Trials@uspto.gov
Tel: 571-272-7822

Paper 11
Entered: February 12, 2015

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*.

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

I. INTRODUCTION

Stryker Corporation ("Petitioner") filed a Corrected Petition (Paper 4, "Pet.") requesting an *inter partes* review of claims 1–21 of U.S. Patent No. 6,241,734 B1 (Ex. 1001, "the '734 Patent"). Orthophoenix, LLC ("Patent Owner") filed a Preliminary Response (Paper 10, "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 1–21 of the '734 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 '734 Patent (*Orthophoenix, LLC. v. Stryker Corporation,* Case No. 13-1628-LPS (D. Del.)). Pet. 1; Paper 6, 2. Petitioner also has filed a petition seeking an *inter partes* review with respect to U.S. Patent No. 7,153,307 B2, which claims priority from the '734 Patent. Pet. 1; Paper 6, 2; *see* Case IPR2014-01434, Paper 1.

B. 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 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 and form a cavity. *Id.* at 3:17–19.

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

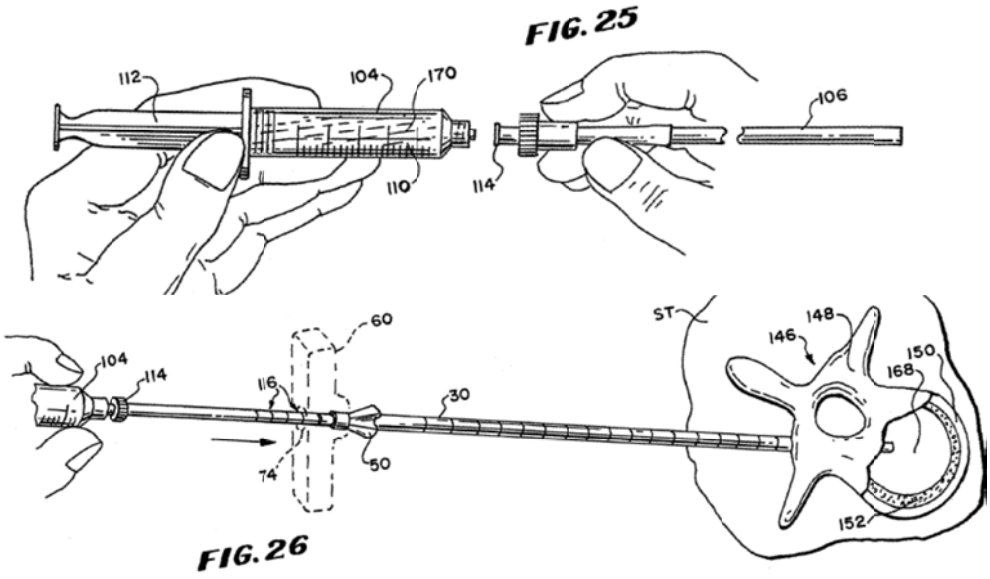

Figure 25 is a perspective view of conventional syringe 104 being joined to injection nozzle 106, and Figure 26 is a perspective view showing the nozzle being deployed through cannula instrument 30 such that the nozzle extends a selected distance beyond the distal end of the cannula instrument and into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

As described in the Specification, 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.

C. Illustrative Claim

Claims 1, 12, and 15 are independent. Claim 1 is illustrative 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.

D. The Asserted References

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

Clark	US 4,801,263	Jan. 31, 1989	Ex. 1004
Müller	US 4,576,152	Mar. 18, 1986	Ex. 1005
Reiley ’404	US 5,108,404	Apr. 28, 1992	Ex. 1006
Reiley II	WO 96/39970 A1	Dec. 19, 1996	Ex. 1007
Baumgartner	CA 2,121,001 A1	Oct. 22, 1994	Ex. 1008
Kuslich	US 5,549,679	Aug. 27, 1996	Ex. 1009

