

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-01294
Patent 6,371,962 B1

Before JAMES T. MOORE, JAMES A. TARTAL,
and AMANDA F. WIEKER, *Administrative Patent Judges*.

MOORE, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. *Background*

Edwards Lifesciences Corporation (“Petitioner”) filed a corrected Petition requesting an *inter partes* review of claims 1–3, 6–13, 20–22, 25–30, 35, and 36 (“the challenged claims”) of U.S. Patent No. 6,371,962 B1 (Ex. 1001, “the ’962 patent”). Paper 8 (“Pet”), 1. Boston Scientific Scimed, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314(a), 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.” *See also* 37 C.F.R. § 42.4(a) (delegating authority to the Board). After considering the Petition and Preliminary Response, for the reasons discussed below, we do not institute an *inter partes* review.

B. *Related Proceeding*

The parties represent that the ’962 patent is at issue in *Boston Scientific Corp. & Boston Scientific SciMed Inc. v. Edwards Lifesciences Corp.*, No. 16-cv-730 (C.D. Cal.). Pet. 88; Paper 4, 2.

C. *The ’962 Patent*

The ’962 patent, titled “Stent Delivery System With Stent Securement Means,” issued April 16, 2002, from U.S. Patent Application No. 09/420,294, which was filed October 19, 1999. Ex. 1001, [45], [54], [21], [22].

Figure 1 of the '962 patent is reproduced below.

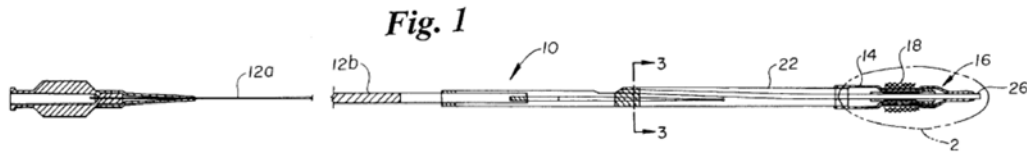


Figure 1 depicts an isometric view of a balloon catheter. Ex. 1001, 2:19–22. As shown in Figure 1, catheter 12 includes balloon 14 at distal end 16, to which stent 18 is fixed. *Id.* at 2:47–50. In use, catheter 12 is advanced through a patient’s vasculature to a desired location and, once reached, balloon 14 and stent 18 are expanded. *Id.* at 3:65–4:7. After expansion, the balloon is deflated and the catheter and balloon are withdrawn, while the stent remains in place to maintain the vessel in an expanded state. *Id.*

Figure 3 of the '962 patent is reproduced below.

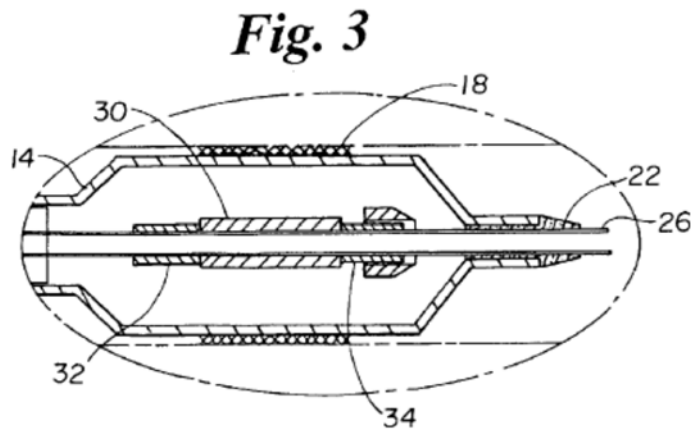


Figure 3 depicts an enlarged cross-sectional view of the distal end of catheter 12, with balloon 14 and stent 18 in expanded states. *Id.* at 2:27–30. As shown in Figure 3, “mounting body 30 . . . is included inside balloon 14 to provide a cushion and/or substrate of enlarged diameter relative to the stent shaft to support and hold the stent and secure it during crimping and

the delivery procedure.” *Id.* at 3:33–38. In Figure 3, mounting body 30 is a cylindrical sleeve carried on inner lumen 26 of the catheter. *Id.* at 3:42–47. However, the ’962 patent also discloses alternate mounting bodies including, for example, a spiral cut mounting body (*id.* at Fig. 4), a cylindrical body comprising separate, adjacent rings 30a (*id.* at Fig. 5), a two-piece interlocked body 30a, 30b (*id.* at Fig. 6), or a body comprising a plurality of separate, spaced bodies 30a, 30b, 30c (*id.* at Fig. 8). *See id.* at 4:6–4:45.

