Paper 8

Entered: September 20, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

MAQUET CARDIOVASCULAR, LLC, Patent Owner.

Case IPR2017-01028 and IPR2017-01029 Patent 9,327,068 B2

Before BART A. GERSTENBLITH, JEREMY M. PLENZLER, and KEVIN W. CHERRY, *Administrative Patent Judges*.

PLENZLER, Administrative Patent Judge.

DECISION
Denying *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH (collectively, "Petitioner") filed Petitions to institute an *inter partes* review of claims 1–22 ("the challenged claims") of U.S. Patent No. 9,327,068 B2 (Ex. 1001¹, "the '068 patent"). IPR2017-01028, Paper 2 ("'1028 Pet.")²; IPR2017-01029, Paper 2 ("'1029 Pet.")³. Maquet Cardiovascular, LLC ("Patent Owner") filed a Preliminary Response in each proceeding. IPR2017-01028, Paper 6 ("'1028 Prelim. Resp."); IPR2017-01029, Paper 7 ("'1029 Prelim. Resp."). We review the Petitions according to 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petitions and Patent Owner's Preliminary Responses, we do not institute an *inter partes* review for any of the challenged claims.

B. Related Matters

Petitioner and Patent Owner identify a number of proceedings related to the '068 patent. '1028 Pet. 2; '1029 Pet. 2; '1028 Paper 4, 1–2; '1029 Paper 3, 1–2.

¹ The Exhibit number is the same in both IPR2017-01028 and IPR2017-01029. References to exhibits and papers include the appropriate '1028 or '1029 prefix to indicate the relevant proceeding. When no prefix is included for an exhibit, the exhibit number (and exhibit) is the same in both proceedings.

² The '1028 Petition challenges claims 1–9 of the '068 patent.

³ The '1029 Petition challenges claims 10–22 of the '068 patent.

C. Asserted Grounds of Unpatentability and Evidence of Record
Petitioner contends that the challenged claims are unpatentable under
35 U.S.C. § 103(a) as set forth below ('1028 Pet. 3–5, 31–93; '1029 Pet. 3, 4, 29–91).

References	Claim(s) Challenged
Aboul-Hosn ⁴ and Siess ⁵	1–5, 7, 8, 10, and 12– 22
Aboul-Hosn, Siess, and Yock ⁶	6 and 11
Aboul-Hosn, Siess, and Wampler ⁷	9

Petitioner provides testimony from John M. Collins, Ph.D. '1028 Ex. 1002; '1029 Ex. 1002 (collectively, "the Collins Declaration").

D. The '068 Patent

The '068 patent "relates generally to blood pumps and, more particularly, to an improved intra-vascular blood pump having a guide mechanism which provides the ability to selectively guide the intravascular pump to a desired location within a patient's circulatory system." Ex. 1001, 1:21–25. Figures 1 and 3 of the '068 patent are exemplary, and are reproduced below.

⁴ WO 99/02204 A1, pub. Jan. 21, 1999 (Ex. 1004, "Aboul-Hosn").

⁵ U.S. Pat. No. 5,921,913, iss. July 13, 1999 (Ex. 1005, "Siess").

⁶ U.S. Pat. No. 5,061,273, iss. Oct. 29, 1991 (Ex. 1007, "Yock").

⁷ Wampler et al., *Clinical Experience with the Hemopump Left Ventricular Assist Device*, Supported Complex and High Risk Coronary Angioplasty, Ch. 14, 231–49 (Springer 1st ed. 1991) (Ex. 1008, "Wampler").

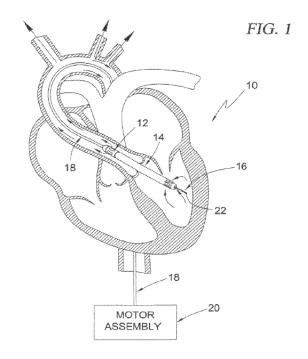


Figure 1 is a fragmentary section view of a human heart including an intravascular blood pump system. *Id.* at 5:7–11.

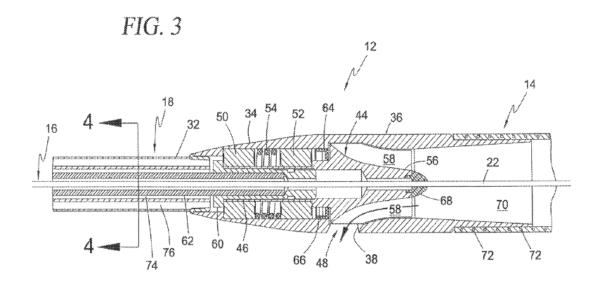


Figure 3 is a section view of the intravascular blood pump system shown in Figure 1. *Id.* at 5:16–19.

