the blood pump where the purge fluid does not go through the rotor bearings and into the bloodstream"	Plain meaning

While varying slightly, all three claim terms above describe the same functionality—"delivering" or "passing" purge fluid to the pump. None of these differences affect the present dispute—which is whether Maquet disclaimed one-way purge systems where the purge fluid passes through the rotor bearings into the blood stream.

As described above, during *inter partes* review, Maquet distinguished prior art on the grounds that it fails to disclose the purge fluid lumen required by the above claim, specifically claim 1 of the '728 patent and claim 1 of the '068 patent. Specifically, Maquet disparaged a one-way purge fluid system because it "***is not, and would never be compatible,*** with a purge fluid line," as claimed, because it is a "***bad idea.***" *Id.*; *see supra* § VII.A. Maquet thus disavowed a system that passes purge fluid to the blood pump where the purge fluid goes through the rotor bearings and into the bloodstream. *See Chi. Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1372 (Fed. Cir. 2012) (applying disclaimer when patent disparaged embodiment as



“antiquated,” having “inherent inadequacies”); *Sightsound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1317 (Fed. Cir. 2015) (“The disadvantages identified by the specification of records, tapes, and CDs amount to implied disclaimer of those three media.”). Because Maquet disparaged the one-way purge fluid system, Maquet is not entitled to claim scope that includes a one-way purge system. *Aylus Networks, Inc.*, 856 F.3d at 1359-61.

Maquet’s disclaimer associated with the ’728 patent, and repeated during *inter partes* review of the ’068 patent, applies “with equal force” to the later-issued patents, which all contain “Purge Fluid Lumen” limitations that similarly are not “and would never be compatible” with a one-way purge fluid system. *See Advanced Cardiovascular*, 182 F. App’x at 998 (“[W]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation.”); *Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1369 (Fed. Cir. 2016).

## VIII. MEANS-PLUS-FUNCTION TERMS

Two terms in claim 16 of ’100 patent—“guide *mechanism*” and “blood pressure detection *mechanism*”—and one term from claim 1 of the ’468 and ’314 patents—“pressure sensing *element*”—are means-plus-function terms and should be construed accordingly. There is no dispute regarding what comprises the corresponding structure disclosed in the specification as Maquet has not identified any such structure; the only question is whether § 112, ¶ 6 applies.

### A. Legal Standards Governing Means-Plus-Function Terms

“Typically, the definiteness requirement of § 112, ¶ 2 prohibits a patentee from describing the invention merely in terms of function.” *Voice Domain Techs., LLC v. Apple Inc.*, No. 13-40138-TSH, 2015 U.S. Dist. LEXIS 101865, at \*17 (D. Mass. Aug. 4, 2015) (citing *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 234 (1942)). Section 112, ¶ 6 creates

an exception and permits “mean-plus-function” claiming for the convenience of patent drafting. *See Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1211 (Fed. Cir. 2003). In return for this drafting convenience, a means-plus-function claim limitation is limited to the structures disclosed in the specification and equivalents. *See id.*

In the absence of the word “means,” a claim term is considered a means-plus-function term if it “fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.” *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (internal citations omitted). Terms like “mechanism” and “element” are nonce words that “typically do not connote sufficiently definite structure” and are considered means-plus-function terms. *See id.* at 1350 (citing *Mass. Inst. of Tech. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006)); MPEP § 2181 (same). When a generic term, such as “mechanism” or “element,” can be replaced in the claim with “means” and retain its meaning, the claim term is a means-plus-function term. *See Williamson*, 792 F.3d at 1350-51.

Under § 112, ¶ 6, construction of a means-plus-function includes two steps: (1) the court must determine the claimed function; (2) the court must identify the corresponding structure in the written description of the patent that performs the function. *Noah Sys. Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012).