D. Illustrative Claim

Of the challenged claims, claims 1, 20, and 35 are independent. Claims 1 and 20 are reproduced below:

1. A stent delivery system for carrying and delivering a stent having a first end and a second end and a contracted state and an expanded state, the system comprising:

a catheter having a shaft having a diameter and ***expandable inflation means*** associated therewith at a distal part of the shaft and including ***mounting and retaining means*** for receiving the stent on the expandable inflatable means whereby the stent is radially expanded upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body, the at least one mounting body having a length and an outer surface diameter and being carried on and surrounding the shaft inside the inflatable means whereby the diameter of the shaft is increased at the distal part for facilitating the mounting and retaining of the stent and wherein, when the stent is mounted on the catheter, the at least one mounting body is between the stent and the shaft, the outer surface diameter of the at least one mounting body being substantially constant along its length.

Ex. 1001, 4:56–5:8. (Emphasis added).

20. A balloon catheter for intraluminal delivery of a stent, the catheter comprising a shaft having a diameter, a balloon associated with a distal portion of the shaft for receiving a stent, the stent having a first end and a second end and a contracted state and an expanded state, and ***means for inflating the balloon***, the shaft including at least one mounting body radially carried on the shaft inside the balloon, whereby the diameter of the shaft is increased inside the balloon to facilitate mounting and retaining of a stent to the catheter over the balloon, the at least one mounting body being positioned on the shaft such that when the stent is loaded onto the ***inflatable means*** and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent, the at least one mounting body having a length and an outer surface diameter, wherein the outer surface diameter is substantially constant along the length.

Id. at 6:14–30. (Emphasis added)

E. Prior Art Relied Upon

Petitioner relies upon the following prior art references, as well as the Declaration of Thomas Trotta (Ex. 1003). Pet. 26.

Reference	Patent No.	Relevant Dates	Exhibit No.
Fischell '507	US 4,768,507	Filed Aug. 31, 1987 Issued Sept. 6, 1988	Ex. 1010
Fischell '274	US 5,639,274	Filed June 2, 1995 Issued June 17, 1997	Ex. 1013
Burton	US 5,026,377	Filed Aug. 17, 1990 Issued June 25, 1991	Ex. 1014
Olympus	JP 1992-64367	Filed July 3, 1990 Published Feb. 28, 1992	Ex. 1015 ¹

¹ Exhibit 1015 includes a Japanese-language version of the reference at exhibit pages 1–15, an English translation of the reference at exhibit pages 16–35, and a notarized Certificate of Translation at exhibit pages 36–37.

Reference	Patent No.	Relevant Dates	Exhibit No.
Jendersee	US 5,836,965	Filed June 7, 1995 Issued Nov. 17, 1998	Ex. 1016
Ravenscroft	US 5,702,418	Filed Sept. 12, 1995 Issued Dec. 30, 1997	Ex. 1017
Williams	US 5,437,083	Filed May 24, 1993 Issued Aug. 1, 1995	Ex. 1028

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–3, 6–13, 20–22, 25–30, 35, and 36 of the '962 patent based on the following grounds. Pet. 27–88.²

References	Basis	Claim(s) Challenged
[1] Olympus in View of the Knowledge of a POSITA and/or Burton, Fischell '274, and/or Fischell '507	§ 103(a)	1–3, 6–8, 11–13, 20–22, 25, 26, 29, 30, 35, and 36

² Although we need not address in depth the asserted grounds of unpatentability in this case, the Petition appears to lack the particularity and specificity required by 35 U.S.C § 312(a)(3) and 37 C.F.R. § 42.104(b)(2). Petitioner's allegation that the challenged claims are unpatentable over "the references identified below, alone or in combination with each other" (Pet. 25), and Petitioner's identification of the grounds as outlined above, amounts to many distinct combinations of references. The function of the Board is not to comb through Petitioner's arguments in order to decipher the strongest argument or to determine the strongest combination of references to challenge the claims. *See generally LG Elecs., Inc. v. Rosetta-Wireless Corp.*, Case IPR2016-01516 (PTAB Apr. 3, 2017) (Paper 25). Moreover, at least Grounds 4 and 5 as stated are repetitive and nonsensical, having references considered a plurality of times in view of themselves.

References	Basis	Claim(s) Challenged
[2] Fischell '274 in View of Burton	§ 103(a)	1–3, 6, 11–13, 20–22, 25, 29, 30, 35, and 36
[3] Ravenscroft	§ 102(b)	1–3, 6, 12, 20–22, and 30
[4] The References in Grounds 1 and 2, in Further View of Jendersee	§ 103(a)	9, 10, 13, 27, and 28
[5] The References in Grounds 1–3, in Further View of the Knowledge of a POSITA and/or Burton, Fischell '274, Fischell '507, and/or Williams	§ 103(a)	8

II. DISCUSSION

A. Claim Construction

The parties agree that the '962 patent has expired. Pet. 23; Prelim. Resp. 6. “[T]he Board’s review of the claims of an expired patent is similar to that of a district court’s review.” *In re Rambus, Inc.*, 694 F.3d 42, 46 (Fed. Cir. 2012). Therefore, we apply the principles set forth by the Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Accordingly, the “words of a claim ‘are generally given their ordinary and customary meaning’” as understood by a person of ordinary skill in the art at the time of the invention. *Id.* at 1312.