The '068 patent explains that its "intravascular blood pump system . . . overcomes the drawbacks of the prior art by providing a guide

mechanism as part of the intravascular blood pump." *Id.* at 6:47–50. Intravascular blood pump system 10 includes intravascular blood pump 12, cannula 14, and guide mechanism 16. *Id.* at 7:9–11. Intravascular blood pump 12 is driven by drive cable assembly 18 and motor assembly 20. *Id.* at 7:11–13. Guide mechanism 16 is described as an "over-the-wire" mechanism having "a suitable guide element dimensioned to pass slideably through a central lumen extending through the drive cable 18, blood pump 12, and cannula 14." *Id.* at 7:13–16. An example guide element may include guide wire 22. *Id.* at 7:19–20.

The '068 patent explains that "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 7:21–24. First, guide wire 22 is introduced into the patient's vascular system and advanced to a desired location in the circulatory system. *Id.* at 7:25–30. Intravascular blood pump 12 and cannula 14 are then advanced along guide wire 22 to the location in the circulatory system. *Id.* at 7:37–41.

E. Illustrative Claim

As noted above, Petitioner challenges claims 1–22 of the '068 patent. Claims 1, 10, and 20 are independent, with claims 2–9, 11–19, 21, and 22 depending, directly or indirectly, from claim 1, 10, or 20. Claim 1 is illustrative, and is reproduced below:

1. A method for perfusing a patient with an intravascular blood pump system, the intravascular blood pump system comprising (i) an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the hub having a distal end extending distally beyond the most distal portion of the blade and a shroud within which the rotor is rotatably disposed; (ii) a cannula extending from the shroud and comprising an outer

cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length; (iii) a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and (iv) a guide mechanism configured as a second lumen having a proximal end and a distal end, the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient, wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface, and wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong, the method comprising the steps of:

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

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

Ex. 1001, 18:41-67.

II. ANALYSIS

A. Claim Construction

Only those terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). We construe the claims using the broadest reasonable construction in light of the '068 patent Specification. *See* 37 C.F.R. § 42.100(b). Applying that standard, we generally interpret the claim terms of the '068 patent according to their ordinary and customary meaning in the context of the patent's written description. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). An inventor is entitled to be his or her own lexicographer of patent claim terms by providing a definition of the term in the specification with

reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). In the absence of such a definition, however, limitations are not to be read from the specification into the claims. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

Petitioner and Patent Owner each propose constructions for multiple terms. '1028 Pet. 28–31; '1029 Pet. 26–29; '1028 Prelim. Resp. 68–70; '1029 Prelim. Resp. 68–70. For purposes of this Decision, we determine that no term requires express construction.

B. Challenges

1. Claims 1–5, 7, 8, 10, and 12–22

Petitioner challenges claims 1–5, 7, 8, 10, and 12–22 as unpatentable over Aboul-Hosn and Siess under 35 U.S.C. § 103(a). '1028 Pet. 32–86; '1029 Pet. 30–89. We have reviewed Petitioner's challenge, as well as Patent Owner's preliminary response to that challenge and the evidence relied on in those papers. Based on our review of the record before us, we determine that Petitioner has failed to establish a reasonable likelihood of prevailing at trial on the issue of whether claims 1–5, 7, 8, 10, and 12–22 would have been obvious over Aboul-Hosn and Siess.

Claims 1, 10, and 20 each recite "progressing a guide wire to a predetermined location in the circulatory system of the patient" and "advancing the blood pump system along the guide wire to the predetermined location." The deficiency in the challenge is similar for each of claims 1, 10, and 20. For simplicity, we address specifically only the challenge to claim 1 with the understanding that the discussion applies equally to the challenge to claims 10 and 20.

In its challenge, Petitioner cites a combination of Aboul-Hosn's embodiments as teaching various claim features. '1028 Pet. 32–68 (citing the embodiments of Figures 1–13 and 23 in Aboul-Hosn). Patent Owner contends that Petitioner has failed to establish sufficiently that the features of those different embodiments are interchangeable or provide sufficient rationale to combine the teachings of those different embodiments. *See, e.g.*, '1028 Prelim. Resp. 20–40. We agree.

Aboul-Hosn "relates to the transport of fluids between various body regions and the increased stabilization of [a] body organ." Ex. 1004, 1:12–14. Aboul-Hosn's Figure 1, reproduced below, illustrates a reverse flow pump located external to the vasculature, while Figure 23, also reproduced below, illustrates an intravascular axial flow pump.

