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Paper 34
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 IPR2014-01433
Patent 6,241,734 B1

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 Corrected Petition (Paper 4, "Petition" or "Pet.") for *inter partes* review of claims 1–21 of U.S. Patent No. 6,241,734 B1 (Ex. 1001, "the '734 Patent"). We instituted an *inter partes* review as to all of the challenged claims. Paper 11 ("Dec."), 2. After institution, Orthophoenix, LLC ("Patent Owner") filed a Patent Owner Response (Paper 19, "PO Resp."), to which Petitioner filed a Reply (Paper 24, "Pet. Reply").

An oral hearing was held on November 4, 2015. The transcript of the hearing has been entered into the record. Paper 33 ("Tr.").

The grounds for trial were as follows:

References	Basis	Claims Challenged
Deramond[1]	§ 102(b)	15, 16, 19, and 20
Deramond	§ 103(a)	1–21
Kuslich[2]	§ 103(a)	12

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] Hervé Deramond et al., *Percutaneous Vertebroplasty*, 1:2 SEMINARS IN MUSCULOSKELETAL RADIOLOGY 285–95 (June 1997) (Ex. 1003).

[2] U.S. Patent No. 5,549,679 to Kuslich, issued August 27, 1996 (Ex. 1009).

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 15, 16, 19, and 20 are unpatentable as anticipated by Deramond and claims 1–21 are unpatentable as obvious over Deramond; however, Petitioner has *not* shown, by a preponderance of the evidence, that claim 12 is unpatentable as obvious over Kuslich.

B. Related Proceedings

Petitioner is named as a defendant in a federal district court case involving the '734 Patent (*Orthophoenix, LLC. v. Stryker Corporation,* Case No. 13-1628-LPS (D. Del.)). Pet. 1; Paper 6, 2. Petitioner also is involved in an *inter partes* review (IPR2014-01434) of U.S. Patent No. 7,153,307 B2, which claims priority from the '734 Patent. Pet. 1; Paper 6, 2.

C. The '734 Patent

The '734 Patent relates to an apparatus for introducing material into bone through a subcutaneous cannula. Ex. 1001, 2:3–5. The apparatus includes a delivery device to convey the material at "a low delivery pressure," which is defined in the patent as "equivalent to the pressure at which liquid is expressed from [a] 1 cc syringe by the application of moderate force to the syringe piston, which amounts to a pressure that is no greater than about 360 psi." *Id.* at 2:5–10. A cavity forming instrument may

be deployed through the cannula to compress cancellous bone[3] and form a cavity. *Id.* at 3:17–19.

Figures 25 and 26 of the '734 Patent are reproduced below.

