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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION, Petitioner,

v.

ORTHOPHOENIX, LLC, Patent Owner.

Case IPR2014-01434 Patent 7,153,307 B2

Before JOSIAH C. COCKS, RICHARD E. RICE, and SCOTT A. DANIELS, *Administrative Patent Judges*.

RICE, Administrative Patent Judge.

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

I. INTRODUCTION

Stryker Corporation ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–18 of U.S. Patent No. 7,153,307 B2 (Ex. 1001, "the '307 Patent"). Orthophoenix, LLC ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). We determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to all of challenged claims 1–18 of the '307 Patent. Accordingly, we institute an *inter partes* review with respect to the challenged claims.

A. Related Proceedings

Petitioner is named in a federal district court case involving the '307 Patent (*Orthophoenix, LLC. v. Stryker Corporation,* Case No. 13-1628-LPS (D. Del.)). Pet. 1; Paper 5, 2. Petitioner also has filed a petition seeking an *inter partes* review with respect to U.S. Patent No. 6,241,734 B1, to which the '307 Patent claims priority. Pet. 1; Paper 5, 2; *see* Case IPR2014-01433, Paper 6.

B. The '307 Patent

The '307 Patent relates to an instrument for tamping material into bone through a subcutaneous path. Ex. 1001, 1:63–64. In one embodiment, a cannula is used to establish the subcutaneous path, and material is

introduced into bone through the cannula. *Id.* at 2:6–8. A nozzle instrument may be advanced through the cannula and used, in conjunction with a delivery device such as a syringe, to convey material through the cannula into bone. *Id.* at 2:11–14, 19–27. Also, a tamping instrument that is capable of advancement through the cannula may be used to urge material residing in the cannula into bone. *Id.* at 2:28–33. A cavity forming instrument may be deployed through the cannula to compress cancellous bone and to form a cavity. *Id.* at 3:24–26.

The Specification discloses stylet 182, which is sized to pass through the interior bore of nozzle 180. *Id.* at 18:31–33. "The presence of the stylet 182 inside the nozzle 180 closes the interior nozzle bore." *Id.* at 18:38–39. When inserted as a nested unit into cannula instrument 184, nozzle 180 and stylet 182 form a tamping instrument that may be advanced through the cannula instrument to displace residual material from the cannula instrument. *Id.* at 18:54–57.

C. Illustrative Claim

Claims 1 and 14 are independent. Claim 1 is illustrative and is reproduced below:

1. A system comprising

an access tool sized and configured to establish an access path through soft tissue to bone having an interior volume occupied, at least in part, by cancellous bone,

a void forming tool sized and configured to be introduced through the access path to form a void in cancellous bone, a nozzle sized and configured to pass through the access path and including an interior bore defining a fixed interior volume to receive and deliver a measured volume of filling material into the void, and

an auxiliary tool sized and configured to be advanced through the interior bore and urge filling material from the nozzle.

Id. at 20:7–20.

D. The Asserted References

Petitioner relies upon the following references (Pet. 3):

Hofsess	US 3,893,445	July 8, 1975	Ex. 1006
Müller	US 4,576,152	Mar. 18, 1986	Ex. 1005
Reiley '404	US 5,108,404	Apr. 28, 1992	Ex. 1003
Kuslich '639	US 5,445,639	Aug. 29, 1995	Ex. 1008
Reiley II	WO 96/39970 A1	Dec. 19, 1996	Ex. 1004
Grosse	WO 97/23174	July 3, 1997	Ex. 1007

E. The Asserted Grounds

Petitioner challenges claims 1–21 of the '307 Patent on the following grounds (Pet. 3–4):

Reference(s)	Basis	Claims Challenged
Reiley II	§ 102(b)	1–7, 10, 13–15, and 18
Reiley II	§ 103(a)	8, 9, 11, 12, and 14–18

Reference(s)	Basis	Claims Challenged
Reiley '404 and Müller	§ 103(a)	1–18
Hofsess	§ 102(b)	1–3, 7, and 10–17
Hofsess	§ 103(a)	8 and 9
Grosse	§ 102(b)	1–3, 7, 10, and 13
Kuslich '639 and Grosse	§ 103(a)	1–3 and 5–18

II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a) for instituting review.

A. Claim Construction

The Board gives claim terms in an unexpired patent their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b).

