IPR2014-01434

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
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Ryan Boucher

Issued: December 26, 2006

Application No. 10/617,976

U.S. Patent No. 7,153,307

Filing Date: July 11, 2003

For: SYSTEMS AND METHODS FOR PLACING MATERIALS INTO BONE

PETITION FOR *INTER PARTES* REVIEW

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EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 7,153,307 ("the '307 patent")
1002	Declaration of Mary E. Jensen, M.D. including c*urriculum vitae*
1003	U.S. Patent No. 5,108,404 (issued Apr. 28, 1992) ("Reiley '404")
1004	WO 96/39970 (published Dec. 19, 1996) ("Reiley II")
1005	U.S. Patent No. 4,576,152 (issued Mar. 18, 1986) ("Muller")
1006	U.S. Patent No. 3,893,445 (issued Jul. 8, 1975) ("Hofsess")
1007	WO 97/23174 (published Jul. 3, 1997) including certified translation ("Grosse") (citations are to translation)
1008	U.S. Patent No. 5,445,639 (issued Aug. 29, 1995) ("Kuslich")
1009	U.S. Patent No. 6,019,776 (filed Oct. 14, 1997)
1010	Hervé Deramond et al., *Percutaneous Vertebroplasty*, Seminars in Musculoskeletal Radiology Vol. 1, No. 2, pp. pp. 285-95(June 1997) ("Deramond")
1011	Afshin Gangi et al., *Percutaneous Vertebroplasty Guided by a Combination of CT and Fluoroscopy*, 15 Am. Soc'y Neuroradiology, pp. 83-86 (1994) ("Gangi")
1012	U.S. Patent No. 5,997,581 (filed Dec. 29, 1997) ("Khalili")
1013	U.S. Patent No. 5,419,765 (issued May 30, 1995) ("Weldon")
1014	U.S. Pat. No. 5,579,774 (issued Dec. 3, 1996) ("Miller")
1015	U.S. Patent No. 4,616,656 (issued Oct. 14, 1986) ("Nicholson")
1016	U.S. Patent No. 3,613,684 (issued Oct. 19, 1971) ("Sheridan")
1017	Excerpts from the prosecution history of the '307 patent (paginated for convenience)

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, Stryker Corporation ("Stryker" or "Petitioner") respectfully petitions for *inter partes* review of claims 1-18 of U.S. Patent No. 7,153,307 ("the '307 patent") (Ex. 1001), which issued on December 26, 2006, and is purportedly assigned to Orthophoenix, LLC ("Orthophoenix"). The earliest application to which the '307 patent claims benefit is Application No. 09/134,323 (filed Aug. 14, 1998), now U.S. Patent No. 6,241,734. Stryker has used the August 14, 1998, 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 '307 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 pending prosecution concerning the '307 patent. Stryker notes that it has filed a petition for *inter partes* review concurrently herewith for U.S. Patent No. 6,241,734, to which the '307 patent claims priority.

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
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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 '307 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 1-18 of the '307 patent on the grounds set forth below and requests that each of the claims be found

unpatentable. An explanation of how claims 1-18 are unpatentable under specified statutory grounds is provided below including an identification of where each element is found in the prior art and the relevance of each reference. Additional explanation and support for each ground of rejection is set forth in the Declaration of Dr. Mary Jensen (Ex. 1002), which is submitted in accordance with 37 C.F.R. § 1.68.

IPR of claims 1-18 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):

- U.S. Patent No. 5,108,404 ("Reiley '404"), issued April 28, 1992 (Ex. 1003);
- WO 96/39970 ("Reiley II"), published December 19, 1996 (Ex. 1004);
- U.S. Patent No. 4,576,152 ("Muller"), issued March 18, 1986 (Ex. 1005);
- U.S. Patent No. 3,893,445 ("Hofsess"), issued July 8, 1975 (Ex. 1006);
- WO 97/23174 ("Grosse"), published July 3, 1997 (Ex. 1007); and
- U.S. Patent No. 5,445,639 ("Kuslich"), issued August 29, 1995 (Ex. 1008).

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 '307 Patent
1	Reiley II anticipates claims 1-7, 10, 13-15, and 18 under § 102(b).
2	Reiley II in combination with the knowledge of one of ordinary skill in the art renders obvious claims 8, 9, 11, 12, and 14-18 under § 103.

Ground	Proposed Statutory Rejections for the '307 Patent
3	Reiley '404 in combination with Muller and the knowledge of one of ordinary skill in the art renders obvious claims 1-18 under § 103.
4	Hofsess anticipates claims 1-3, 7, and 10-17 under § 102(b).
5	Hofsess in combination with the knowledge of one of ordinary skill in the art renders obvious claims 8 and 9.
6	Grosse anticipates claims 1-3, 7, 10, and 13 under § 102(b).
7	Kuslich in combination with Grosse and the knowledge of one of ordinary skill in the art renders obvious claims 1-3 and 5-18 under § 103.

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

A claim in IPR is given the broadest reasonable interpretation in light of the specification to one having ordinary skill in the art. 37 C.F.R. § 42.100(b). See Section V below.

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 methods for delivering bone cement and other material into the spine or vertebra through a subcutaneous cannula were well known in the art at the time of invention of the '307 patent. (*See, e.g.,* Ex. 1002, Jensen Decl. at ¶¶ 25-29, 35-36; Ex. 1001 at 1:16-45.)