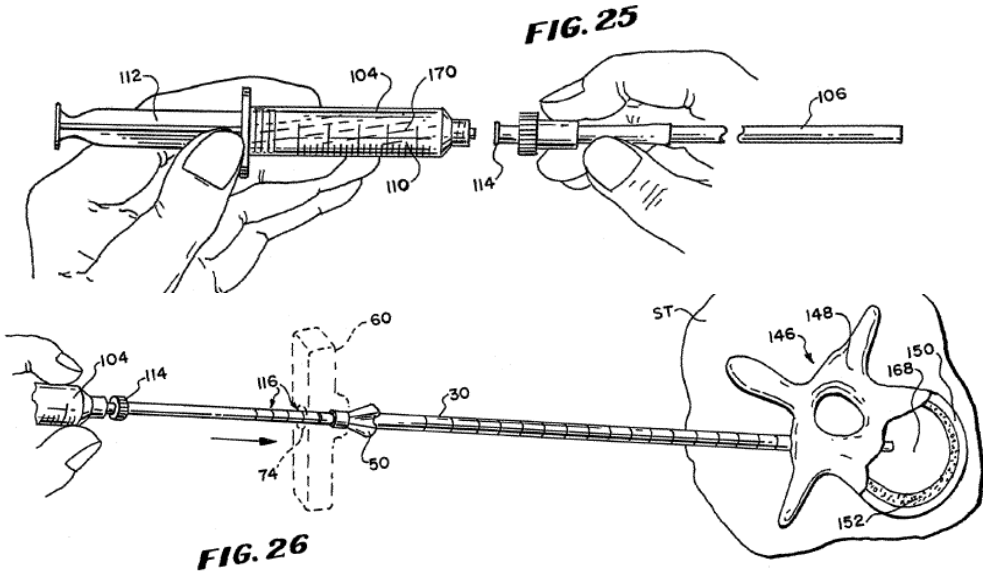

Figure 25 is a perspective view of conventional syringe 104 being joined to injection nozzle 106, and Figure 26 is a perspective view showing the nozzle being deployed through cannula instrument 30 such that the nozzle extends a selected distance beyond the distal end of the cannula instrument and into cavity 168 of vertebral body 148. *Id.* at 4:41–47, 10:32–33, 16:1–9.

As described in the patent, tamping instrument 108 is used to displace residual material that remains in the cannula instrument after the nozzle has been withdrawn. *Id.* at 16:42–59; Fig. 30.

[3] "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).

D. Illustrative Claim

Claims 1, 12, and 15 are independent. Claim 1 is illustrative of the claimed subject matter, and is reproduced below:

> 1. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including
>
> a subcutaneous cannula,
>
> a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,
>
> a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure, and
>
> a tamping instrument capable of advancement into the subcutaneous cannula and having a tamping terminus which, during the advancement, urges material residing in the subcutaneous cannula into bone.

Id. at 19:63–20:8.

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. "subcutaneous cannula"

In the Decision to Institute, we determined that the broadest reasonable interpretation consistent with the Specification of "subcutaneous cannula" is a cannula that has an interior lumen running throughout its entire length and that is capable of being extended through soft tissue into bone. Dec. 7. Neither party 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 instrument"

In the Decision to Institute, we determined that the broadest reasonable interpretation consistent with the Specification of "nozzle instrument" is a device with an opening through which fluid can be expelled. *Id.* at 8. Neither party 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. "a delivery device to convey the material at a delivery pressure of no greater than about 360 psi"

All the independent claims require "a delivery device to convey the material at a delivery pressure of no greater than about 360 psi," or the equivalent. Patent Owner contends that the "delivery device" limitation *excludes* any delivery device that is capable of conveying the material at a delivery pressure *greater than about 360 psi*. *See* PO Resp. 1, 14, 16, 19, 24; Tr. 40:24–41:8, 41:25–43:1, 43:24–46:3, 50:10–52:22. For example, Patent Owner contends that "2- or 3-cc syringes would have peak pressures exceeding 360 psi" and, therefore, do not meet the delivery device limitation, even though such syringes also can convey the material at a delivery pressure below 360 psi. PO Resp. 16; *see id.* at 9–10 (citing Ex. 2021 ¶¶ 18–24, 26).[4]

Petitioner replies that Patent Owner's "attempt to avoid the prior art by construing the claims to be inconsistent with the specification and to exclude the preferred embodiment is legally wrong." Pet. Reply 2. Petitioner asserts that the '734 Patent "makes clear that the preferred and only embodiment for the claimed low pressure delivery device is a

[4] Relying on testimony from its expert, Dr. Baroud, Patent Owner asserts, for example, that a physician can convey material in 2- and 3-cc syringes at delivery pressures within the range 339.69 psi to 703.69 psi, i.e., 521.69 psi +/- 182 psi. PO Resp. 9–10 (citing Ex. 2021 ¶¶ 18–24, 26).

'conventional syringe.'" *Id.* at 12. According to Petitioner, "conventional syringes are the claimed delivery device and need only be capable of conveying material at pressures no greater than 360 psi." *Id.* at 2; *see also id.* at 9 ("[A]s long as the prior art discloses a structure (e.g., a syringe) that is capable of performing the claimed function (e.g., conveying material at a pressure no greater than about 360 psi), the art satisfies the limitation.") (citing *In re Schreiber*, 128 F.3d 1473, 1478–79 (Fed. Cir. 1997)). Petitioner argues that "nothing in the patent or claims require[s] the delivery device to 'always . . . reside below 360 psi.'" *Id.* at 1–2.

