

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

IPR2023-00894
Patent 11,298,166 B2

Before JEFFREY N. FREDMAN, ROBERT A. POLLOCK, and
JAMIE T. WISZ, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

PRELIMINARY GUIDANCE
PATENT OWNER'S MOTION TO AMEND

I. INTRODUCTION

On November 17, 2023 we instituted trial as to claims 1–15 of U.S. Patent No. 11,298,166 B2 (“the ’166 patent”). Paper 15 (“Institution Decision” or “Dec.”). After institution, Patent Owner filed a Motion to Amend that is contingent on the patentability of claims 1–15. Paper 26¹ (“Motion” or “Mot.”). Petitioner filed an opposition on May 3, 2024. Paper 29 (“Opposition” or “Opp.”)

In the Motion, Patent Owner requested that we provide preliminary guidance concerning the Motion in accordance with the Board’s pilot program concerning motion to amend practice and procedures. Mot. 1; *see also* Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019) (providing a patent owner with the option to receive preliminary guidance from the Board on its motion to amend) (“Notice”). We have considered Patent Owner’s Motion and Petitioner’s Opposition.

In this Preliminary Guidance, we provide information indicating our initial, preliminary, non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in an *inter partes* review and whether Petitioner (or the record) establishes a reasonable likelihood that the substitute claims are unpatentable. *See* Notice, 84 Fed. Reg. at 9,497 (“The preliminary guidance . . . provides preliminary, non-binding guidance from the Board to the parties about the [motion to amend]”); *see also* 35 U.S.C. § 316(d) (statutory

¹ Paper 26 is a corrected Motion to Amend as per the Board’s authorization to replace the first Motion to Amend (Paper 23) which contains a typographical error. *See* Ex. 3003 (e-mail communication authorizing such filing).

requirements for a motion to amend); 37 C.F.R. § 42.121 (regulatory requirements and burdens for a motion to amend); *Lectrosonics, Inc. v Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential) (providing information and guidance regarding motions to amend).

For purposes of this Preliminary Guidance, we focus on the proposed substitute claims, and specifically on the amendments proposed in the Motion. *See* Notice, 84 Fed. Reg. at 9,497. We do not address the patentability of the originally challenged claims. *Id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties' other substantive papers on the underlying merits of Petitioner's challenges. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision. *See id.* at 9,500.

II. PRELIMINARY GUIDANCE

A. Statutory and Regulatory Requirements

For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Patent Owner has not shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend.

1. Reasonable Number of Substitute Claims

Does Patent Owner propose a reasonable number of substitute claims? (35 U.S.C. § 316(d)(1)(B))
Yes, Patent Owner proposes no more than 1 substitute claim for each challenged claim. More particularly, Patent Owner proposes substitute

claims 16–30 for original claims 1–15, respectively. Mot. 1. Petitioner does not argue otherwise.

2. Respond to Ground of Unpatentability

Does the Motion respond to a ground of unpatentability involved in the trial? (37 C.F.R. § 42.121(a)(2)(i))

Yes. Patent Owner responds to the grounds of unpatentability at pages 15–25 of the Motion. At least one amendment presented is responsive to a ground of unpatentability. Petitioner does not argue otherwise.

3. Scope of Amended Claims

Does the amendment seek to enlarge the scope of the claims? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii))

No. Each of the proposed substitute claims include narrowing limitations. Petitioner does not argue otherwise.

4. New Matter

Does the amendment seek to add new subject matter? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii))

Yes. On this record, we find Patent Owner has not set forth written description support for the proposed amendments at pages 5–14 of the Motion. Patent Owner asserts written description support for all limitations of the substitute claims, more particularly the following.

Claims 16 and 27: “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture.” Mot. 8, 13 (citing Ex. 2020,² 17–20, 34–38, 43–45, Figs. 9–11, 18; Ex. 2021,³ 21–27, 35–37, 40–54, Figs. 9–11, 18). This is the sole claimed

² File history of Application No. 17/323,923 (“’923 application”), which issued as the ’166 patent. *See* Ex. 1001, code (21).

³ File history of Application No. 12/658,680 (“’680 application”), which the ’166 patent claims priority to. *See* Ex. 1001, code (60).

subject matter that Petitioner contends is not supported by the original disclosure, as discussed in detail below.

Patent Owner does not elaborate how these newly added features are supported by the original disclosure other than providing the string citations above and replicating Figure 18 in its claim chart and providing annotations of Figures 18 and 9 with brief discussions thereof. *See* MTA 8, 11, 13, 17–18. Petitioner argues that this claimed subject matter lacks written description support as explained in detail below.