1. "Sized and configured"

Patent Owner contends that the claim term "sized and configured" means having a specified size, set up for operation in a particular way. Prelim. Resp. 16. Petitioner does not propose an express claim construction for this claim term. Below, we interpret the claim term "an access tool *sized and configured* to establish an access path through soft tissue to bone (emphasis added)." We determine that the included term "sized and configured" does not need to be interpreted at this time.

2. "An access tool sized and configured to establish an access path through soft tissue to bone"

Neither party proposes an express claim construction for the claim term "an access tool sized and configured to establish an access path through soft tissue to bone." Patent Owner argues, however, that the "access tool" recited in claim 1 must remain in place to establish the required path through soft tissue to bone:

in Grosse, the drilling jig 20 is retracted before the instrument 40 (which is used to insert the implant) is placed. Ex. 1007, pg. 10. In contrast, in the '307 patent, the cannula must remain in place in order "to establish a path through the soft tissue to bone."

Prelim. Resp. 45 (quoting Ex. 1001, 20:5–13). We largely agree with Patent Owner's implied claim construction. The Specification describes several instruments, in addition to cannula instrument 30, that function to establish a path through soft tissue to bone. Ex. 1001, 6:6–7:16. Each of the instruments, once in place, is used to guide one or more following instruments. *Id.* The Specification explains, for example, that spinal needle assembly 20, which comprises stylet 22, "establishes the initial subcutaneous path leading to the targeted treatment site;" and guide pin instrument 26, which "serves to guide the establishment of the main operative pathway to the targeted treatment site," is deployed through this path, by exchange with needle stylet 22." *Id.* at 6:14–28.

We determine that that the broadest reasonable interpretation consistent with the Specification of the claim term "an access tool sized and configured to establish an access path through soft tissue to bone" is an access tool that is capable of defining an access path through soft tissue to bone and guiding another instrument along that path.

3. "Nozzle"

Claims 1 and 14 recite "a nozzle." Petitioner does not propose any express construction for that term. Patent Owner contends that a "nozzle instrument is a device capable of advancement through the cannula into bone," that "[t]he nozzle can be coupled to a delivery device to convey material through the nozzle terminus into bone," and that "[i]n use, the distal end of the nozzle extends beyond the distal end of the cannula into the cavity formed in the cancellous bone." Prelim. Resp. 17 (citing Ex. 1001, 2:19–25, 11:12–14). We are not persuaded, however, that any of the exemplary embodiments from the Specification should be read into our interpretation "nozzle" as Patent Owner contends. *See Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). We determine that the broadest reasonable interpretation consistent with the Specification of a "nozzle" is a device with an opening through which fluid can be expelled. *See, e.g.*, Ex. 1001, 16:20–22, 36–39, Fig. 27.

4. "Void forming tool" and "nozzle"

Patent Owner argues that "void forming tool" and "nozzle" are "two separate elements," and the bone cutting assembly of Hofsess "cannot serve to meet both elements." Prelim. Resp. 42 (citing *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999); other citations omitted). Petitioner has not expressed a position on the claim interpretation/application issue raised by Patent Owner's argument. While we agree that "void forming tool" and "nozzle"

are distinct features of claims 1 and 14, we determine at this stage of the proceeding that the broadest reasonable construction consistent with the Specification of these limitations does not require two devices that are completely separate or independent from one another. As discussed below, we are persuaded at this stage of the proceeding that different, but overlapping aspects of Hofsess's bone cutting assembly satisfy the two limitations.

None of our determinations regarding Petitioner's proposed grounds of unpatentability requires us to construe any other claim term expressly.

B. Asserted Anticipation

To anticipate a patent claim under 35 U.S.C. § 102, "a single prior art reference must expressly or inherently disclose each claim limitation." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates, even though artisans of ordinary skill may not have recognized the inherent characteristics or functioning of the prior art. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed.Cir.1999) (citation omitted); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349–50 (Fed.Cir.2002). With these standards in mind, we address each challenge below.

1. Claims 1–7, 10, 13–15, and 18 as Anticipated by Reiley II

Petitioner challenges claims 1–7, 10, 13–15, and 18 as anticipated by Reiley II. Pet. 14–20. As discussed below, we are not persuaded that Reiley II anticipates the challenged claims.

Claims 14 pertinently requires: (1) a "nozzle" that is sized and configured to pass through a "cannula;" and (2) an "auxiliary tool" that is sized and configured to be advanced through an interior bore of the nozzle. Claim 1 is similar, but requires the nozzle to be sized and configured to pass through an "access path" established by an access tool.