We agree with Petitioner. The '734 Patent Specification discloses that applying "moderate force" to the piston of a 1-cc syringe can convey the bone-filling material at a delivery pressure less than, or equal to, 360 psi. Ex. 1001, 2:5–10 ("the pressure at which liquid is expressed from [a] 1 cc syringe *by the application of moderate force to the syringe piston* . . . is no greater than about 360 psi" (emphasis added)). A person of ordinary skill reading the Specification would understand, moreover, that applying more than just "moderate force" to the piston of a 1-cc syringe can convey the material at a delivery pressure higher than 360 psi. *Id.* At the oral hearing, Patent Owner agreed that a person of ordinary skill would have that understanding. Tr. 41:25–42:8. Accordingly, the patent disclosure supports Petitioner's argument that a delivery device capable of conveying the material at a delivery pressure less than, or equal to, 360 psi meets the delivery device limitation, even if the device also is capable of conveying the material at a delivery pressure higher than 360 psi.

Contradicting the patent disclosure that a 1-cc syringe is capable of conveying bone-filling material at a pressure less than 360 psi, Patent Owner asserts in its Patent Owner Response that "the delivery pressure generated in the 1-cc syringe, which is disclosed in the '734 patent and discussed by [Dr.] Jensen in her Declaration, is estimated to be in the range of 1640.76 +/- 575.24 psi," i.e., from 1065.52 psi to 2,216.00 psi. PO Resp. 10 (citing Ex. 2021 ¶ 25).[5] Dr. Baroud testifies in paragraph 24 of his Declaration, based on an analysis of the Krebs reference (Ex. 1012),[6] that "the delivery pressure generated in the 1-cc syringe is in the range of 1640.76 ± 575.24 psi," as Petitioner asserts. Ex. 2021 ¶ 24. Dr. Baroud also testifies, however, based on an analysis of the Hayward reference (Ex. 1011),[7] "that, with 68 percent confidence[,] the measured pressure of delivery [for the 1-ml syringe in Hayward] will be in the range 472-256=216 psi to 472+265= 728 psi." Ex. 2021 ¶ 25. Dr. Baroud does not explain whether there is any difference between the 1-ml syringe in Hayward and the 1-cc syringe in Krebs,[8] or otherwise reconcile the apparently-contradicting opinions in

[5] The citation to paragraph 25 of Dr. Baroud's Declaration is a clear typographical error. The correct citation is to paragraph 24.

[6] Jörg Krebs et al., *Clinical Measurements of Cement Injection Pressure During Vertebroplasty*, 30:5 SPINE E118–22 (2005) (hereinafter "Krebs").

[7] W.A.P. Hayward et al., *Pressure generated by syringes: implications for hydrodissection and injection of dense connective tissue lesions*, 40 SCAND. J. RHEUMATOL. 379–82 (2011) (hereinafter "Hayward").

[8] We note that "1 cc" and "1 ml" are equivalent units of measurement.

paragraphs 24 and 25 of his Declaration. Accordingly, we give his testimony regarding the 1-cc syringe in Krebs little weight.

Furthermore, as Petitioner argues, the Specification describes a preferred embodiment in which "the material is injected by use of a conventional syringe 104." Ex. 1001, 10:32–33; *see* Pet. Reply 5. As described, conventional syringe 104 conveys the material at low delivery pressure, i.e., "no greater than 360 psi." Ex. 1001, 16:65–67. The description in the Specification of conventional syringe 104 is consistent with Petitioner's contention that "the claimed delivery device . . . need only be capable of conveying material at pressures no greater than 360 psi." Pet. Reply 2. At the oral hearing, Patent Owner conceded that the conventional syringe disclosed in the Specification is capable of conveying material at pressures either lower or higher than 360 psi. Tr. 51:10–52:22.

For these reasons, we determine that the broadest reasonable interpretation consistent with the Specification of "a delivery device to convey the material at a delivery pressure of no greater than about 360 psi" is a delivery device that is capable of conveying the material at a delivery pressure less than, or equal to, about 360 psi, and does not exclude such a device if it also is capable of conveying the material at a delivery pressure greater than about 360 psi.

