IPR2014-01433

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

In re Application of:

Robert M. SCRIBNER

Michael L. Reo

Mark A. Reiley

Ryan Boucher

Issued: June 5, 2001

Application No. 09/134,323

U.S. Patent No. 6,241,734

Filing Date: August 14, 1998

For: SYSTEMS AND METHODS FOR PLACING MATERIALS INTO BONE

PETITION FOR *INTER PARTES* REVIEW

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EXHIBITS

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1001	U.S. Patent No. 6,241,734 ("the 734 patent")
1002	Declaration of Dr. Mary Jensen with *Curriculum Vitae*
1003	Hervé Deramond, et al., "*Percutaneous Vertebroplasty*," Seminars in Musculoskeletal Radiology, Vol. 1, No. 2, pp. 285-95 (June 1997) ("Deramond")
1004	U.S. Patent No. 4,801,263 (issued Jan. 31, 1989) ("Clark")
1005	U.S. Patent No. 4,576,152 (issued Mar. 18, 1986) ("Muller")
1006	U.S. Patent No. 5,108,404 (issued Apr. 28, 1992) ("Reiley 404")
1007	WO 96/39970 (published Dec. 19, 1996) ("Reiley II")
1008	Canadian Patent Application 2,121,001 (published Oct. 22, 1994) ("Baumgartner")
1009	U.S. Patent No. 5,549,679 (issued Aug. 27, 1996) ("Kuslich")
1010	U.S. Patent No. 6,019,776 (filed Oct. 14, 1997) ("Priessman")
1011	Hayward, et al., "Pressure Generated By Syringes: Implications For Hydrodissection and Injection of Dense Connective Tissue Lesions," Scand. J. Rheumatol 2011; 40:379-382 ("Hayward")
1012	Krebs, et al., "Clinical Measurements of Cement Injection Pressure During Vertebroplasty," Spine, 1 March 2005, Volume 30, Issue 5, pp. E118-22 ("Krebs")
1013	U.S. Patent No. 4,671,263 (issued Jun. 9, 1987) ("Draenert")
1014	U.S. Patent No. 4,892,550 (issued Jan. 9, 1990) ("Huebsch")
1015	U.S. Patent No. 4,274,163 (issued Jun. 23, 1981) ("Malcolm")
1016	U.S. Patent No. 3,893,445 (issued Jul. 8, 1975) ("Hofsess")
1017	U.S. Patent No. 5,419,765 (issued May 30, 1995) ("Weldon")
1018	U.S. Patent No. 3,613,684 (issued Oct. 19, 1971) ("Sheridan")
1019	U.S. Patent No. 4,616,656 (issued Oct. 14, 1986) ("Nicholson")
1020	U.S. Patent No. 5,579,774 (issued Dec. 3, 1996) ("Miller")

Exhibit	Description
1021	U.S. Patent No. 5,989,260 (filed Mar. 27, 1996) (“Yao”)
1022	U.S. Patent No. 5,429,617 (issued Jul. 4, 1995) (“Hammersmark”)
1023	U.S. Patent No. 4,005,527 (issued Feb. 1, 1977) (“Wilson”)
1024	U.S. Patent No. 4,419,095 (issued Dec. 6, 1983) (“Nebergall”)
1025	U.S. Patent No. 5,997,581 (filed Dec. 29, 1997) (“Khalili”)
1026	U.S. Patent No. 5, 203,777 (filed Mar. 19, 1992) (issued Apr. 20, 1993) (“Lee”)
1027	Excerpts from prosecution history of 734 patent

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, Stryker Corporation ("Stryker") respectfully petitions for *inter partes* review (IPR) of claims 1-21 of U.S. Patent No. 6,241,734 ("the 734 patent"), which was filed on August 14, 1998, and is purportedly assigned to Orthophoenix, LLC ("Orthophoenix"). Stryker has used August 14, 1998, as the priority date for this Petition.

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(A)(1)

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Petitioner Stryker Corporation is the real party-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The 734 patent is asserted against Stryker in the following litigation pending in the District of Delaware: *Orthophoenix, LLC. V. Stryker Corporation; John and/or Jane Does 1-100,* Case No. 13-1628-LPS, filed October 1, 2013. Stryker is not aware of any pending prosecution concerning the 734 patent. Stryker notes that it has also filed a request for *inter partes* review concurrently herewith for U.S. Patent No. 7,153,307, which claims priority to the 734 patent.

C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel.

LEAD COUNSEL	**BACK-UP COUNSEL**
Sandra A. Frantzen (Reg. No. 48,799) (sfrantzen@mcandrews-ip.com) McAndrews, Held & Malloy Ltd.	Deborah A. Laughton (Reg. No. 54,253) (dlaughton@mcandrews-ip.com) McAndrews, Held & Malloy Ltd.

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D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to the lead counsel at the address provided in Section I.C of this Petition. Petitioner also consents to electronic service by email at: **StrykerIPR@mcandrews-ip.com**.

II. PAYMENT OF FEES – 37 C.F.R. § 41.103

Petitioner authorizes the USPTO to charge Deposit Account No. 13-0017 for the fees set forth in 37 C.F.R. § 42.15(a) for this petition and further authorizes payment for any additional fees to be charged to this Deposit Account.

III. REQUIREMENTS FOR IPR UNDER 37 C.F.R § 42.104

A. Grounds For Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies that the 734 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR.

B. Identification Of Challenge Under 37 C.F.R. § 42.104(b) And Relief Requested

Petitioner requests *inter partes* review of claims 1-21 of the 734 patent on the grounds set forth below and requests that each claim be found unpatentable. An explanation of how claims 1-21 are unpatentable under the statutory grounds is identified below including the identification of where each element is found in

the prior art references and the relevance of each of the prior art references. Additional explanation and support for each ground is set forth in the Declaration of Dr. Mary Jensen (Ex. 1002), submitted in accordance with 37 C.F.R. § 1.68.

IPR of claims 1-21 is requested in view of the knowledge of one of ordinary skill in the art and the following references, which are prior art under § 102(b). Additional references cited herein and in the Jensen Declaration demonstrate the knowledge of ordinary skill in the art at the time of the invention.

Ground	Proposed Statutory Rejections for the 734 Patent
1	Deramond anticipates claims 15, 16, 19, and 20 under § 102(b).
2	Deramond in combination with the knowledge of one of ordinary skill in the art renders claims 1-21 obvious under § 103.
3	Clark anticipates claims 1, 3, and 15 under § 102(b).
4	Clark in combination with the knowledge of one of ordinary skill in the art renders claims 2,4, 5, 7, 8, 16, 17, and 19 obvious under §103.
5	Muller anticipates claims 15, 16 and 19 under § 102(b).
6	Muller in combination with Reiley 404 and the knowledge of one of ordinary skill in the art renders obvious claims 1-21 under § 103.
7	Muller in combination with Reiley II and the knowledge of one of ordinary skill in the art renders obvious claims 1-21 under § 103.
8	Muller in combination with Baumgartner and the knowledge of one of ordinary skill in the art renders obvious claims 1-21 under § 103.
9	Kuslich in combination with the knowledge of one of ordinary skill in the art renders obvious claim 12 under § 103.

C. Claim Construction Under 37 C.F.R. § 42.104(b)(3)

A claim subject to *inter partes* review is given its "broadest reasonable

construction in light of the specification of the patent in which it appears," which is a broader construction than applied by courts during claim construction.[1] 37 C.F.R. § 42.100(b); *see also In re Trans Texas Holding Corp.*, 498 F.3d 1290, 1298 (Fed. Cir. 2007). The broadest reasonable interpretation of the terms in the 734 patent are their plain and ordinary meaning to an ordinary skilled artisan which is evident from the claims themselves. Specific legal issues are addressed herein.

IV. BACKGROUND OF THE ART AND THE 307 PATENT

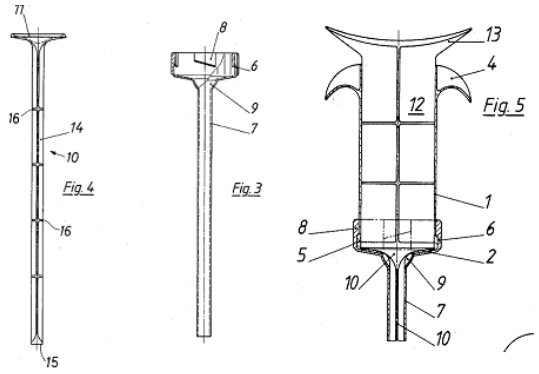
A. Background of the Art

Physicians have been using various techniques for delivering bone cement and other material into bone for over fifty years. As explained in the attached Declaration of Mary E. Jensen, MD, several systems for delivering bone cement or other material into the spine or vertebra were well-known to the art at the time of invention of the 734 patent. (*See* Ex. 1002, Jensen Decl. at ¶¶ 25-29, 35-36.)

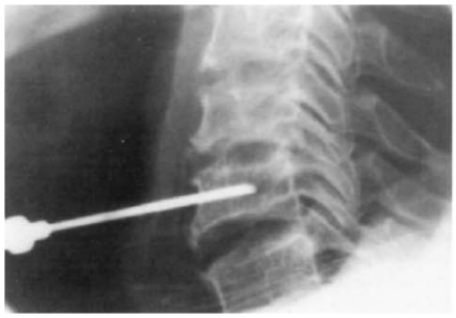
In the early days, bone filling materials would be inserted into bone in open surgery. A deep incision would be made into the patient's soft tissue and the physician is able to access the portion of bone to be treated, for example, by

[1] Because of the different claim construction standard in litigation, Petitioner reserves all of its rights with regard to constructions during litigation.

drilling into bone. (Jensen Decl. at ¶¶ 26-27.) Filling materials were packed into the bone manually or delivered into the bone with syringe-like devices. (*Id.* at ¶¶ 27-28.) Muller described using a bone cement injector "comprised of a cylinder tube for receiving the bone cement, a piston, a nozzle element and a ram." (Ex. 1005 at 1:40-43; Figs. 3-5.) Cement was delivered through a nozzle and pushed into the bone cavity with a "piston" or "ram."



In the mid-1980s, physicians in France (Hervé Deramond and others) developed a minimally-invasive procedure to deliver filling materials into vertebra, which was called percutaneous vertebroplasty. (*Id.* at ¶ 29.) Vertebroplasty involves introducing a cannula (e.g., a hollow needle) through the soft tissue into the vertebral body and then injecting bone cement or other filling material through cannula into the bone. (*Id.* at ¶¶ 29, 31-32; Ex. 1003.) The hollow needle was generally in the form of a trocar that included a stylet, which allowed the needle to push through the tissue and bone as needed. (*Id.* at ¶ 32.) The figure shown here is from Deramond depicting the stylet placed within the cannula in a vertebra.



There were several known methods for delivering the cement in vertebroplasty. It was well known that material could be manually pushed into vertebral bodies using a tamping instrument as in open procedures. (*Id.* at ¶ 35.) For example, in a typical procedure, a luer-lock syringe was attached to the proximal end of the cannula and cement was injected through the cannula into the vertebral body. The physician then detached the syringe and reinserted the stylet to urge residual bone cement from the cannula. (*Id.* at ¶ 85; Ex. 1003 at 287.) By delivering cement to a targeted area in a minimally-invasive manner, i.e., via a subcutaneous cannula, vertebroplasty was a major improvement over open techniques and offered a new treatment option for painful compression fractures. Moreover, physicians were now better able to monitor the delivery of cement fluoroscopically to prevent undesirable leakage of bone cement. (*Id.* at ¶ 30.)

