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Paper 29
Entered: February 5, 2016

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.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73(b)

I. INTRODUCTION

A. Background/Summary

Stryker Corporation ("Petitioner") filed a Petition (Paper 1, "Petition" or "Pet.") for *inter partes* review of claims 1–18 of U.S. Patent No. 7,153,307 B2 (Ex. 1001, "the '307 Patent"). We instituted an *inter partes* review as to all of the challenged claims. Paper 7 ("Dec."), 2. After institution, Orthophoenix, LLC ("Patent Owner") filed a Patent Owner Response (Paper 15, "PO Resp."), to which Petitioner filed a Reply (Paper 19, "Pet. Reply").

An oral hearing was held on November 4, 2015. The transcript of the hearing has been entered into the record. Paper 28 ("Tr.").

The grounds for trial were as follows:

References	Basis	Claims Challenged
Hofsess[1]	§ 102(b)	1–3, 7, and 10–17
Reiley '404[2] and Müller[3]	§ 103(a)	1–18

Petitioner relied on first and second Declarations of Mary E. Jensen, M.D. (Exs. 1002, 1041), and Patent Owner relied on a Declaration of Gamal Baroud, Ph.D. (Ex. 2021).

[1] U.S. Patent No. 3,893,445 to Hofsess, issued July 8, 1975 (Ex. 1006).

[2] U.S. Patent No. 5,108,404 to Reiley et al., issued April 28, 1992 (Ex. 1003).

[3] U.S. Patent No. 4,576,152 to Müller et al., issued March 18, 1986 (Ex. 1005).

We have jurisdiction under 35 U.S.C. § 6(c). The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons explained below, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–3, 7, and 10–17 are unpatentable as anticipated by Hofsess and claims 1–18 are unpatentable as obvious over Reiley '404 and Müller.

B. Related Proceedings

Petitioner is named as a defendant 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 is involved in an *inter partes* review (IPR2014-01433) of U.S. Patent No. 6,241,734 B1, to which the '307 Patent claims priority. Pet. 1; Paper 5, 2.

C. 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 the terminus of the tamping instrument is advanced through the cannula to urge material residing in the cannula into bone. *Id.* at 2:6–10, 28–33. A cavity forming

instrument may be deployed through the cannula to compress cancellous bone,[4] and to form a cavity to receive the material. *Id.* at 3:24–28.

Figure 33 of the '307 Patent is reproduced below.

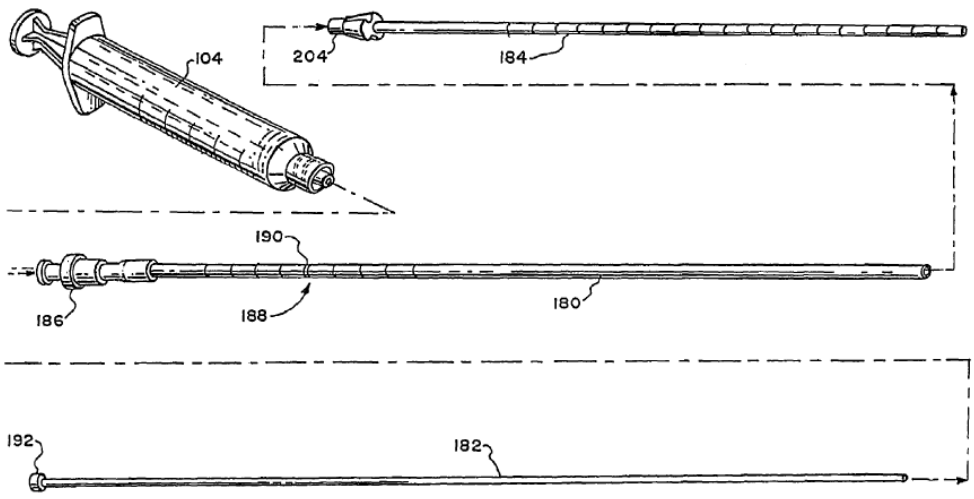

FIG. 33

Figure 33 is a perspective view illustrating a group of reduced-diameter instruments, including cannula instrument 184, stylet 182, and nozzle 180. *Id.* at 18:13–15, 17–18, and 31–32. Nozzle 180 includes measured markings along its length. *Id.* at 18:25–26. Stylet 182 is sized to pass through the interior bore of nozzle 180 and to close the interior nozzle bore. *Id.* at 18:31–38. When inserted as a nested unit into cannula instrument 184, nozzle 180 and stylet 182 form a tamping instrument that

[4] "Spongy porous bone tissue, which forms the interior of a bone and has a lower density than the surrounding cortical bone." Elizabeth Martin et al., A DICTIONARY OF NURSING (5th ed. 2008).

may be advanced through the cannula instrument to displace residual material from that instrument into the cavity. *Id.* at 18:55–61.