B. Anticipation of Claims 15, 16, 19, and 20 by Deramond

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).

Petitioner contends that Deramond anticipates claims 15, 16, 19, and 20. Pet. 11. Deramond describes tools used in vertebroplasty procedures where bone cement is delivered through needles into vertebral bodies weakened by disease. Ex. 1003, 285–290. Patent Owner presents arguments only as to independent claim 15 and relies on those arguments as to dependent claims 16, 19, and 20. PO Resp. 14.

Petitioner provides argument and a claim chart, supported by the testimony of its expert, Dr. Jensen, demonstrating that Deramond discloses, expressly or inherently, each limitation of claims 15, 16, 19, and 20. Pet. 11–17; Ex. 1002 ¶¶ 56–68. Claim 15 recites:

> 15. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus comprising a subcutaneous cannula, a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi, and a tamping instrument having a tamping terminus which, during advancement of the tamping instrument in the subcutaneous cannula, urges material residing in the subcutaneous cannula into bone.

Ex. 1001, 20:63–21:3.

1. "a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi"

With respect to the "delivery device" limitation, Petitioner asserts, and we agree, that Deramond discloses 2- and 3-cc luer-lock syringes, and that those syringes, inherently, are capable of conveying bone-filling material into a subcutaneous cannula at a delivery pressure less than, or equal to, about 360 psi. Pet. 12–14 (citing Ex. 1002 ¶¶ 40, 59, 61; Ex. 1003, 285; Ex. 1011 (Hayward), 379; Ex. 1012 (Krebs), E1118). These facts are undisputed. *See* PO Resp. 9–10 (asserting, based on testimony from Dr. Baroud (Ex. 2021 ¶ 23), that a physician can convey material in 2- and 3-cc syringes at delivery pressures within the range 339.69 psi to 703.69 psi); Tr. 51:10–52:22.

In response, Patent Owner argues that "the pressures in Deramond are not inherently constrained to remain below [about 360 psi]" and "do not always necessarily reside below 360 psi, negating any inherency." PO Resp. 1, 13. Patent Owner also argues that Deramond's 2- and 3-cc syringes are capable of conveying bone-filling material at a delivery pressure considerably greater than 360 psi and, therefore, do not meet the delivery pressure limitation, even though such syringes also can convey material at a delivery pressure below 360 psi. *See supra* Section II.A.3; PO Resp. 9–10 (citing Ex. 2021 ¶¶ 18–24, 26). Based on these arguments, Patent Owner contends that Petitioner has failed to demonstrate that Deramond discloses the "delivery device" limitation of claim 15 (and claims 16, 19, and 20, which depend from claim 15). PO Resp. 13–14.

Patent Owner's arguments are based on an erroneous claim construction. As interpreted above, the "delivery device" limitation requires a delivery device that is capable of conveying bone-filling material at a delivery pressure less than, or equal to, about 360 psi, and does not exclude such a device if it also is capable of conveying the material at a delivery pressure greater than about 360 psi. It is undisputed that Deramond's 2- and 3-cc syringes are capable of conveying bone-filling material at a delivery pressure less than, or equal to, about 360 psi, which is all that the delivery pressure limitation requires under a proper claim interpretation.

2. "a subcutaneous cannula"

Dr. Jensen testifies, and we agree, that Deramond discloses the use of 10- and 15-gauge needles as subcutaneous cannulas for introducing material into bone. Ex. 1002 ¶ 65. Patent Owner does not challenge Dr. Jensen's testimony. PO Resp. 9–14.

3. "a tamping instrument having a tamping terminus which, during advancement of the tamping instrument in the subcutaneous cannula, urges material residing in the subcutaneous cannula into bone"

With respect to the "tamping instrument" limitation, Dr. Jensen testifies, and we agree, that Deramond discloses the use of a mandrel or stylet as a tamping instrument:

> The Deramond Article describes the use of a mandrel (stylet) as a tamping instrument, i.e., after cement is delivered through the cannula, the mandrel is inserted into the needle urging residual material in the cannula into the vertebral body: "Once the cement injection is achieved, the needle is slowly pulled back to the cortical bone while pushing the mandred [sic, mandrel] into

> the needle." (p. 287.) The mandrel is a tamping instrument and the end of the mandrel is the tamping terminus. An example of a mandrel/stylet in the cannula is shown in Figure 4A, p. 288. Moreover, a photograph after tamping is shown in Figure 4F, p. 290 . . . .