Deramond	Hervé Deramond et al., *Percutaneous Vertebroplasty*, 1:2 Seminars in Musculoskeletal Radiology, 285–95 (June 1997)	June 1997	Ex. 1003

E. The Asserted Grounds

Petitioner challenges claims 1–21 of the '734 Patent on the following grounds (Pet. 3):

Reference(s)	Basis	Claims Challenged
Deramond	§ 102(b)	15, 16, 19, and 20
Deramond	§ 103(a)	1–21
Clark	§ 102(b)	1, 3, and 15
Clark	§ 103(a)	2, 4, 5, 7, 8, 16, 17, and 19
Müller	§ 102(b)	15, 16, and 19
Müller and Reiley '404	§ 103(a)	1–21
Müller and Reiley II	§ 103(a)	1–21
Müller and Baumgartner	§ 103(a)	1–21
Kuslich	§ 103(a)	12

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. "Subcutaneous cannula"

Claims 1 and 12 each recite "[a]pparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a subcutaneous cannula . . . ." Claim 15 contains nearly identical language. Patent Owner contends that "the cannula is a device that establishes a subcutaneous path through soft tissue into bone. The cannula has an interior lumen running throughout its entire length." Prelim. Resp. 14.

Petitioner's Declarant, Mary E. Jensen, M.D., uses "subcutaneous" to "refer to access below the skin." Ex. 1002, 15 n.1. Petitioner otherwise does not propose an express claim construction for "subcutaneous cannula."

We are persuaded that the Specification largely supports Patent Owner's proposed claim construction. *See*, *e.g.*, Ex. 1001, Abstract: 1–3, 6:1–3, 11–13, 42–44. We note, moreover, that the prosecution history also

lends support to that construction. To traverse a rejection by the Examiner over two prior art references, Coutts[1] and Yao[2], Patent Owner argued:

> Coutts is directed to the fixation of a rod implanted in a long bone (i.e., the femur). The distal end of the implanted rod is anchored to the distal end of the bone by introducing cement through a bore in the rod. Coutts does not teach or suggest apparatus for introducing material into bone through a subcutaneous cannula (i.e., a cannula that extends through soft tissue into bone). Coutts deploys a rod implanted directly into exposed bone (i.e., in an open procedure) (see, e.g., column 19, lines 58 to 60). In Coutts, there is no subcutaneous cannula.

Sept. 18, 2000 Amendment 3, Ex. 1027, 83. During prosecution, therefore, Patent Owner confirmed that a "subcutaneous cannula" must be capable of being extended through soft tissue into bone. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) ("[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.") (citations omitted).

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.

[1] US 5,514,137.
[2] US 5,989,260.

2. "Nozzle instrument"

Claims 1 and 12 recite "a nozzle instrument." Petitioner does not propose any express construction for that term. Patent Owner contends that "the 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. 16 (citing Ex. 1001, 10:52–67, 11:1–5). We are not persuaded, however, that any of the exemplary embodiments from the Specification should be read into our interpretation of the claim term "nozzle instrument." *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 instrument" is a device with an opening through which fluid can be expelled. *See, e.g.*, Ex. 1001, 16:14–16, 30–33, Fig. 27.

At this stage of the proceeding, none of our determinations regarding Petitioner's proposed grounds of unpatentability requires us to construe any other claim term expressly.

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

Petitioner challenges claims 15, 16, 19, and 20 as anticipated by Deramond. Pet. 11–17. 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). As discussed below, we are persuaded on the current record that Deramond anticipates the challenged claims.