Figure 34 of the '307 Patent is reproduced below.

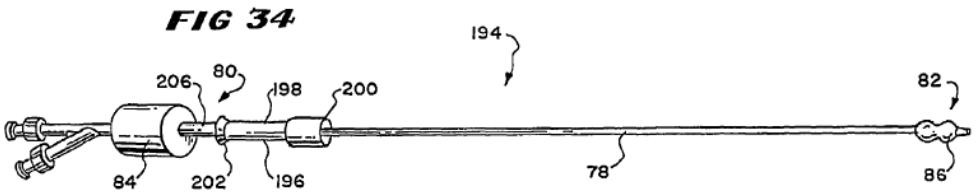

Figure 34 depicts cavity forming instrument 194, which is deployed through cannula instrument 184 (shown in Figure 33, reproduced above). *Id.* at 19:4–6.

D. Illustrative Claim

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

> 14. A system comprising
>
> a cannula 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 cannula to form a void in cancellous bone,
>
> a nozzle that can be manipulated independent of the cannula and that is sized and configured to pass through the cannula, the nozzle including an interior bore to receive and deliver a measured volume of filling material into the void, and

> an auxiliary tool that can be manipulated independently of the nozzle and the cannula and that is sized and configured to be advanced through the interior bore and urge filling material from the nozzle, the auxiliary tool, when fully advanced, substantially fully occupying the entire interior bore of the nozzle.

Id. at 20:60–21:10.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278, 1279 (Fed. Cir. 2015) ("We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA" and "the standard was properly adopted by PTO regulation."), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 84 U.S.L.W. 3218 (Jan. 15, 2016) (No. 15-446). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). The claims, however, "'cannot be divorced from the specification and the record evidence.'" *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed.Cir.2011)). Applying these principles, we interpret certain claim limitations as follows:

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

In the Decision to Institute, we determined that the broadest reasonable interpretation consistent with the Specification of "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. Dec. 6–7.[5] Neither of the parties proposes any change to that interpretation, and our review of the evidence does not indicate that any change is necessary. Consequently, we maintain our interpretation.

2. "nozzle"

In the Decision to Institute, we determined that the broadest reasonable interpretation consistent with the Specification of "nozzle" is a device with an opening through which fluid can be expelled. *Id.* at 7. Neither of the parties proposes any change to that interpretation, and our review of the evidence does not indicate that any change is necessary. Consequently, we maintain our interpretation.

3. "Void forming tool" and "nozzle"

In the Preliminary Response, Patent Owner argued that the claim terms "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);

[5] We also determined that the included term "sized and configured" did not need to be interpreted. Dec. 5, 13.

other citations omitted). In the Decision to Institute, we noted our agreement that the terms "void forming tool" and "nozzle" are distinct features of claims 1 and 14, but determined that the broadest reasonable interpretation consistent with the Specification of those limitations does not require two devices that are completely separate or independent from one another. Dec. 7–8. We also stated that "different, but overlapping aspects of Hofsess's bone cutting assembly satisfy the two limitations," as further discussed in Section II.B.2.b of our Decision, and below. *Id.* at 8, 13.

In the Patent Owner Response, Patent Owner renews its argument that "it is improper to rely on the same structure as disclosing two separate claimed elements." PO Resp. 9 (citing *Lantech, Inc. v. Keip Machine Co.*, 32 F.3d 542 (Fed. Cir. 1994) and *In re Robertson*, 169 F.3d at 743). In reply, Petitioner argues, persuasively, that:

> Contrary to [Patent Owner's] arguments, "the use of two terms in a claim requires that they connote different meanings, not that they necessarily refer to two different *structures*." *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006) (emphasis in original). An argument similar to [Patent Owner's] was made, and rejected, in *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221 (Fed. Cir. 2011). There, the defendant argued that a single structure in the accused product, a saw guard, could not satisfy two claim limitations, "cutting box" and "dust collection structure." *Id.* at 1231. The Federal Circuit disagreed, finding that nothing in the specification or claim "requires that 'cutting box' and 'dust collection structure' be wholly separate structures." *Id.* at 1231–32; *see also Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1303 (Fed. Cir. 2011) ("The claims and the specifications indicate that the 'needle holder' and the 'retainer member' need not be separately molded pieces.").