**B. The Means-Plus-Function Terms of Claim 16 of the '100 Patent**

Claim 16 of the '100 patent comprises a preamble and three elements. The preamble states that the claim is to “[a]n intravascular blood pump system comprising: . . .” ('100 at 20:20), and the three elements define what that system comprises. The first element requires a particular structure: “an intravascular blood pump having a cannula coupled thereto.” *Id.* at 20:21-22. The latter two elements require a “guide mechanism” and a “blood pressure

mechanism” defined solely by their function (*id.* at 20:23-28) and, accordingly, are means-plus-function terms.

**1. “Guide Mechanism” in Claim 16 of the ’100 Patent**

Claim Term	Claim	Abiomed’s Proposal	Maquet’s Proposal
“a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient”	100: 16	<p>This is a means-plus-function term:</p> <p>Claimed function:</p> <p>guiding said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient</p> <p>Disclosed structure:</p> <p>(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 a guide catheter, a rotor shroud, and a cannula, which is capable of docking to a separate pump assembly.</p>	Plain meaning

The claim term “mechanism,” without more, is routinely held to trigger § 112, ¶ 6. *See, e.g., Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1372 (Fed. Cir. 2015) (“We have never found that the term ‘mechanism’—without more—connotes an identifiable structure”); *Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1096-97 (Fed. Cir. 2008) (affirming construction of “mechanism for moving said finger” as a means-plus-function term); *Mass. Inst. of Tech.*, 462 F.3d at 1354 (construing “colorant selection mechanism” as a means-plus-function term).

“*Guide mechanism*” in claim 16 of the ’100 patent is a means-plus-function term. Unlike other claims in the patents referring to “guide mechanisms,” claim 16 of the ’100 patent recites only the function that the “*guide mechanism*” is adapted to perform. *Compare* ’100, claim 16

(“*guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient*”) with ’728, claim 1 (“*guide mechanism is configured as a second lumen.*”). Like in *Williamson*, replacing “mechanism” with “means” retains the claim meaning: “*a guide [mechanism] / [means] adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient.*” See *Williamson*, 792 F.3d at 1350-51; see also *Voice Domain Techs., LLC v. Apple Inc.*, No. 13-40138-TSH, 2015 U.S. Dist. LEXIS 101865, at \*21 (D. Mass. Aug. 4, 2015) (“This format is ‘consistent with traditional means-plus-function claim limitations,’ because it replaces the word ‘means’ with ‘mechanism,’ and recites a function to be performed by the ‘coupling mechanism.’”).

Since § 112, ¶ 6 is implicated, the court must (1) determine the claimed function and (2) the corresponding structure in the written description. See *Noah Sys.*, 675 F.3d at 1311. The claimed function of the “*guide mechanism*” is explicitly recited in the claim: “*guid[ing] said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient.*” See ’100 at 20:23-25; see also *id.* at 1:12-16; 19:49-51. The ’100 patent discloses only three structures that perform this function: (a) the “over the wire” arrangement, (b) the “side rigger” arrangement, and (c) the “guide catheter” arrangement. See *supra* § II.C (discussing disclosed embodiments of guide mechanisms). “Guide mechanism” in claim 16 of the ’100 patent must be construed to be limited to these three structures and their equivalents as Abiomed proposes. *Noah Sys.*, 675 F.3d at 1311.

## 2. “Blood Pressure Detection Mechanism” in Claim 16 of the ’100 Patent

Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“blood pressure	100: 16	This is a means-plus-function term:	Plain meaning

detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.”		<p>Claimed function:</p> <p>to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula</p> <p>Disclosed structure:</p> <p>(a) fluid filled column disposed within at least a portion of the cannula, (b) a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, (c) a strain gauge coupled to at least one of the intravascular blood pump and cannula, and (d) calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive the rotor</p>	
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“Blood pressure detection mechanism” in claim 16 of the ’100 patent is similarly a means-plus-function term. *See Media Rights*, 800 F.3d at 1372. Claim 16 provides no structure for the blood pressure detection mechanism; instead, it states only a function (“detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.”) ’100 at 20:26-28. Replacing “mechanism” with “means” retains the claim meaning, demonstrating that the term is a means-plus-function term: “a blood pressure detection [mechanism] / [means] to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.” *See Voice Domain Techs.*, 2015 U.S. Dist. LEXIS 101865, at \*21.