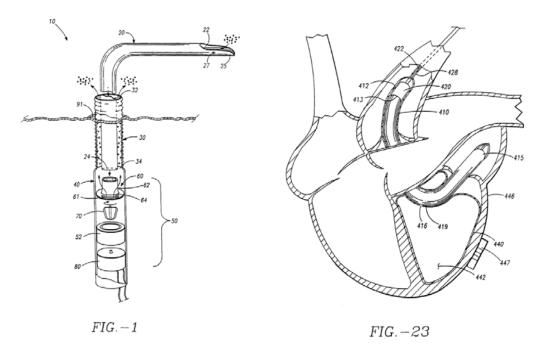


Figure 1 is an exploded perspective section view of a reverse flow pump system with a conduit extending into a blood vessel and the pump located external to the blood vessel; Figure 23 is a partial section view of the heart

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and a stabilization system used in cooperation with an intravascular pump. *Id.* at 8:20–23, 10:10–11.

Petitioner's challenge treats the various features of Aboul-Hosn's different embodiments as if they are interchangeable with one another. *See* '1028 Pet. 32–68. For example, Petitioner contends that

Aboul-Hosn discloses that the axial flow pump system of FIGS. 1–13 with reverse flow feature can be delivered to the heart percutaneously as shown in FIG. 23, below, by connecting the pump components illustrated in FIGS. 1–13 with the multilumen catheter 428 and adapting the inner cannula 20 and the outer conduit 30 as the stabilization cannula 411 in FIG. 23.

'1028 Pet. 33 (citing '1028 Ex. 1002 ¶¶ 153–158; Ex. 1004, 8:20–9:13, 14:13–16, 29:18–30:28). The citations to Aboul-Hosn, however, do not support Petitioner's contentions. Page 8, line 20 through page 9, line 13 of Aboul-Hosn are simply a brief description of Figures 1–12. Page 14, lines 13 through 16 of Aboul-Hosn provide a general explanation that "[t]he lengths of the inner cannula 20 and outer conduit 30 may further be varied in accordance with particular applications such as open heart surgery, or during closed heart or other laproscopic procedures which involve forming other openings to provide percutaneous access to inner body regions." Finally, page 29, line 17 through page 30, line 28 of Aboul-Hosn describes Figures 21 and 23, noting that "stabilization apparatus 410 and a pump 420 may be introduced into the body as shown in Fig. 21 through the femoral artery 430 with a catheter 428 linking the device to the exterior of the body" ('1028 Ex. 1004, 29:17–19), and, importantly, that "Figure[] 23 . . . illustrate[s a] different embodiment[] of the present invention" (id. at 30:20– 21).

The cited portions of the Collins Declaration also fail to support sufficiently Petitioner's contentions. For example, paragraph 154 of the Collins Declaration states that "pump 420 could include a variety of known blood pumps, including the pump system of FIGS. 1–13" and paragraph 155 states that "pump 420 would flexibly accommodate the pump described in FIGS. 1–13." Dr. Collins' opinion as to what pump 420 *could* include or *would* accommodate, however, is not the same as what Aboul-Hosn teaches.

Petitioner also fails to provide a sufficient rationale to combine the teachings of Aboul-Hosn's different embodiments. With respect to the recited step of "advancing the blood pump system along the guide wire to the predetermined location," for example, the Petition simply alleges that "[t]his method step is also conventionally taken in any method of delivering an intravascular blood pump to the vasculature using a guide wire," discusses the features of the embodiments shown in Aboul-Hosn's Figures 1–13 (referencing page 22 of Aboul-Hosn), and then concludes that "Fig. 23 illustrates the predetermined location to which Aboul-Hosn guides his blood pump system with the aid of the guide wire" without further explanation or citation to supporting evidence. '1028 Pet. 66–67.

Ultimately, the '1028 and '1029 Petitions are deficient because of the failure to explain sufficiently and support the challenges therein. Based on the record before us, we are left unpersuaded that the features of Aboul-Hosn's various embodiments are interchangeable or that one skilled in the art would have combined those features in the manner proposed by Petitioner. Accordingly, we determine that Petitioner has failed to establish a reasonable likelihood of success of showing that claims 1, 10, and 20, and

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claims 2–5, 7, 8, 12–19, 21, and 22, which depend therefrom, are unpatentable over Aboul-Hosn and Siess.

2. Claims 6, 9, and 11

Claims 6 and 9 depend from claim 1, and claim 11 depends from claim 10. Petitioner's challenges to those claims fail for the reasons set forth above regarding claims 1 and 10. Accordingly, we determine that Petitioner has failed to establish a reasonable likelihood of prevailing in showing that claims 6 and 11 are unpatentable over Aboul-Hosn, Siess, and Yock, and that claim 9 is unpatentable over Aboul-Hosn, Siess, and Wampler.

III. SUMMARY

Petitioner has failed to establish a reasonable likelihood of prevailing on any of its challenges. Accordingly, we do not institute *inter partes* review with respect to any of the challenged claims.

IV. ORDER

For the reasons given, the '1028 Petition and the '1029 Petition are each *denied* and no *inter partes* review is instituted.

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