Petitioner argues that "Reiley II discloses a typical balloon-assisted vertebroplasty system, i.e., using a cannula (cannula 26) to establish an access path through soft tissue to bone; creating a cavity in the bone with a balloon (10, 21) that is sized to be advanced through the cannula; and then delivering bone cement into the cavity via the access cannula." *Id.* at 15 (citing Ex. 1004, 24:30–25:23, Fig. 8). Petitioner further argues that "Reiley II also discloses how to manually deliver materials into a vertebral cavity via the cannula *by using a 'long pin' to push materials down 'a tube' that has a diameter that is narrower than the cannula." <i>Id.* (emphasis added) (citing Ex. 1004, 40:32–41:3).

Petitioner relies on the following passage of Reiley II:

To insert materials which do not flow into the balloon-made cavity, like hydroxyapatite granules or bone mineral matrix, the surgeon can push them down <u>a tube</u> [nozzle] with a long pin [auxiliary tool] whose diameter is slightly more narrow than the inner diameter of the canula through procedures which the minimally-invasive procedure is taking place.

¹ We cite to the page numbers of the printed reference, rather than the page numbers of Petitioner's exhibit.

Id. (quoting Ex. 1004, 40:32–41:3 (emphasis by Petitioner; bracketed additions by Petitioner)). In asserting that the quoted passage discloses using a long pin (asserted "auxiliary tool") to push materials down a tube (asserted "nozzle") that has a diameter that is narrower than the cannula, Petitioner appears to read the phrase "whose diameter is slightly more narrow than the inner diameter of the cannula" to modify "a tube" (rather than "a long pin"). *Id.* (citing Ex. 1004, 40:32–41:3).

Patent Owner disagrees with Petitioner's analysis of Reiley II and argues, persuasively, that "it is not clear from [the passage of Reiley II on which Petitioner relies] that the 'tube' corresponds to the nozzle element as required by the '307 [patent]. Rather, the 'tube' more likely corresponds to the cannula element in the '307 patent." Prelim. Resp. 27. Patent Owner reads the phrase "whose diameter is slightly more narrow than the inner diameter of the cannula" to modify "a long pin" (not "a tube") in arguing:

[T]he diameter of the "pin" is supposed to be slightly smaller than that of the "cannula" — and not of that of the "tube." If the "tube" were a separate element in the sense of a nozzle, then the "pin" would have to have a slightly smaller diameter than the "tube."

Prelim. Resp. 27.

We determine that the passage of Reiley II on which Petitioner relies for disclosure of an "auxiliary tool" is not clear and, therefore, cannot be used to support Petitioner's anticipation challenge. *See In re Turlay*, 304 F.2d 893, 899 (CCPA 1962) ("It is well established that an anticipation rejection cannot be predicated on an ambiguous reference."). In particular, the passage does not disclose clearly that the "tube" is distinct from the

"cannula" and sized and configured to pass through the cannula, and that the "long pin" is sized and configured to be advanced through the tube, as required by claims 1 and 14. *See* Ex. 1004, 40:32–41:3. Accordingly, we are not persuaded that Petitioner is reasonably likely to show that Reiley II anticipates claims 1 and 14, or their dependent claims 2–7, 10, 13, 15, and 18.

2. Claims 1–3, 7, and 10–17 as Anticipated by Hofsess

Petitioner asserts that Hofsess anticipates claims 1–3, 7, and 10–17. Pet. 38–44. At this stage of the proceeding, we agree.

a. Overview of Hofsess

Figure 1 of Hofsess is reproduced below, with annotations identifying certain of the numbered elements.²

² The panel added annotations to Figure 1 to identify numbered elements based on their descriptions in the Specification. *See* Ex. 1006, 4:17–20, 41–44, 49–50).

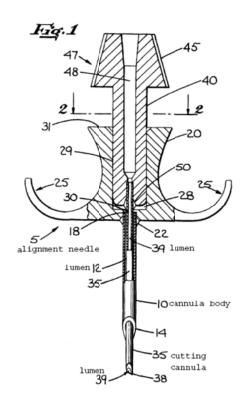


Figure 1 of Hofsess provides a partial cross-sectional view of a bone marrow biopsy apparatus (alignment needle 5). Ex. 1006, 2:36–37, 3:17–18.