Because “blood pressure detection mechanism” is a means-plus-function term, the court must (1) determine the claimed function and (2) the corresponding structure in the written description. *Noah Sys.*, 675 F.3d at 1311. The claimed function is explicitly recited in the claim: “detect[ing] the pressure of the blood proximate at least one of the intravascular blood pump and cannula.” *See* ’100 at 20:26-28; *see also id.* at 4:18-21. The specification describes only four structures to detect blood pressure: (a) fluid filled column disposed within at least a portion of the cannula, (b) a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, (c) a strain gauge coupled to at least one of the intravascular blood pump and

cannula, and (d) calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive the rotor. *See* '100 at 4:22-33; 18:30-35. Abiomed's proposed construction is consistent with these four structures.

### C. “Pressure Sensing Element” in Claim 1 of the '468 and '314 Patents

The term “pressure sensing element” in both claim 1 of the '468 patent and claim 1 of the '314 patent is a means-plus-function term and should be construed accordingly.

Like the word “mechanism,” the word “element” is a “non-structural generic placeholder[] that may invoke 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, paragraph 6.” MPEP § 2181; *Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1214 (Fed. Cir. 1998) (construing “lever moving element” as a means-plus-function term). Similar to “blood pressure detection mechanism,” the claims provide no structure for the “pressure sensing element;” it is instead defined only in terms of its function (“configured to sense pressure proximate the intravascular blood pump”). Consequently, as above, replacing “element” with “means” retains the claim meaning: “a pressure sensing [element] / [means] configured to sense pressure proximate the intravascular blood pump.” *See, e.g.*, '468 at 34:37-38; *see Voice Domain Techs.*, 2015 U.S. Dist. LEXIS 101865, at \*21.

“Pressure sensing element” explicitly recites the same function as “blood pressure detection mechanism” and should therefore be construed to have the same meaning as “blood pressure detection mechanism,” as Abiomed has proposed. *See supra* § VIII.B.2.

## IX. CLAIMS TO METHODS OF PERFUSING A PATIENT

Claim Term	Claims	Abiomed's Proposal	Maquet's Proposal
“perfusing / perfusion [of a patient]”	068: 1, 10, 20	“rerouting blood to a point downstream from the introduction site of the intravascular blood pump into the vasculature of the patient”	Plain meaning

Unique among the patents, the '068 patent claims methods for “perfusion of a patient” or “perfusing a patient.” *See* '068 at 18:41; 19:38; 20:33 (claims 1, 10, 20). The consistent and repeated use of “perfusion” in the patent specification to describe a particular type of blood pump assembly defines the term. “Perfusion” must be construed consistent with this definition as the term “breathes life” into the independent claims of the '068 patent.

The specification explains that the “use of a guide catheter 132 to transport fluid to and from the patient” such as by using a perfusion assembly, is a “significant feature of the present invention.” '437 at 16:8-24. Thereafter, the specification consistently and repeatedly refers to the “perfusion assembly” as a version of the intravascular blood pump that “rerout[es] blood from within the guide catheter to a point downstream from the introduction site.” '437 at 4:26-30; *see also id.* at 6:6-9 (“optional perfusion assembly for perfusing the vasculature downstream from the incision site”); 16:20-24 (“The perfusion assembly 140 may then be employed to selectively reroute blood from within the guide catheter 132 to a point within the patient’s vasculature downstream from the point where the guide catheter 132 enters the body.”); Fig. 11. In other words, the perfusion assembly “perfuses” a point downstream from the pump introduction site with blood. *See* Fig. 11 (showing how blood passes through the blood pump in the heart through the Control 140 and into the leg). The “perfusion assembly” stands out as the remainder of the specification, and the other method of treatment claims in the patents, focus on the more “typical” use of intravascular blood pumps: “to provide left and/or right heart support.” *See* '437 at 1:67-2:1, 8:62-9:3 (describing how “the intravascular pump assembly of the present invention is particularly suited for trans-valvular use”); *see supra* § II.C (discussing Figs. 1, 6, and 10). The term “*perfusion*” is used in no other context in the patent.

