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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION, Petitioner,

v.

KARL STORZ ENDOSCOPY-AMERICA, INC., Patent Owner.

> Case IPR2015-00679 Patent 8,439,821

Before KEN B. BARRETT, BRYAN F. MOORE, and BARRY L. GROSSMAN, *Administrative Patent Judges*.

MOORE, Administrative Patent Judge.

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

I. INTRODUCTION

Petitioner, Stryker Corporation, filed a Petition requesting an *inter partes* review of claims 1–11 of U.S. Patent No. 8,439,821 (Ex. 1001, "the '821 patent"). Paper 2 ("Pet."). In response, Patent Owner, Karl Storz Endoscopy-America, Inc., filed a Preliminary Response. Paper 8 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . 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."

Upon consideration of the Petition, and for the reasons explained below, we determine that Petitioner has not established a reasonable likelihood that it would prevail with respect to any of the challenged claims.

A. Related Matter

The parties identify the following case involving the '821 patent: *Karl Storz Endoscopy-Am., Inc. v. Stryker Corp.*, Case No. 3:14-cv-00876-RS (N.D. Cal., Feb. 26, 2014). Pet. 1. The parties also identify seven other pending requests for *inter partes* review involving the '821 patent or a patent related to the '821 patent. Pet. 1–2.

B. The '821 Patent

The '821 patent is titled "System and Method for the Central Control of Devices Used During an Operation." The Abstract describes the subject matter as follows:

The present invention relates to a system for the central control of devices used during an operation, comprising a first control unit for control of said devices. The system is characterized in that a second control unit is provided which is connected to the first control unit for exchange of information. The first control unit may be embodied as closed system for control of at least those devices which carry out safety-related functions (safety-related devices), and the second control unit may be embodied as open system for control of the remaining devices which carry out non safety-related functions (non safety-related devices). The invention further relates to a method for the central control of devices.

Ex. 1001, Abstract.

C. Illustrative Claim

Petitioner challenges claims 1–11 of the '821 patent. Independent

claim 1 is illustrative of the claimed subject matter and is reproduced below:

1. A system for controlling medical devices, comprising: a first controller;

at least one medical device having safety-related functions controlled by said first controller;

a second controller in communication with said first controller;

at least one device having non-safety-related functions controlled by said second controller;

wherein said second controller can only control devices

that do not have safety-related functions;

a touch panel that communicates a control command associated with said at least one medical device having safetyrelated functions and a control command associated with said at least one device having non-safety related functions to said second controller;

wherein said second controller controls said at least one device having non-safety-related functions based on the control command associated therewith received from said touch panel; and

wherein said second controller communicates the control command associated with said at least one medical device having safety related functions received from said touch panel to said first controller.

Ex. 1001, 7:5–28.

D. Prior Art Relied Upon

Petitioner relies upon the following prior art references:

Bucholz	US 6,928,490	filed May 20, 1999 ¹	(Ex. 1003)
Brant	US 6,278,975	filed Oct 25, 1995 ²	(Ex. 1004)
Engleson	US 5,781,442	issued July 14, 1998	(Ex. 1005)

¹ Via a provisional application

² Via a provisional application

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Challenged Claims	Basis	References
1–10	§ 102	Bucholz
1–10	§ 103	Bucholz and the knowledge of a person of ordinary skill in the art
8 and 11	§ 103	Bucholz and Brant
3 and 9	§ 103	Bucholz and Engleson

II. ANALYSIS

A. Claim Construction

We construe claims in an unexpired patent by applying the broadest reasonable interpretation in light of the specification. *See* 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, No. 2014-1301, 2015 WL 4097949, *7–8 (Fed. Cir. July 8, 2015). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). On the other hand, a "claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer" and clearly set forth a definition of the claim term in the specification. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

In light of Petitioner's challenges to the patentability of the claims, we address the following terms in the challenged claims: "medical device

having safety-related functions" and "said second controller can only control devices that do not have safety-related functions." Other terms in the challenged claims need no express construction at this time.

Petitioner contends that "*medical device having safety-related functions*" means the "a device whose breakdown or failure during a medical procedure may be life-threatening for a patient." Petitioner asserts that this "construction comports with the special meaning given to this term by the patentee." Pet. 5 (citing Ex. 1001, '821 patent at 1:54:62; Abstract, 1:66–2:40, 3:18–31, 3:46–48, 4:15–20, 5:22–33, 5:66–6:4). We are persuaded by Petitioner's contention in this regard.

