UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC., Petitioner,

v.

MOSKOWITZ FAMILY LLC, Patent Owner.

> IPR2020-01310 Patent 10,251,643 B2

Before MEREDITH C. PETRAVICK, NEIL T. POWELL, and JAMES J. MAYBERRY, *Administrative Patent Judges*.

PETRAVICK, Administrative Patent Judge.

DECISION Denying Institution of *Inter Partes* Review 35 U.S.C. § 314(a)

I. INTRODUCTION

Petitioner Globus Medical, Inc. filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–3, 6–8, 10, 12–17, 19, and 20 of U.S. Patent No. 10,251,643 B2 (Ex. 1001, "the '643 Patent"). Patent Owner Moskowitz Family LLC filed a Preliminary Response (Paper 6, "Prelim. Resp.").

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the Petition and any response thereto shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Taking into account the arguments presented in the parties' briefs, we conclude that the information presented in the Petition fails to establish that there is a reasonable likelihood that Petitioner would prevail in challenging at least one of claims 1–3, 6–8, 10, 12–17, 19, and 20 of the '643 Patent as unpatentable under the grounds presented in the Petition.

Pursuant to § 314, we decline to institute an *inter partes* review as to these claims of the '643 Patent.

A. Related Matters

The '643 Patent is the subject of *Moskowitz Family LLC v. Globus Medical Inc.*, Case No. 2:20-cv-03271 in the U.S. District Court for the Eastern District of Pennsylvania. Pet. 3; Paper 4, 2.

B. The '643 Patent

The '643 Patent is titled "Bi-directional Fixating Transvertebral Body Screws, Zero-Profile Horizontal Intervertebral Miniplates, Expansile

Intervertebral Body Fusion Devices, and Posterior Motion-Calibrating Interarticulating Joint Stapling Device for Spinal Fusion" and issued on April 9, 2019. Ex. 1001, code (45), (54). Figures 7A and 7B of the '643 Patent are reproduced below side-by-side.



Figure 7A and 7B depicts an embodiment of an expandable intervertebral device in a partially and fully expanded position, respectively. *Id.* at 7:28–30. Device 700 has shells 710, 711, an expansion mechanism 712, and spikes 713. *Id.* at 7:25–58.

C. Challenged Claims

Petitioner challenges claims 1–3, 6–8, 10, 12–17, 19, and 20. Of the challenged claims, claim 1 is independent.

Claim 1 is illustrative of these claims and reproduced below:

1. An artificial expansile spinal implant comprising first and second shells and an expansion mechanism positioned between the first and second shells and configured to expand the artificial expansile spinal implant, wherein the expansion mechanism comprises first and second threaded bodies and a rotatable tool engagement portion configured to rotate the first threaded body with respect to the second threaded body to drive expansion between the first shell and the second shell in response to turning the rotatable tool engagement portion, wherein the artificial

> expansile spinal implant is configured to be introduced into an intervertebral space with the first and second shells engaging opposing vertebral bodies when inserted into the intervertebral space and wherein the tool engagement portion is positioned and configured to be engaged by a tool extending along a direction of insertion for rotating the rotatable tool engagement portion, wherein each of the first and second shells comprises a first set of engagement features extending from the first and second shells that are configured for engaging vertebral endplates of the opposing vertebral bodies to hold the artificial expansile spinal implant in place and a second set of engagement features extending from the first and second shells that are configured for engaging the vertebral endplates of the opposing vertebral bodies to hold the artificial expansile spinal implant in place, wherein the second set of engagement features are larger than the first set of engagement features, extend further than the first set of engagement features, and have substantially tapered tips configured for piercing the vertebral endplates when introduced into the intervertebral space and expanded.

Ex. 1001, 10:46–11:8.

D. Alleged Grounds of Unpatentability

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 6, 7, 12–15, 17, 19, 20	103(a)	Gutlin ¹ and Barber ²
8, 10, 16	103(a)	Gutlin, Barber, and Sutcliffe ³

Petitioner asserts the following grounds of unpatentability:

¹ Int'l Patent Publication Application No. WO 2004/052245, published June 24, 2004 (Ex. 1028) ("Gutlin"). An English language translation appears in the record as Exhibit 1029.

