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Paper No. 8
November 7, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

MAQUET CARDIOVASCULAR, LLC,
Patent Owner.

Case IPR2017-01209
Patent 9,597,437 B2

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

GERSTENBLITH, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Abiomed, Inc. and Abiomed R&D, Inc. (collectively, "Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of *inter partes* review of claims 5, 10, 16, and 25 of U.S. Patent No. 9,597,437 B2 (Ex. 1001, "the '437 patent"). Maquet Cardiovascular, LLC ("Patent Owner") filed a Preliminary Response (Paper 6).

Pursuant to 35 U.S.C. § 314(a), an *inter partes* review may be instituted only if "the information presented in the petition . . . and any [preliminary] response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *See* 37 C.F.R. § 42.108(c).

For the reasons given below, on this record, Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of claims 5, 10, 16, and 25 of the '437 patent. Accordingly, we do not institute an *inter partes* review of the '437 patent.

B. Related Proceedings

Petitioner and Patent Owner identify a number of proceedings related to the '437 patent. Pet. 1; Paper 7, 1–2.

C. Real Parties in Interest

The Petition identifies "Abiomed, Inc. and Abiomed R&D, Inc." as real parties in interest. Pet. 1. Patent Owner identifies itself, "Maquet Cardiovascular, LLC," as the sole real party in interest. Paper 7, 1.

D. The References

Petitioner relies on the following references:

International Application Publication No. WO 99/02204, published January 21, 1999 (Ex. 1004, "Aboul-Hosn");

U.S. Patent No. 5,921,913, issued July 13, 1999 (Ex. 1005, "Siess");

U.S. Patent No. 5,061,273, issued October 29, 1991 (Ex. 1006, "Yock");

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. 1007, "Wampler");

U.S. Patent No. 4,625,712, issued December 2, 1986 (Ex. 1008, "Wampler '712"); and

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").

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 5, 10, 16, and 25 of the '437 patent on the following grounds:

References	Basis	Claim(s) challenged
Aboul-Hosn, Jegaden, Siess, and Wampler	§ 103(a)	10
Aboul-Hosn, Jegaden, Siess, Wampler, and Wampler '712	§ 103(a)	5, 16, and 25
Aboul-Hosn, Yock, Siess, and Wampler	§ 103(a)	10
Aboul-Hosn, Yock, Siess, Wampler, and Wampler '712	§ 103(a)	5, 16, and 25

Petitioner supports its challenge with a Declaration by John M. Collins, Ph.D., dated April 18, 2017 (Ex. 1002).

F. 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.

FIG. 1

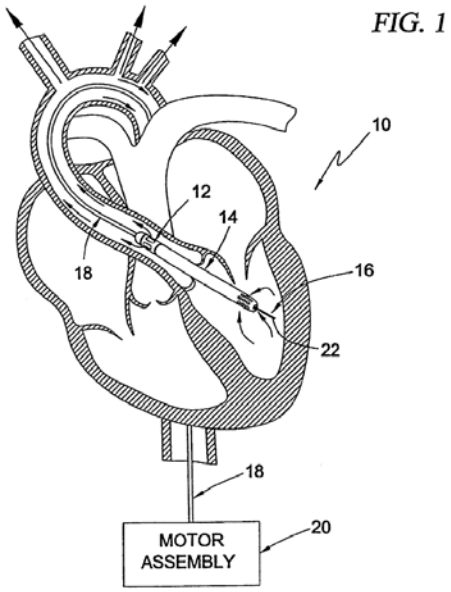

Figure 1 "is a partial sectional view of a human heart illustrating an intravascular blood pump system having an 'over-the-wire' type guide mechanism . . . positioned, by way of example, in a trans-valvular configuration to provide left-heart assist." *Id.* at 5:25–30.

FIG. 3

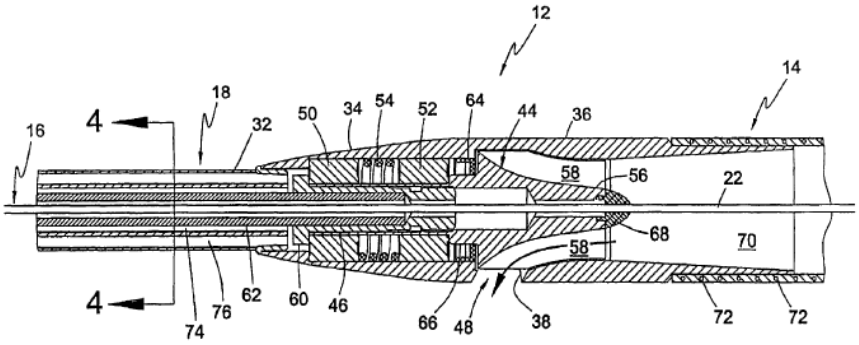

Figure 3 "is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, and cannula of the intravascular blood pump system." *Id.* at 5:35–38.