Several years after the introduction of vertebroplasty, but prior to the invention of the '734 patent, another method for the fixation and stabilization of vertebral bodies (as well as non-vertebral bones) was developed. This procedure was called "balloon-assisted vertebroplasty" or "kyphoplasty" and is generally described in U.S. Patent No. 5,108,404 (Reiley 404, Ex. 1006). (Jensen Decl. at ¶ 36; *See also* Ex. 1007.) Like vertebroplasty, this technique involved delivering bone cement through a subcutaneous cannula into a vertebral or non-vertebral

body. However, balloon-assisted vertebroplasty, as its name implies, uses expandable bodies, such as inflatable balloons (e.g. 76), to compress cancellous bone inside the vertebral body to create a cavity prior to the injection of cement. (*Id.*) While other methods of delivering cement were known, Reiley 404 described delivering cement through the cannula using an injection gun, which was also a known method of delivering cement at the time. (Ex. 1006 at 7:42-51; Ex. 1001 at 1:10-19.) Another later Reiley patent application (Reiley II), also described balloon-assisted vertebroplasty and delivering filling material manually using hand actuation to push material through a nozzle with a long pin/stylet – consistent with known methods at the time. (Ex. 1007 at p. 40, l. 32 – p. 41, l. 3.)

As discussed further below, it was understood by August 1998 that the instruments used in these procedures, like most medical devices, could be made of flexible or rigid materials depending on the application; it was also understood that they could include calibration markings and radiopaque markers in order to better monitor the procedure. (Jensen Decl. at ¶¶ 38, 41, 42.) It was also understood by August 1998 that the bone cement could be delivered at "low pressures" including pressures less than 360 psi. (*See, e.g.,* Jensen Decl. at ¶¶ 39, 165; Ex. 1013 at 5:1-6 ("pressure exerted on the bone cement can be precisely adjusted and controlled, so that pressures of from [29 psi] to about [290 psi] can

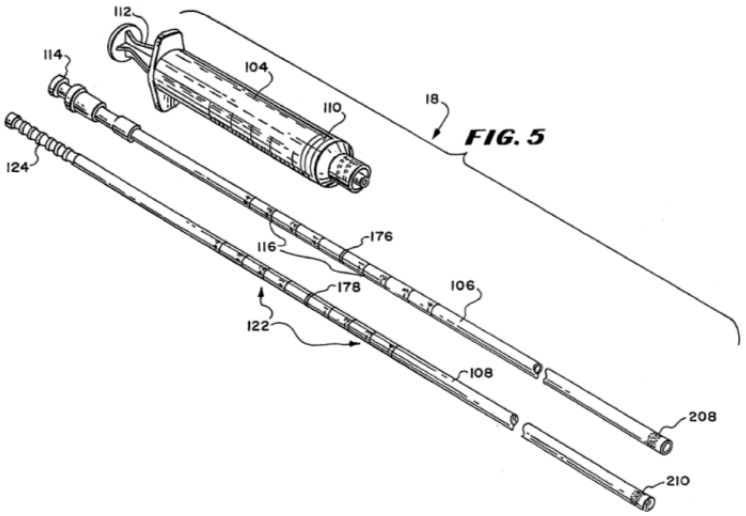
build up."); Ex. 1014 at 7:49-50 (pressure of 350 psi preferred); Ex. 1015 at 5:20-22). Indeed, the delivery pressure used during vertebroplasty procedures relying on manual hand-actuation, including those involving syringes, were generally relatively low pressure, i.e., less than 360 psi. (Jensen Decl. at ¶¶ 39-41.)

B. Brief Description of the 734 Patent

The 734 patent, which was filed in August 1998 and also names Reiley as an inventor, claims systems for delivering material into bone through a subcutaneous cannula (i.e., a minimally-invasive procedure) generally by hand. (Ex. 1001 at Abstract, Claims.) The focus of the 734 specification was to address purported problems with "high pressure" injection of filling material such as the injection gun of Reiley 404. (*Id.* at 1:20-62.) The 734 patent states that "once the spring-actuated mechanism [in the gun] is triggered, conventional cement injection devices do not permit the injection volume or inject rate to be adjusted or controlled in real time, in reaction to cancellous bone volume and density conditions encountered inside bone" (*Id.* at 1:20-28.) The 734 patent also claims that, in vertebroplasty, "bone cement is injected at high pressure…" but does not identify any literature supporting this claim and does not describe the "high pressure" vertebroplasty procedure to which it is referring. (*Id.* at 1:29-32.)

The patent purports to solve this alleged problem by providing a "low

pressure" system using a syringe with a hand-actuated tamping instrument to push filling material from the cannula into the bone. (*See, e.g., id*. at 1:60-2:10, 10:33-39.) This system purportedly allowed for greater rate and volume control and faster response time. (*Id*. at 1:15-48.) However, as discussed above, these types of "low pressure" systems for injecting filling material into bone, and in particular through a subcutaneous cannula into a vertebral body, were well known at the time of the 734 patent.



Specifically, as shown in Figures 5 and 28 of the 734 patent, the apparatus includes a cannula for accessing the bone, a "delivery device to convey the material at a delivery pressure of no greater than about 360 psi" (such as "conventional syringe 104"),[2] and a tamping instrument 108 for

[2] The syringe may be a "manual[ly] actuated syringe with a push plunger" or "LeVeen Inflation Syringe with threaded plunger." (Ex. 1001 at 10:34-39.) According to the patent, liquid is delivered from a 1 cc syringe at a pressure "which amounts to a pressure that is no greater than about 360 psi." (2:5-11.)

urging residual filling material from the cannula 30 into bone. (*Id.* at 6:40; 2:53-55; 14:53-56; 10:26-33; 11:42-57.) According to the patent, this arrangement "allows the physician to respond to fill volume and flow resistance conditions in a virtually instantaneous fashion." (*Id.* at 16:65-17:2.)

In one embodiment, a "nozzle" (106) is first coupled to the "delivery device," e.g., the syringe, (see, e.g., Fig. 25) and advanced through the cannula 30 for delivery of the material into bone. Once the nozzle is removed, the tamping instrument is then used to expel any material remaining in the cannula. (*Id.* at 10:45-53; 16:3-59.) Alternatively, a stylet (e.g., 182 in Fig. 33) may be advanced through the nozzle (180) and together with the nozzle form a tamping instrument to displace residual material in the cannula (184).

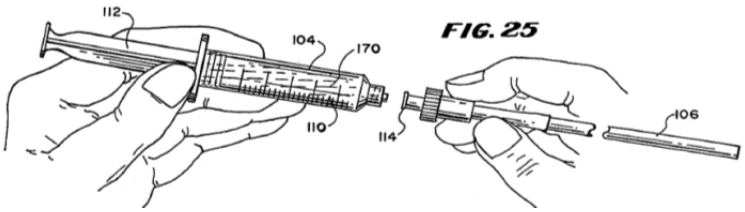


FIG. 25

Figures 30 and 31 illustrate the advancement of the tamping instrument into the cannula to displace material from the cannula into bone. (*Id.* at Figs. 30-31, 4:57-64). The specification explains that "advancement of the tamping instrument 108 displaces progressively more of the residual material 170 from the cannula instrument 30, forcing it into the cavity 168. (*Id.* at 16:52-55).

The 734 patent has 21 claims. Claims 1, 12, and 15 are independent claims.

Claim 15 is the broadest claim and generally claims an apparatus for introducing material into bone including 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," which when advanced through the cannula, urges material residing in the cannula into bone. ***Claim 1*** is similar to Claim 15 but also requires "a nozzle instrument" that is coupled to the delivery device. ***Claim 12*** claims a "subcutaneous cannula," "delivery device," and "nozzle instrument," along with a stylet that is capable of advancing into the nozzle and, "with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula." The dependent claims are directed to known characteristics of the tools of the independent claims as described further below.

V. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE 734 PATENT IS UNPATENTABLE

Petitioner seeks *inter partes* review of claims 1-21 of the 734 patent. Claims 1, 12, and 15 are independent claims. Claims 2-11, 13-14, and 16-21 depend on claims 1, 12, and 15 respectively.

A. Ground 1: Deramond Anticipates Claims 15, 16, 19 and 20

As discussed above, Deramond and others were the first to perform what became known in the art as percutaneous vertebroplasty. (Jensen Decl. at ¶ 57.)

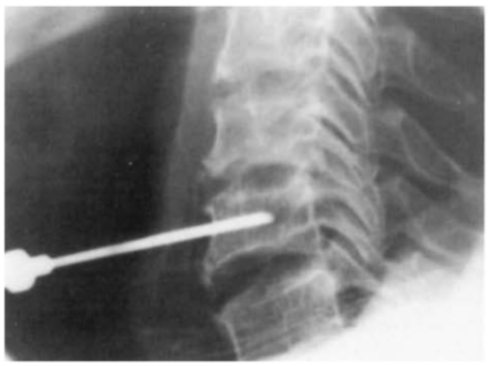
Several papers were written on the topic including the Deramond paper that is Ex. 1003, which was published in June 1997. In the Deramond reference, Deramond describes several typical vertebroplasty procedures where bone cement such as polymethylmethacrylate is delivered into vertebral bodies weakened by osseous lesions via access cannulas (called "needles" in the paper). (Ex. 1003; Jensen Decl. at ¶ 59.) Deramond describes the tools used in the procedures including: ten- and fifteen-gauge needles,[3] which are hollow cannulas used to access bone and which include stylets (or mandrels) nested within them to allow for penetration through soft tissue and bone; luer-lock syringes of 2 or 3 cc[4]; a syringe handle; and bone cement. (Ex. 1003 at 285; Jensen Decl. at ¶ 59.)

Specifically, Deramond describes placing a ten- or fifteen-gauge needle in the vertebral body. (Ex. 1003 at 285, 286.) These needles are used as a subcutaneous cannula for gaining access to the patients' vertebra, and include stylets or mandrels nested within the needles to allow for penetration through

[3] Fifteen-gauge needles are smaller in diameter than ten-gauge needles and can be inserted within ten-gauge needles. (*See* infra; Jensen Decl. at ¶ 59, n. 4.)