² U.S. Patent No. 5,236,460, issued Aug. 17, 1993 (Ex. 1030) ("Barber").

³ U.S. Patent Application Publication No. 2002/0143399 A1, published Oct. 3, 2002 (Ex. 1031) ("Sutcliffe").

Pet. 5. In addition to the references listed above, Petitioner relies on the Declaration of Jorge A. Ochoa, Ph.D., P.E. (Ex. 1003).

II. ANALYSIS

It is Petitioner's burden to prove unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). At this stage of the proceeding, Petitioner must establish a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. 35 U.S.C. § 314(a). We analyze Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a). For the reasons explained in the analysis below, we determine that Petitioner fails to meet its burden.

A. Claim Construction

"[I]n an *inter partes* review proceeding, a claim of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). In applying a district court-type claim construction, we are guided by the principle that 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. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (citation omitted). "In determining the meaning

of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing Phillips, 415 F.3d at 1312–17). There is a "heavy presumption," however, that a claim term carries its ordinary and customary meaning. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (citation omitted).

"Petitioner submits that the claim terms require no express construction and that they should be given their ordinary and customary meaning" except for certain terms listed in a table, which is reproduced below. Pet. 8.

Claim Term	Petitioner's Proposed Construction
"an intervertebral space"	"the disc space between two adjacent
	vertebrae"
"first and second shells"	"the ends of an implantable
	intervertebral device, which ends are
	capable of moving in at least two
	directions defined by at least two axes"
"rotatable tool	"the portion of the implant separate
engagement portion"	from the threaded bodies that engages a
	tool to rotate the first threaded body
	with respect to the second threaded
	body"
"configure to be extended	"originating in and extending from
from the [first/second]	within the shell"
shell"	
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Pet. 8–9.

Patent Owner argues that Petitioner does not meet our requirements for construing claim language. Prelim. Resp. 7–15. Patent Owner contends that Petitioner did not explain adequately its bases for the claim constructions that the Petition does propose. *Id.* at 12–14. Noting that

Petitioner offers no construction for claim 17, Patent Owner also argues that this omission violates 37 C.F.R. § 42.104(b)(3). *Id.* at 7–12. Patent Owner argues, "there is no dispute that" 35 U.S.C. § 112, ¶ 6 "controls" claim 17's recitation of "means for placement of bone material." *Id.* at 8–9. In support of this, Patent Owner notes that Petitioner identified this claim language as a means-plus-function term in the related district court proceeding. *Id.* at 9.

If a petitioner believes that a claim term requires an express construction, the petitioner must include a statement identifying a proposed construction of the particular term and where the intrinsic and/or extrinsic evidence supports that meaning.

Consolidated Patent Trial Practice Guide⁴, 44 (Nov. 2019). Petitioner provides no explanation and citations to evidence to support its proposed constructions. Pet. 7–9. For example, Petitioner provides no explanation as to why the claim term "first and second shells" should be construed to require that the shells are "capable of moving in at least two directions defined by at least two axes." *See id.* For this reason, Petitioner does not persuade us that its proposed constructions are the correct constructions.

Nonetheless, as discussed in detail below, we have applied Petitioner's proposed construction of "first and second shell" in evaluating the Petition's combination of Gutlin and Barber. As discussed in detail below, the Petition's combination of Gutlin and Barber is deficient even applying Petitioner's proposed construction.

As to the Petition's omission of any construction for claim 17's language "means for placement of bone material," our Rules require that the

⁴ Available at https://www.uspto.gov/about-us/news-updates/consolidated-trial-practice-guide-november-2019.

Petition "set forth . . . [h]ow the challenged claim is to be construed," and "[w]here the claim to be construed contains a means-plus-function or stepplus-function limitation . . . , the construction of the claim 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). Additionally, where, as here, the claim language contains the word "means," we presume that the language is means-plus-function claim language. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (citing *Personalized Media Commc 'ns, LLC v. Int'l Trade Comm 'n*, 161 F.3d 696, 703 (Fed. Cir. 1998)).