Ex. 1002 ¶ 65. Patent Owner does not challenge Dr. Jensen's testimony. PO Resp. 9–14.

Based on the evidence set forth in the Petition, and for the reasons given, we conclude that Petitioner has shown, by a preponderance of the evidence, that Deramond anticipates claims 15, 16, 19, and 20.

C. Obviousness of Claims 1–21 over Deramond

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.[9] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Petitioner contends that Deramond, in view of the knowledge of a person of ordinary skill in the art, renders obvious each of claims 1–21. Pet. 17–27; Ex. 1002 ¶¶ 69–93. 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 734 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. 17–18 (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.

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

1. Claim 1

Petitioner asserts that all but two of the limitations of claim 1 overlap the limitations of claim 15. *Id.* at 18. With respect to the overlapping limitations, including the delivery pressure limitation, Petitioner largely relies upon its anticipation analysis, discussed above. *Id.*; *see supra* Section II.B. The two non-overlapping limitations are: (1) a nozzle instrument that is capable of advancement into the subcutaneous cannula, and that comprises a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure; and (2) a tamping instrument capable of advancement into the subcutaneous cannula. *Id.* As discussed below, Petitioner asserts that Deramond discloses, or suggests, both the nozzle and tamping instrument limitations. *Id.* at 18–19. Dr. Jensen supports Petitioner's obviousness contentions as to claim 1 with testimony and a claim chart. Ex. 1002 ¶ 71.

Dr. Jensen testifies that Deramond, in Figure 4A, discloses a coaxial embodiment for removing cancellous bone, where a 10-gauge needle is used as a subcutaneous cannula and a 15-gauge needle (with stylet) is advanced through the 10-gauge needle. *Id.* (citing Ex. 1003, Fig. 4A). Dr. Jensen also testifies that Deramond, in Figure 1, discloses a different embodiment utilizing a 15-gauge needle for delivering cement, where a "luer-lock syringe is coupled to the 15-gauge needle and cement is delivered through the 15-gauge needle to the vertebral body through the terminus at the delivery pressure." *Id.* In Dr. Jensen's opinion, given Deramond's disclosure of

using a 15-gauge needle for delivering cement, a person of ordinary skill would have used Deramond's coaxial embodiment for delivering cement as well as removing cancellous bone. *Id.* Dr. Jensen explains:

> This type of coaxial system was well known at the time the '734 patent was filed. Because it may be more desirable to access a part of the vertebral body with a smaller needle, a physician would be motivated to deliver cement in this coaxial system if he or she wanted delivery to a precise location (e.g., to a metastasis).

Id. We agree with Dr. Jensen's rationale for combining the two embodiments in Deramond; and we further agree, as Petitioner asserts, that Deramond discloses, or suggests: the luer-lock syringe includes a "proximal fitting"; the 10-gauge needle is a "subcutaneous cannula"; the 15-gauge needle corresponds to the "nozzle instrument"; and the mandrel or stylet (discussed *supra* in Section II.B.3) is a "tamping instrument." Pet. 18–19; *see* Ex. 1002 ¶¶ 70–71.

Patent Owner responds that the requirement for a delivery device having a delivery pressure of "no greater than about 360 psi" is not met by Deramond. PO Resp. 16. As discussed above, however, Patent Owner's arguments are based on an erroneous claim construction, and we are persuaded that Deramond's 2- and 3-cc luer-lock syringes, inherently, disclose the "delivery device" limitation. *See supra* Section II.B.1. Furthermore, we are persuaded that substituting a conventional syringe meeting the "delivery device" limitation for Deramond's 2- or 3-cc luer-lock syringe would have amounted to the mere substitution of one element for another known in the field, to yield predictable results. *See* Pet. 21; *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)).