[4] Luer-lock syringes have a proximal fitting that allow coupling to a cannula. (Jensen Decl. at ¶ 62.)

soft tissue and bone, as can be seen from Fig. 1 (shown here), which depicts a 15-gauge needle inserted into a vertebral body. (*id.*; Jensen Decl. at ¶ 60.) The spherical element shown here is the proximal end of the stylet or mandrel and the needle, which fit together to permit the physician to push the instrument through tissue and bone. Figures 4C and 4D depict use of a 10-gauge needle. (*Id.*)



Deramond explains that, "once the needle is in good position in the vertebral body, the PMMA [bone cement] can be injected." (Ex. 1003 at 286.) Deramond discloses loading the cement into the luer-lock syringes and introducing the cement via the needle into the vertebral body. (Ex. 1003 at.287.) Specifically, once the stylet is removed, luer-lock syringes of 2 or 3 cc are attached to these needles/cannulas to manually deliver filling material, such as polymethlmethacrylate cement through the needle (cannula). (*Id.* at 285; Jensen Decl. at ¶ 61.) Because 2 and 3 cc syringes are larger than a 1 cc syringe (and thus have a greater area), Deramond describes "a delivery device to convey the material at a delivery pressure of no greater than about 360 psi" as claimed in the 734 patent. (*Id*.) Indeed, the 734 patent expressly identifies a "conventional syringe" as the delivery device. (Ex. 1001 at

10:33-39.) And the 734 patent notes that "the pressure at which liquid is expressed from 1 cc syringe by the application of moderate force…amounts to a pressure that is no greater than about 360 psi." (*Id.* at 2:7-11.) A larger syringe (e.g., 2 or 3 cc) will necessarily result in lower pressures.[5],[6]

After the cement is introduced through the cannula, the mandrel is used as a tamping instrument to urge remaining filling material residing in the needle

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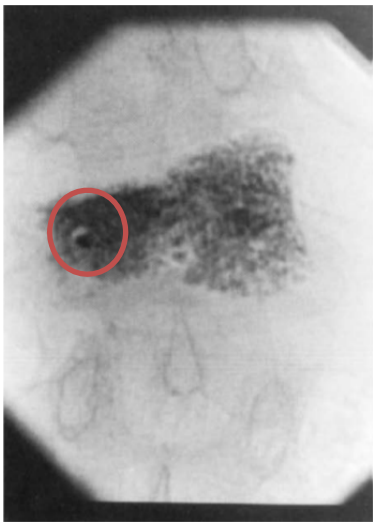
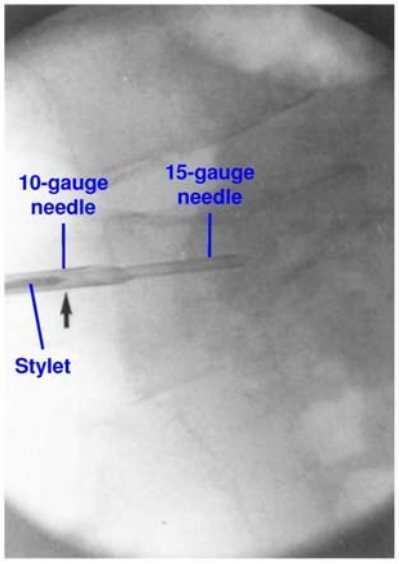
[5] Jensen Decl. at ¶ 40; Ex. 1011 at 379 ("smaller syringes generated significantly more injection pressure than did larger syringes"; maximum mean pressure of 1 cc syringe about 360 psi and 180 psi for 3 cc); Ex. 1012 at E1118 ("pressures approaching 20 atm [294 psi] are reached during conventional vertebroplasty").

[6] Moreover, while the claimed delivery device is in fact disclosed, as long as the prior art discloses a structure (e.g., a syringe) that is *capable of* performing a claimed function (e.g., conveying material at less than 360 psi), the art satisfies the limitation. *See In Re Schreiber*, 128 F.3d 1473, 1478-79 (Fed. Cir. 1997); *Bettcher Indus. v. Bunzl USA Inc.*, 661 F.3d 629, 654 (Fed. Cir. 2011) ("Where all structural elements of a claim exist in a prior art product, and that prior art product is capable of satisfying all functional or intended use limitations, the claimed invention is…unpatentable.").

(cannula) into the vertebral body. Deramond states: "Once the cement injection is achieved, the needle is slowly pulled back to the cortical bone while pushing mandred [sic] into the needle." (Ex. 1003 at 287.) Figure 4F is a photograph of the vertebra after injection. The black dot shown on the photograph (circled here) depicts bone cement that has been urged through the cannula with the stylet/mandrel. (Jensen Decl. at ¶ 63.)



The Deramond article also discloses another approach to the vertebroplasty procedure. In Figure 4A (shown here, indications added in blue), Deramond depicts a "coaxial technique" where a first, larger needle (10-gauge) is used as an access cannula and a second, smaller needle (15-gauge) is sized and configured to fit within the larger needle. As shown, the smaller needle extends beyond the larger needle. The stylet/mandrel of the 15-gauge needle (arrow pointing at tip) is also depicted. Deramond discloses using the 15-gauge needle to remove cancellous bone before cement delivery with the 10-gauge needle. (Fig. 4A.)



As shown in the claim chart below and paragraph 65 of the Jensen

Declaration, Deramond discloses all the elements of independent claim 15.

734 Patent	Deramond (Ex. 1003)
15. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus comprising a subcutaneous cannula,	Deramond discloses the use of ten- and fifteen-gauge needles as cannulas for introducing material into bone: "Ten-gauge needles of 10 to 15 cm long with a beveled extremity (these needles are used at the thoracic or lumbar level); Fifteen-gauge needles of 5 to 7 cm long with a tapered tip (these needles are used at the cervical level;" (Ex. 1003 at 285.) "Once the needle is in good position in the vertebral body, the PMMA can be injected." (*Id.* at 286.)
a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi,	Deramond describes using 2-, 3- or 5- cc luer lock syringes to deliver the filling material. (*Id.* at 285, 287; Jensen Decl. at ¶¶ 39, 40, 65.)
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.	"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." (Ex. 1003 at 287; see also Jensen Decl. at ¶ 65.) An example of a mandrel/stylet (including its tamping terminus) in the cannula is shown in Figure 4A. Moreover, Figure 4F depicts a vertebra after material has been pushed through the cannula with the stylet as discussed above.

Dependent Claim 16 requires an "Apparatus according to claim 15 wherein the delivery device comprises a syringe." As discussed above, Deramond discloses all the elements of claim 15 and the "delivery device" is a luer-lock syringe.

Dependent Claim 19 requires "Apparatus according to claim 15 wherein the tamping instrument is made of a generally rigid material." The 734 patent explains that "The tamping instrument 108 is made from generally rigid, inert

plastic or metal material." (Ex. 1001 at 11:17-18.) As discussed above, Deramond discloses all the elements of claim 15. The 10- and 15-gauge needles in Deramond, along with their accompanying mandrel/stylet, are made from metal (a generally rigid material) so that the needle with the nested stylet can penetrate soft tissue and bone. (Jensen Decl. at ¶ 67.)

Dependent Claim 20 requires "Apparatus according to claim 15 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone." As discussed above, Deramond discloses all the elements of claim 15. As shown above, Figure 4A, p. 288, of Deramond depicts a 15-gauge needle advanced through a 10-gauge needle creating a cavity in the cancellous bone. (Jensen Decl. at ¶ 68.)

Thus claims 15, 16, 19 and 20 are anticipated.

B. Ground 2: Deramond Renders Obvious Claims 1-21 In View of the Knowledge Of An Ordinarily Skilled Artisan

To the extent not anticipated, Deramond also renders all the claims of the 734 patent obvious in view of the knowledge of an ordinarily skilled artisan. 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. (Jensen Decl. at ¶ 13.)

In *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007), the Supreme Court held that a "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." "Common sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 420.

1. Independent Claims 1, 12, and 15

Independent claim 1 includes all the elements of independent claim 15 but also requires the apparatus to include "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." Claim 1 also requires the tamping instrument be "capable of advancement into the subcutaneous cannula." The analysis of claim 15 is incorporated herein and the additional elements of claim 1 are discussed below.

Figure 1 depicts a 15-gauge needle used to deliver cement and, thus, for

that embodiment, the luer-lock syringe has a proximal fitting to couple to the 15-gauge needle and cement is delivered through the needle to the vertebral body through the terminus of the 15-gauge needle at the delivery pressure. (Ex. 1003 at Fig. 1; Jensen Decl. at ¶ 71.) Moreover, as discussed above, Deramond discloses a coaxial embodiment where the 15-gauge needle is inserted into a 10-gauge needle (with a stylet shown as being capable of advancement in the 15-gauge needle). (Ex. 1003 at Fig. 4A; Jensen Decl. at ¶ 71.) Because Deramond teaches delivering material through a 15-gauge needle, an ordinarily skilled artisan would understand that material could be delivered with the coaxial embodiment with the 15-gauge needle serving as a nozzle in that context as an obvious alternate design choice suggested by Deramond. (Jensen Decl at ¶. 71.) As Dr. Jensen explains, because in certain circumstances it would desirable to access 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 (just as the coaxial system described in Deramond facilitated removal from a precise location.) (*Id.*) Thus, claim 1 is obvious in view of Deramond and the knowledge of the ordinary skilled artisan.

Independent claim 12 is similar to claim 1 but requires the nozzle instrument have a "nozzle bore through which the material conveyed by the

delivery device enters bone at the delivery pressure" and, for the tamping instrument, "a stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore and, with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula." The analyses of claims 1 and 15 are incorporated here. Additional elements are discussed below.

As discussed above, Deramond teaches 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 Ex. 1003 at Figure 4A.) As discussed above, it was understood 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 as an obvious alternate design choice. The stylet within the 15-gauge needle (shown in Fig. 4A) could be nested with the 15-gauge needle to clear residual material from the cannula just as it is Deramond describers when it is not in the coaxial system. (Jensen Decl. at ¶ 72.) Moreover, once the stylet was nested within the 15-gauge needle, Dr. Jensen explains that the skilled artisan would understand that (and have reason to), rather than uncoupling the stylet from the nozzle to use the stylet as a tamping instrument, the nested stylet/needle combination could also alternatively be used as a

tamping instrument to clear any material in the 10-gauge needle as an obvious design option (in the same way the needle/stylet can be used to penetrate through tissue and bone as an access cannula). (*Id.*) Thus, claim 12 is also obvious in view of Deramond.

Independent claim 15 is the broadest claim and is anticipated as discussed in Ground 1 above. However, Deramond also renders claim 15 obvious as it 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.) The other claims, which contain the same limitation, would likewise be rendered obvious for the same reason. (*Id.*)

2. Dependent claims 2 and 3 – Flexible and Rigid Materials for Nozzle

Claims 2 and 3 depend on claim 1 and require that the nozzle instrument "is made of a generally flexible material" or a "is made of a generally rigid material." The 734 patent states that the nozzle shown in Figure 25 "is made from a generally flexible, inert plastic material, such as…polyethylene or another suitable polymer." The patent further states that, "[a]lternatively, the nozzle 106 can be

made from a generally rigid plastic or metal material." (Ex. 1001 at 10:46-51.) As discussed above with regard to claim 19, Deramond discloses that the use of needles as access cannulas (which also can be used as nozzles as discussed above). As Dr. Jensen explains, these needles are made of generally rigid materials and thus claim 3 is also obvious. (Jensen Decl. at ¶¶ 67, 76.)

Using flexible materials as an alternative would have been an obvious design choice. A person of ordinary skill in the art at the time of the invention understood that there were generally two types of materials to choose from when designing or selecting instruments for use in such procedures: instruments made from flexible materials or instruments made from rigid materials. (*Id.* at ¶ 74.) The 734 patent claimed both known design choices. Nozzles made of both flexible and rigid materials were thus conventional, off-the-shelf options available to the ordinary skilled artisan by August 1998. (*Id.* at ¶ 75; Ex. 1016 at 3:3-15; Ex. 1017 at 5:15-25; Ex. 1018 at 3:25-65.) A person of ordinary skill would thus be motivated to select a nozzle made from generally flexible or rigid materials and found it an obvious design choice based on the specific procedure being performed, physician preference, and enhanced patient safety. (*Id.* at ¶ 74.) Dr. Jensen explains the various reasons why a nozzle made from flexible or rigid materials would be selected by the physician. (*Id.* at ¶¶ 75-77.) Thus, because

they claim both known design choices, claims 2 and 3 would have been obvious.

3. Dependent claims 4 , 14, and 16 – Syringe

Claims 4, 14, and 16 depend on claims 1, 12, and 15 respectively and require that "the delivery device comprises a syringe." As discussed above, Deramond discloses the use of luer-lock syringes. (Ex. 1003 at 285.)