Petitioner and its Declarant, Mary E. Jensen, M.D., assert that Deramond discloses all of the recited features of claims 15, 16, 19, and 20. Pet. 16–17; Ex. 1002 ¶¶ 65–68. Petitioner relies on Dr. Jensen's testimony to explain the manner in which Deramond discloses an "[a]pparatus for introducing material into bone . . . comprising . . . *a delivery device to convey the material at a delivery pressure of no greater than about 360 psi* (emphasis added)," as recited in independent claim 15. *Id.* at 13–14, n. 5, n. 6 (citing Ex. 1002 ¶¶ 40, 61; Ex. 1003, 285; Ex. 1011,[3] 379; Ex. 1012,[4] E1118). Petitioner asserts that Deramond expressly discloses 2- and 3-cc luer-lock syringes and that those syringes are capable of conveying bone-filling material into a subcutaneous cannula at a delivery pressure of no greater than about 360 psi. *Id.*; Ex. 1002 ¶¶ 39–40, 61, 65 (claim chart).

[3] 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").
[4] Jörg Krebs et al., *Clinical Measurements of Cement Injection Pressure During Vertebroplasty*, 30:5 Spine E118–22 (2005) (hereinafter "Krebs").

Petitioner also asserts that the Specification of the '734 Patent "expressly identifies a 'conventional syringe' as the delivery device" and "notes that 'the pressure at which liquid is expressed from a 1 cc syringe by the application of moderate force . . . amounts to a pressure that is no greater than about 360 psi.'" *Id*. at 13–14 (citing Ex. 1001, 2:7–11, 10:33–39).

In response, Patent Owner argues that Petitioner and Dr. Jensen have not shown that Deramond discloses the "no greater than about 360 psi" limitation. Prelim. Resp. 24–28. Patent Owner asserts that Petitioner improperly relies on extrinsic evidence, in the form of Dr. Jensen's Declaration, to fill the gap in Deramond's disclosure. *Id.* at 25. Patent Owner also asserts that Dr. Jensen, in turn, mistakenly relies in her Declaration on two references—Hayward and Krebs. *Id.* at 25–27. Patent Owner argues that Hayward is not prior art to the challenged claims, and that the data in Krebs is unreliable. *Id.*

Upon review of the record at this preliminary stage of the proceeding, we are persuaded that the syringes disclosed in Deramond necessarily function in accordance with the "no greater than about 360 psi" limitation and, therefore, inherently disclose that limitation. *See In re Cruciferous Sprout Litig.*, 301 F.3d at 1349 ("It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it."). We also are persuaded that Petitioner and Dr. Jensen do not rely on Hayward as prior art, but rather as evidence that the prior art syringes disclosed in Deramond necessarily function in accordance with the limitation on delivery pressure.

We appreciate, as Patent Owner asserts (Prelim. Resp. 10–11, 26–27), that the Patent Office previously reexamined the '734 Patent and determined that: (1) "none of the alleged anticipatory references cited by the third party requester, including . . . Deramond, disclose delivery pressure and any limitation to delivery pressure;" and (2) "the additionally cited prior art references fail to provide sufficient extrinsic evidence to support an argument that the characteristic 'at a delivery pressure of no greater than about 360 psi' is inherent in any of the alleged anticipatory references." Aug. 24, 2006 Notice of Intent to Issue a Reexamination Certificate 2, Ex. 2006, 1. The current record, however, is different from the reexamination record, and contains persuasive evidence that the limitation on delivery pressure is inherent in Deramond.

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its challenge that Deramond anticipates claims 15, 16, 19, and 20.

C. Asserted Obviousness of Claims 1–21 over Deramond

Petitioner challenges claims 1–21 as obvious over Deramond in view of the knowledge of an ordinarily skilled artisan. Pet. 17–27. 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.

Here, Petitioner and its Declarant, Dr. Jensen, assert that Deramond renders obvious each of claims 1–21 in view of the knowledge of a person of ordinary skill in the art. Pet. 17–27; Ex. 1002 ¶¶ 13 (providing testimony on the level of skill in the art), 69–93.