Pet. Reply 5; *see also id.* at 7 n.1 (distinguishing the cases cited by Patent Owner, *Lantech* and *Robertson*, on the basis that "the claim language at issue in those cases unambiguously limited the claims to separate structures").

Upon consideration of the parties' competing arguments, we maintain our interpretation that the terms "void forming tool" and "nozzle," as recited in claims 1 and 14, do not require two devices that are completely separate or independent from one another. *See* Dec. 7–8; Pet. Reply 5–7.

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

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 claim 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).

Here, Petitioner asserts that Hofsess anticipates claims 1–3, 7, and 10–17. Pet. 38–44.

1. Overview of Hofsess

Hofsess discloses a bone marrow biopsy apparatus. Ex. 1006, 3:17–18. Figure 1 of Hofsess is reproduced below, with annotations identifying certain elements.

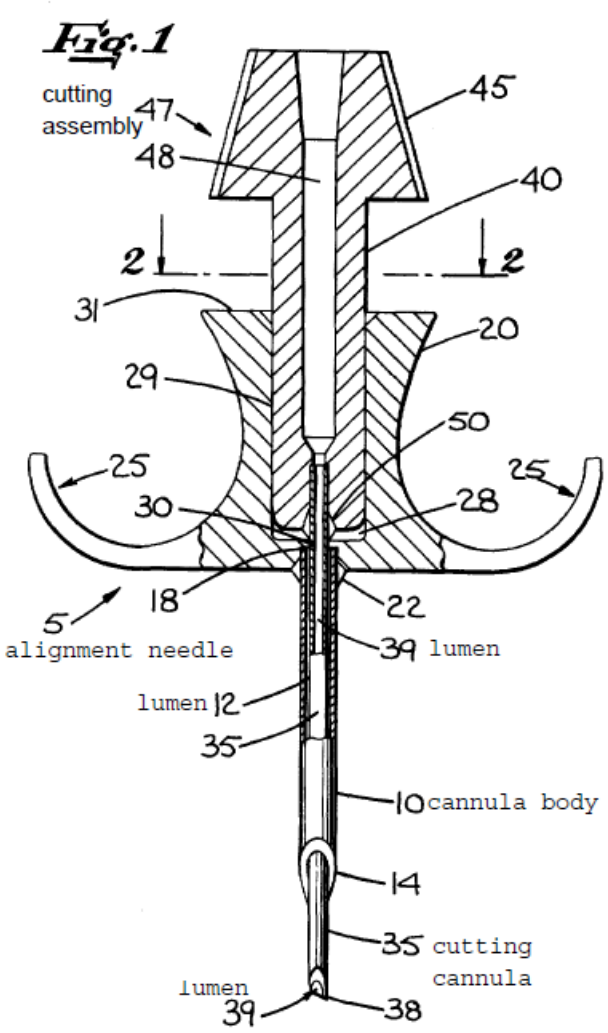

Figure 1 is a partial cross-sectional view of a bone marrow biopsy apparatus comprising alignment needle 5 and cutting assembly 47. Ex. 1006, 2:36–37, 3:17–21, 41–44. Cutting assembly 47 fits axially in bore 28 of alignment needle 5. *Id.* at 3:41–44. Alignment needle 5 includes

cannula body 10, which defines lumen 12 and soft-tissue-penetrating-and-bone-indenting point 14. Cutting assembly 47 includes bone cutting cannula 35, which is moveable linearly and axially in lumen 12, and defines bone cutting point 38 and lumen 39. *Id.* at 3:41–44, 49–50. Cutting assembly 47 also 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. "[C]onduit 48 provides a means of passing a stylet to clear out bone chips which accumulate in lumen 39." *Id.* at 4:4–6.