As an initial matter, Petitioner’s Opposition provides a section dedicated to the construction of three claim terms. Opp. 1–3. First, as to the term “at a terminal end,” Petitioner contends that Patent Owner does not address the Institution Decision’s invitation to develop the meaning of this term and refers to arguments made in other substantive papers. *Id.* at 1 (citing Dec. 13–16; Patent Owner’s Response (Paper 22, “POR”), 9–14; Petitioner’s Reply (Paper 28, “Reply”), 14–17). Second, as to the term “wherein the second angle is in the range of about 0 to about 90 degrees,” Petitioner argues that Patent Owner’s citation for support, however, only indicates that these angles “may be any angles *less than* 90 degrees” which excludes a 90-degree angle. *Id.* at 1–2 (quoting with emphasis Ex. 2020, 37:15, citing Ex. 2020, 44:12–13). And third, as to the term “substantially perpendicular,” Petitioner contends that this term is not recited anywhere in the Specification of the ’166 patent nor the priority application, i.e., the ’680 application. *Id.* at 2.

Because these three terms are not newly added by Patent Owner’s amendments, they do not concern the newly added limitations via the proposed substitute claims. *See* MTA 5–14 (Patent Owner’s claims chart). As indicated above, in formulating our preliminary views on the Motion and Opposition, we focus specifically on the amendments proposed in the Motion and we do not consider the parties’ other substantive papers on the underlying merits of Petitioner’s challenges, which include Patent Owner’s Response and Petitioner’s Reply—to which Petitioner references above.

Concerning the newly added “abuts” limitation replicated above, Petitioner first argues that Patent Owner has not carried its burden of production to show support from its single, identical citation to 16 pages of the specification and drawings. Opp. 3 (citing MTA 5–14). To this end, we appreciate Petitioner’s contention to the effect that a mere string citation to passages of the specification “leaves the Board to sift through

every possible relevant scrap of information to sort out whether and where support might be found.” *Id.* at 4. Petitioner further contends that the language of the limitation at issue does not appear anywhere in Specification nor is there any discussion therein. *Id.* Nonetheless, as recognized by Petitioner, Patent Owner cites to figures 9–11 and 18 in the Specification with a particular focus on Figures 9 and 18. *See e.g.*, Opp. 4–5 (citing MTA 17–18). We thus determine whether Figures 9 and 18 support the limitation at issue: “wherein the exterior surface of the head of the first member abuts the *interior* surface of the first bore *at the second aperture*.”

Petitioner contends that the drawings do not actually show the limitation at issue. Opp. 3. Petitioner reproduces detailed portions of Figures 9 and 18 and contends that “these drawings do not actually show the screw head abutting the *interior* surface, because they do not show the area of *contact* between these surfaces” and that “the surfaces supposedly involved in the abutment are not illustrated in the drawings.” *Id.* at 5 (emphases added). As to Figure 18, Petitioner contends that the interior surface of the first bore is concealed by the external surface of the third member. *Id.* at 6. Petitioner contends Figure 9 suffers from the same shortcoming and demonstrates this by annotating a detailed portion of Figure 9 in which the screw head is colored blue and a countersunk area is colored red. *Id.* Petitioner also annotates a detailed portion of Figure 11 in which a countersunk area is colored red. *Id.*

Petitioner argues that in annotated Figure 9, “a portion of the interior surface of the first bore at the second aperture in the drawing is clearly shown to be a counter sink [(in red)] extending around the visible circumference of the second aperture.” *Id.* Petitioner argues, “[t]he head (shaded in blue) is constrained by the first bore and consequently clearly is not (and cannot be) abutting the countersunk area.” *Id.* (citing Ex. 1018⁴ ¶¶ 66–67). In essence, Petitioner argues that the blue surface (the exterior surface of the head of the first member) *does not necessarily contact* the red surface (the countersunk area of the first bore which Petitioner regards as an interior surface of a first bore at the second aperture of the third member) and, thus, the figures do not support the limitation, “wherein the exterior surface of the head of the first member abuts the *interior* surface of the first bore *at the second aperture*.” *See* Opp. 7; *see also id.* at 13

⁴ Petitioner’s Second Expert Declaration of Leonel Dominquez.

(citing Ex. 1018 ¶¶ 75–78). *See also id.* at 9 (citing *Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy’s Laboratories Inc.*, 923 F.3d 1368, 1382 (Fed. Cir. 2019) for the proposition that “although a patent owner may rely on an inherent property not expressly disclosed in a specification, the circumstances under which this may be done are ‘narrow’ and require a showing that the supposedly inherently feature is ‘necessarily’ present”). To support this argument, Petitioner provides 3D models and videos thereof, including stills, of Figures 9 and 18. *Id.* at 11 (citing Exs. 1047–1050).