1. The Parties' Positions

For purposes of this proceeding, Petitioner adopts Patent Owner's proposed constructions from co-pending district court litigation. Pet. 24–25. Accordingly, Petitioner adopts the following positions:

Claim Limitation	Applicability of 35 U.S.C. § 112 ¶ 6	Construction
“expandable inflatable means” (<i>see</i> claim 1)	Not subject to § 112 ¶ 6	“a structure capable of being expanded and inflated”
“mounting and retaining means” (<i>see</i> claim 1)	Not subject to § 112 ¶ 6	“a structure on which another structure can be mounted and retained”
“means for inflating the balloon” (<i>see</i> claim 20)	Subject to § 112 ¶ 6	“fluid (gas or liquid) from an inflation port and equivalents thereof.”

See id. at 23–25 (citing Ex. 1007). Patent Owner “agrees . . . that Patent Owner’s proposed constructions . . . in the district court litigation are the proper constructions.” Prelim. Resp. 6–7.³

2. Means-Plus-Function Claiming

Means-plus-function claiming is allowed pursuant to 35 U.S.C. § 112 ¶ 6, which provides that:

³ After the Petition was filed, the parties filed a Joint Claim Construction Statement in district court, in which both Patent Owner’s and Petitioner’s positions differed somewhat from those identified in the Petition. *Compare* Ex. 2003, B1–10 *with* Pet. 23–25 (citing Ex. 1007). Indeed, Petitioner’s interpretations were narrower in some respects in the litigation. *See also* Prelim. Resp. 6–7 (citing Pet. 23–25).

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.⁴

Claim limitations that include the term “means” or “means for” are presumed to invoke 35 U.S.C. § 112 ¶ 6. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348–49 (Fed. Cir. 2015) (en banc in relevant part) (“The converse presumption remains unaffected: ‘use of the word “means” creates a presumption that § 112, ¶ 6 applies.’” (quoting *Personalized Media Commc’ns, LLC v. Int’l Trade Comm’n*, 161 F.3d 696, 703 (Fed. Cir. 1998))); *Greenberg v. Ethicon Endo–Surgery, Inc.*, 91 F.3d 1580, 1584 (Fed. Cir. 1996) (“[U]se of the term ‘means’ has come to be so closely associated with ‘means-plus-function’ claiming that it is fair to say that the use of the term ‘means’ (particularly as used in the phrase ‘means for’) generally invokes [§ 112 ¶ 6] . . .”).

This presumption may be rebutted, however, “if the evidence intrinsic to the patent and any relevant extrinsic evidence so warrant.” *Personalized Media Commc’ns*, 161 F.3d at 704. For example, the presumption may be overcome where the claim specifically identifies structure sufficient to perform the recited function. *See TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259–60 (Fed. Cir. 2008) (“Sufficient structure exists when the claim

⁴ Section 4(c) of the Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (“AIA”) re-designated 35 U.S.C. § 112 ¶ 6, as 35 U.S.C. § 112(f). However, because the ’962 Patent has a filing date before September 16, 2012, the effective date of § 4(c) of the AIA, we will refer to the pre-AIA version of 35 U.S.C. § 112.

language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure.”); *see also Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427–28 (Fed. Cir. 1997).

3. Means-Plus-Function Limitations in the '962 Patent

In this case, as emphasized in independent claims 1 and 20 above (but also applicable to independent claim 35), the challenged claims all recite the term “means.”

With respect to these limitations, Petitioner contends that these limitations in some instances do and in others do not invoke 35 U.S.C. § 112 ¶ 6. Pet. 24–25. Petitioner, however, does not discuss the presumption associated with use of the word “means” in these limitations and does not provide a single citation to persuasive intrinsic or extrinsic evidence to suggest that the presumption is either warranted or unwarranted in any case.

Instead, Petitioner incorporates by reference a letter between counsel in the co-pending district court litigation. *Id.* (citing Ex. 1007). Even if Petitioner’s incorporation of counsel’s positions in litigation by reference were proper,⁵ the cited letter also fails to explain how or why applicable intrinsic or extrinsic evidence warrants in selected instances only deviating from the presumption that use of the term “means” invokes 35 U.S.C. § 112 ¶ 6.