Although the term “*perfusing*” appears in the preamble of the ’068 claims, the Federal Circuit has emphasized that preambles operate as a claim limitation “when reciting additional structure or steps underscored as important by the specification.” *Catalina Mktg. Int’l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). “*Perfusing*” in the preamble here “breathes life” into the claims. Without the perfusion language, the ’068 claims merely recite a blood pump and two method steps that are already disclosed by necessity in the other elements of the claims. *See, e.g.*, ’068 at claim 1 (the steps of “*progressing a guide wire*” and “*advancing the blood pump system along the guide wire.*” are implicitly recited in the earlier language “*the guide mechanism adapted to guide . . . said intravascular blood pump system to a predetermined location within the circulatory system of a patient*”). As a result, the only substantive difference between the ’068 and ’728 claims is the addition of the method in the preamble of the ’068 claims; thus, the method is necessary to differentiate the claims. *See* Ex. 30 (comparison of the ’068 and ’728 patent claims).

However, Maquet did not simply claim a method—it claimed a “*method for perfusing a patient with an intravascular blood pump system,*” and one cannot pick and choose what parts of the preamble are descriptive of the invention. As a result, the “*method for perfusing*” claim language “breathes life” into the claims and should be therefore be construed as a claim limitation. *See GE Co. v. Nintendo Co., LTD.*, 179 F.3d 1350, 1361-62 (Fed. Cir. 1999) (holding the preamble “breath[ed] life and meaning into the claim . . . making it a limitation of the claim” when the specification made clear the inventors were working on a particular type of display system rather than “all types of display systems”).



**X. OTHER CLAIMED FEATURES****A. The Pressure Detection Elements Require Measuring Blood Pressure  
“at the opening of the blood pump or cannula”**

<b>Claim Term</b>	<b>Claims</b>	<b>Abiomed’s Proposal</b>	<b>Maquet’s Proposal</b>
“detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula”	100: 16 728: 6, 10 068: 7, 10 468:1, 22	“at the opening of the blood pump or the cannula”	Plain meaning
“detect the pressure of the blood / sense pressure] proximate the intravascular blood pump”	314: 1, 20, 27 437:1, 8, 12		
“[measuring pressure / calculating blood pressure] adjacent the intravascular blood pump”			

The dispute is whether Maquet is bound by its *inter partes* review statements about where blood pressure is measured in the claimed invention—namely whether it is measured “at the opening of the blood pump or the cannula.” The terms listed above were originally identified as two separate terms for construction, but given their overlap, they are addressed jointly below.

The claim terms are ambiguous: “proximate” and “adjacent” are relative terms that do not define objective boundaries and must be read in light of the intrinsic evidence. *See UCB*, 837 F.3d at 1260 (“content of the specification and actions and arguments during prosecution must also be considered, in defining the scope of a generic term in a claim.”).

The specification fails to clarify these ambiguous claim terms. In the original, un-appended specification (associated with the ’100, ’728, and ’068 patents), no figure depicts pressure sensors. Only a single sentence, which merely recites the claim language verbatim, makes any reference to the location of pressure sensors. *See* ’437 at 4:36-39. In the appended specification (associated with the ’468, ’437, and ’314 patents), Appendix B (from U.S. Appl.

No. 09/280,970) was added, entitled “Pressure Sensing Cannula.”<sup>8</sup> Appendix B does not describe any pressure sensors located on the blood pump, as required by each claim. Instead, as its title states, the sensors are located on the cannula only. *See, e.g. id.* at 29:25-40. Moreover, the specification provides no guidance on how to combine the disclosure of Appendix B (the pressure sensing cannula) with the blood pump system described in the original specification.