Although Figure 18 does not clearly show a countersunk area at a second aperture of a first bore relative to lag screw 1805, the deviation in the edge profile of the third member in this region is consistent with a countersunk portion. *See, e.g.*, MTA 17 (deviation from linear beginning at tip of red annotation arrow passing through 1845 label). Figure 9, however, *clearly shows* a countersunk area on the distal face of the second aperture. *See, e.g., id.* at 5, 11, 17–18. And as Petitioner points out, the Specification⁵ discloses that Figures 9 and 18 are “substantially similar.” Opp. 14 (citing Ex. 1001, 13:26–31; Ex. 2020, 43:23–44:2⁶).

We agree with Petitioner that the blue colored “head of the first member” *does not necessarily contact* the red colored countersunk area as annotated in its annotated portions of Figures 9 and 11, and demonstrated via its 3D models, videos,⁷ and stills of Figures 9 and 18 (*see* Opp 6, 11–15). In other words, it is not inherent that from Figures 9 and 18 that “the exterior surface of the head of the first member abuts the *interior* surface of the first bore *at the second aperture*” and thus, it appears at this juncture of the proceeding that Patent Owner has not shown a reasonable likelihood that the limitation at issue is supported by the original disclosure. We provide

⁵ We refer to either our citation of Exhibit 2020 or Exhibit 2021 when we refer to the “Specification.”

⁶ Petitioner inadvertently refers to the actual page number of the filed Specification rather than the numbered page of Exhibit 2020 for this citation. *See* Opp. 14. For consistency, we refer to the number added to Exhibit 2020.

⁷ Petitioner provides 3D models and videos because Figures 9 and 18 “are two-dimensional oblique views that necessarily cannot convey any information about features that are hidden by the chosen view.” Opp. 10 (citing Ex. 1018 ¶ 65). Petitioner argues that its 3D models (and videos thereof) are consistent with Figures 9 and 18 and demonstrate that there is not necessarily an abutment between the head and the countersink surfaces as intimated by Patent Owner. *Id.* at 11.

the following comments as guidance per Patent Owner's request in its Motion.

Petitioner's contention rests on the presumption that the countersunk area corresponds to "the interior surface of the first bore at the second aperture" limitation. On the limited record before us, we agree with Petitioner that in viewing Figure 9, a person of ordinary skill in the art would reasonably regard the countersunk area as an *interior* surface of a bore *at the second aperture* rather than an exterior surface of a first member. This interpretation is consistent with our preliminary construction in the Institution Decision that "the term 'bore' as a hole or passage made by or as if by the turning or twisting movement of a tool such that its interior walls have cylindrical lateral cross-sections, and which *do not exclude* holes or passages having *tapered* or stepped longitudinal cross-sections." Dec. 13.

Petitioner concedes that the Specification discloses that relative to Figures 9 and 18, a tapered bulbous member is received in a first bore with a "locked interference fit" for a "fixed angle." Opp. 8 (citing Ex. 2020, 34:18–19, 35:11–14 (Figs. 9–11), 44:8, 45:11–13 (Fig. 18)). And Petitioner explains that the Specification discloses a locked interference exists at the *first* aperture, rather than at the second aperture. *Id.* Both the '923 application and the '680 application disclose locked interference fit at *aperture 1130* which corresponds to the *first* aperture, not the second aperture. Ex. 2020, 35:12–15, Fig. 11; Ex. 2021, 23:2–7, Fig. 11). And Petitioner's declarant, Dr. Dominquez explains that contact of a head at the second aperture is *not necessary* to create locked interference fit for a fixed angle. *Id.* at 9 (citing Ex. 1018 ¶¶ 69–70). On this record, we agree with Petitioner that with sufficient abutment between a head at the first aperture and portions of the bore other than at the second aperture, abutment at the second aperture is *not necessary* for locked interference fit for a fixed angle. Opp. 15 (reproducing Ex. 1049, 10; Ex. 1050, 10; citing Ex. 1018 ¶¶ 74,78).