Cannula body 10 of alignment needle 5 is used to penetrate soft tissue and to access bone. Ex. 1006, 3:19–21. Bone cutting cannula 35 includes bone cutting point 38 and lumen 39 and is capable of moving axially in lumen 12 of cannula body 5. *Id.* at 3:43–44, 49–50. The embodiment shown in Figure 1 includes "an optional feature in conduit 48 which passes through shank 40 and handle 45 to link with lumen 39 thereby giving continuous passage traversing the entire bone cutting component 47." *Id.* at 3:66–4:2. Hofsess discloses that "conduit 48 provides a means of passing a stylet to clear out bone chips which accumulate in lumen 39 during use." *Id.* at 4:4–6.

b. Analysis

Petitioner asserts that Hofsess discloses all of the recited features of claims 1–3, 7, and 10–17 and sets forth the evidence from Hofsess to support its contentions in detailed claim charts and the Declaration of its Declarant, Mary E. Jensen, M.D. Pet. 38–45; Ex. 1002 ¶¶ 118–130. For example, Petitioner asserts that bone cutting assembly 47, which includes bone cutting cannula 35 and cutting point 38, satisfies the "void forming tool" limitation; and that "optional conduit 48 and lumen 39 that traverses the bone cutting component" satisfy the "nozzle" limitation. Pet. 40 (claim chart).

In response, Patent Owner argues that "[t]he bone cutting assembly cannot serve to meet both elements, namely, the 'void forming tool' and 'nozzle' as these are two separate elements required by the '307 patent." Prelim. Resp. 42 (citations omitted). As discussed above, however, the broadest reasonable interpretation consistent with the Specification of these limitations does not require two devices that are completely separate or independent from one another. *See* section II.A.4 *supra*. At this stage of the proceeding, we are persuaded that the different, but overlapping aspects of the bone cutting assembly identified by Petitioner satisfy the "void forming tool" and "nozzle" limitations.

Patent Owner also argues that Hofsess's stylet does not satisfy the "auxiliary tool" limitation because "the stylet is only used after the bone cutting cannula 35 is withdrawn from the patient and only used in the instance when the biopsy apparatus is optionally configured to be nondisposable." *Id.* Patent Owner further argues that "[h]ow such a stylet equates to an auxiliary tool which is used to urge material, such as flowable

cement and fully occupies the interior bore of the nozzle is unclear." *Id.* at 42–43. At this stage of the proceeding, however, we are persuaded that Hoffsess's stylet is capable of performing the functions recited in the claims. Further, on this record, we are persuaded that a person of ordinary skill in the art would understand that the stylet "substantially fully" occupies the entire lumen as required by claim 14. *See* Ex. 1002 ¶ 128 (claim chart).

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its challenge that Hofsess anticipates claims 1–3, 7, and 10–17.

3. Claims 1–3, 7, 10, and 13 as Anticipated by Grosse

Petitioner asserts that Grosse anticipates claims 1–3, 7, 10, and 13. Pet. 46–44. As discussed below, we are not persuaded that Grosse anticipates the challenged claims.

Claim 1 requires "an access tool sized and configured to establish an access path through soft tissue to bone" and "a nozzle sized and configured to pass through the access path." As discussed above, the broadest reasonable interpretation consistent with the Specification of the claim term "an access tool sized and configured to establish an access path through soft tissue to bone" is an access tool that is capable of defining an access path through soft tissue to bone and guiding another instrument along that path. *See* section II.A.2 *supra*.

Petitioner asserts that Grosse's drilling jig 20 corresponds to the "access tool" limitation and that Grosse's tubular body 41 corresponds to the "nozzle" limitation. Pet. 47 (claim chart). We are not persuaded, however,

that Grosse's tubular body 41 is "sized and configured to pass through the access path," i.e., the access path established by drilling jig 20, as claim 1 requires. Rather, we are persuaded, as Patent Owner argues, that drilling jig 20 is retracted before tubular body 41 of instrument 40 is deployed and that tubular body 41 is not sized and configured to pass through drilling jig 20. *See* Prelim. Resp. 45 (citing Ex. 1007, 10).

Accordingly, we are not persuaded that Petitioner is reasonably likely to show that Grosse anticipates claim 1 or dependent claims 2, 3, 7, 10, and 13.

C. Asserted Obviousness

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *Id.* at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the

patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. With these standards in mind, we address each challenge below.

1. Claims 8, 9, 11, 12, and 14–18 as Obvious over Reiley II

Petitioner asserts that claims 8, 9, 11, 12, and 14–18 would have been obvious over Reiley II in view of the knowledge of a person of ordinary skill in the art. Pet. 20–27. Petitioner does not contend, however, that the knowledge of a person of ordinary skill in the art would have remedied the deficiency in Reiley II discussed in section II.B.1 *supra*. Accordingly, we are not persuaded that Petitioner is reasonably likely to show that claims 8, 9, 11, 12, and 14–18 would have been obvious over Reiley II in view of the knowledge of a person of ordinary skill in the art.