In use, after establishing the required access, cutting assembly 47 is withdrawn, leaving alignment needle 5 in place. *Id.* at 5:62–6:1. A conventional hypodermic needle then may be inserted through axial passage 12, 28 of alignment needle 5 to obtain a blood sample. *Id.* at 6:1–5.

2. Analysis

Petitioner asserts that Hofsess discloses, expressly or inherently, each limitation of claims 1–3, 7, and 10–17, as set forth in detailed claim charts and explained by its expert, Dr. Jensen. Pet. 38–45; Ex. 1002 ¶¶ 118–130. With respect to claims 1 and 14, Petitioner asserts, and we agree, that cutting assembly 47, which includes bone cutting cannula 35 and cutting point 38, satisfies the "void forming tool" limitation; and that bone cutting assembly 47, which also includes optional conduit 48 and lumen 39, also satisfies the "nozzle" limitation. Pet. 40, 43–44. We credit Dr. Jensen's testimony: "The nozzle (the bone cutting component which includes a conduit lumen) is sized and configured to pass through the access path" (Ex. 1002 ¶ 120), and "the

nozzle has an interior bore to receive and deliver a measured volume of fil[l]ing material into the void" (*id.* at ¶ 128). We also credit Dr. Jensen's testimony that the asserted "nozzle" includes an opening through which fluid can be expelled, as required under our claim interpretation. Ex. 1041 ¶ 3. We agree, moreover, with Dr. Jensen's analysis that:

> [A] person of ordinary skill would understand that, to deliver the material, the bone cutting assembly would first need to be removed and cleared of its bone chips and then replaced through the access path or cannula to be used as the nozzle for injection (where it would then be kept in place during delivery of the material). This is consistent with the disclosure of the 307 patent, which requires removal of the void forming tool before placement of the nozzle.

Ex. 1041 ¶ 3.

In opposition, Patent Owner argues that: "once the surface of the bone or the bone cortex is cut open [using Hofsess's apparatus], the bone cutting assembly 47 is removed and thus cannot be available to serve as a nozzle." PO Resp. 12 (citing Ex. 1006, Fig. 12, 5:63–67, 6:1; Ex. 2021 ¶¶ 21–23). Patent Owner contrasts Hofsess with embodiments described in the '307 Patent in which the nozzle "remains in-place during injection of material such as cement." *Id.* at 13. Patent Owner also asserts that "the claim requires the nozzle element to be present." *Id.* (citing Ex. 1001, 20:13–20).

We are not persuaded by Patent Owner's arguments. In particular, Patent Owner has not explained sufficiently why bone cutting assembly 47 is not a "nozzle" under a proper claim construction, *see supra* Section II.A.2,

or why bone cutting assembly 47 is not capable of performing the functional limitations recited in the claims.

We do not credit the testimony of Patent Owner's expert, Dr. Baroud, with respect to the "nozzle" limitation. *See* Ex. 2021 ¶¶ 21–23. Dr. Baroud's testimony is conclusory and fails to explain why, if Hofsess's cutting assembly were removed, as Petitioner argues, it could not be cleared of bone chips, re-inserted, and used as a nozzle for injection of material.

Further, to the extent Patent Owner maintains its argument in the Preliminary Response that the bone cutting assembly cannot serve to meet both the "void forming tool" and "nozzle" limitations, we disagree. We are persuaded that the different, but overlapping aspects of the bone cutting assembly identified by Petitioner satisfy both limitations. *See* Pet. 40; Ex. 1002 ¶ 120.

For the reasons given, we conclude that Petitioner has shown, by a preponderance of the evidence, that Hofsess anticipates claims 1 and 14. Further, Dr. Jensen's testimony supports Petitioner's contention that Hofsess anticipates the dependent claims. *See* Pet. 41–44; Ex. 1002 ¶¶ 121–127, 129–130. Patent Owner presents arguments only as to claims 1 and 14 and relies on those arguments as to dependent claims 2–3, 7, 10–13, and 15–17. For the reasons set forth above and in the Petition, we conclude that Petitioner has shown, by a preponderance of the evidence, that Hofsess anticipates claims 2, 3, 7, 10–13, and 15–17.

C. Obviousness of Claims 1–18 over Reiley '404 and Müller

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. The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, if in evidence.[6] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

[6] Patent Owner does not assert any secondary considerations in the Patent Owner Response.