Taken together, Petitioner's annotated Figures 9 and 11 (Opp. 6) illustrate that the blue colored head does *not necessarily* contact the lower edge of the red colored countersunk area. *See In re Mraz*, 455 F.2d 1069, 1072 (CCPA 1972) (stating that figures may be relied on for aspects shown with "great particularity"); *In re Aslanian*, 590 F.2d 911 (CCPA 1979) (the drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art). *See also* Opp. 9 citing *Vas-Cath Inc. v.*

Mahurkar, 935 F.2d 1555, 1566 (Fed. Cir. 1991) for the proposition that “[d]rawings constitute an adequate description if they describe what is claimed and convey to those of skill in the art that the patentee actually invented what is claimed.”). As indicated above, this reading is consistent with our understanding of the deviation from linear in the profile of the third member of Figure 18.

Coupled to the Specification’s disclosure that a tapered bulbous member is received in a *first* aperture of a first bore with a “locked interference fit,” and with Petitioner’s explanations above, we presently find no evidence that the exterior surface of the head of a first member necessarily abuts any portion of the interior surface of the first bore of the third member at the second aperture.

For the reasons set forth above, we are persuaded by Petitioner’s argument that proposed substitute claims 16 and 27 lack written description support.

B. Patentability

For the reasons discussed below, at this stage of the proceeding, and based on the current record,⁸ it appears that Petitioner (or the record) has shown a reasonable likelihood that proposed substitute claims 16–30 are unpatentable.

Does the record establish a reasonable likelihood that the proposed substitute claims are unpatentable?

Yes as to claims 16–30. On this record, it appears that Petitioner has shown a reasonable likelihood that claims 16–23 and 25–30 are anticipated

⁸ We express no view on the patentability of original claims 1–15 in this Preliminary Guidance. Instead, we focus on limitations added to those claims in the Patent Owner’s Motion to Amend.

by Lopez⁹ and alternatively, claims 16–30 would have been obvious over Lopez and Brumfield.¹⁰

Anticipation:

Petitioner contends that claims 16–23 and 25–30¹¹ are anticipated by Lopez. Opp. 16. Petitioner asserts that Lopez’s Figure 12 shows the newly added feature, i.e., that the header of the first member abuts the interior of the first bore at the second aperture on the exterior surface of the third member. *Id.* at 16–17 (citing Ex. 1018 ¶ 86). Petitioner provides a claim chart mapping each element of claims 16–23 and 25–30 to “adapted” (detail and annotated) Figures 9, 1, 12, 3, and 2, and passages of Lopez, respectively. *Id.* at 17–23 (citing Lopez, 4:29–30, 4:35–36).

On the present record, we are persuaded by Petitioner’s argument that 16–23 and 25–30 are unpatentable as anticipated by Lopez.

Obviousness:

Petitioner further contends that claims 16–30 would have been obvious over Lopez and Brumfield. Opp. 23. Petitioner argues that even if Lopez does not disclose its first aperture is at a terminal end of the third member, Brumfield discloses this feature. *Id.* at 23–25 (annotating Fig. 1 of Brumfield to show a first bore axis at a terminal end of an intramedullary nail). Petitioner contends that given the conceptually similar geometries of the Lopez and Brumfield assemblies, it would have been obvious to adapt one to the other (i.e., adapt Lopez’s nail to be suitable for a longer nail of Brumfield for repair of long-bone fractures) and there would have been a reasonable expectation of success because lengthening the nail would not change any of its functional characteristics. *Id.* at 23–24 (citing Ex. 1018 ¶¶ 106–109).

⁹ Lopez, English-language translation of Spanish Patent No. ES 2,164,543 B1 to López-Oliva Munõs, pub. Jan. 22, 2002. Ex. 1033. Lopez is a newly cited reference.

¹⁰ Brumfield, US 4,827,917, issued May 9, 1989. Ex. 1006. Brumfield is a previously cited reference.

¹¹ In the header on page 16 of the Opposition, Petitioner does not list claim 30. However, claim 30 is included in Petitioner’s chart which is discussed below.

As to claim 24, Petitioner argues that Brumfield discloses a first bore axis and a second bore axis intersecting outside the third member. *Id.* at 24–25 (annotating Fig. 1 of Brumfield to show the intersection).

On the present record, we are persuaded by Petitioner’s argument that claims 16–30 would have been obvious over Lopez and Brumfield.

III. CONCLUSION

This concludes the Preliminary Guidance, which is Patent Owner’s first option under the Board’s pilot program. Notice, 84 Fed. Reg. at 9,497. Patent Owner has an additional option under the Board’s pilot program to file a revised MTA by DUE DATE 3. Paper 16.

In addition to those two options under the Board’s pilot program, Patent Owner is reminded that amendments of the challenged claims may also be pursued in a separate reissue or reexamination proceeding before, during, or after an AIA trial proceeding, including subsequent to the issuance of the Final Written Decision. We draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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