With respect to claim 1, for example, Petitioner asserts that Deramond discloses or suggests the following: a conventional luer-lock syringe (alleged "delivery device") capable of conveying material at a delivery pressure of no greater than about 360 psi; 10- and 15-gauge needles, the 15-gauge needle (alleged "nozzle instrument") being capable of advancement into the 10-gauge needle (alleged "subcutaneous cannula"); a "proximal fitting" to couple the 15-gauge needle to the syringe; a "nozzle terminus" through which material conveyed by the syringe enters bone; and a mandrel or stylet (alleged "tamping instrument" having a "tamping terminus") capable of advancement into the 10-gauge needle and urging residual material into bone. Pet. 18–19; *see* Ex. 1002 ¶¶ 70–71.

With respect to the independent claims, Patent Owner responds that "Deramond lacks any indication of a specific limitation on the delivery pressure." Prelim. Resp. 28. As discussed above, however, we are persuaded on the record at this preliminary stage of the proceeding that Deramond inherently discloses that limitation. Moreover, we are persuaded on this record that a person of ordinary skill in the art would have known that a conventional syringe is capable of conveying material at a delivery pressure of no greater than about 360 psi. *See* Pet. 13–14; Ex. 1002, 39–40; *see also* Ex. 1001, 11:9–11 (disclosing that conventional syringe 104 ejects material in a "low pressure stream"), 16:65–17:2 (describing the "low pressure" applied by conventional syringe 104 and tamping device 108 as "no greater than 360 psi").

Patent Owner also argues that "Deramond lacks a cannula and a nozzle" and "there is no indication that [Deramond's 15-gauge] biopsy needle is even suitable or could have been adapted for the purposes envisioned by the '734 patent." *Id.* at 30. That argument, however, fails to address Dr. Jensen's testimony that: Deramond "explains that material can be delivered through a 15-gauge needle;" and "a person of ordinary skill in the art would have understood 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." Ex. 1002 ¶ 71 (citing Ex. 1003, Fig. 1).

Patent Owner's argument that "Deramond also lacks a 'tamping instrument'" (Prelim. Resp. 30) does not address Dr. Jensen's testimony

with respect to claim 1 (or similarly with respect to claim 15) that Deramond's mandrel or stylet satisfies that requirement:

> 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 as discussed above.

Ex. 1002 ¶¶ 65 (claim 15 analysis), 71 (incorporating claim 15 analysis).

Patent Owner also does not address Dr. Jensen's testimony with respect to claim 12. Claim 12 contains limitations similar to claims 1 and 15, but also recites a "nozzle bore," a "stylet capable of advancement into the nozzle bore . . . 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. With respect to those limitations, Dr. Jensen testifies:

> 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. 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, 12, and 15 as obvious over Deramond.

For the reasons discussed below, we also determine that Petitioner has established a reasonable likelihood of prevailing on its challenge to dependent claims 2–11, 13–14, and 16–19 as obvious over Deramond in view of the knowledge of a person of ordinary skill in the art. We are persuaded on the current record as follows.

Deramond discloses a "syringe" as recited in claims 4, 14, and 16. *See* Ex. 1002 ¶ 78.

Deramond discloses the "generally rigid" limitations of claims 3, 7, and 19. *See id.* ¶¶ 76, 86.

A nozzle instrument that is "generally flexible" as recited in claim 2 would have been an obvious design choice/substitution based on evidence that "[n]ozzles made of both flexible and rigid materials were . . . conventional, off-the-shelf options available to the ordinary skilled artisan by August 1998." *Id.* ¶ 75; *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)).

Adding the "markings" required by claims 5 and 17 (as well as claims 8 and 13) would have been obvious based on evidence that it was known 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 ¶¶ 80, 87; *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 needles and stylets disclosed in Deramond are made of metal and thus satisfy the "radiopaque marker" requirement of claims 6, 9, and 18. *See* Ex. 1002 ¶ 82.

Deramond discloses the "cavity forming instrument" of claims 10 and 20. *See id.* ¶ 90.

A cavity forming instrument that includes "expandable structures" as required by claims 11 and 21 would have been obvious based on evidence that "at the time of the invention (August 1998), balloon-assisted vertebroplasty (or kyphoplasty) was known in the art." *Id.* ¶ 91; *see also KSR*, 550 U.S. at 417 (stating that a predictable variation likely would have been obvious to a person of ordinary skill in the art).

