Trials@uspto.gov
571.272.7822

Paper No. 8
September 26, 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 IPR2017-01025
Patent 7,022,100 B1

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., Abiomed R&D, Inc., and Abiomed Europe GmbH (collectively, "Petitioner") filed a Petition (Paper 2, "Pet.") requesting institution of *inter partes* review of claims 16–18 of U.S. Patent No. 7,022,100 B1 (Ex. 1001, "the '100 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 16–18 of the '100 patent. Accordingly, we do not institute an *inter partes* review of the '100 patent.

B. Related Proceedings

Petitioner and Patent Owner identify a number of proceedings related to the '100 patent. Pet. 1–2; Paper 7, 1–2.

C. Real Parties in Interest

The Petition identifies "Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH" 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"); and

U.S. Patent No. 6,176,822 B1, issued January 23, 2001 (Ex. 1019, "Nix").

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 16–18 of the '100 patent on the following grounds:

References	Basis	Claim(s) challenged
Aboul-Hosn and Siess	§ 103(a)	16 and 17
Aboul-Hosn, Siess, and Nix	§ 103(a)	18

Petitioner supports its challenge with a Declaration by John M. Collins, Ph.D., dated March 10, 2017 (Ex. 1002).

F. The '100 Patent

The '100 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, 1:12–16. Figures 1 and 3 of the '100 patent are exemplary and are reproduced below.

FIG. 1

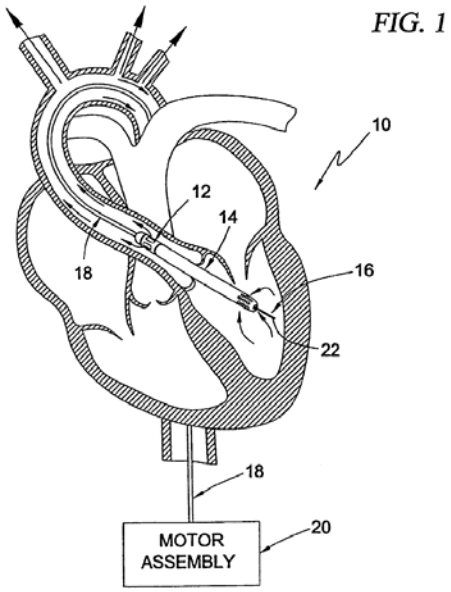

Figure 1 "is a partial sectional view of a human hart illustrating an intravascular blood pump system having an 'over-the-wire' type guide mechanism . . . positioned, by way of example, in a trans-valvular configuration to provide left-heart assist." *Id.* at 5:8–13.

FIG. 3

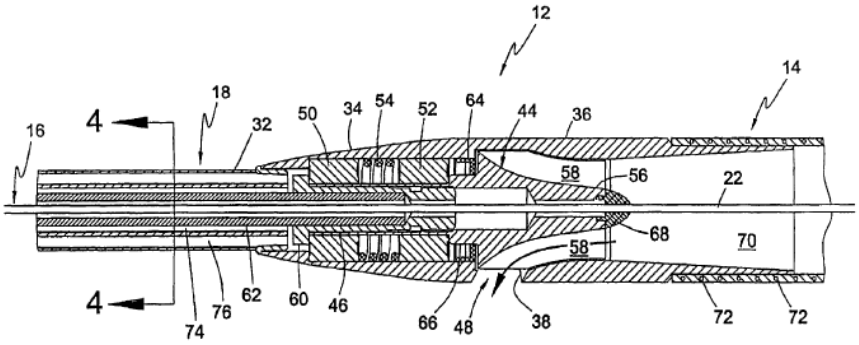

Figure 3 "is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, and cannula of the intravascular blood pump system." *Id.* at 5:18–21.

The '100 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 6:50–53. Intravascular blood pump system 10 includes intravascular blood pump 12,

cannula 14, and over-the-wire type guide mechanism 16. *Id.* at 7:12–16. Intravascular blood pump 12 is driven by drive cable assembly 18 and motor assembly 20. *Id.* at 7:16–17. 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 7:17–21. The guide element may include guide wire 22. *Id.* at 7:23–24.

The '100 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 7:25–28. First, guide wire 22 is introduced into the patient's vascular system and advanced to a desired location in the circulatory system. *Id.* at 7:30–39. Intravascular blood pump 12 and cannula 14 are then advanced along guide wire 22 to the location in the circulatory system. *Id.* at 7:42–46.

G. Illustrative Claim

Claim 16 is the sole independent claim challenged in this proceeding and is reproduced below:

> 16. An intravascular blood pump system comprising:
>
> an intravascular blood pump having a cannula coupled thereto,
>
> a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient, and
>
> a blood pressure detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.

Ex. 1001, 20:20–28.

II. CLAIM CONSTRUCTION

Neither Petitioner nor Patent Owner contends that we need to construe expressly any claim terms. For purposes of this Decision, we agree. *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. 27 (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. 66.