Petitioner provides the following definition of a person of ordinary skill in the art:

> A person of ordinary skill in the art relating to the subject matter of the '307 Patent would be a physician or a biomedical engineer with a number of years of experience, e.g., three to five years, in the field of orthopedic technology or minimally-invasive surgery and, in particular, minimally invasive radiological procedures. This person would be experienced in performing, and/or designing devices for performing, minimally invasive procedures such as vertebroplasty.

Pet. 20–21 (citing Ex. 1002 ¶ 13).

Patent Owner does not dispute Petitioner's assessment of a person of ordinary skill in the art, and we accept it in the context of this Final Written Decision.

Petitioner contends that claims 1–18 would have been obvious over Reiley '404 and Müller, in view of the knowledge of one of ordinary skill in the art. *Id.* at 28–38; Ex. 1002 ¶¶ 89–117.

1. Overview of Reiley '404

It is undisputed that Reiley '404 (Ex. 1003) "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," as Petitioner asserts. Pet. 28; *see* PO Resp. 14–18. Figure 25 of Reiley '404 is reproduced below:

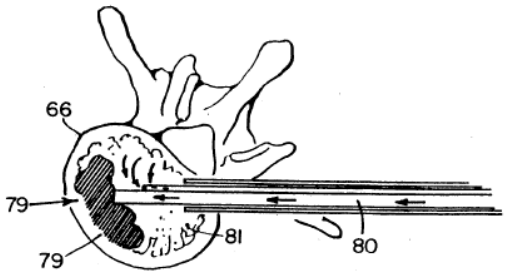

FIG.25

Figure 25 depicts the injection of material, after creation of a void in a vertebral body, using an injection gun nozzle comprising material delivery tube 80 and aspirating tube 82 (shown, but not identified by number, in the figure). *Id.* at 7:42–50. Petitioner contends, and Patent Owner does not dispute, that delivery tube 80: (1) is a nozzle; (2) includes an interior bore for receiving and delivering a measured volume of filling material into the void; and (3) is capable of manipulation independent of cannula 30 (shown, but not identified by number, in Figure 25). Pet. 29–30 (citing Ex. 1002 ¶ 93); *see* PO Resp. 14–18.

2. Overview of Müller

Petitioner contends that Müller (Ex. 1005) "teaches using an auxiliary tool to urge filling material such as bone cement out of a nozzle." Pet. 31. Figures 3 and 4 of Müller are reproduced below.

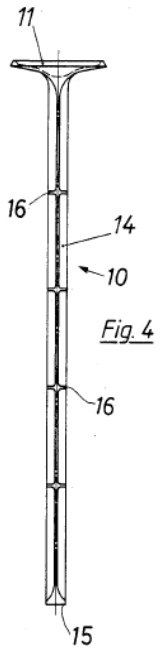

Fig. 4

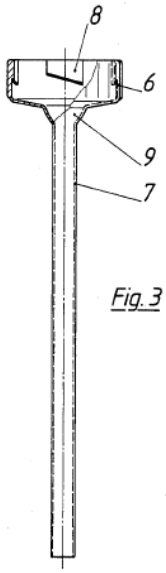

Fig. 3

Figure 3 illustrates a part cross-sectional view of nozzle element 6, and Figure 4 illustrates a side view of ram 10. Ex. 1005, 2:41–45, 3:3–5, 19–21. Müller discloses that "[t]he ram is movably mounted in the nozzle tube to eject bone cement therefrom." *Id.* at 1:54–55. Petitioner contends that "[t]he ram, shown in figure 4, is an auxiliary tool for urging filling material from the nozzle, just as claimed in the '307 patent." Pet. 32.

Figure 5 of Müller is reproduced below.