For the reasons given, we conclude that Petitioner has shown, by a preponderance of the evidence, that claim 1 would have been obvious over Deramond.

2. Claim 12

Claim 12 contains limitations similar to claims 1 and 15, but also recites a "nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure," a "stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore," and a "tamping instrument" (formed by combining the nozzle instrument with the stylet) to urge residual material from the subcutaneous cannula. Ex. 1001, 20:48–55; *see* Pet. 19–21. With respect to those limitations, we agree with Dr. Jensen's obviousness analysis:

> Deramond discloses a coaxial embodiment where a 15-gauge needle is inserted into a 10-gauge needle with a stylet shown within the 15-gauge needle. (See Figure 4A.) The article separately explains that material can be delivered through a 15-gauge needle (Fig. 1). . . . [I]t would have been obvious to a person of ordinary skill in the art that material could be delivered (as well as removed) with the coaxial embodiment with the 15-gauge needle serving as a nozzle in that context. Likewise, a person of ordinary skill in the art would have understood that the stylet within the 15-gauge needle (shown in Fig. 4A) could be nested with the 15-gauge needle to form a tamping instrument for the 10-gauge cannula.

Ex. 1002 ¶ 72.

Patent Owner responds that the co-axial embodiment disclosed in Deramond is not capable of performing the functional requirements recited in claim 12. PO Resp. 14–20; *see* Ex. 2021 ¶¶ 30–33. In particular, Patent Owner asserts that Deramond's 15-gauge needle is 5 cm – 7 cm in length, while Deramond's 10-gauge needle is 10 cm – 15 cm in length, and, thus, the 15-gauge needle (alleged nozzle instrument) cannot serve as a tamping instrument (in combination with the stylet) to urge residual material from the 10–gauge needle (alleged subcutaneous cannula), as required by the claim. PO Resp. 17; *see* Ex. 2021 ¶ 30 (citing Ex. 1003, 2). Further, Patent Owner argues that the outer diameter of the 15-gauge needle is 1.829 mm, while the inner diameter of the 10-gauge needle is 2.692 mm, allowing for the existence of a space between the needles. PO Resp. 18; *see* Ex. 2021 ¶¶ 31–32. Patent Owner argues:

> Even assuming for the sake of argument that a stylet occupied the entire internal space of a 15-gauge needle as well as extended beyond the 15-gauge needle and beyond the 10-gauge needle, the space between the 10-gauge and 15-needles would remain. [Ex. 2021 ¶¶ 31–34]. If material such as [polymethylmethacrylate (PMMA) bone cement] were delivered through the 15-gauge needle, the material would leak into the space between the 10- and 15-gauge needles. *Id.* Thus, the 15-gauge needle together with the stylet could not be used as a tamp to effectively push material out of the 10-gauge needle (cannula) because the material would back up into the space between the 10-gauge needle and the 15-gauge needle. *Id.*

PO Resp. 18. Patent Owner further argues that a person of ordinary skill would not have used the co-axial arrangement for delivery of cement because "the geometry of the 10-gauge and 15-gauge needles is such that this arrangement is impossible." *Id.* at 19.

Petitioner replies that Patent Owner's "geometric" arguments are incorrect. Pet. Reply 17–21. With respect to the length of the 15-gauge needle depicted in Figure 4A of Deramond, Petitioner argues, and we agree, that the 15-gauge needle is shown extending beyond the 10-gauge needle. *Id.* at 17–18 (citing Ex. 1003, Fig. 4A; Ex. 1002 ¶ 64; Ex. 1041 ¶ 9). In deposition, Patent Owner's expert, Dr. Baroud, conceded this point. Ex. 1040, 239:19–240:2. We are persuaded that Figure 4A depicts a 15-gauge needle that is longer than the 10-gauge needle.

With respect to the diameter of the 15-gauge needle, we agree with Petitioner that claim 12 does not require "any particular level of tamping 'effectiveness' or that there be no space between the tamping instrument and the subcutaneous cannula." Pet. Reply 19. Further, Dr. Jensen testifies persuasively that the residual material could be cleared from the cannula by repeatedly pushing the tamping instrument (formed by combining the 15-gauge needle with the stylet) within the lumen of the 10-gauge needle. Ex. 1041 ¶ 10.