While Appendix B describes locating pressure sensors in different regions of the cannula, during *inter partes* review Maquet expressly narrowed the scope of the claim term to a single location—the opening of the cannula or blood pump (even though nothing in either the original specification or Appendix B shows where to locate a sensor on the pump). Maquet argued that the prior art reference Aboul-Hosn “never states that pressure should be measured near the intravascular blood pump.” Ex. 10 (’100 POPR, IPR2017-01025) at 53. Therefore, according to Maquet, Aboul-Hosn measures “‘body conditions’ *not* pump conditions.” *Id.* at 54 (emphasis in original). Maquet explained that pressure detection “located proximate the intravascular pump or cannula,” as claimed, requires measuring pressure “***directly, either at the cannula opening or the pump opening.***” *Id.* at 53-54 (emphasis added). While Maquet offered no support in the specification for sensor placement “at the opening” of any component, it asserted that measuring pressure “at the opening” of either the pump or cannula is necessary to “assist[] operators in locating and operating the pump.” *See id.* Detecting the blood pressure at any other place would only serve to measure the patient’s blood pressure “generally,” which, as Maquet explained would not serve the intended purpose of the claimed invention. *See id.*

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<sup>8</sup> Abiomed disputes that Maquet is entitled to the claimed priority date for the ’468, ’437, and ’314 patents at least because Maquet amended the specifications to add Appendices A & B after the priority date stated on the face of the patents.

In taking these positions to gain allowance of its claims, Maquet expressly bargained away and disclaimed any blood pressure detection mechanisms that detect pressure in any position other than “at the opening” of the cannula or pump. While Abiomed contends this term also lacks sufficient written disclosure and enablement, the terms must be construed consistent with this disclaimer. *Aylus Networks*, 856 F.3d at 1359-61.

**B. “Distal tip member”**

Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“distal tip member”	314:21 437:22	“rod bonded to the end of the cannula”	Plain meaning

The dispute is over Maquet’s explicit disclaimer during *inter partes* review regarding “distal tip member.” Abiomed’s construction incorporates this statement and remains consistent with the specification.

The “distal tip member” is not disclosed or discussed in the original specification. *See* ’100, ’068, and ’728 patents. Only with the integration of the disclosure from U.S. Appl. No. 09/280,988 (“Appendix A”), does the specification purport to describe a structure distal to the cannula. ’437 at 26:29-46. Even with this added disclosure, the patents dedicate only a single paragraph, which mentions in passing two “distal tip” configurations: (1) “a thermoplastic rod **1174** formed into a loop at the distal end of the cannula **1120**” attached “by bonding or thermal welding”; or (2) a “J-tip wire” which “can be a conventional guidewire movable or fixedly supported in a dedicated lumen.” *Id.* at 26:33-43; *see also* Figs. 30 & 31 (compare the rod bonded to the end in Fig. 30, **1174**, to the guidewire protruding from the lumen in Fig. 31, **1176**).

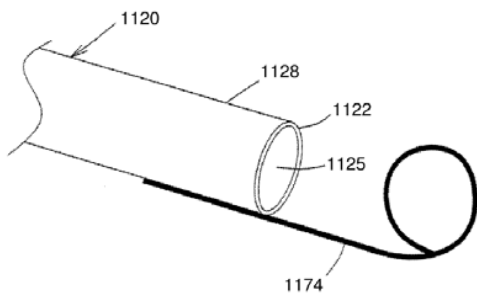


Figure 30

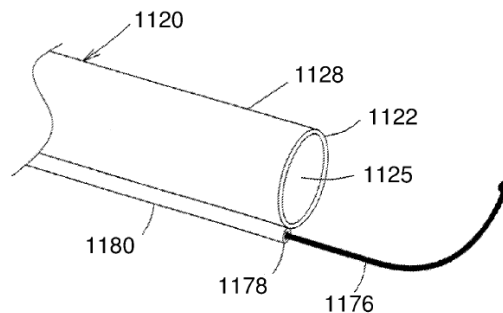


Figure 31

This minimal disclosure fails to enable either “distal tip” configuration, as the Examiner correctly concluded during prosecution of the ’468 patent. *See supra* § X.B.