4. Dependent Claims 5, 8, 13 and 17 – Calibration Markings

Claims 5 and 17 depend on claims 1 and 15, respectively, and require "the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula." Likewise, claims 8 and 13 depend on claims 1 and 12, respectively, and require that "the nozzle instrument includes markings to visually gauge the advancement of the nozzle terminus [or nozzle instrument] through the subcutaneous cannula."

As Dr. Jensen explains, such calibration markings on instruments were well known and conventional as of August 1998 to visually gauge the advance of such instruments within another instrument such as a cannula. (*Id.* at ¶¶ 79. 80, 87.) For example, one patent describes graduated markings that "indicate…the depth of the probe unit's distal end when the wire is properly sheathed in the cannula." (Ex. 1019 at 4:44-49.) Another patent describes graduated markings 14, which are used to assist accurate depth of probe insertion." (Ex. 1020 at 7:12-14; fig. 1.)

Likewise, yet another patent discloses "[m]easurement indicia 38 can be provided on the sleeve 36 and on the nozzle 30 to help gauge insertion depth of the nozzle and of the spacer 10 within the reamed canal 26." See also Ex. 1025 at 3:67-43; Fig. 6; Ex. 1017 at 6:27; Ex. 1021. Because such markings were conventional in the art as of August 1998, it would have been obvious for a person of ordinary skill to include them on the Deramond instruments (the stylet/mandrel or needle of Deramond) for the reasons known in the art, i.e., to gauge depth of the instrument within the cannula. (Jensen Decl. at ¶¶ 81, 87-89.) Thus, claims 5, 8, 13, and 17 would have been obvious.

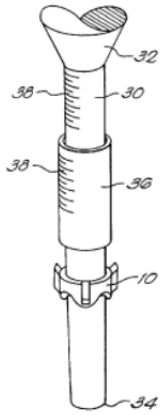


FIG. 6

5. Dependent claims 6, 9 and 18 – Radiopaque Marker

Claims 6 and 18 require the tamping instrument of claims 1 and 15 to include "at least one radiopaque marker." Claim 9 requires the nozzle instrument of claim 1 to have "at least one radiopaque marker." As shown by the figures (e.g., Fig. 4A), the metal needles and stylets in Deramond are radiopaque. Deramond further recognizes that the procedure should be monitored fluoroscopically and discloses that the filling material is mixed with tantalum powder "to obtain a good radiopacity of the cement." (Ex. 1003 at 286.) Thus, Deramond acknowledges the utility of radiopacity. (Jensen Decl. at ¶ 82.)

In any event, as Dr. Jensen explains, surgical instruments with radiopaque markings along their length to determine the depth of insertion were well known in the art by August 1998. (*Id.* at ¶ 83.) Dr. Jensen provides several examples including examples on both tamping instruments and nozzle instruments. (*Id.* at ¶ 83-85.) These types of markers were ubiquitous in the art at the time of the invention. (*See, e.g.,* Ex. 1018 at 4:58-59, 3:60-65 (x-ray indicator tips on the stylet of a trocar catheter); Ex. 1023 at 4:12-18; Ex. 1022 at 3:65-4:10; Ex. 1024 at abstract.) Thus, if the instrument itself were not radiopaque as in Deramond, as Dr. Jensen explains, a person of ordinary skill in the art would have understood that it would be preferred to include at least one radiopaque marker along the tamping instrument and nozzle to determine depth of the instrument for the reasons as known in the art for such markers, particularly because of Deramond's disclosuree of radiopaque filling material for use in fluoroscopic control. (Jensen Decl. at ¶ 85.) Indeed, it was common sense to do so to avoid piercing of the vertebral body. (*Id.*) Thus, claims 6, 9, and 18 would have been obvious.

6. Dependent Claims 7 and 19 – Rigid Tamping Instrument

As with dependent claim 19 discussed above in Section A, claim 7 requires the "tamping instrument is made of a generally rigid material." As discussed above, the stylet of Deramond is part of a stylet/needle combination and would

be made of a rigid material (metal) to pierce through skin and tissue. (See also ¶ 86.) In any event, requiring the tamping instrument to be made from a rigid material is an obvious design choice as explained in Section V.B.2; indeed, it is common sense to require that the tamping instrument be made of a generally rigid material to facilitate the purpose of the instrument, i.e., to push materials into the bone. (Jensen Decl. at ¶ 128.) Thus, claims 7 and 19 are disclosed in Deramond and are otherwise obvious.

7. Dependent Claims 10, 11, 20, and 21 – Cavity Forming Instrument

As with claim 20 discussed above in Section A, claim 10 requires the claimed apparatus to further include "a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone." Claims 11 and 21 require the "Apparatus according to claim 10 [or claim 15[7]] wherein the cavity forming instrument includes an expandable structure."

As discussed above, Figure 4A of Deramond depicts a 15-gauge needle advanced through a 10-gauge needle forming a cavity in the cancellous bone. (Ex. 1003 at Fig. 4A; Jensen Decl. at ¶ 90.) Moreover, as discussed above in Section

[7] "The cavity forming instrument" in claim 21 lacks antecedent basis because claim 15 does not recite a cavity forming instrument.

IV.A., and will be discussed further below, at the time of the invention (August 1998), balloon-assisted vertebroplasty was known in the art. (See Ex. 1006.) As described in Reiley 404, a balloon catheter is used to create a cavity in cancellous bone as part of the procedure. (*Id.* at 6:57-7:35.) Likewise, Reiley II describes using balloons of varying shapes to compress cancellous bone during vertebral procedures. (Ex. 1007 at p. 25, fig. 8.) These balloon catheters are "expandable structures." As Dr. Jensen explains, and as explained below, since balloon-assisted vertebroplasty was merely an adaptation of Deramond's vertebroplasty procedure in the first instance, by August 1998, a person of ordinary skill in the art would have been motivated to use balloons in the Deramond procedure for the very reasons known in the art and explained for example in Reiley 404. (Jensen Decl. at ¶ 92.) Thus, claims 10, 11, 20 and 21 would have been obvious.

C. Ground 3: Clark Anticipates Claims 1, 3, and 15

Clark discloses an osseous implant syringe with a delivery nozzle for delivering filling material through "very small incisions" in tissue to bone, e.g., dental defects. (Ex. 1004 at Abstract, 2:15-17, 1:25-28) Specifically, the device includes "a syringe plunger [10] that is passed through an outer syringe barrel [20] which contains the

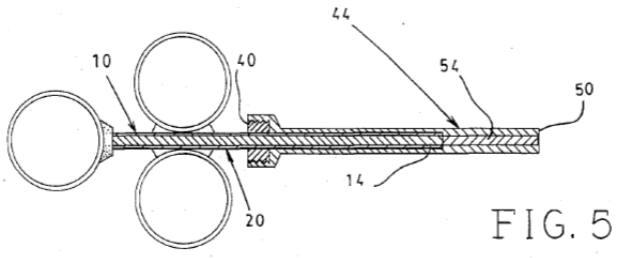


FIG. 5

implant substances." (*Id.* at 2:59-63.) The syringe plunger is used as a tamping instrument within the outer syringe barrel 20l, which is a nozzle. (*Id.*) The device also includes an "extension nozzle member 44," which attaches to the syringe barrel member 20 and acts as a subcutaneous cannula. (*Id.* at 4:47-55.) There is also another tamping instrument in the cannula: "In order to assure displacement of the osseous implant substance all the way through the extension nozzle lumen 52, a plunger extension 54 is placed on the second end 14 of syringe plunger member 10." (*Id.* at 4:66-5:2.)

A "filling device member 68" with a reservoir can be attached to the device to serve as a receptacle for holding the filling material. (*Id.* at 5:30-55.) Material is gravity-fed through the filling device into the implant device (atmospheric pressure is less than 15 psi) and further assisted with manual shaking by the user. (*Id.* at 6:22-44; Jensen Decl. at ¶ 97.)

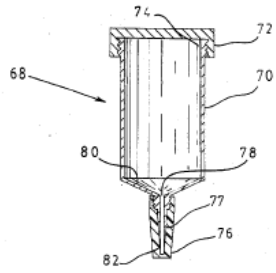
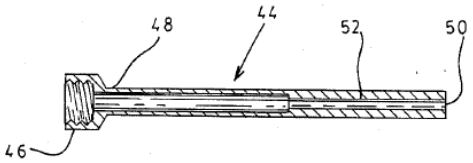
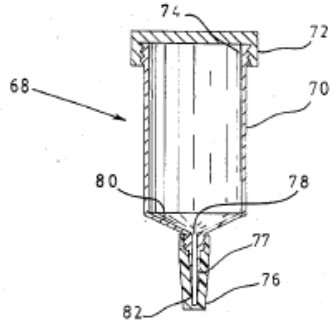
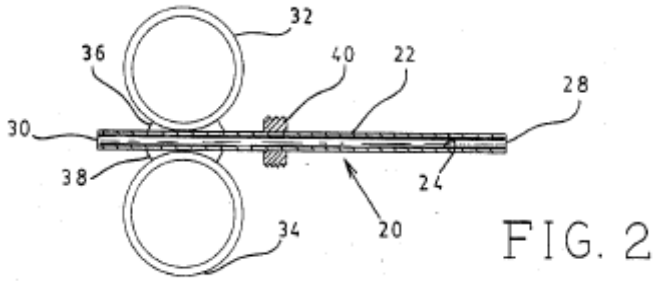


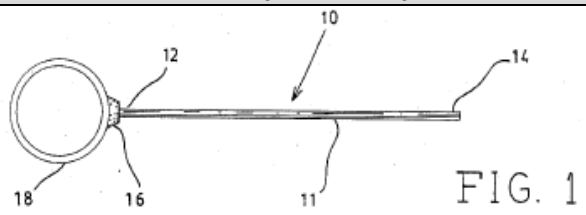
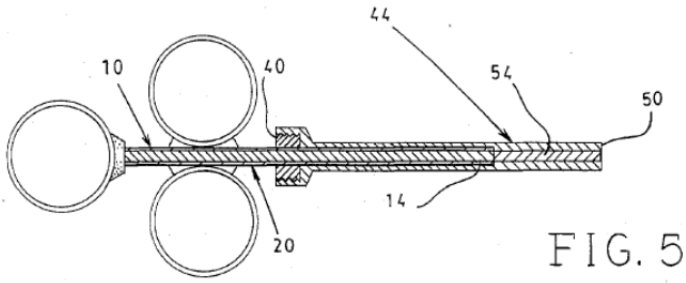
FIG. 8

As shown in the claim chart below and paragraphs 97-99 of the Jensen Declaration, Clark discloses all the elements of independent claim 1.

734 Patent	Clark (Ex. 1004)
1. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a	"The present invention provides an osseous implant syringe capable of injecting osseous implant substances into interdental alveolar defects." (Ex. 1004 at 2:56-58.) "[E]xtension nozzle member 44

734 Patent	Clark (Ex. 1004)
subcutaneous cannula,	can be provided for the implant syringe to reach those more distant areas of the mouth." (*Id.* at 4:47-61.) "[V]ery small incisions" are made through tissue to insert the device to the bone defect and hemorrhaging is possible. (*Id.* at 2:15-17; 1:25-28)  FIG. 4
a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,	"Referring now to FIG. 8 of the drawings, it will be seen that a filling device member 68 can be provided. This consists mainly of a filling device reservoir 70 which contains the implant substance until it is loaded into the syringe barrel member 20." (*Id.* at 5:31-35.) Material is gravity-fed (less than 360 psi) through the filling device into the implant device and assisted with manual shaking by the user. (*Id.* at 6:22-44; Jensen Decl. at ¶ 97)  FIG. 8
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	"Looking now to FIG. 2 of the drawings, it will be seen that the implant syringe includes a syringe barrel member 20 [nozzle instrument]." (3:65-67.) Material can be delivered through the barrel outlet 28 [nozzle terminus] at the delivery pressure: "As the piston rod 11 slides through the axial lumen 24, any implant substance therein is displaced and forced through the axial lumen 24 and out the syringe barrel outlet 28." (4:7-11.)