Patent Owner also argues that the requirement for a delivery device having a delivery pressure of "no greater than about 360 psi" is not met by Deramond. PO Resp. 16. As discussed above, however, we are persuaded that Deramond's 2- and 3-cc luer-lock syringes, inherently, disclose the "delivery device" limitation. *See supra* Section II.B.1. We also are

persuaded that substituting a conventional syringe meeting the "delivery device" limitation for Deramond's 2- or 3-cc luer-lock syringe would have amounted to the mere substitution of one element for another known in the field, to yield predictable results. *See supra* Section II.C.1.

For the reasons given, we conclude that Petitioner has shown, by a preponderance of the evidence, that claim 12 would have been obvious over Deramond.

3. Claim 15

To support its challenge of claim 15 as obvious over Deramond, Petitioner relies upon its anticipation analysis, discussed above. Pet. 21; *see supra* Section II.B. We agree with Petitioner's argument that the "delivery device" limitation would have been obvious to a skilled artisan:

> [I]t would have been obvious to select "a delivery device to convey the material at a pressure no greater than about 360 psi" (which the 734 patent describes as a "conventional syringe") since the use of such devices at such pressures were well known in the art and the skilled artisan would be motivated to select, and would prefer, such pressures for controlled delivery of cement. (Jensen Decl. at ¶¶ 39, 40, 69 n. 5, 164, 165; *see also* footnote 6.)

Pet. 21.

Patent Owner responds that the requirement for a delivery device having a delivery pressure of "no greater than about 360 psi" is not met by Deramond. PO Resp. 16. As discussed above, however, we are persuaded that Deramond's 2- and 3-cc luer-lock syringes, inherently, disclose the "delivery device" limitation. *See supra* Section II.B.1. We also are persuaded that substituting a conventional syringe meeting the "delivery

device" limitation for Deramond's 2- or 3-cc luer-lock syringe would have amounted to the mere substitution of one element for another known in the field, to yield predictable results. *See supra* Section II.C.1.

For the reasons given, we conclude that Petitioner has shown, by a preponderance of the evidence, that claim 15 would have been obvious over Deramond.

4. Claims 2–11, 13, 14, and 16–21

Patent Owner presents arguments only as to independent claims 1, 12, and 15 and relies on those arguments as to dependent claims 2–11, 13, 14, and 16–21. PO Resp. 20. Dr. Jensen's testimony supports Petitioner's contention that the dependent claims would have been obvious over Deramond. Ex. 1002 ¶¶ 73–92. For the reasons set forth in the Petition and the Decision to Institute, we conclude that Petitioner has shown, by a preponderance of the evidence, that claims 2–11, 13, 14, and 16–21 would have been obvious over Deramond. *See* Pet. 21–27; Dec. 15–16.

D. Obviousness of Claim 12 over Kuslich

Petitioner challenges claim 12 as obvious over Kuslich in view of the knowledge of a person of ordinary skill in the art. Pet. 56–60. As discussed above, claim 12 requires, *inter alia*, a "nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure," a "stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore," and a "tamping instrument" (formed by combining the nozzle instrument with the stylet) to urge residual material from the subcutaneous cannula. Ex. 1001, 20:48–55.

Kuslich discloses boring a cavity through a disc and the adjoining vertebrae, inserting expandable bag 40 into the cavity through guide tube 54, and then filling bag 40 with graft medium or fill material. Ex. 1009, Fig. 5, 8:3–11, 9:10–12, 62–63. Kuslich also discloses using gun-like device 90 with plunger 96 to inject graft material from a cartridge into bag 40. Ex. 1009, 10:19–36. Figures 34 and 35 of Kuslich are reproduced below.