2. Claims 1–18 as Obvious over Reiley '404 and Müller

Petitioner asserts that claims 1–18 would have been obvious over Reiley '404 and Müller in view of the knowledge of a person of ordinary skill in the art. Pet. 28–38; *see* Ex. 1002 ¶¶ 28–38.

Petitioner asserts that Reiley '404 "teaches performing balloon-assisted vertebroplasty by using an access cannula to create an access path into the bone, creating a void in the bone with an expandable balloon, and thereafter delivering bone cement into the cavity using an injection gun with a nozzle." *Id.* at 28. Petitioner contends that Reiley '404 "discloses every element of independent claims 1 and 14 of the '307 patent except for the 'auxiliary tool.'" Pet. 30 (citing Ex. 1002 ¶¶ 92–94). Petitioner relies on the knowledge of a person of ordinary skill in the art and Müller to remedy this

acknowledged deficiency in Reiley '404. Pet. 30–32. With respect to the knowledge of a person of ordinary skill in the art, Dr. Jensen testifies as follows:

[A]n auxiliary tool sized and configured to be advanced through the interior bore and urge filling material from the nozzle, and that can be manipulated independently of the nozzle and substantially fully occupies the entire interior bore of the nozzle, was known to (sic) person of ordinary skill in the art at the time of the invention and was a known alternative to using an injection gun for cement delivery. Indeed, as evidenced by numerous prior art references, it was well known in the art at the time of the invention that a physician could deliver filling material to a vertebral body using hand-actuation of "an auxiliary tool" (e.g., manually pushing material with a tool such as a pin through a tube rather than using an injection gun).

Ex. $1002 \, \P \, 94$ (citations omitted). As to Müller, Petitioner and Dr. Jensen assert that it "teaches using an auxiliary tool to urge filling material such as bone cement out of a nozzle." Pet. 31; Ex. $1002 \, \P \, 95$.

In response, Patent Owner contends that "Muller does not disclose an auxiliary tool that is sized and configured to be advanced through the interior bore of the nozzle and when fully advanced, substantially fully occupying the entire interior bore of the nozzle." Prelim. Resp. 38. Patent Owner argues that "Muller's ram 10 cannot be advanced through the nozzle of Reiley '404." *Id.* This argument misapprehends the law of obviousness and is unpersuasive. It is not necessary that references be physically combinable in order to render obvious the invention under review. *See In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983). Patent Owner further argues that Müller's ram 10 cannot fully occupy the entire interior bore of

Reiley '404's nozzle because of its cross-shaped profile and dish-type bearing plate at its upper end. *Id.* This argument is unpersuasive because it does not address Dr. Jensen's testimony with respect to the knowledge of a person of ordinary skill in the art, specifically, that an auxiliary tool "substantially fully occupying the entire interior bore of the nozzle," as required by claim 14, was a known alternative to using an injection gun for cement delivery. *See* Ex. 1002 ¶ 94 (citations omitted).

Upon review of the record at this preliminary stage of the proceeding, we determine that Petitioner has established a reasonable likelihood of prevailing on its challenge to claims 1 and 14 as obvious over Reiley '404 and Müller in view of the knowledge of a person of ordinary skill in the art.

For the reasons discussed below, we also determine that Petitioner has established a reasonable likelihood of prevailing on its challenge to dependent claims 2–13 and 15–18 as obvious over Reiley '404 and Müller in view of the knowledge of a person of ordinary skill in the art. We are persuaded on the current record as follows.

Reiley '404 discloses an access tool comprising a "cannula" as recited in claim 2. See Ex. $1002 \, \P \, 105$ (claim chart).

Reiley '404 discloses the "void forming tool" limitations of claims 3–6 and 18. *See* Ex. 1002 ¶¶ 106–108 (claim chart).

Reiley '404 discloses the "filling material" limitations of claims 13 and 15. See Ex. $1002 \, \P \, 110$ (claim chart).

Müller discloses the "elongate tube" requirement of claim 7. *See* Ex. 1002 ¶ 112 (claim chart).

Müller discloses the "receptacle" and "connector" limitations of claim 8. *See* Ex. 1002 ¶ 113 (claim chart).