Petitioner has not argued that this presumption is rebutted, nor has Petitioner cited any evidence to rebut this presumption. *See generally*, Pet. Petitioner also has not identified the specific portions of the Specification that describe the structure, material, or acts corresponding to the function recited in claim 17. *See id.* Given our requirements and the presumption that claim 17 contains means-plus-function language, Petitioner's silence regarding the meaning of claim 17 supports denial of the Petition. To the extent the Petition does not violate Rule 42.104(b)(3) by omitting any discussion of claim 17's meaning, this omission creates burdensome issues for Patent Owner and the Board. In combination with certain deficiencies discussed in detail below, the Petition's silence regarding the meaning of claim 17 contributes to our decision to deny the Petition.

B. Principles of Law

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness under § 103 that requires consideration of four factors: (1) the "level of ordinary skill in

the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior art and the claims at issue," and (4) "secondary considerations" of non-obviousness such as "commercial success, long-felt but unsolved needs, failure of others, etc." *Id.* at 17–18. "While the sequence of these questions might be reordered in any particular case," *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007), the Federal Circuit has "repeatedly emphasized that an obviousness inquiry requires examination of all four *Graham* factors and that an obviousness determination can be made only after consideration of each factor." *Nike*, *Inc. v. Adidas AG*, 812 F.3d 1326, 1335 (Fed. Cir. 2016). We note that, with respect to the fourth *Graham* factor, the record in this proceeding does not include any argument or evidence directed to secondary considerations of nonobviousness.

Additionally, the obviousness inquiry typically requires an analysis of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")); *see In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (citing *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006)).

C. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the

technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends that a person having ordinary skill in the art ("PHOSITA") at the time of the invention of the '643 Patent would have had the following education and experience:

a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience. The experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. Alternatively, a P[H]OSITA could have an advanced degree, in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

Pet. 9 (citing Ex. 1003 ¶¶ 25–29).

Patent Owner does not dispute Petitioner's definition of the level of ordinary skill in the art. *See generally* Prelim. Resp.

For purposes of this Decision, we adopt Petitioner's proposal as reasonable and consistent with the prior art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art may reflect an appropriate level of skill in the art).

D. Gutlin and Barber

1. Overview of Gutlin

Gutlin is titled "Intervertebral Implant" and published on June 24, 2004. Ex. 1028, codes (43), (54). Figure 1 of Gutlin is reproduced below.



Figure 1 depicts an embodiment of intervertebral implant 1. Ex. 1029, 4:30– 31. Intervertebral implant 1 has lower implant part 2 and upper implant part 5. *Id.* at 4:11–14. Lower implant part 2 and upper implant part 5 have a lower apposition part 4 and upper apposition part 8, respectively. *Id.* at 4:14–15. Lower apposition part 4 has an apposition surface 19, and upper apposition part 8 has an apposition surface 19. *Id.* at 4:14–19. The apposition surfaces are "provided with three-dimensional texturing." *Id.* at 4:19. Threaded spindle 9 connects to lower implant part 2 and is complementary to thread 7 inside shaft 6 of upper implant 5. *Id.* at 5:4–8. "By turning the threaded spindle 9 about the central axis 11, the two implant parts 2; 5 are therefore displaced relative to one another." *Id.* at 5:9–11.

2. Overview of Barber

Barber is titled "Vertebral Body Prosthesis" and issued August 17, 1993. Ex. 1030, codes (45), (54). Figure 1 of Barber is reproduced below.



Figure 1 depicts an embodiment of vertebral prosthesis 11. *Id.* at 1:49–52. Vertebral prosthesis 11 has inner body 23 telescopically mounted to outer body 13. *Id.* at 2:19–20. Inner body 23 has upper platform 29 with sharp pins 31 and axial pin 33 extending upward to pierce the vertebral bones. *Id.* at 2:27–37. Likewise, outer body 13 has lower platform 19 with pins 21. *Id.* at 2:14–18, Fig. 2. Brackets 45 are flat plates that move laterally on platforms 29 and 19. *Id.* at 2:46–50. Brackets 45 have flanges 47 with holes 48 for receiving a screw to secure prosthesis 11 the vertebral bones. *Id.* at 2:53–57.

3. Analysis

Petitioner contends that the combination of Gutlin and Barber teaches all of the limitations of independent claim 1. Pet. 14–23. In particular, Petitioner relies upon Gutlin to teach "first and second shells," as construed by Petitioner to mean "the ends of an implantable intervertebral device, which ends are capable of moving in at least two directions defined by at least two axes." *Id.* at 8.