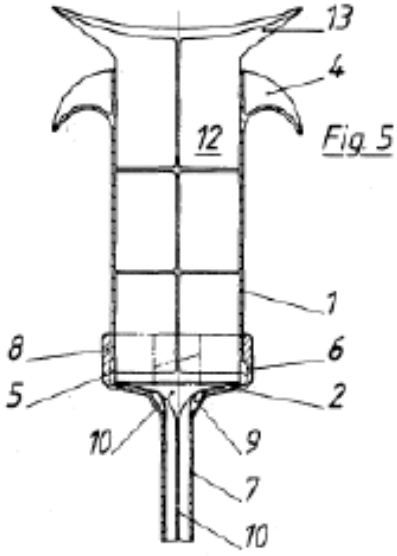

Figure 5 is a partial view of Müller's injector, which includes four elements: (1) cylinder tube 1 defining a volume of about 125 cc for receiving bone cement; (2) nozzle element 6; (3) ram 10; and (4) piston 12. Ex. 1005, 2:46–54. With nozzle element 6 removed, the injector can deliver "a relatively large quantity of bone cement . . . under low pressure." *Id.* at 1:57–61. "*[W]ith the nozzle element attached, the injector can be used to inject relatively small quantities of bone cement at a high pressure.*" *Id.* at 4:4–8 (emphasis added). Müller describes the high pressure injection as follows:

> For a high pressure injection of bone cement into a bone cavity, the nozzle element is secured to the cylinder tube. At this time, the piston in the cylinder tube is used to fill the nozzle tube of the nozzle element with bone cement. Further, the ram serves to eject the bone cement from the filled nozzle tube. Of note, when the nozzle element is attached to the cylinder tube, the ram is guided through the cylinder tube and through the injection nozzle into the nozzle tube. *Alternatively, the nozzle*

> *element can be detached from the cylinder tube and used as a separator [sic] injector.*

Id. at 1:62–2:4 (emphasis added).

3. Analysis

Petitioner argues 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 that deficiency. Pet. 30–32. Dr. Jensen testifies in support of Petitioner's argument that "[a]n auxiliary tool, such as the ram disclosed in Muller (or a long pin or mandrel), to manually push cement through the interior bore of the nozzle into bone was a known and predictable alternative to the injection gun system disclosed in Reiley 404." Ex. 1002 ¶ 101. Dr. Jensen further testifies: "In place of this injection gun, a person of ordinary skill would have known that he or she could manually deliver filling materials such as cement via a syringe and use a separate nozzle with an auxiliary tool to urge the cement into the cavity, especially if more controlled delivery was desired." *Id.* In her Reply Declaration, Dr. Jensen also testifies that a person of ordinary skill in the art would have known how to adapt Müller's apparatus for delivery of an appropriate volume of bone cement:

> [B]y the time of the invention, the ordinarily skilled artisan understood and knew how to adapt larger instruments for use in minimally-invasive procedures and had already done so. Thus, selecting nozzles, rams, and syringes of appropriate size and shape for minimally-invasive procedures (such as balloon-assisted vertebroplasty) was already being done well before the

> time of the invention. Again, the size of the devices was a matter of physician preference and there were a myriad of syringe and nozzle with stylet choices (commensurate with the ram/nozzle disclosure in Muller) available off-the-shelf and described in the prior art.

Ex. 1041 ¶ 7. We agree with Petitioner's arguments and Dr. Jensen's testimony.

In opposition, Patent Owner argues that "[o]ne of ordinary skill in the art would not turn to the Muller apparatus for a design element such as a ram since the Muller apparatus is designed to deliver large volumes of bone cement" that would be "inappropriate for vertebrae." PO Resp. 15. Patent Owner asserts that the Müller apparatus is designed to deliver about 125 cubic centimeters of bone cement. *Id.* (citing Ex. 1005, 2:10–20; Ex. 2021 ¶ 27). In support of Patent Owner's arguments, Dr. Baroud testifies that the Müller apparatus "is designed for use with open surgery such as hip replacement" and "cannot be used or even modified for intravertebral cement injection." Ex. 2021 ¶ 27 (citing Ex. 1005, 1:5–7, 2:10–20).

