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Entered: October 18, 2017

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,
Petitioner,

v.

MAQUET CARDIOVASCULAR, LLC,
Patent Owner.

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Cases IPR2017-01207 and IPR2017-01253
Patent 9,597,437 B2

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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 1–4, 18–24, and 26–29 ("the challenged claims") of U.S. Patent No. 9,597,437 B2 (Ex. 1001[1], "the '437 patent"). IPR2017-01207, Paper 2 ("'1207 Pet.")[2]; IPR2017-01253, Paper 1 ("'1253 Pet.")[3]. Maquet Cardiovascular, LLC ("Patent Owner") filed a Preliminary Response in each proceeding. IPR2017-01207, Paper 6 ("'1207 Prelim. Resp."); IPR2017-01253, Paper 6 ("'1253 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 '437 patent. '1207 Pet. 1; '1253 Pet. 1; '1207 Paper 3, 1–2; '1253 Paper 3, 1–2.

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[1] The Exhibit number is the same in both IPR2017-01207 and IPR2017-01253. References to exhibits and papers include the appropriate '1207 or '1253 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 '1207 Petition challenges claims 1–4, 18–24, 26, and 27 of the '437 patent.

[3] The '1253 Petition challenges claims 28 and 29 of the '437 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 ('1207 Pet. 4, 25–109; '1253 Pet. 4, 29–101).

| **References** | **Claim(s) Challenged** |
|---|---|
| Aboul-Hosn[4], Jegaden[5], Siess[6], and Wampler[7] | 1–4, 18–22, 24, and 26–28 |
| Aboul-Hosn, Jegaden, Siess, Wampler, and Crowley[8] | 23 |
| Aboul-Hosn, Yock[9], Siess, and Wampler | 1–4, 18–21, 26, and 28 |
| Aboul-Hosn, Yock, Siess, Wampler, and Jegaden | 22, 24, and 27 |
| Aboul-Hosn, Yock, Siess, Wampler, and Crowley | 23 |
| Aboul-Hosn, Jegaden, Siess, Wampler, and Wampler '712[10] | 29 |
| Aboul-Hosn, Yock, Siess, Wampler, and Wampler '712 | 29 |

Petitioner provides testimony from John M. Collins, Ph.D. '1207 Ex. 1002; '1253 Ex. 1002 (collectively, "the Collins Declaration").

[4] WO 99/02204 A1, pub. Jan. 21, 1999 (Ex. 1004, "Aboul-Hosn").
[5] Jegaden, *Clinical Results of Hemopump Support in Surgical Cases*, published in Temporary Cardiac Assist with an Axial Pump System, p. 61–65 (Springer 1991) (Ex. 1033, "Jegaden").
[6] U.S. Pat. No. 5,921,913, iss. July 13, 1999 (Ex. 1005, "Siess").
[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) ('1207 Ex. 1007, "Wampler").
[8] U.S. Pat. No. 5,421,338, iss. June 6, 1995 (Ex. 1049, "Crowley").
[9] U.S. Pat. No. 5,061,273, iss. Oct. 29, 1991 (Ex. 1006, "Yock").
[10] U.S. Pat. No. 4,625,712, iss. Dec. 2, 1986 (Ex. 1008, "Wampler '712").

*D. The '437 Patent*

The '437 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, 1:30–34. Figures 1 and 3 of the '437 patent are exemplary, and are reproduced below.

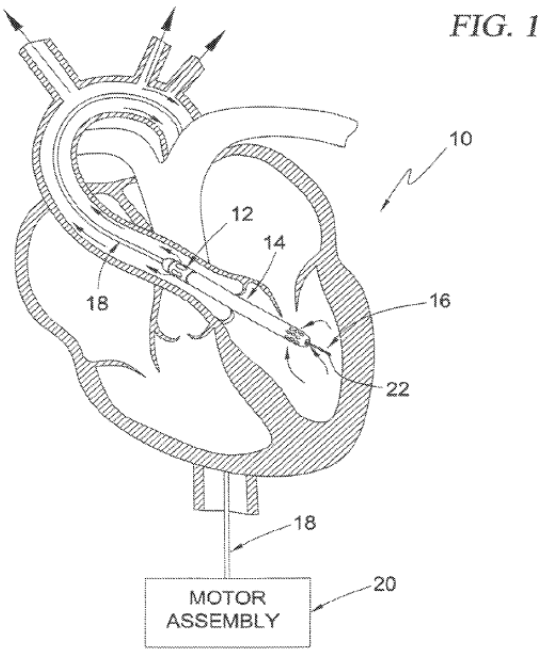


Figure 1 is a fragmentary section view of a human heart including an intravascular blood pump system. *Id.* at 5:25–30.