Patent Owner responds, "Petitioner fails to meet its burden of showing *with particularity* how Gutlin teaches 'first and second shells' under Petitioner's own construction." PO Resp. 14–16. Patent Owner asserts "Petitioner does not even allege that [Gutlin's] upper and lower implant parts 5 and 3 are 'capable of moving in at least *two directions* defined by at least *two axes*,' let alone how they move." *Id.* at 16.

We agree with Patent Owner.

Under the heading "[2] *first and second shells and*" on page 14, the Petition states:

Gutlin discloses that the intervertebral implant 1 includes upper and lower implant parts 5, 2 having upper and lower apposition parts 8, 4 with upper and lower apposition surfaces 20, 19 (together, i.e., first and second shells). EX1029 at 4:6-24; FIG. 1.

A PHOSITA would have understood that Gutlin discloses an artificial expansile spinal implant as recited at [2]. EX1003 at ¶48.

Pet. 14. As can be seen from the above passage, the Petition equates Gutlin's upper and lower impart parts 5, 2, having apposition parts 8, 4, and apposition surfaces 20, 19, to the claimed first and second shells. *See also* Ex. 1003 ¶ 48 (corresponding testimony of Dr. Ochoa). Gutlin discloses upper and lower implant parts 5, 2 moving along central axis 11 to expand intervertebral implant 1 (*see* Ex. 1029, 5:6–32), but Gutlin does not disclose upper and lower implant parts 5, 2 being capable of moving in a second direction defined by a second axis. And, Petitioner provides no other sufficient explanation, under this heading of the Petition, of how Gutlin

teaches the claimed first and second shells under Petitioner's own construction.

We note that under a heading related to the claimed engagement features (Pet. 17–23), the Petition states: "To the extent that Gutlin does not disclose first and/or second shells and a first and/or second set of engagement features as claimed, Gutlin in view of Barber teaches the artificial expansile spinal implant of claim 1" (id. at 19). The Petition also points to Barber's bracket 45 to suggest that Barber's implant 11 expands laterally as well as vertically. Id. at 19–20. These statements may suggest that Petitioner is relying not only on Gutlin to teach the first and second shells, but also on Barber. The Petition, however, does not assert with any clarity or particularly that it would have been obvious to modify Gutlin's implant parts 5, 2 to expand laterally like Barber's brackets 45 or provide any sufficient rational underpinning that such a modification would have been obvious. See id. at 19–23. Instead, the Petition points to screw 53 of Barber's bracket 45 as a second set of engagement features and asserts that it would have been obvious to modify Gutlin's implant to include Barber's engagement features, such as spikes and screws, to enhance stability and reduce migration. Id. at 22-23.

Accordingly, we determine that Petitioner fails to meet its burden of establishing a reasonable likelihood that independent claim 1 is unpatentable under 35 U.S.C. § 103 over Gutlin and Barber.

a) Dependent Claims 2, 3, 6, 7, 12–15, 17, 19, and 20

Claims 2, 3, 6, 7, 12–15, 17, 19, and 20 depend directly or indirectly from claim 1. Accordingly, we determine that Petitioner fails to establish a reasonable likelihood that claims 2, 3, 6, 7, 12–15, 17, 19, and 20 are

unpatentable under 35 U.S.C. § 103 over Gutlin and Barber. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.").

E. Gutlin, Barber, and Sutcliffe

Claims 8, 10, and 16 depend directly or indirectly from claim 1. Petitioner contends that "Gutlin in view of Barber and further in view of Sutcliffe . . . renders the *expansile spinal fusion implant* recited in dependent claims 8, 10 and 16 obvious." Pet. 31. Petitioner does not rely upon Sutcliffe to cure the deficiencies of the combination of Gutlin and Barber. Accordingly, we determine that Petitioner fails to establish a reasonable likelihood that claims 8, 10, and 16 are unpatentable under 35 U.S.C. § 103 over Gutlin, Barber, and Sutcliffe.

III. CONCLUSION

We conclude that the information presented in the Petition fails to establish that there is a reasonable likelihood that Petitioner would prevail in challenging at least one of claims 1–3, 6–8, 10, 12–17, 19, and 20 of the '643 Patent. Accordingly, we deny institution of *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby: ORDERED that the Petition is denied.

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