Patent Owner asserts that "[t]he broadest reasonable construction of this term is 'medical devices which have functions for which a breakdown or failure thereof during a medical procedure may be safety-critical or lifethreatening for the patient including, e.g., functions of endoscopic devices, operating table controls, insufflators, pumps, or RF-surgery devices.'" Prelim. Resp. 5. The Specification also indicates that the safety-related devices may be devices "which may be life-threatening for a patient in the event of a breakdown or failure." Ex. 1001, 1:54–62. Patent Owner asserts that the Specification also indicates that safety-related devices may be devices that have "safety-critical" functions. Prelim Resp. 6 (citing Ex. 1001, 5:22–25 ("The first computer unit **12** serves at least for the control of medical devices, which carry out safety-related and safety critical functions, respectively.")).

6

The text cited by Patent Owner suggests that safety-related and safetycritical functions are alternatives by use of the word "respectively" suggesting that the terms are disassociated from each other. The claims only use the term safety-related. Thus, safety-critical does not appear to be related to the claim language.

Finally, we note the examples disclosed in the Specification for safety-related devices are "endoscopic devices, preferably insufflators, pumps, light sources, video devices and for example op-table-controllers, [RF generators], etc." Ex. 1001, 5:24–28, *see id.* at 3:46–48. Further, the examples disclosed in the Specification for non-safety-related devices includes "picture archiving, op-lighting, room lighting, telephone, air conditioning, pager, internet, hospital system, consumption parts, management systems, etc." Ex. 1001, 6:1–4; *see id.* 3:49–52.

For the reasons stated above, we construe medical device having safety-related functions to mean "a device whose breakdown or failure during a medical procedure may be life-threatening for a patient." Thus, "said second controller can only control devices that do not have safetyrelated functions" is construed to mean "wherein said second controller can only control devices whose breakdown or failure during a medical procedure are not life-threatening for a patient."

B. Anticipation by Bucholz

Petitioner asserts that claims 1–10 are unpatentable under 35 U.S.C. § 102 as anticipated by Bucholz. Pet. 13. To support its contentions, Petitioner provides detailed explanations as to how the prior art meets each claim limitation. *Id.* at 8–25. Petitioner also relies upon a Declaration of Harold J. Walbrink, who has been retained as an expert witness by Petitioner for the instant proceeding. Ex. 1007.

Bucholz describes "a simplified infrastructure for an operating room that allows control of highly complex devices and provides for communication among devices." Ex. 1003, 1:9–13.

Independent claims 1 and 10 recite "at least one medical device having safety-related functions controlled by said first controller." Petitioner relies on Bucholz's bipolar coagulators. *See* Pet. 14; Ex. 1003, 6:11–51. Petitioner asserts:

Bipolar coagulators are devices having safety-related functions because their breakdown or failure during a medical procedure may be life-threatening for a patient. . . . In particular, bipolar coagulators are used during surgical procedures to stop bleeding at the surgical site. If the bipolar coagulator were to breakdown or fail, the surgeon may be unable to stop the patient from bleeding at the surgical site, which could result in life-threatening injury to the patient.

Pet. 14–15 (citing Ex. 1007 \P 60). Based on the record before us, we are persuaded by Petitioner's contention in this regard. As discussed above, we construe the recited to mean an "a device whose breakdown or failure during a medical procedure may be life-threatening for a patient." Thus, we are persuaded that Bucholz meets this limitation.

Independent claims 1 and 10 recite "wherein said second controller can only control devices that do not have safety-related functions."

Petitioner relies on Bucholz's microscope as having non-safety-related functions because its breakdown or failure during a medical procedure would not be life-threatening for a patient. *See* Pet. 16; Ex. 1003, 6:17–20. Petitioner asserts:

Surgical microscopes are optical devices, although they may include a controller and related electronic components for actuating their physical position. If the electronic components of the surgical microscope were to break down or fail during a procedure, the surgeon could still look through the microscope (i.e., the optical function of the microscope would not be adversely affected). (Ex. 1007, Walbrink Decl. at ¶ 60.) Moreover, the surgeon or a nurse in the operating room could manually adjust the position of the microscope, even if the electronic position control failed. (*See id.*) Therefore, a microscope is properly considered a "*non-safety-related device.*" (*See id.*)

Pet. 16. Based on the record before us, we are not persuaded by Petitioner's contention in this regard. Patent Owner argues:

A surgical microscope, which is also known as an "operating microscope," is defined as "[a] binocular microscope *used to visualize fine structures* within the area of a surgical procedure" or "one *designed for use in performance of delicate surgical procedures*, e.g. on the middle ear, eye or small vessels of the heart." (Ex. 2002 at 1-3 (emphasis added).) Bucholz describes the microscope as, *inter alia*, having an attached camera that provides video which is viewable on the display and user interface of the bipolar coagulator. (Ex. 1003 at 7:20-35.)