D. Asserted Anticipation or Obviousness Based on Clark

Petitioner challenges claims 1, 3, and 15 as anticipated by Clark and claims 2, 4, 5, 7, 8, 16, 17, and 19 as obvious over Clark in view of the knowledge of a person of ordinary skill in the art. Pet. 27–34. Clark discloses "an osseous implant syringe having a cross-sectional diameter that fits easily into graft sites through very small incisions." Ex. 1004, 2:12–15;

see Pet. 38 (claim chart); Ex. 1002 ¶ 97 (claim chart). Petitioner has not persuaded us that Clark's nozzle member is a "subcutaneous cannula" as required by the challenged claims, i.e., a cannula that is capable of being extended through soft tissue into bone. *See* section II.A.1 *supra*. In particular, Petitioner has not explained why the graft sites and small incisions disclosed in Clark necessitate extension of Clark's device through soft tissue into bone, as opposed to being inserted directly into exposed bone (i.e., in an open procedure). We determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge to claims 1, 3, and 15 as anticipated by Clark and claims 2, 4, 5, 7, 8, 16, 17, and 19 as obvious over Clark.

E. Asserted Anticipation of Claims 15, 16, and 19 by Müller

Petitioner challenges claims 15, 16, and 19 as anticipated by Müller. Pet. 35–39. Müller relates to "an injector for injecting expandable bone cement into a surgically prepared bone cavity." Ex. 1005, 1:5–7. For reasons similar to those discussed above with respect to Clark, Petitioner has not persuaded us that Müller discloses a "subcutaneous cannula." *See* Pet. 28–29 (claim chart); Ex. 1002 ¶ 110 (claim chart). We determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge to claims 15, 16, and 19 as anticipated by Müller.

F. Asserted Obviousness Based in Part on Müller

Petitioner challenges claims 1–21 as obvious over the combinations of: Reiley '404 and Müller; Reiley II and Müller; and Baumgartner and Müller. Pet. 39–56. Petitioner and Dr. Jensen assert that Müller discloses a

delivery device, i.e., syringe-like cylinder tube 1, capable of conveying material at a delivery pressure of no greater than about 360 psi with nozzle element 6 attached. *E.g.*, Pet. 36–37, 41, 49, 53; Ex. 1002 ¶ 110 (claim chart). Dr. Jensen provides the opinion that, because nozzle tube 7 (of nozzle element 6) has a volume of a few cubic centimeters, cylinder tube 1 necessarily would convey material at a lower delivery pressure than a conventional 1 cc syringe. Ex. 1002 ¶ 110 (claim chart). It is not apparent to us, however, that Dr. Jensen's opinion accounts for the size of cylinder tube 1, i.e., about 125 cubic centimeters (Ex. 1004, 2:51–54), or Müller's disclosure that shank 14 of ram 10 "functions as a piston within the nozzle tube 7 during a 'high pressure' injection" (*id.*, 3:25–29). We note Dr. Jensen's alternative opinion that: "In any event, it would be understood that an appropriately sized syringe would be selected for the procedures as was known in the art." Ex. 1002 ¶ 120 (claim chart). Dr. Jensen does not explain why a person of ordinary skill in the art would have selected such an "appropriately sized syringe" instead of using the syringe-like device disclosed in Müller.

For the reasons discussed above, it is not apparent to us that Müller discloses or suggests the delivery pressure limitation of "no greater than about 360 psi." In any event, however, we do not institute a trial on any of Petitioner's asserted obviousness grounds that are based in part on Müller in view of our determination on the current record that claims 1–21 would have been obvious over Deramond. *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.").