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 the combination of Aboul-Hosn and Siess would have rendered the subject matter of claims 16 and 17 obvious to one of ordinary skill in the art at the time of the invention. Pet. 28–50. Also, Petitioner contends that the combination of Aboul-Hosn, Siess, and Nix would have rendered the subject matter of claim 18 obvious to one of ordinary skill in the art as of the time of the invention. *Id.* at 50–54. 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. 28–47 (discussing modifications and combinations of the embodiments illustrated in Aboul-Hosn's Figures 1–13 and 23). 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. 19–42. 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:

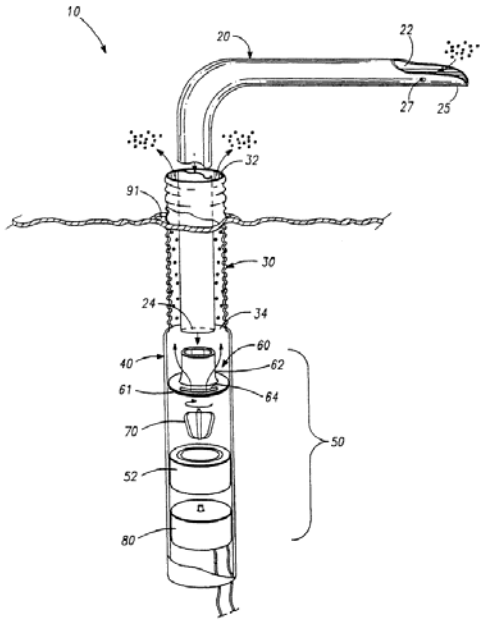

FIG.–1

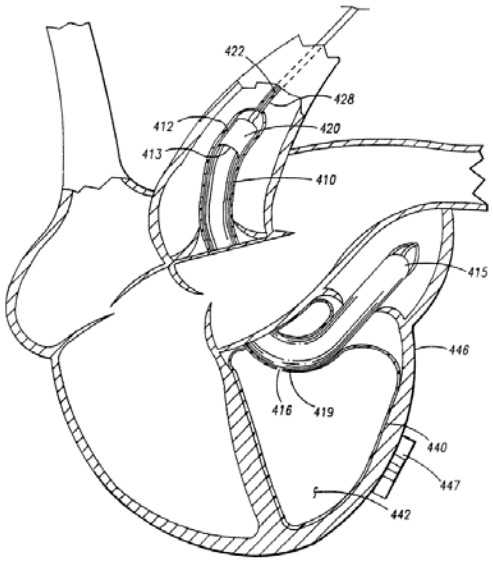

FIG.–23

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* Pet. 32–68. For example, Petitioner contends:

> 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.

Pet. 29 (citing Ex. 1002 ¶¶ 128–129; Ex. 1004, 8:20–9:15, 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 15 of Aboul-Hosn are simply a brief description of Figures 1–13. 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." Additionally, 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 129, 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 130, he opines that "pump 420 would flexibly accommodate the pump described in FIGS. 1–13." Dr. Collins' opinions as to what pump 420 *could* include or *would* accommodate, however, is not the same as what Aboul-Hosn expressly teaches.

Petitioner also fails to provide a sufficient rationale to combine the teachings of Aboul-Hosn's different embodiments. With respect to the recitations "an intravascular blood pump having a cannula coupled thereto" and "a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a

patient," 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. 34 (discussing an axial flow pump configuration without the reverse flow features), 37 (discussing modifications to the blood pump system of Figures 1–13). In short, in attempting to map Aboul-Hosn onto the challenged claims, Petitioner provides the following: "A POSITA would have readily understood that the pump 420 could also be configured without the reverse flow feature of the pump system of FIGS. 1–13 and delivered by a similar over-the-wire guide mechanism." Pet. 24 (citing Ex. 1002 ¶ 113; Ex. 1004, 31:6–9). Petitioner goes on to discuss various modifications required to achieve that result. *Id.* at 24–25. Dr. Collins's Declaration testimony is similar. *See, e.g.*, Ex. 1002 ¶¶ 113–120. 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 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

[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."

showing that (1) claims 16 and 17 would have been obvious over the combination of Aboul-Hosn and Siess and (2) that claim 18 would have been obvious over the combination of Aboul-Hosn, Siess, and Nix.

C. Conclusion

For the foregoing reasons, on this record, Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that claims 16–18 of the ’100 patent are unpatentable.

IV. ORDER

Accordingly, it is:

ORDERED that the Petition is *denied* as to the challenged claims of the ’100 patent; and

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

For PETITIONER:

David Tennant
Charles Larsen
Nathan Zhang
WHITE & CASE LLP
dtennant@whitecase.com
charles.larsen@whitecase.com
nathan.zhang@whitecase.com

For PATENT OWNER:

Michael Connor
Christopher Douglas
Benjamin Pleune
Travis Iams
Christopher Kelly
ALSTON & BIRD LLP
mike.connor@alston.com
christopher.douglas@alston.com
ben.pleune@alston.com
travis.iams@alston.com
chris.kelly@alston.com