Patent Owner also argues that "the Muller apparatus either does not function as described in the Muller patent or does not work." PO Resp. 17 (citing Ex. 2021 ¶¶ 28–30). Petitioner's argument is based on the following statement in Müller:

> For "high pressure" injection, the nozzle element 6 is attached to the end of the cylinder tube 1 via the bayonet connection. As the piston 12 is then depressed, bone cement is expelled through the injection nozzle 3 into the reservoir 9 and then into the nozzle tube 7 which is of smaller cross-sectional area. *As a result, the pressure on the bone cement increases without a significant increase in the force supplied to the piston 12.*

Ex. 1005, 3:46–53 (emphasis added). Citing Dr. Baroud's Declaration, Patent Owner asserts that "the statement by Muller about the pressure applied on the cement increasing without a corresponding increase in the force supplied to the piston is physically impossible." PO Resp. 17 (citing Ex. 2021 ¶¶ 28–30). Patent Owner further argues:

> Petitioner's argument fails because the combination of the nozzle and ram cannot work as proposed without an increase in the force applied to the syringe. This absence of an increase in force as contended by the Petitioner would violate Newton's 3rd law. This violation is tantamount to changing the principle of operation of the reference. *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) – a proposed modification cannot change the principle of operation of a reference; *see also In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

Id. at 18.

We are not persuaded by Patent Owner's arguments. Patent Owner's argument that the 125-cc capacity of Müller's cylinder tube is too large for vertebrae does not acknowledge or explain Müller's disclosure that, with the nozzle element attached to the cylinder tube, the injector can be used to inject relatively small quantities of bone cement at a high pressure. Ex. 1005, 4:4–8. This capability of Müller's apparatus to inject relatively small quantities of bone cement at a high pressure is consistent with Müller's teaching that "during some surgical operations, it is necessary . . . to inject a small quantity of bone cement at relatively high pressure." *Id.* at 1:19–23. Patent Owner's argument, which focuses on the size of the cylinder tube, also does not take into account Müller's disclosure that the nozzle element can be detached from the cylinder tube and used with the

ram as a separate injector. *Id.* at 2:2–4. For these reasons, Patent Owner's argument that the Müller apparatus is designed to deliver large volumes of bone cement that would be inappropriate for vertebrae is unpersuasive.

We also are not persuaded by Patent Owner's argument that Müller's apparatus does not function as described or does not work. In particular, Petitioner has not explained why the nozzle element cannot be detached from the cylinder tube and used with the ram as a separate injector, as disclosed by Müller (*see* Ex. 1005, 2:2–4), regardless of the amount of force that must be applied to the syringe with the nozzle attached to the cylinder tube.

Further, Patent Owner's argument misreads Müller, which states merely that the pressure on the bone cement increases "without a significant increase" in the force supplied to the piston. Müller does not state, as Patent Owner argues, that the pressure applied on the cement increases "without a corresponding increase in the force supplied to the piston." We credit Dr. Jensen's testimony that a skilled artisan would understand Müller's statement as simply teaching that, if the nozzle is attached, pressing the piston results in "high pressure" injection and that, if the nozzle is not attached, pressing the piston results in "low-pressure" injection. Ex. 1041 ¶¶ 9–11. We also credit Dr. Jensen's testimony that, based on the entirety of Müller's disclosure, a person of ordinary skill in the art would understand that the Müller apparatus "functions as a simple syringe-like system" where the ram and nozzle "will work as an ordinary nozzle and stylet system already well known in the art at the time of the invention." *Id.* ¶ 12.

Based on the arguments and evidence of record, and for the reasons given, we conclude that Petitioner has shown by a preponderance of the evidence that claims 1 and 14 would have been obvious over Reiley '404 and Müller, in view of the knowledge of one of ordinary skill in the art. The cited evidence, including Dr. Jensen's testimony, supports Petitioner's contention that the dependent claims also would have been obvious over Reiley '404 and Müller, in view of the knowledge of one of ordinary skill in the art. *See* Pet. 34–37; Ex. 1002 ¶¶ 104–116. Patent Owner presents arguments only as to claims 1 and 14 and relies on those arguments as to dependent claims 2–3, 7, 10–13, and 15–17. *See* PO Resp. 18. For the reasons set forth in the Petition, the Reply, and our Decision to Institute, we conclude that Petitioner has shown, by a preponderance of the evidence, that dependent claims 2–3, 7, 10–13, and 15–17 would have been obvious over Reiley '404 and Müller, in view of the knowledge of one of ordinary skill in the art. *See* Pet. 34–37; Ex. 1002 ¶¶ 104–116; Dec. 18–19.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–3, 7, and 10–17 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Hofsess and claims 1–18 are unpatentable under 35 U.S.C. § 103(a) as obvious over Reiley '404 and Müller.

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–18 of U.S. Patent No. 7,153,307 B2 are unpatentable.

This is a Final Written Decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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