734 Patent	Clark (Ex. 1004)
delivery pressure,	 FIG. 2 The nozzle instrument can be proximally coupled to the delivery device: "Looking now at FIG. 9 it will be seen that the filling device member 68 is engaged with the syringe barrel member 20." (*Id.* at 5:50-52; 6:30-33; 4:19-24.) The nozzle instrument is capable of advancement into the subcutaneous cannula: "Looking now at FIG. 5 of the drawings,…the extension nozzle member 44 [subcutaneous cannula] is placed on the syringe barrel member 20 by attaching the threaded nozzle coupler 40 to the threaded extension member connector 46." (4:62-66.) Figure 5 shows the nozzle within the cannula.
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.	"FIG. 1 shows a syringe plunger member 10 as used in the invention. The syringe plunger member 10 consists of a piston rod 11 having a first end 12 and a second end 14." (3:57-64.) "The difference in the outer diameter of the piston rod 11 and the inner diameter of the axial lumen 24 is large enough to allow the piston rod 11 to readily slide through the axial lumen 24 without allowing the implant substance to get between the piston rod 11 and the wall of the barrel sleeve axial lumen 24. As the piston rod 11 slides through the axial lumen 24, any implant substance therein is displaced and forced through the axial lumen 24 and out the syringe barrel outlet 28." (*Id.* at 4:2-11.)

734 Patent	Clark (Ex. 1004)
	 FIG. 1 As shown in Fig. 5, the plunger extension 54 urges material residing in the extension nozzle member 44 [subcutaneous cannula]: "In order to assure displacement of the osseous implant substance all the way through the extension nozzle lumen 52, a plunger extension 54 is place on the second end 14 of the syringe plunger member 10." (*Id.* at 4:66-5:2)  FIG. 5

Dependent claim 3 requires that the nozzle instrument ["the syringe barrel member"] in the apparatus of independent claim 1 "is made of a generally rigid material." As discussed above, Clark discloses every element of claim 1. Furthermore, Clark states that components (including the nozzle) are "preferably made of delrin or any sterilizable material capable of withstanding the forces necessary to apply the implant substance." (Ex. 1004 at 5:67-6:3.) Delrin is a rgid material. (Jensen Decl. at ¶ 98.) Thus, Claim 3 is anticipated.

Independent claim 15, which is broader than (and has fewer elements than) claim 1, is also anticipated as shown by the claim chart below:

734 Patent	Clark (Ex. 1004)
15. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus comprising a subcutaneous cannula,	Clark discloses an apparatus for introducing material into bone through a subcutaneous cannula (the extension nozzle member 44). See claim 1 above.
a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi,	Filling device member 68 conveys the material into the extension nozzle member at a delivery pressure of less than 360 psi. See claim 1.
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.	Clark discloses a tamping instrument (plunger extension member 54) which urges material residing the extension nozzle member into bone. (4:66- 5:2.) See claim 1.

D. Ground 4: Clark Renders Obvious Claims 2, 4, 5, 7, 8, 16, 17 and 19 In View of the Knowledge Of An Ordinarily Skilled Artisan

Dependent claim 2 requires that the nozzle instrument in the apparatus of independent claim 1 "is made of a generally flexible material." As discussed above, Clark discloses all the elements of claim 1. While Clark discloses that the nozzle instrument is preferably made of a rigid material (Ex. 1004 at 5:67-6:3), a person of ordinary skill in the art at the time of the invention understood that a flexible material was the other optional design choice for such instruments as discussed in Section V.B.2 above and as explained by Dr. Jensen. (See Jensen

Decl. at ¶¶ 73-75, 77, 101.) In fact, Clark also discussed making other components from flexible materials such as "surgical quality rubber or the like." (Ex. 1004 at 5:27-30.) Thus, Clark teaches that selecting an instrument that is either made from generally flexible or generally rigid materials would have been a matter of design choice based on the specifics of the procedure being performed and physician preference. Thus, Clark in view of the knowledge of the ordinary skilled artisan renders claim 2 obvious. (Jensen Decl. at ¶ 101.)

Dependent Claims 4 and 16 require an "Apparatus according to claim 1 [claim 15] wherein the delivery device comprises a syringe." As discussed above, all the elements of claims 1 and 15 are disclosed in Clark. Clark discloses an "Osseous implant syringe." (Ex. 1004 at Title.) While the "delivery device" referenced in claim 1 is a device that is coupled to the syringe barrel member [nozzle], it is evident that Clark intended syringe-like delivery as well. It would have been obvious to a person of ordinary skill in the art to use the syringe barrel member as a syringe. This motivation would be particularly strong if a paste-like substance were injected into bone. (Jensen Decl. at ¶ 102.) Thus, Clark in view of the knowledge of the ordinary skilled artisan renders claims 4 and 16 obvious.

Dependent Claims 5, 8, and 17 require an "Apparatus according to claim 1 [or claim 15] wherein the tamping [or nozzle] instrument includes markings to

visually gauge the advancement of the tamping [or nozzle] terminus through the subcutaneous cannula." As discussed in Section V.B.4., it was well known to include markings on such instruments to visually gauge the advancement of such instruments and would have been obvious to do so with regard to the Clark device for the reasons explained in the prior art. (See Section V.B.4.; Jensen Decl. at ¶¶ 103-104, 80-81, 88-89.) Thus, Clark renders claims 5, 8 and 17 obvious.

Dependent claims 7 and 19 requires the tamping instrument in the apparatus of claims 1 or 15 "is made of a generally rigid material." While Clark suggests that "the flexible plunger extensions 54, 66 can be fabricated of surgical quality rubber or the like" (Ex. 1004 at 5:27-30), Clark also recognizes the two design options for components as discussed above with regard to claim 2 and the selection of an alternate material choice would have been obvious to the skilled artisan. (Jensen Decl. at ¶ 105.) Moreover, as Dr. Jensen explains, if an ordinary skilled artisan were using the curved nozzle extension disclosed in Clark, the artisan would have been motivated to select a plunger extension made of flexible materials. (*Id.*) Dr. Jensen confirms that these are ordinary design principles well understood to a person of ordinary skill in the art as part of their background knowledge and as shown by the Clark disclosure itself. (*Id.*) Thus, Clark in view of the knowledge of the ordinary skilled artisan renders claim 19 obvious.

E. Ground 5: Muller Anticipates Claims 15, 16 and 19

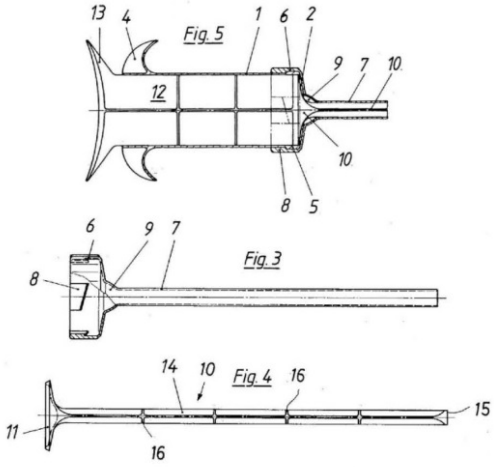
Muller, entitled "Injector for Bone Cement," teaches a system for manually injecting bone cement into bone along with a tamping instrument for clearing cement out of a cannula just as claimed in the 734 patent. Muller explains that, depending on the surgical operation, varying amounts of cement injection pressure may be necessary or preferred. (Ex. 1005 at 1:19-23.) To solve the need for pressure variability, Muller teaches a detachable cement delivery system for delivering cement to bone that allows a user to: (1) deliver high-volume flow through the end of a syringe; or (2) deliver low-volume flow by attaching a narrower tube (called a nozzle element) to the syringe.[8] (*Id.* 1:1-5.) Muller also describes a tool to manually tamp materials through the narrow tube as claimed in the 734 patent. (*Id.* at 1:54-2:4.)

Specifically, Muller teaches using an injector "comprised of a cylinder tube for receiving the bone cement, a piston, a nozzle element and a ram." (*Id.* at 1:41-43.) Cement is loaded into a syringe (the "cylinder tube," shown in Fig. 5),

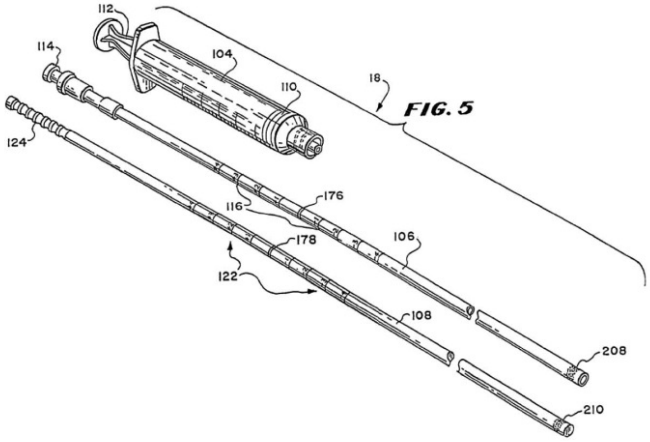
[8] Muller refers to the two systems as "high pressure" and "low pressure;" nonetheless, both systems are hand-actuated systems using a syringe and thus deliver cement at pressures less than 360 psi (as claimed in the 734 patent).

which serves as a delivery device and is connected to a "nozzle 7" (shown in Fig. 3). Cement is delivered from the tube by depressing the piston, ejecting cement through the cylinder tube into and through the nozzle element. (*Id.* at 3:25-35.) The ram 10, shown in Fig. 4 below, is a tamping instrument for urging filling material from a subcutaneous cannula, just as claimed in the 734 patent.

Muller



734 Patent



For high-volume flow, material is dispensed directly through the syringe (cylinder tube) without the nozzle attachment: "In use, with the nozzle element removed, a relatively large quantity of bone cement can be extruded through the injection nozzle in the bottom of the cylinder tube." (*Id.* at 1:56-59.) Muller refers to this high-volume flow as "low pressure" delivery given the volume of the cylinder tube. (*Id.* at 1:61, 2:52-55 (tube may hold 125 cc); *see also* Jensen Decl. at ¶ 40.) Alternatively, for low-volume flow, material is dispensed through the

syringe with the "nozzle element" attached. (Ex. 1005 at 63-67.) The "nozzle element 6 also includes a reservoir 9 between the cup shaped portion and the nozzle tube 7," which "is sized to have a volume of a few cubic centimeters." (*Id.* at 3:13-18.) The ram 10 is then used as a tamping instrument "to eject the bone cement from the filled nozzle tube." (*Id.* at 1:65-2:3.)