During *inter partes* review, Maquet adopted the first configuration (the rod) and disclaimed the second configuration (the guide wire) to overcome prior art. Maquet argued that Jegaden “does not disclose a distal tip member” because “Jegaden simply shows a conventional guide wire, which cannot be repurposed to be the claimed distal tip member.” Ex. 18 (’314 POPR, IPR2017-01204) at 57.



Jegaden, Fig. 1

Maquet reinforced this point later, stating that “the ‘distal tip member’ is claimed to be distinct from the claimed ‘guide wire.’” *Id.* at 58; Ex. 20 (’437 POPR, IPR2017-01207) at 61-63 (same). At the same time, Maquet explicitly adopted the distal tip configuration of a rod bonded to the end of the cannula:

The specification further establishes a guide wire is not a ‘distal tip member,’ [the patent] stat[es] how this feature can include a “**pigtail shape formed by bonding or thermal welding** or otherwise attaching a thermoplastic rod at the distal end of the cannula.” *Petitioners ignore this fundamental difference between the claimed ‘distal tip member’ and the separately referenced guide wire explained throughout the claims and specification.*

Ex. 18 (’314 POPR, IPR2017-01204) at 59 (internal citations omitted) (emphasis added).

Explicitly disclaiming one embodiment, while adopting another informs the meaning of the term “distal tip member.” *See Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1378-79

(Fed. Cir. 2008) (excluding “laptops” from computer limitations because of distinguishing prior art statements during prosecution even though the specification had arguably broader language capturing a “microcomputer”); *Saffran v. Johnson & Johnson*, 712 F.3d 549, 559 (Fed. Cir. 2013) (holding that asserting how “the device is used” is sufficient for “an affirmative definition of the disputed term”); *Aylus Networks*, 856 F.3d at 1359-61.

**C. “Cannula coupled to a distal end of the intravascular blood pump”**

Claim Term	Claims	Abiomed’s Proposal	Maquet’s Proposal
“cannula coupled to a distal end of the intravascular blood pump”	468: 1, 22	Maquet disclaimed a cannula with a “pigtail, J-shaped, helical or helix shape, or stem/tail on the distal end of the cannula.”	Plain meaning

The dispute is whether Maquet disclaimed a cannula that has an attachment at the distal tip that is pigtail-shaped, J-shaped, helical, or helix-shaped, or is a stem or tail. During prosecution of the ’468 patent, Maquet sought claims that recited various distal tip features that could be attached to the end of the cannula. *See* Ex. 9-A (’468 PH, Aug. 17, 2016 Preliminary Amendment) at MAQ\_00007621-76265 (independent claim 49 and dependent claims 39, 40, 50, 53). The USPTO rejected claims to these features (“*pigtail, J-shaped, helical or helix shape, or stem/tail on the distal end of the cannula*”) because such features were not enabled under 35 U.S.C. § 112. Ex. 9-B (’468 PH, Oct. 17, 2016 Non-Final Rejection) at MAQ\_00008885. In response, Maquet did not contest the examiner’s rejection but instead cancelled the claims. *See* Ex. 9-C (’468 PH, Oct. 18, 2016 Amendment and Response) at MAQ\_00009039. The consequence of this cancellation is that Maquet disclaimed any blood pump systems with “*pigtail, J-shaped, helical or helix shape, or stem/tail*” on the distal end of the cannula. *J & M Corp. v. Harley-Davidson, Inc.*, 269 F.3d 1360, 1367-68 (Fed. Cir. 2001) (holding that

cancelling claims in response to rejection under written description constitutes acquiescence that original claim scope is not supported by specification); *UCB*, 837 F.3d at 1260-61. Abiomed's proposed construction is consistent with Maquet's choice to cancel claims to particular attachments at the distal end of the cannula.

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**CERTIFICATE OF SERVICE**

I hereby certify that the above document was filed on the date appearing in the header of this page through the ECF system, which will send true copies of the document to the attorneys of record for each party.

/s/ Charles Larsen  
Charles Larsen