FIG. 3

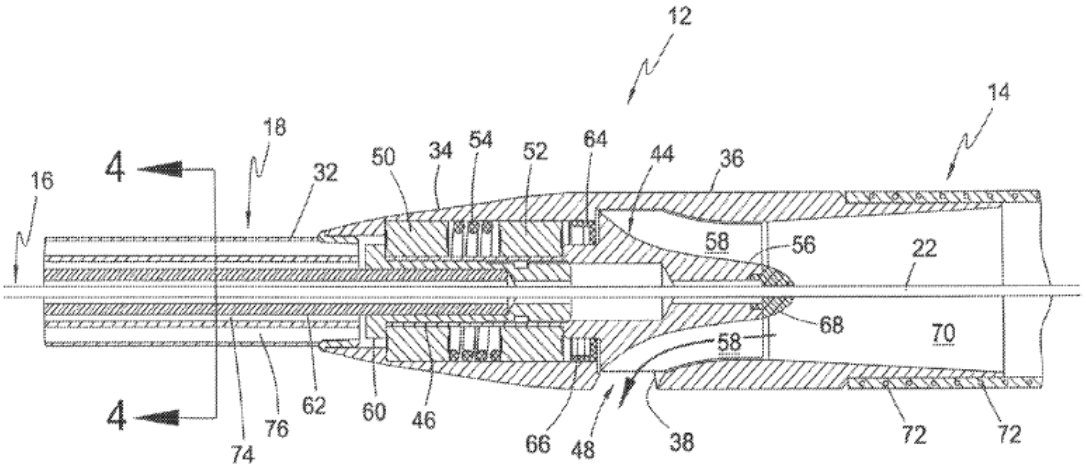


Figure 3 is a section view of the intravascular blood pump system shown in Figure 1. *Id.* at 5:35–38.

The ’437 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 8:53–56. Intravascular blood pump system 10 includes intravascular blood pump 12, cannula 14, and guide mechanism 16. *Id.* at 9:16–19. Intravascular blood pump 12 is driven by drive cable assembly 18 and motor assembly 20. *Id.* at 9:19–20. 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 9:20–24. An example guide element may include guide wire 22. *Id.* at 9:26–27.

The ’437 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 9:28–32. First, guide wire 22 is introduced into the patient’s vascular system and

advanced to a desired location in the circulatory system. *Id.* at 9:33–38. Intravascular blood pump 12 and cannula 14 are then advanced along guide wire 22 to the location in the circulatory system. *Id.* at 9:45–49.

*E. Illustrative Claim*

As noted above, Petitioner challenges claims 1–4, 18–24, and 26–29 of the '437 patent. Claims 1 and 28 are independent, with claims 2–4, 18–24, 26, 27, and 29 depending, directly or indirectly, from claim 1 or 28. Claim 1 is illustrative, and is reproduced below:

> 1. A method for providing left-heart support using an intravascular blood pump system, wherein the intravascular blood pump system comprises:
>
> an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and configured to provide left-heart support, the 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 rotor hub having a distal end extending distally beyond a most distal portion of the at least one blade;
>
> a catheter coupled to a proximal end of the intravascular blood pump, a purge lumen extending through the catheter;
>
> a cannula coupled to a distal end of the intravascular blood pump, one or more first ports and one or more second ports establishing fluid communication between a cannula lumen and an exterior region of the cannula, wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port; and
>
> an elongate lumen associated with the cannula and sized to slidably receive the guide wire and dimensioned such that the guide wire passes slidably and coaxially through the elongate lumen, the elongate lumen is sized smaller cross sectionally than the cannula lumen, both the elongate lumen and the cannula lumen not extending through the rotor hub;

wherein the method for providing left-heart support comprises the steps of

passing the guide wire into the patient such that a distal end of the guide wire is positioned in the left ventricle of the patient's heart;

placing the guide wire through both the cannula and the elongate lumen such that the guide wire extends proximally away from the intravascular blood pump, the guide wire not passing through the rotor hub or the catheter, and the guide wire extends out of the intravascular blood pump system in a distal direction through the elongate lumen;

advancing the cannula into the patient using the guide wire and positioning the cannula across an aortic valve of the patient such that a distal end of the cannula and the at least one second port are positioned in the left ventricle and a proximal end of the cannula and the at least one first port are positioned in the aorta;

passing purge fluid through the purge lumen to the intravascular blood pump;

measuring pressure adjacent the intravascular blood pump; and

spinning the rotor so as to pump blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support.

Ex. 1001, 33:42–34:30.

## 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 '437 patent Specification. *See* 37 C.F.R. § 42.100(b). Applying that standard, we

generally interpret the claim terms of the ’437 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. ’1207 Pet. 22–24; ’1253 Pet. 25–28; ’1207 Prelim. Resp. 12–13; ’1253 Prelim. Resp. 13–14. For purposes of this Decision, we determine that no term requires express construction.

*B. Challenges*

*1. Aboul-Hosn/Jegaden/Siess/Wampler Grounds*

Petitioner challenges claims 1–4, 18–22, 24, and 26–28 as unpatentable over Aboul-Hosn, Jegaden, Siess, and Wampler under 35 U.S.C. § 103(a). ’1207 Pet. 25–79; ’1253 Pet. 29–79. Petitioner additionally challenges claim 23, which depends from claim 1, as unpatentable over Aboul-Hosn, Jegaden, Siess, Wampler, and Crowley, and claim 29, which depends from claim 28, as unpatentable over Aboul-Hosn, Jegaden, Siess, Wampler, and Wampler ’712. ’1207 Pet. 79–80; ’1253 Pet. 79–82. We have reviewed Petitioner’s challenges, as well as Patent Owner’s preliminary responses to those challenges 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 any of the challenges noted above.