Given the volumes of the devices involved (e.g., 125 cc and "a few cubic centimeters"), Muller discloses "a delivery device to convey the material at a delivery pressure of no greater than about 360 psi." As discussed above, the 734 patent notes, "the pressure at which liquid is expressed from 1 cc syringe by the application of moderate force to the syringe piston...amounts to a pressure that is no greater than about 360 psi [pounds per square inch]. (Ex. 1001 at 2:5-11.) The application of such force on a larger device (e.g., greater than 1 cc) will result in even *lower* delivery pressures, e.g., less than 360 psi. (See, e.g., Jensen Decl at ¶ 40; Ex. 1011, Hayward, p. 379-80 ("Smaller syringes generated significantly more injection pressure than did larger syringes").) Indeed, Muller recognizes this by referring to delivery through the larger-volume cylinder tube as "low pressure" and delivery through the smaller-volume ("few cubic centimeters") nozzle as "high pressure" (Ex. 1005 at 1:60-65) – even though both result in delivery pressures less than 360 psi. (Jensen Decl. at ¶ 110.) See also footnote 6 above.

As shown in the claim chart below (and explained in the Jensen Declaration at ¶ 110), Muller discloses all the elements of claim 15 and therefore anticipates.

734 Patent	Muller (Ex. 1005.)
15. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus comprising a subcutaneous cannula,	Muller describes an "injector for injecting expandable bone cement into a surgically prepared bone cavity." (Ex. 1005 at 1:4-7.) In one embodiment, cement is introduced through the "nozzle element," which serves as a subcutaneous cannula to access bone. (*Id.* at 1:62-2:1.)[9]
a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi,	A syringe ("cylinder tube") serves as a delivery device to convey the material: "Referring to FIG. 1, the tube 1 is in the form of a cylinder and defines a volume of about 125 cubic centimeters for receiving bone cement…." (*Id.* at 2:52-55.) Manual pressure is applied to the piston in the cylinder tube, ejecting cement through the cylinder tube into and through the nozzle element. (*Id.* at 3:25-35.)
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.	"When the nozzle element [subcutaneous cannula] is attached to the cylinder tube, the ram is guided through the cylinder tube and through the injection nozzle into the nozzle tube." (*Id.* at 1:67-2:4.) (See also Jensen Decl. at ¶ 110.) "[R]am 10 includes a dish type bearing plate 11 at an upper end, as viewed, and an elongated shank 14 of contoured cross-sectional shape." (Ex. 1005 at 3:19-21.) "Since the shank 14 of the ram 10 extends through the injection nozzle 3, the shank 14 is suitably shaped in cross-section so as to permit the bone

[9] To clarify, for purposes of claim 15, the Muller "nozzle" is the subcutaneous cannula but, in other grounds, the Muller "nozzle" will be the claimed "nozzle."

734 Patent	Muller (Ex. 1005.)
	cement to be expelled." (*Id.* at 3:53-56; *see also id.* at 1:66-67 ("Further, the ram serves to eject the bone cement from the filled nozzle tube.")

Dependent Claim 16 requires an "Apparatus according to claim 15 wherein the delivery device comprises a syringe." As discussed above, Muller discloses all the elements of claim 15 and the "delivery device" is a syringe (see Fig. 5.).

Dependent Claim 19 requires "Apparatus according to claim 15 wherein the tamping instrument is made of a generally rigid material." Muller explains that the "injector may consist of a plastic which is common for such injectors, for example polymethyl pentene (TPX)" and "can be manufactured primarily by injection molding or as pressed parts." (Ex. 1005 at 2:26-31.) These materials are generally rigid. (Jensen Decl. at ¶ 112.) Thus, claims 16 and 19 are also anticipated by Muller.

F. Ground 6: Muller In View of Reiley 404 and the Knowledge Of An Ordinarily Skilled Artisan Renders Obvious Claims 1-21

As discussed above, Reiley 404 (Ex. 1006) is one of the original balloon-assisted vertebroplasty patents and describes systems and methods for delivering materials into vertebral and non-vertebral bones. Specifically, as in typical vertebroplasty procedures, Reiley 404 describes the use of a subcutaneous cannula 30 to establish an access path to bone. (Ex. 1006 at 6:7-46.) After an access path is created, a balloon (e.g., 76) is advanced through the cannula to

form a void in the bone as shown in Figure 21. (*Id.* at 7:27-35.) Reiley 404 then describes inserting a double-barrel injection gun in the cannula to deliver cement into the cavity. (*Id.* at 7:42-55.) According to Reiley 404, "[s]uch injection gun nozzle is shown in FIGS. 25 and 26 and includes a material delivery tube 80 and an aspirating tube 82, both of which have open ends 84 and 86, respectively." (*Id.* at 7:47-50.)

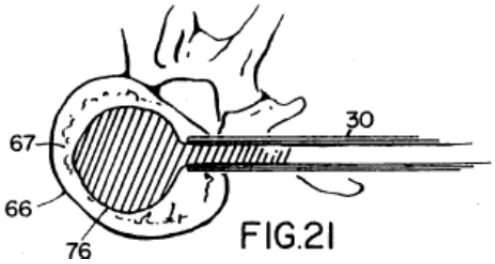
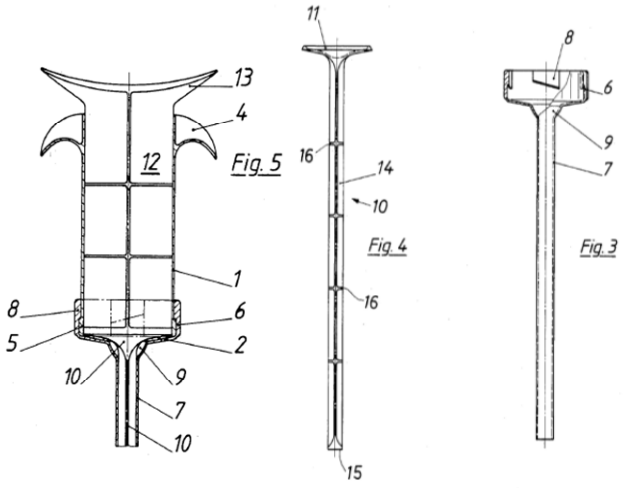


FIG.21

As discussed above in Section E, Muller discloses using a delivery device to convey material such as bone cement through a nozzle that is coupled to a syringe delivery device. The delivery device (e.g., cylinder tube) in Muller delivers cement at less than 360 psi. (See above.) The device includes a piston that, when depressed, displaces cement in the device and nozzle into bone. As shown, the nozzle is detachable from the delivery device and includes a separate tamping device, i.e., a ram, that can be used to urge cement from the nozzle into bone. (*Id.*; Jensen Decl. at ¶ 117.)



As discussed above, Muller discloses that its design is useful for varying the

delivery pressure of the cement – the very same issue that the later-issued 734 patent purports to address. (Compare Ex. 1001 at 1:19-23 with Ex. 1005 at Abstract.) For example, Muller states that "it is an object of the invention to provide a bone cement injector which is capable of extruding a relatively large quantity of bone cement at relatively low pressure and of extruding a small quantity of bone cement at relatively high pressure," both of which are manual delivery methods. (Ex. 1005 at 1:28-32.) One way that Muller accomplishes the stated objective is by using ram 10 to advance through the interior bore of the nozzle 7 and urge materials from the nozzle into bone.

As discussed above, while Reiley 404 describes an injection gun, skilled artisans knew that syringe systems could be used in vertebroplasty instead of guns. (See Section E.) Given Muller's suggestions about controlling delivery, a person of ordinary skill in the art would have had reason to substitute the Muller cement injector and tamping instrument for the Reiley 404 injection gun in the Reiley 404 balloon-assisted vertebroplasty system. (Jensen Decl. at ¶ 119.) There would have been no unexpected results from using the Muller device in this fashion and, in fact, Muller suggests that its device should assist in controlled delivery providing motivation to the ordinary skilled artisan to do so. (*Id.*) The combination is discussed at paragraphs 120-122 of the Jensen Declaration.

Specifically, with regard to ***independent claim 15***, as discussed above, Reiley 404 discloses "an apparatus for introducing material into bone through a ***subcutaneous cannula*** [30], the apparatus including [or comprising] a subcutaneous cannula." (Ex. 1006 at 6:30-46; Fig. 18.) As discussed above, Muller discloses "***a delivery device*** to convey the material at a delivery pressure of no greater than about 360 psi," i.e., the cylinder tube,[10] and the claimed ***tamping instrument***, i.e., ram 10, which is used to clear material out of a hollow tube (*Id.* at 1:40-67) and thus can be used for that purpose in the Reiley 404 subcutaneous cannula without unexpected results. (See Section E; Jensen Decl. at ¶ 121.)

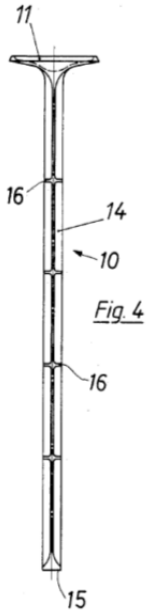


Fig. 4

With regard to ***independent claim 1***, Muller further discloses the additional element, i.e., "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

[10] Moreover, delivering cement at pressures less than 360 psi (e.g., using a syringe of 1 cc or greater) was known in the art as of August 1998 and was merely an obvious design choice. (Jensen Decl. at ¶¶ 39-40, 165, 120-122.)

material conveyed by the delivery device enters bone at the delivery pressure." Specifically, Muller discloses a nozzle element 6 with a bayonet connection (proximal fitting) for coupling to cylinder tube 1 (delivery device). (Ex. 1005 at 3:3-12.) The nozzle tube is sized to have a volume of a few cubic centimeters. (*Id.* at 3:15-18.) The material exits the nozzle terminus and enters bone at the delivery pressure. (*Id.* at 1:50-53.) For the reasons described above, a ordinarily skilled artisan would understand that the Muller syringe injector could be used in a subcutaneous cannula instead of the injection gun. (Jensen Decl. at ¶¶ 118-119.)

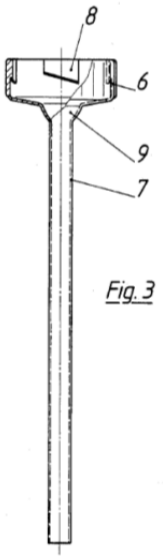


Fig. 3

With regard to ***independent claim 12***, Muller further teaches that nozzle includes "a nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure" as claimed: "bone cement is expelled through the injection nozzle 3 into the reservoir 9 and then into the nozzle tube 7 which is of small cross-sectional area." (Ex. 1005 at 3:46-51.)

Claim 12 also requires "a stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore and, with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula." The ram 10 is a stylet capable of advancement into the bore of the nozzle 6. (Ex.

1005 at 1:40-56; Jensen Decl. at ¶ 121.) See Figure 5, which shows the ram 10 nested in nozzle tube 7. Moreover, Muller teaches to use the system in various modes and also explains that "the nozzle element can be detached from the cylinder tube and used as a separate injector." (*Id.* at 3:60-63, 2:2-5.) Muller therefore suggested to a person of ordinary skill in the art that one option for urging material from the cannula would be to separate the nozzle element and use the ram 10 nested within the nozzle 7 as a tamping instrument, particularly since the nozzle tube with nested ram would provide greater cross-sectional area in the cannula than just the ram alone. (Jensen Decl. at ¶ 121.)

In sum, the 734 patent addresses the purported problem of injecting filling material into bone using low pressure for additional controlled delivery. However, Muller addressed the issue of low pressure delivery of bone cement into a surgically prepared bone cavity before the 734 patent and thus one of ordinary skill in the art interested in controlling delivery would have had reason to consider the teaching of Muller. (Jensen Decl. at ¶ 132.) Muller's disclosure of syringe injectors for the delivery of bone cement into a surgically prepared bone cavity would have taught one having ordinary skill in the art to use the ram 10 of Muller to urge material from the cannula in the balloon-assisted vertebroplasty system of Reiley 404. Thus, Reiley '404 and Muller render independent claims 1,

12 and 15 obvious. The dependent claims, which simply claim obvious variants of known devices, are likewise obvious in view of Reiley 404 and Muller.