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 over-the-wire type 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" guide mechanism having "a suitable guide element dimensioned to pass slidably through a central lumen extending through the drive cable 18, blood pump 12, and cannula 14." *Id.* at 9:20–24. The 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. Guide wire 22 is introduced into the patient's vascular system and advanced to a desired location in the circulatory system. *Id.* at 9:33–36. 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.

G. Illustrative Claim

Each of challenged claims 5, 10, 16, and 25 depend from claim 1. Claim 1, although not challenged expressly by Petitioner, is illustrative of the challenged subject matter 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, 33:43–34:30.

II. CLAIM CONSTRUCTION

Petitioner and Patent Owner propose that we construe the terms "distal" and "proximal." Pet. 26–29; Prelim. Resp. 13–14. For purposes of this Decision, we need not construe any terms expressly. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy).

III. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art would have had:

> (i) a Bachelor's degree in mechanical or biomedical engineering, or a similar field, and two to three years of work experience with intravascular cardiac assist devices, (ii) a Master's degree in mechanical or biomedical engineering, or a similar field, and two to three years of work experience in medical device or related fields, or (iii) a Ph.D. in mechanical or biomedical engineering, or a similar field.

Pet. 29–30 (citing Ex. 1002 ¶ 33).

Patent Owner contends that a person of ordinary skill in the art would have either:

> (1) an undergraduate degree in mechanical engineering or bioengineering or similar subject matter and at least 10 years of experience designing intravascular heart assist devices; or (2) have an advanced degree in mechanical engineering or bioengineering (either a masters, Ph.D., or equivalent course

> work) and at least five years of experience designing intravascular heart assist devices.

Prelim. Resp. 73–74.

For the purposes of this Decision, we determine that no express finding is necessary on this record and that the level of ordinary skill in the art is reflected by the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc*., 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

B. Obviousness Challenges Based on Aboul-Hosn

Petitioner contends that several references in combination with Aboul-Hosn would have rendered obvious the subject matter of claims 5, 10, 16, and 25 of the ’437 patent. *Id.* at 30–96. Each of Petitioner’s challenges is based on combinations and modifications of various embodiments shown in Aboul-Hosn, which challenges suffer from the same deficiencies noted below. Thus, we discuss the challenges together.

Petitioner relies upon a combination of Aboul-Hosn’s embodiments as teaching various claim features. *See, e.g.*, Pet. 32–33 (discussing modifications and combinations of the embodiments illustrated in Aboul-Hosn’s Figures 1–13 and 23), 81 (relying on the same position). Patent Owner asserts that Petitioner has failed to establish sufficiently that the features of those different embodiments are interchangeable or provide a sufficient rationale to combine the teachings of those different embodiments. *See, e.g.*, Prelim. Resp. 14–31. 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 Figures 1 and 23 are reproduced below:

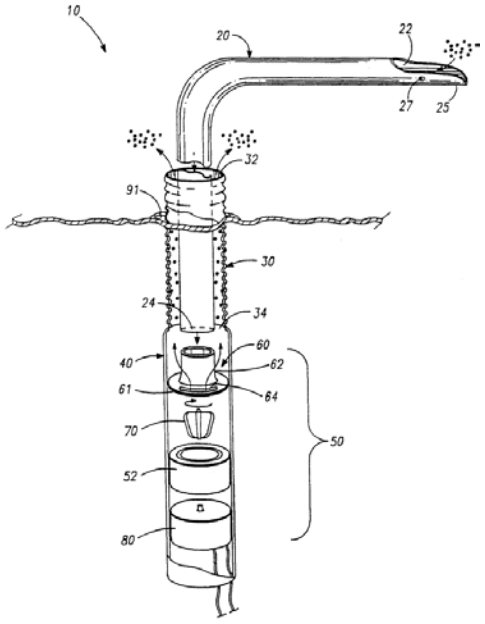

FIG.–1

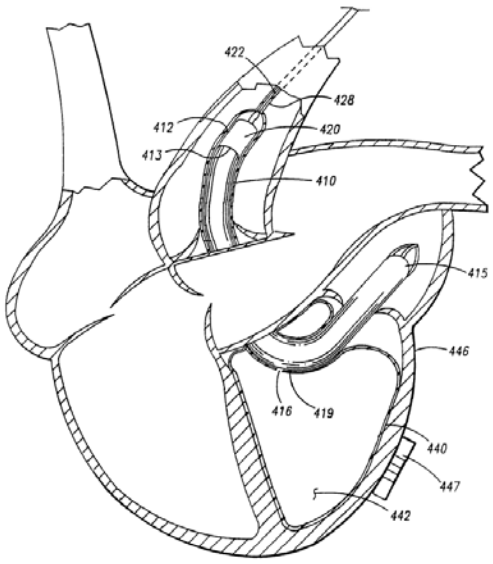

FIG.–23

Figure 1 "is an exploded perspective sectional view of a reverse flow system generally showing the reverse flow pump in relation to an inner and an outer conduit which direct and control the flow of fluids between different body regions." *Id.* at 8:20–23. Figure 23 "is a partial sectional view of the heart and a stabilization system used in cooperation with an intravascular pump." *Id.* at 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, e.g.*, Pet. 32–33. For example, Petitioner contends:

> Aboul-Hosn discloses that the axial flow blood pump system of FIGS. 1–13, either with or without the reverse flow feature (*See* Section VII.A), can be delivered to the heart percutaneously as shown in FIG. 23.

Pet. 32–33 (citing Ex. 1002 ¶¶ 239; 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 contain a brief description of Figures 1–12. Page 14, lines 13 through 16 of Aboul-Hosn provide a general statement 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 [sic] procedures which involve forming other openings to provide percutaneous access to inner body regions." Ex. 1004, 14:13–16. Additionally, page 29, line 17 through page 30, line 28 of Aboul-Hosn describe 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).

Paragraphs 228 through 239 of the Collins Declaration also fail to support sufficiently Petitioner's contentions. For example, in paragraph 232, Dr. Collins' opines that "pump 420 could include a variety of known blood pumps, including the pump system of FIGS. 1–13," and, in paragraph 233, he opines that "pump 420 would flexibly accommodate the pump described in FIGS. 1–13 either with or without the reverse flow features." Dr. Collins' opinions as to what pump 420 *could* include or *would* accommodate, however, is not the same as what Aboul-Hosn expressly teaches. *See also* Ex. 1002 ¶ 239 (relying on the same premise with respect to Aboul-Hosn).

Petitioner also fails to provide a sufficient rationale to combine the teachings of Aboul-Hosn's different embodiments. With respect to the recitation "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," for example, the Petition relies upon modifying the axial flow pump of Aboul-Hosn to remove its reverse flow features and modifying the blood pump system of Figures 1–13 for percutaneous access. *See, e.g.*, Pet. 32–33 (discussing an axial flow pump configuration without the reverse flow features). In short, in attempting to map Aboul-Hosn onto the challenged claims, Petitioner provides the following: "The pump 420 could also be configured without the reverse flow feature of the pump system of FIGS. 1–13." *Id.* at 20 (citing Ex. 1002 ¶ 145; Ex. 1004, 31:6–9). Petitioner goes on to discuss various modifications required to achieve that result. *Id.* at 20–21. Dr. Collins's Declaration testimony is similar. *See, e.g.*, Ex. 1002 ¶ 145. Neither Petitioner nor Dr. Collins, however, provides any reason as to why one of ordinary skill in the art would modify Aboul-Hosn's teachings as they propose.[1]

Ultimately, the Petition is 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

[1] The citation to Aboul-Hosn at page 31, lines 6 through 9, fails to provide adequate support for the specific modifications proposed by Petitioner and Dr. Collins. That disclosure simply states that "[t]he stabilization systems shown in Figs. 23 and 24 illustrate only some of the various types of commercially available intravascular and extracorporeal pumps that are compatible or provided for by the present invention."

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 showing that claims 5, 10, 16 and 25 would have been obvious over the combinations of (1) Aboul-Hosn, Jegaden, Siess, and Wampler; (2) Aboul-Hosn, Jegaden, Siess, Wampler, and Wampler '712; (3) Aboul-Hosn, Yock, Siess, and Wampler; or (4) Aboul-Hosn, Yock, Siess, Wampler, and Wampler '712.

C. Conclusion

For the foregoing reasons, on this record, Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that claims 5, 10, 16, and 25 of the '437 patent are unpatentable.

IV. ORDER

Accordingly, it is:

ORDERED that the Petition is *denied* as to the challenged claims of the '437 patent; and

FURTHER ORDERED that no *inter partes* review is instituted.

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