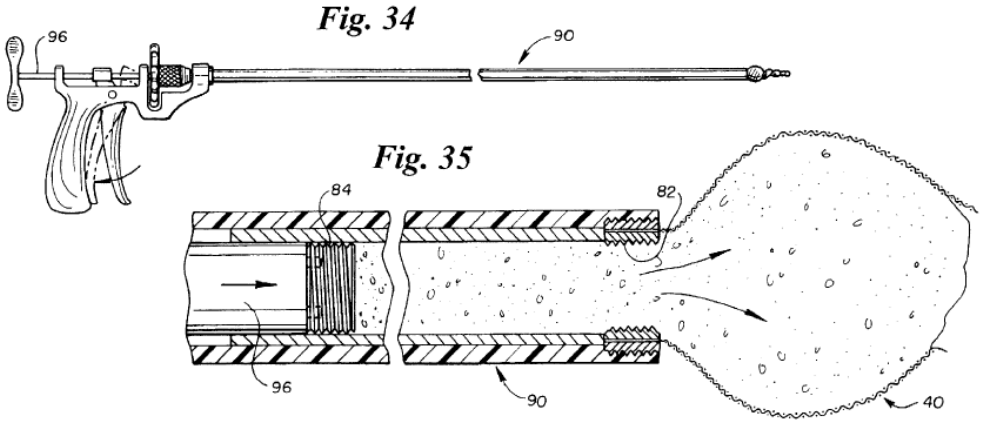

Figure 34 depicts using the gun-like device to fill the bag, and Figure 35 depicts a cross-section of the end of the device. *Id.* at 5:30–32. As shown in Figure 35, the bag includes a threaded fill port with internal threads 82 to receive threaded screw 84. *Id.* at 10:20–22. Plunger 96 pushes screw 84 along with the graft material towards bag 40 and, at the end of the stroke, turns the screw to seal the bag. *Id.* at 10:31–34.

According to Petitioner, Kuslich discloses all the limitations of claim 12 except it does not specify any particular delivery pressure for device 90. Pet. 57; *see id.* at 59–60; Ex. 1002 ¶ 166. As discussed below, we are *not* persuaded that Kuslich discloses or suggests a "tamping

instrument," formed by combining the nozzle instrument with the stylet, to urge residual material from the subcutaneous cannula, as the claim requires.

Petitioner asserts that guide tube 54 is a "subcutaneous cannula," the barrel of Kuslich's gun-like device 90 is a "nozzle," and "plunger 96 is a stylet that is advanced through the nozzle, closing the nozzle bore." Pet. 59–60. Nowhere does Petitioner even assert, however, that plunger 96 and the barrel of device 90 are capable of use, together, as a tamping instrument to urge residual material from guide tube 54, as required by claim 12. *See* Pet. 57–60; Pet. Reply 21–24; Ex. 1002 ¶ 166; Ex. 1041 ¶¶ 12–14.

Moreover, Patent Owner argues persuasively that residual materials do not accumulate in Kuslich's guide tube 54. PO Resp. 24 (citing Ex. 1009, Fig. 21). Patent Owner asserts: "After extrusion of the bag, there are no residual materials left in the delivery tube device. The plunger . . . empties all graft materials into the bag." *Id*. Patent Owner's argument is consistent with Kuslich's teaching to insert the unexpanded bag into the cavity before injecting the graft materials into the bag. *E.g.*, Ex. 1009, 12:5–27. As such, materials would not leak from the bag into the guide tube 54. Petitioner has not addressed this argument, or otherwise shown how residual materials would accumulate in Kuslich's guide tube 54, or, if they did, why or how they should be expelled. Pet. Reply 21–24; Ex. 1041 ¶¶ 12–14; *see* Pet. 57–60; Ex. 1002 ¶ 166.

For the reasons given, we conclude that Petitioner has *not* shown, by a preponderance of the evidence, that claim 12 would have been obvious over Kuslich.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 15, 16, 19, and 20 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Deramond and claims 1–21 are unpatentable under 35 U.S.C. § 103(a) as obvious over Deramond. We further determine that Petitioner has *not* shown, by a preponderance of the evidence, that claim 12 is unpatentable under 35 U.S.C. § 103(a) as obvious over Kuslich.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–21 of U.S. Patent No. 6,241,734 B1 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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