Dependent claims 2 and 3 require that the nozzle instrument of claim 1 "is made of a generally flexible material" or a "generally rigid material." Muller states that "the injector may consist of a plastic which is common for such injectors, for example polymethyl pentene (TPX)." (Ex. 1005 at 2:26-28.) However, as discussed, it was common knowledge at the time of the invention that plastics that were common for such injectors included plastics made of generally rigid and generally flexible materials and that one could select a nozzle made of generally flexible or generally rigid materials depending on the intended clinical use. Thus, it would have been known to a person of ordinary skill in the art reviewing Muller that the nozzle in Muller could be made from both generally flexible and generally rigid materials for the same reasons as discussed above. (See Section V.B.2. above; Jensen Decl. at ¶ 124.)

Dependent Claims 4, 14 and 16 require an "Apparatus according to claim 1 [claim 12, or claim 15] wherein the delivery device comprises a syringe." As discussed above, claims 1, 12, and 15 are obvious in view of Muller and Reiley

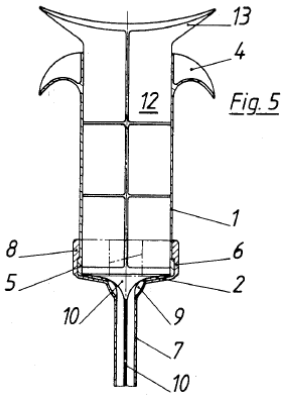


Fig. 5

404. As shown in Figure 5 of Muller, the delivery device disclosed therein is a syringe. (Jensen Decl. at ¶ 125.)

Dependent Claims 5 and 17 require an "Apparatus according to claim 1 [or claim 15] wherein the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula." *Likewise,* ***dependent claims 8 and 13*** require "Apparatus according to claim 1 [claim 12] wherein the nozzle instrument includes markings to visually gauge the advancement of the nozzle terminus [instrument] through the subcutaneous cannula." As discussed in Section V.B.4. above, it was known in the art to include markings on instruments to visually gauge the advancement of such instruments including tamping instruments. It would be obvious to include such markings on the Muller device for the same reasons known in the art. (Jensen Decl. at ¶ 126.)

Dependent Claims 6, 9, and 18 require an "Apparatus according to claim 1 [claim 15] wherein the tamping [or nozzle] instrument includes at least one radiopaque marker." As discussed above in Section V.B.5., the use of radiopaque markers on such instruments was well known in the art. Moreover, Reiley 404 discloses the advantage of monitoring surgical procedures fluoroscopically using radiopaque material, e.g., disclosing monitoring the procedure fluoroscopically by inflating the balloon with a radiopaque medium. (Ex. 1005 at 6:62-65.) For the

same reasons as discussed above, it was an obvious design choice to use radiopaque markers on these instruments as was known in the art.

Dependent claims 7 and 19 require the tamping instrument in the apparatus of claim 1 and 15 "is made of a generally rigid material." As discussed above, Muller discloses that the injector may be made of polymethyl pentene, a rigid material. (*Id.* at 2:25-30; Jensen Decl. at ¶ 128.)

Dependent claims 10 and 20 claims the "Apparatus according to claim 1 [claim 15] and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone." As discussed above, Reiley 404 discloses the use of a balloon, which is introduced through the access cannula, as a cavity forming instrument to compress cancellous bone: "As balloon 76 is inflated, it forces the osteoporotic bone marrow 67 laterally and outwardly of the wall of the vertebral body 66. This compacts the bone marrow and leaves a void in the interior of the vertebral body to be treated." (Ex. 1006 at 7:26-30; Jensen Decl. at ¶ 129.) ***Dependent claims 11 and 21*** require that the cavity forming instrument of claims 10 and 15 "includes an expandable structure." The balloon 76 disclosed in Reiley 404 is an expandable structure. (Ex. 1006 at 7:26.)

Thus, the claims would have been obvious at the time of the invention.

G. Ground 7: Muller In View of Reiley II and the Knowledge Of An Ordinarily Skilled Artisan Renders Obvious Claims 1-21

Reiley II (Ex. 1007) is a published patent application that focused on balloons of varying shapes and sizes that can be used to create voids in bone. Like Reiley 404, Reiley II discloses a typical balloon-assisted vertebroplasty system, i.e., using a cannula (cannula 26) to establish an access path through soft tissue to bone; creating a cavity in the bone with using a balloon catheter (10, 21) that is introduced through the cannula; and then delivering cement into the bone via the cannula. (Ex. 1007 at 24 –25; Fig. 8). Unlike Reiley 404 which discusses delivering material via an injection gun in the cannula, Reiley II also discloses manually delivering materials through the cannula using a tamping instrument:

> To insert materials which do not flow into the balloon-made cavity, like hydroxyapatite granules or bone mineral matrix, the surgeon can push them down a tube with a long pin whose diameter is slightly more narrow than the inner diameter of the canula through procedures which the minimally-invasive procedure is taking place. . . . . If the material to be inserted does not flow and should not be pushed into the cavity through a canula (as in the case of the hydroxyapatite block, because that can cause damage), the surgeon can make the cavity using the "minimally invasive approach,…"

(*Id.* at 40, l. 32 – p. 41, l. 12 (emphasis added).) The "tube" is a nozzle and the "long pin" is the stylet /tamping instrument as later claimed in the 734 patent.

A person of ordinary skill in the art would understand that the long pin or tube in Reiley II should have a construction similar to the nozzle and ram of Muller

(shown in Figures 3 and 4.) (Jensen Decl. at ¶ 138.) In fact, because the nozzle tube 7 of Muller has a reservoir 9 for holding material, it would be particularly useful for holding "the materials which do not flow" described in Reilly II. (*Id.*) And Muller specifically suggests that "the nozzle element can be detached form the cylinder tube and used as a separator injector." (Ex. 1005 at 2:2-5.) Thus, the ordinary skilled artisan would be motivated to use the Muller ram/nozzle tube as the long pin/tube in the Reiley II procedure. (Jensen Decl. at ¶ 138.) Moreover, the skilled artisan would understand that the Muller injector could be used in Reiley II, e.g., for applications involving flowable materials (as described in Section F). (*Id.* at ¶ 139.) Thus, it would have been obvious to a person of ordinary skill in the art to use the Muller cement injector in the Reilly II system. (*Id.*)

Specifically, with regard to ***independent claims 1, 12, and 15***, as discussed above in Sections E and F, Muller discloses the claimed ***delivery device*** and ***nozzle instrument*** required by the claims. To the extent that the nozzle tube itself is not used as a ***subcutaneous cannula***, Reiley II discloses delivering materials via a subcutaneous cannula (Ex. 1007 at 24 –25; Fig. 8) including a description of how non-flowable materials can be pushed with a long pin down a tube in the subcutaneous cannula (*id.* at 40-41). A person of ordinary skill in the art would understand that the Muller injector can be used in the Reiley subcutaneous

cannula as discussed above and that Muller provides an alternative option for delivering flowable materials into the cannula without any unexpected result. (Jensen Decl. at ¶¶ 139-140.) The skilled artisan would have been further motivated to use the Muller instrument because Muller has an advantage due to its detachable nozzle/stylet, which can serve to push materials down the cannula as expressly envisioned by Reiley II. (*Id.*)

Regard the ***tamping instrument*** in independent claims 1 and 15, the Reiley II "long pin"/Muller "ram," which is capable of advancement in the cannula and has a tamping terminus, urges residual material in the cannula into the bone. (Ex. 1007 at p. 40, l. 32 ("the surgeon can push them down a tube with a long pin whose diameter is slightly more narrow than the inner diameter of the canula through procedures which the minimally-invasive procedure is taking place"); Ex. 1005 at 1:66-67 ("the ram serves to eject the bone cement from the filled nozzle tube"); *Id.* at ¶ 139.) For ***claim 12***, it would have been obvious to use the Muller ram/nozzle as a tamping instrument in the same manner as described above for Reiley 404. (*See* Section F; Jensen Decl. at ¶ 140.) Thus, the independent claims are obvious in view of Muller and Reiley II. (See Jensen Decl. at ¶¶ 138-142.)

As discussed above in Section F, ***dependent claims 2-9, 13, 14, and 16-19*** are disclosed in Muller or were well known in the art at the time of the invention.

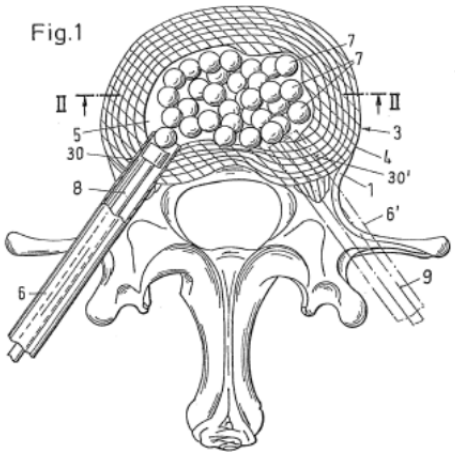
Dependent claims 10, 11, 20 and 21 require the apparatus to include a "cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone" or require the cavity forming instrument to include an "expandable structure". Like Reiley 404, Reiley II disclose the use of a balloon as a cavity forming instrument, which passes through the access cannula, to compress cancellous bone. (Ex. 1007 at 25 ("The balloon is then inflated to compact the bone marrow and/or cancellous bone in the cavity."); Fig. 8.) Thus, the dependent claims would also have been obvious in view of Reiley II, Muller and the knowledge of the ordinary skilled artisan.

H. Ground 8: Muller In View of Baumgartner and the Knowledge Of An Ordinarily Skilled Artisan Renders Obvious Claims 1-21

Baumgartner discloses methods and tools for implanting a prosthesis into a cavity formed in the core region of an intervertebral disk. (Ex. 1008 at Abstract.) Specifically, Baumgartner discloses forming a cavity between vertebral bodies by inserting a gouge through a subcutaneous cannula (tube 6) to remove tissue. (*Id.* at 6, lns. 13-24.) Once a cavity is formed, filling materials (support members 7) are introduced through the tube 6 and into the bone. (*Id.* at 6, lns. 25-35.)

Plunger 6 is a tamping instrument to urge the material into the cavity in the vertebral space: "The support members 7 are packed into the cavity 5, if necessary by means of a plunger 8, until the cavity is substantially filled by the

support members 7 resting against one another and the support members 5 form a new core region of the intervertebral disk 3 capable of the transfer of compressive forces." (*Id.* at 6–7.) Simply put, Baumgartner clearly depicts delivering materials through a subcutaneous cannula and using a tamping instrument to push materials into the space.