The deficiency is similar for each of the challenges noted above. For simplicity, we address specifically only the challenge to claim 1 with the understanding that our discussion applies equally to Petitioner's other challenges.

In its challenge, Petitioner cites a combination of Aboul-Hosn's embodiments as teaching various claim features. '1207 Pet. 25–63 (citing, for example, the embodiments of Figures 1–13 and Figure 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.*, '1207 Prelim. Resp. 21–35. 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.

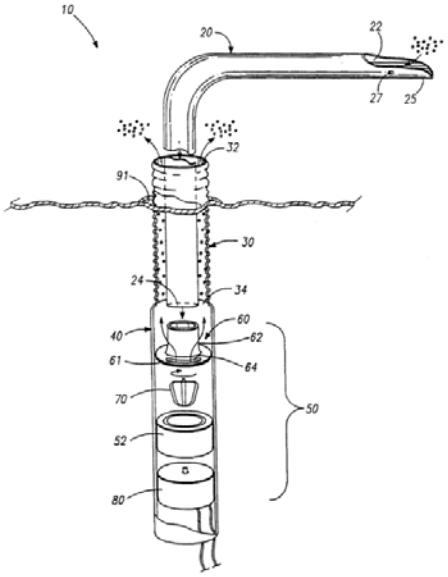


FIG.–1

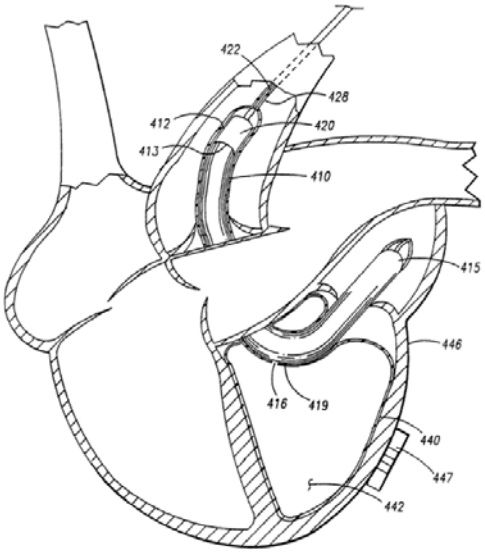


FIG.–23

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 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* '1207 Pet. 25–63. For example, Petitioner contends that "Aboul-Hosn discloses that the axial flow pump system of FIGS. 1–13, either with or without reverse flow feature . . . can be delivered to the heart percutaneously as shown in FIG. 23." '1207 Pet. 27 (citing '1207 Ex. 1002 ¶¶ 231–35, 237; 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" (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, in paragraph 231, Dr. Collins refers, generally, to 17 pages of prior testimony and concludes that "the pump 420 [from FIG. 23] would flexibly accommodate the pump described in FIGS. 1–13, either with or without the reverse flow features, which increases the versatility of the blood pump system." In the preceding paragraph, and referring back to the same 17 pages of earlier testimony, Dr. Collins concludes that "pump 420 could include a variety of known blood pumps, including the pump system of FIGS. 1–13." '1207 Ex. 1002 ¶ 230. Dr. Collins's 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. Petitioner simply fails to explain sufficiently *why* one skilled in the art would have found it obvious to combine those teachings.

Ultimately, the '1207 and '1253 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 prevailing in showing that claims 1–4, 18–22, 24, and 26–28 are unpatentable over Aboul-Hosn, Jegaden, Siess, and Wampler, that claim 23 is unpatentable over Aboul-Hosn, Jegaden, Siess, Wampler, and Crowley, or that claim 29 is unpatentable over Aboul-Hosn, Jegaden, Siess, Wampler, and Wampler '712.

*2. Aboul-Hosn/Yock/Siess/Wampler Grounds*

Petitioner additionally challenges claims 1–4, 18–21, 26, and 28, as unpatentable over Aboul-Hosn, Yock, Siess, and Wampler, claims 22, 24, and 27 as unpatentable over Aboul-Hosn, Yock, Siess, Wampler, and Jegaden, claim 23 as unpatentable over Aboul-Hosn, Yock, Siess, Wampler, and Crowley, and claim 29 as unpatentable over Aboul-Hosn, Yock, Siess, Wampler, and Wampler '712. Those challenges also fail for the reasons set forth above. *See, e.g.*, '1207 Pet. 81 ("See element 1(a) – 1(g), Sections X.A.1(a)-(g), above. Elements 1(a) – 1(g) are the same as in Ground I and rely on Aboul-Hosn.").

## 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 '1207 Petition and the '1253 Petition are each *denied* and no *inter partes* review is instituted.

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