Adding the "markings" required by claim 9 would have been obvious based on evidence that it was known generally in the art to include graduated markings on instruments to gauge visually the advancement of one instrument within another instrument such as a cannula. *See* Ex. 1002 ¶¶ 75–78, 114; *see also KSR*, 550 U.S. at 417 ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.").

The "elongate body" requirement of claim 10 would have been obvious in view of Müller and the knowledge of one of ordinary skill in the art. See Ex. $1002 \, \P \, 115$ (claim chart).

The "general rigid" and "generally flexible" requirements of claims 11, 12, 16, and 17 would have been obvious in view of Müller and the knowledge of one of ordinary skill in the art. *See* Ex. 1002 ¶ 116 (claim chart); *see KSR*, 550 U.S. at 416 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.") (citing *United States v. Adams*, 383 U.S. 39, 50–51 (1966)).

3. Claims 8 and 9 as Obvious over Hofsess

Petitioner asserts that claims 8 and 9 would have been obvious over Hofsess in view of the knowledge of a person of ordinary skill in the art. Pet. 44–45. It is not apparent, however, that Patent Owner's obviousness rationale for claim 8 (using a receptacle to deliver filling material to a nozzle

and coupling the receptacle to the nozzle with a connector to prevent leakage) is consistent with its argument in connection with claim 1 that Hofsess's optional conduit 48 and lumen 39 satisfy the "nozzle" limitation. It also is not apparent that one of ordinary skill in the art would have known, as Petitioner contends with respect to claim 9, to provide "conventional calibration markings" on the bone cutting assembly or nozzle of Hofsess's bone marrow biopsy apparatus to gauge the insertion depth. *See* Pet. 45 (citing Ex. 1002 ¶ 134). In any event, however, we do not institute a trial on Petitioner's asserted obviousness ground based on Hofsess in view of our determination, discussed *supra*, that claims 8 and 9 would have been obvious over Reiley '404 and Müller in view of the knowledge of a person of ordinary skill in the art. *See* 37 C.F.R. § 42.208(a) (providing us with discretion to authorize review "to proceed on all or some of the grounds of unpatentability asserted for each claim.").

4. Claims 1–3 and 5–18 as Obvious over Kuslich '639 and Grosse

Petitioner asserts that claims 1–3 and 5–18 would have been obvious over Kuslich '639 and Grosse in view of the knowledge of a person of ordinary skill in the art. Pet. 50–57; *see* Ex. 1002 ¶¶ 144–166. With respect to claims 1 and 14, Petitioner asserts that "Kuslich teaches using an 'access tool,' which is a 'cannula' (locating cylinder 104), to establish an access path through soft tissue to a vertebral body" (*id.* at 51 (citing Ex. 1008, 8:25–40, Fig. 16)), and introducing a void forming tool (shaft 22) through the cannula to form a void in cancellous bone (*id.* at 52 (citing Ex. 1008, 8:4–8, 40–46,

9:44–51, Figs. 16–20)). Petitioner does not assert, however, that Kuslich '639 teaches a nozzle sized and configured to pass through the access path established by cylinder 104, and it is not apparent why a person of ordinary skill in the art would have been "motivated to select an access cannula (cylinder 104) of Kuslich such that it could appropriately receive the nozzle 41 of Grosse," as Petitioner contends. *See id.* at 53 (citing Ex. 1002 ¶ 154). In any event, however, we do not institute a trial on Petitioner's asserted obviousness ground based on Kuslich '639 and Grosse in view of our determination, discussed *supra*, that claims 1–3 and 5–18 would have been obvious over Reiley '404 and Müller in view of the knowledge of a person of ordinary skill in the art. *See* 37 C.F.R. § 42.208(a).

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has established a reasonable likelihood of prevailing on its challenges to: claims 1–3, 7, and 10–17 under 35 U.S.C. § 102(b) as anticipated by Hofsess; and claims 1–18 under 35 U.S.C. § 103(a) as obvious over Reiley '404 and Müller in view of the knowledge of a person of ordinary skill in the art. The Board has not made a final determination concerning patentability of any of the challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that an *inter partes* review of claims 1–18 of the '307 Patent is granted;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter* partes review of the '307 Patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the following grounds: claims 1–3, 7, and 10–17 under 35 U.S.C. § 102(b) as anticipated by Hofsess; and claims 1–18 under 35 U.S.C. § 103(a) as obvious over Reiley '404 and Müller in view of the knowledge of a person of ordinary skill in the art.

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