Because the implant materials in Baumgartner are preferably "rotational solids" (*Id.* at 6, lns. 31-32), Baumgartner does not discuss a known delivery device such as a syringe for delivering flowable, amorphous materials such as bone cement. Thus, a skilled artisan would be motivated to consider such a device for flowable injections. (Jensen Decl. at ¶ 150.) As discussed above in Sections E and F, Muller discloses an injector for bone cement. A person of ordinary skill in the art would recognize that if one desired to perform the Baumgartner procedure to deliver flowable materials such as bone cement into the vertebral space, one could turn to a syringe-like device such as Muller and deliver the materials through the subcutaneous cannula (tube 6) of Baumgartner. (*Id*.) The Baumgartner tamping instrument (plunger 8) could then be used to push excess material down the cannula, just as it is used to push the round

support members. There is no unexpected result from such a substitution. (*Id.*)

For ***independent claim 15***, which is the broadest claim, Baumgartner teaches "an apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a ***subcutaneous cannula***," which is tube 6 (shown above). (*See id.* at 6, lns. 21-24; abstract.) While Baumgartner focuses on delivering rotational solids, Muller discloses delivering flowable materials such as bone cement. As discussed above in Sections E and F, Muller discloses a cylinder tube with a piston, which is a "***delivery device*** to convey the material at a delivery pressure of no greater than about 360 psi." (Jensen Decl. at ¶¶ 151-153; see also footnotes 6 and 9.) Finally, Baumgartner discloses the claimed ***tamping instrument***. Baumgartner discloses a plunger 8, which advances through the subcutaneous cannula (tube 6) and which has a tamping terminus which urges material residing in the cannula into bone. (Ex. 1008 at 6-7 ("The support members 7 are packed into the cavity 5, if necessary by means of a plunger 8, until the cavity is substantially filled…").) A person of ordinary skill in the art would understand that, after flowable materials are injected with the Muller injector, the plunger 8 of Baumgartner could urge residual materials in cannula 6 into bone. (Jensen Decl. at ¶ 151.) There would be no unexpected results from such an application of the plunger; indeed, that is its purpose. (See Jensen Decl.

at ¶¶ 146-158.)

For ***independent claim 1***, the analysis is the same as claim 15 except that it is noted that Muller further discloses the claimed ***nozzle instrument*** with a proximal fitting that couples it to the delivery device as explained in Section F above. (*Id.*) Because these types of systems were common at the time of the invention, a person of ordinary skill in the art would understand that the nozzle tube of Muller (which is sized to hold a few milliliters of material) could be used as a nozzle within the cannula in Baumgartner (tube 6) and would be motivated to use it for applications involving, e.g., flowable materials. (*Id.* at ¶ 151.)

For ***independent claim 12***, the analysis is the same as claim 1 except that claim 12 further requires "a stylet" that is capable of being nested in the nozzle and together forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the cannula. As discussed above in Section F, the ram 10 of Muller is capable of advancement into the bore of the Muller nozzle tube 7 and forms a tamping instrument capable of advancement into the cannula of Baumgartner to urge residual material from the cannula. As Dr. Jensen explains, it would have been obvious to an ordinarily skilled artisan that, instead of using the Baumgartner plunger 8 to push residual materials in the cannula, an alternative design option for urging filling material

from the subcutaneous cannula would be to use the Muller ram 10 nested within the Muller nozzle tube 7, particularly since that embodiment would provide greater cross-sectional area in the cannula than just the ram 10 alone and Muller teaches to use the injector separately. (Jensen Decl. at ¶ 152; Ex. 1005 at 3:60-63, 2:2-5.) There are no unexpected results from using the tools of Baumgartner and Muller in this manner.

As discussed above in Section F, ***dependent claims 2-9, 13, 14, and 16-19*** are disclosed in Muller or were well known in the art at the time of the invention and are thus obvious for the same reasons.

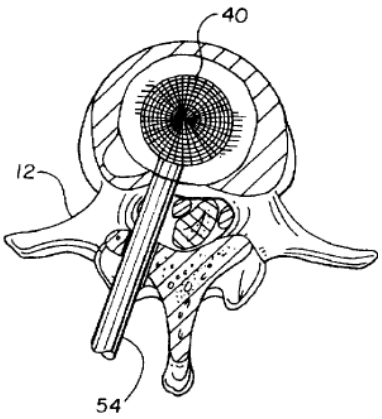
Dependent claims 10 and 20 require a "cavity forming instrument" as discussed above. Baumgartner discloses using auxiliary tools such as a gouge, which is inserted through the subcutaneous cannula, to create a cavity in the intervertebral disk space before introducing the implant: "A gouge in inserted into the core region through the inserted tube 6, by which the cavity 5 is created and the cut out tissue parts are removed." (Ex. 1008 at 6.) Thus, these claims also would have been obvious. (Jensen Decl. at ¶ 157.) ***Dependent claims 11 and 21*** require the cavity forming instrument to include an "expandable structure." As discussed above in Section IV.A., balloon-assisted vertebroplasty was a known option in the prior art at the time of the invention. The skilled artisan would have

known that such devices could be incorporated into the procedure for the reasons, e.g., addressed in the Reiley 404 patent, and there are no unexpected results from using a balloon in the Muller/Baumgartner procedure. (Jensen Decl. at ¶ 157.) Thus, these claims also would have been obvious.

I. Ground 9: Kuslich In View of the Knowledge Of An Ordinarily Skilled Artisan Renders Obvious Claim 12

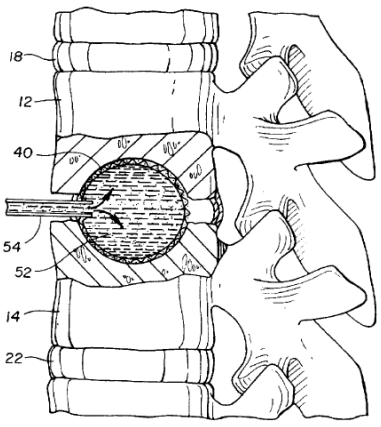
Kuslich (Ex. 1009) describes procedures for delivering graft medium to a cavity in an intervertebral disk via a subcutaneous cannula. However, unlike the references discussed above (Deramond and Muller) that describe delivery using a syringe, Kuslich describes delivering material with a gun-like device (90) that uses a trigger to push a stylet (96) through the device's nozzle.

Fig. 7b



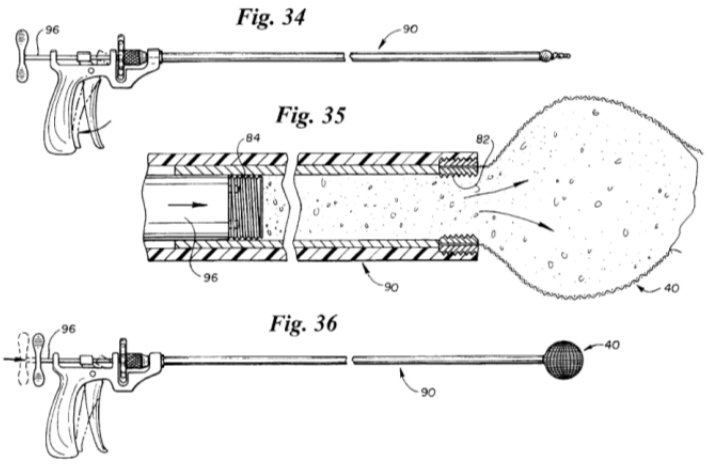
Specifically, Kuslich describes delivering filling material to an expandable implant bag 40 that is inserted through a subcutaneous cannula 54 into a cavity in bone. As shown for example in Figures 5, 6 and 7b, "the bag 40 may be filled by packing the graft medium 52 through a guide tube 54." (Ex. 1009 at 9:62-63.) The

Fig. 6



filling material includes "finely chopped cortical or cancellous bone chips for fusion or connective tissue when a fibrous union is desired." (*Id.* at 9:55-60.)

As shown in Figures 34, 35 and 36, the filling material is delivered via a gun-like device 90, which includes a threaded plunger 96 that pushes graft medium through the nozzle of the device (see figure 35) into the implant bag 40. (*Id.* at 10:19-37.) The device is hand-actuated to advance the plunger through the nozzle and urge filling material into the cavity. Specifically, "plunger 96 pushes the screw 84 toward the internal threads 82, pushing the graft medium 52 into the bag. As the stroke is completed, the plunger 96 is rotated to turn the screw 84 in and seal the implant 40." (*Id.* at 10:31-34.)



As shown in the claim chart below, Kuslich discloses all the elements of claim 12 except it does not specify any particular delivery pressure for the device 90. Instead, Kuslich teaches that the user should "[i]nject or insert the graft material into the device using sufficient pressure to fill the internal cavity of the device, thus producing rigidity and tension on the wall of the device." (*Id.* at

12:24-27.) A person of ordinary skill in the art would understand this to mean that a reasonable delivery pressure should be used and would desire a low pressure delivery (e.g., under 360 psi) so that delivery can be controlled (as was explained in the prior art). (Jensen Decl. at ¶ 164.) 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; *s*ee 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.)

734 Patent	Kuslich (Ex. 1009)
12. Apparatus for introducing material into bone through a subcutaneous cannula, the	As shown in figures 5, 6, and 7B, Kuslich describes an apparatus for introducing graft materials into bone through a subcutaneous cannula 54: "bag 40 may be filled by packing the graft medium 52

734 Patent	Kuslich (Ex. 1009)
apparatus including a subcutaneous cannula,	through a guide tube 54." (Ex. 1009 at 9:61-67.)
a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,	The bag is filled via device 90. The delivery device comprises a cartridge 92 that is loaded with bone graft material and then inserted into the opening 88, a nozzle (the tube at the distal end of the delivery device 90), and a plunger 96. Kuslich teaches using a "sufficient pressure to fill the internal cavity of the device." (Ex. 1009 at 12:24-27; see Jensen Decl. at ¶¶ 164-166.)
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 bore through which the material conveyed by the delivery device enters bone at the delivery pressure,	Kuslich includes a nozzle instrument (the tube at the end of the delivery device) fit to the handle at the proximal end of the delivery device that can be advanced through the guide tube 54 to deliver the filling material into the bag. The nozzle includes a bore through which the material is conveyed as depicted in Figure 35 shown above. (Ex. 1009 at Fig. 35; see Jensen Decl. at ¶ 166.)
and a stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore and, with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula.	The plunger 96 is a stylet that is advanced through the nozzle, closing the nozzle bore. When filling of the implant bag 40 is complete, the plunger 96 completely closes the interior bore of the nozzle. The plunger is rotated to turn a screw onto the implant 40, sealing the implant and leaving the graft in place in the cavity (and thereby injecting the material from the subcutaneous cannula). "The device 90 is threaded or otherwise attached to till port 80. A plunger 96 pushes the screw 84 toward the internal threads 82, pushing the graft medium 52 into the bag. As the stroke is completed, the plunger 96 is rotated to turn the screw 84 in and seal the implant 40. The plunger may contact the screw via a pair of studs 98 that project into screw

734 Patent	Kuslich (Ex. 1009)
	recesses 100. The device 90 is then withdrawn." (Ex. 1009 at 10:30-36.)

IV. SECONDARY CONSIDERATIONS

Stryker is not aware of any secondary considerations that would tend to show non-obviousness that would have a nexus with the claimed inventions. (Jensen Decl. at ¶¶ 168-169.)

V. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *inter partes* review of claims 1-21 of the 734 patent.

Respectfully submitted,

Dated: September 3, 1014

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

In re Application of:

Robert M. SCRIBNER — Issued: June 5, 2001

Michael L. Reo
Mark A. Reiley
Ryan Boucher — Application No. 09/134,323

U.S. Patent No. 6,241,734

Filing Date: August 14, 1998

For: SYSTEMS AND METHODS FOR PLACING MATERIALS INTO BONE

CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 6,241,734 and Exhibits 1001-1027 were served on September 3, 2014, via pre-paid, overnight Federal Express to the correspondence address of record for the subject patent pursuant to 37 C.F.R. § 42.105:

Medtronic, Inc. (Spinal/Haynes Boone)
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Attn: Legal Patents MS: LC340
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