Prelim. Resp. 11. Patent Owner further argues that an interruption of the ability to view fine structures during an operation may result in a life-

threatening situation for the patient. *Id.* We agree. Petitioner assertion, above, that the microscope may be used manually if the electrical components breakdown does not preclude that it may result in a life-threatening situation.

We also note that the Specification states that an endoscope and devices for communicating medical imaging data are safety-related. Prelim. Resp. 12. Petitioner has not explained a surgical microscope is different than an endoscope and devices for communicating medical imaging data. In fact, Bucholz does not have any disclosure that suggests that a surgical microscope is "non-safety related" as required by claim 1. We note that Figure 4 and its associated description shows the endoscope and microscope reside in the operating room and are treated the same way in all respects. *See, e.g.*, Ex. 1003, 9:27–46, Fig. 4.

We have reviewed the proposed ground of anticipation by Bucholz against claims 1-3, 6, 9-12, 15, and 16, and we are not persuaded that Petitioner has established a reasonable likelihood that Petitioner would prevail in its challenge to claims 1-3, 6, 9-12, 15, and 16 on this ground.

C. Obviousness of Claims over Bucholz and The Knowledge Of A Person Of Ordinary Skill In The Art

Petitioner asserts that claims 1–10 are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Bucholz and the knowledge of a person of ordinary skill in the art. Pet. 35–38. As noted above we find that Bucholz does not disclose a second controller that can only control devices that do not have safety-related functions as required by independent claims 1

and 10. Petitioner asserts that one of ordinary skill would know how to reconfigure the controllers of Bucholz to separate safety-related functions from non-safety related functions. Pet. 37. Petitioner also asserts that prioritizing safety and non-safety-related functions was well known in the art based on the testimony of its declarant. Pet. 37–38. Petitioner's reliance on the conclusory testimony of its declarant to support the unpatentablility of a claim limitation is not supported by the reference or by other evidence.

We further note that under 37 C.F.R. § 42.65(a), "[e]xpert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight." It is within our discretion to assign the appropriate weight to the testimony offered by Mr. Walbrink. *See, e.g., Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (holding the Board has discretion to give more weight to one item of evidence over another "unless no reasonable trier of fact could have done so"); *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations."); *Velander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) ("In giving more weight to prior publications than to subsequent conclusory statements by experts, the Board acted well within [its] discretion.").

The only record evidence regarding separating safety and non-safety related functions is found in the Specification of the '821 patent. "The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art

would have followed, as evidenced by the pertinent prior art." *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012).

Thus, upon review of the proposed ground of obviousness over Bucholz and the knowledge of one of ordinary skill in the art against claims 1–10 and we are not persuaded that Petitioner has established a reasonable likelihood that Petitioner would prevail in its challenge to claims 1–10 on this ground.

D. Obviousness of Claims over Bucholz and Brant

Petitioner asserts that claims 8 and 11 are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Bucholz and Brant. Pet. 38–44. As noted above we find that Bucholz does not disclose a second controller that can only control devices that do not have safetyrelated functions as required by claim 1 and we find that Petitioner did not provide a sufficient rationale to combine Bucholz and the knowledge of one of ordinary skill in the art. Brant does not make up for the deficiencies of Bucholz. Thus, upon review of the proposed ground of obviousness over Bucholz and Brant against claims 8 and 11, we are not persuaded that Petitioner has established a reasonable likelihood that Petitioner would prevail in its challenge to claims 8 and 11 on this ground.

E. Obviousness of Claims over Bucholz and Engleson

Petitioner asserts that claims 3 and 9 are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Bucholz and Engleson. Pet.

44–55. As noted above we find that Bucholz does not disclose a second controller that can only control devices that do not have safety-related functions as required by claim 1 and we found that Petitioner did not provide a sufficient rationale to combine Bucholz and the knowledge of one of ordinary skill in the art. Engleson does not make up for the deficiencies of Bucholz. Thus, upon review of the proposed ground of obviousness over Bucholz and Engleson against claims 3 and 9, we are not persuaded that Petitioner has established a reasonable likelihood that Petitioner would prevail in its challenge to claims 3 and 9 on this ground.

III. CONCLUSION

For the foregoing reasons, we are not persuaded that Petitioner has demonstrated a reasonable likelihood that it would prevail on any of the challenges to patentability of the '821 patent set forth in the Petition.

IV. ORDER

For the reasons given, it is

ORDERED that the Petition is *denied* as to all challenged claims, and no trial is instituted.

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