Although this letter suggests that the parties may agree that § 112 ¶ 6 should or should not apply to these limitations, a non-binding agreement

⁵ *See* 37 C.F.R. § 42.6(a)(3), prohibiting incorporation by reference of arguments.

between parties does not constitute persuasive evidence and does not suspend operation of our Rules requiring the Petitioner to identify the corresponding structure and function, or explain otherwise. Further, claim construction, and whether § 112 ¶ 6 applies, is a legal determination made based on a hierarchy of evidence—intrinsic evidence being the most persuasive. Lawyer argument is among the least persuasive.

In addition to stating that 35 U.S.C. § 112 ¶ 6 does only occasionally apply, the Petition also provides constructions for these limitations. Pet. 24–25. However, the proposed constructions simply reiterate the functions recited by the claims. For example, Petitioner construes “expandable inflatable means” as “a structure capable of being expanded and inflated.” *Id.* at 24. Petitioner’s contentions in this regard fail to explain how or why Petitioner believes any applicable evidence overcomes the presumption that use of the term “means” invokes § 112 ¶ 6. It is not this panel’s charge to divine the reasoning or justification for Petitioner’s position, without any guiding explanation from Petitioner.

Accordingly, absent any persuasive rebuttal, we presume that “expandable inflatable means,” “mounting and retaining means,” and “means for inflating the balloon” invoke 35 U.S.C. § 112 ¶ 6.

(a) Identification of Corresponding Structure

In proceedings before this Board, our Rules require that if a challenged claim contains a means-plus-function limitation under 35 U.S.C. § 112 ¶ 6, Petitioner is required to construe the limitation and “**must** identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function.” 37 C.F.R. § 42.104(b)(3). (Emphasis added). Here, the Petition fails to identify any portion of the ’962

patent Specification that describes the structure, material, or acts that correspond to the functions recited in the above-referenced limitations, and references a different document. *See* Pet. 24–25; *see also* 37 C.F.R.

§ 42.6(a)(3). It is not this panel’s responsibility to identify the portions of the Specification upon which it believes Petitioner may rely to support its positions with respect to 35 U.S.C. § 112 ¶ 6. Our Rules place this burden on Petitioner, so that the panel may evaluate effectively the challenged claims vis-à-vis the asserted prior art, as discussed below.

B. Asserted Grounds of Unpatentability

To show that a challenged claim containing a means-plus-function limitation is unpatentable over the asserted prior art, Petitioner must show that the structure that corresponds to a claimed function, or its equivalent, is found in, or obvious over, the applied prior art. *See Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 582 F.3d 1288, 1299–1300 (Fed. Cir. 2009) (“It is firmly established in our precedent *that a structural analysis is required* when means-plus-function limitations are at issue; *a functional analysis alone will not suffice.*” (emphases added)).

In this case, Petitioner’s failure to construe the claims in accordance with our Rules is determinative. By failing to identify the structure, material, or acts in the ’962 patent Specification that correspond to the claimed functions, Petitioner necessarily has not shown where that structure, material, acts, or their equivalents are disclosed in the applied prior art. *Compare* Pet. 24–25, *with id.* at 37 (discussing “expandable inflatable means”), 37–38 (discussing “mounting and retaining means”), 45–46 (discussing “means for inflating”).

This is not merely an academic exercise. Much of the rationale of the Petition depends upon why a person of ordinary skill in the art would be motivated to alter the primary references. For example, Petitioner urges for Ground 1:

A POSITA would be motivated in light of Fischell '507's teachings to add spiral grooves corresponding to the spiral stent into the mounting body of Olympus in order to improve the securement of the compacted stent during delivery, reducing its profile while still allowing it to be expanded by the balloon at the deployment site. Ex. 1003 (Trotta Decl.) ¶ 125. Likewise, a POSITA would understand that the presence of these grooves would improve the flexibility and trackability of the portion of the catheter containing the mounting body. *Id.* ¶126; *accord* Ex. 1013 (Fischell '274) at 10:3-6 (teaching that making a helical cut in a catheter tube results in "greatly increased flexibility").

Pet. 34.

Which parts of which reference pertain to the "mounting and retaining means" as used in the claims, for example, becomes critical to understanding not only how the elements are found to satisfy the claim elements, but also the motivation for combining and modifying the prior art. This deficiency affects the rationale throughout the Petition. *See also* Pet. 45–46. (Claim 20, incorporating by reference also Petition sections 1.0 – 1.4 pertaining to Claim 1).

While the panel has no doubt it could undertake a form of analysis to determine the range of equivalents, under the unique facts of this case, it declines to do so on behalf of the Petitioner.

For these reasons, Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of independent claims 1, 20, or 35 based on any of the asserted grounds of unpatentability. Petitioner's challenges to claims which depend therefrom fail for the same reasons.

Conclusion

For the foregoing reasons, we determine Petitioner has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of the challenged claims of the '962 patent.

III. ORDER

Upon consideration of the record before us, it is:

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

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Patent 6,371,962 B1

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