G. Asserted 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. Petitioner asserts that Kuslich discloses gun-like device 90, which pushes stylet 96 through a nozzle. *Id.* at 56; *see* Ex. 1002 ¶ 160. While noting that Kuslich does not specify any particular delivery pressure for device 90, Petitioner argues that a pressure less than 360 psi would have been an obvious design option, relying on Dr. Jensen's Declaration. Pet. 57–58 (citing Ex. 1002 ¶¶ 164, 166). In her Declaration, Dr. Jensen testifies that a person of ordinary skill in the art would have been "motivated to select a low pressure (e.g., under 360 psi), a known preferred option, so that delivery could be controlled." Ex. 1002 ¶ 164 (claim chart).

Patent Owner argues, *inter alia*, that no weight should be given to Dr. Jensen's Declaration testimony with respect to Kuslich because it relies on "two additional references that are not found in the formal presentation of the Petition, Draenert (Ex. 1013)[5] and Huebsch (Ex. 1014).[6]" Prelim. Resp. 54–55. Patent Owner further argues:

> By not raising these references in the body of the original Petition, the Petitioner has failed to present a reasonable likelihood that the claim is obvious over these references. Accordingly, the Petition is fatally deficient (37 CFR §42.104) and request for *Inter Partes* review of the present petition based on these references should be denied.

[5] US 4,671,263.
[6] US 4,892,550.

Id. at 55. We note, however, that the Petition contains a discussion of the asserted relevance of both of those references:

> As discussed above, it was known in the art that a sufficient pressure for delivery of bone cement is less than 360 psi. For example, as Dr. Jensen explains, one patent discloses a gun-like device injecting bone cement at pressures less than 360 psi: "[t]he pressure exerted on the bone cement can be precisely adjusted and controlled, so that pressures of from 2 bar [29 psi] to about 20 bar [290 psi] can build up." (Jensen Decl. at ¶ 165; Ex. 1013 at 5:3-6; see also claim 2.) Another patent discloses a device for delivering "suitable rigidly settable material such as epoxy or plaster" at "a desired pressure, such as 350 psi or any other superatmospheric value chosen by the surgeon as desirable. Pressures between 200 and 450 psi are suitable but a lower pressure may be selected." (Ex. 1014 at 7:48-52; see also Ex. 1015 at 5:15-23. Thus, a pressure less than 360 psi would have been a desirable, "sufficient pressure," and obvious design option. (Jensen Decl. at ¶¶ 164, 166.)

Pet. 58 (citations omitted).

Patent Owner further argues that Draenert "specifically criticizes the use of syringes with nozzles." Prelim. Resp. 55 (citing Ex. 1013, 2:20–38). That argument, however, does not address Dr. Jensen's testimony that a person of ordinary skill in the art would have been motivated to select a low-pressure delivery (less than 360 psi) for Kuslich's gun-like device 90. *See* Ex. 1002 ¶ 164 (claim chart).

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 claim 12 as obvious over

Kuslich in view of the knowledge of a person of ordinary skill in the art.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has established a reasonable likelihood of prevailing on its challenges to: claims 15, 16, 19, and 20 under 35 U.S.C. § 102(b) as anticipated by Deramond; claims 1–21 under 35 U.S.C. § 103(a) as obvious over Deramond in view of the knowledge of a person of ordinary skill in the art; and claim 12 under 35 U.S.C. § 103(a) as obvious over Kuslich 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 1–21 of the '734 Patent is granted;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of the '734 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 15, 16, 19, and 20 under 35 U.S.C. § 102(b) as anticipated by Deramond; claims 1–21 under 35 U.S.C. § 103(a) as obvious over Deramond in view of the knowledge of a person of ordinary skill in the art;

and claim 12 under 35 U.S.C. § 103(a) as obvious over Kuslich in view of the knowledge of a person of ordinary skill in the art.

For Petitioner:

Sandra Frantzen
sfrantzen@mcandrews-ip.com

Deborah Laughton
dlaughton@mcandrews-ip.com

For Patent Owner:

Tarek Fahmi
tarek.fahmi@ascendalaw.com

Michael Davitz
michael.davitz@ascendalaw.com