One of these methods, called percutaneous vertebroplasty (or "vertebroplasty"), was developed in France in the mid-1980s. Vertebroplasty assists in pain relief and prevention of vertebral body collapse in patients with fractured or otherwise unhealthy vertebral bodies. (Jensen Decl. at ¶¶ 29-30; Ex. 1010, Deramond at 285; Ex. 1011, Gangi at 83.) By delivering bone cement to a targeted area in a minimally invasive manner, i.e., via a cannula, vertebroplasty was a major improvement over prior "open" surgical techniques. (Jensen Decl. at ¶ 30.) Several techniques have been described in the literature; however, the general vertebroplasty procedure that has been in use since the 1980s involves introducing a hollow needle or subcutaneous access cannula into the vertebral body, injecting bone cement or other filling material through the interior bore of the cannula, and then removing the cannula. (*Id*. at ¶¶ 31-35; Ex. 1011, Gangi at 83-84; Ex. 1010, Deramond at 286-287.)

Various techniques for delivering the filling material into the bone during vertebroplasty were used. Indeed, since the outset of vertebroplasty, it was well know that filling material could be manually pushed into the vertebral bodies using a tamping instrument. (*See* Jensen Decl. at ¶ 35.) For example, it was well known to use a syringe to deliver the bone cement into the vertebral body through the cannula, and then manually push excess bone cement from the

cannula using a stylet or mandrel. (Jensen Decl. at ¶ 35; Ex. 1010, Deramond at 287; Ex. 1011, Gangi at 83-84.)

In the late 1980s, after the introduction of vertebroplasty, but prior to the invention of the '307 patent, another system for the fixation and stabilization of vertebral bodies (as well as non-vertebral bones) was developed. This system was called "balloon-assisted vertebroplasty" or "kyphoplasty," and is generally described in US Patent No. 5,108,404, which issued to Scholten and Reiley ("Reiley '404 patent," Ex. 1003). (Jensen Decl. at ¶36.) Like vertebroplasty, balloon-assisted vertebroplasty involved delivering bone cement through a subcutaneous cannula into a vertebral or non-vertebral body. (*Id.*; Ex. 1003 at 2:3-23.) However, this technique also used expandable bodies, such as inflatable balloon, to compress cancellous bone and create a cavity in the bone prior to delivery of the filling materials. (*See id.*; Ex. 1003 at Fig. 21, 6:57-7:31, 7:42-51.)

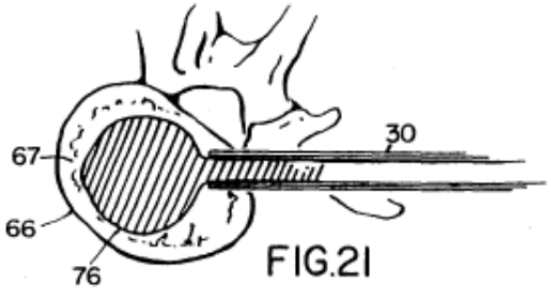

FIG.21

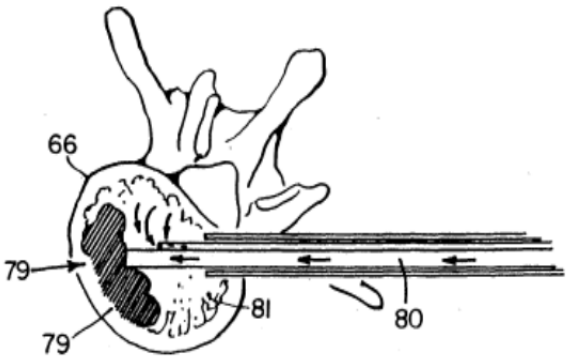

FIG.25

The filling material was then injected through the access cannula into the cavity in the vertebral body using various methods. (*See, e.g.,* Ex. 1003 at 7:42-51, fig. 25.) Reiley '404 disclosed the use of injection guns—devices similar to a household caulking gun—where the nozzle of the gun was inserted into the access cannula to deliver filling materials. (Ex. 1003 at 7:42-51; Ex. 1001, '307 patent at 1:19-28.) Another later Reiley patent application, WO 96/39970 ("Reiley II") (Ex. 1004), also described delivering filling material manually using hand actuation to push material through a nozzle into the vertebral body with a long pin or stylet – much like the system used in vertebroplasty. (Ex. 1004, Reiley II at p. 40, l. 32 – p. 41, l. 3.) Indeed, as explained further below, pushing material down a nozzle in a subcutaneous cannula was well known by August 1998.

B. Brief Description Of The '307 Patent

The '307 patent, entitled "Systems and Methods for Placing Materials Into Bone," also names Reiley as an inventor and claims priority to an application filed on August 14, 1998. (Ex. 1001.) The '307 patent generally relates to tamping instruments (or "auxiliary tools") for urging filling materials such as bone cement or other materials into bone after a void is formed. (See claims.) The focus of the '307 patent specification was to address purported problems with "high pressure" delivery of filling material with an injection gun such as the injection gun of Reiley

'404. (*See* Ex. 1001 at 1:29-62.) The patent purports to solve this problem by providing a system with a hand-actuated tamping instrument to push filling material into the bone. (*See, e.g., id*. at 1:60-2:10, 10:42-45.) However, these types of systems for delivering filling material into bone and, in particular, through a subcutaneous cannula into a vertebral body, were known by August 1998 and were disclosed in Reiley's own prior publications.

The '307 patent has 18 claims. Claims 1 and 14 are the only independent claims and represent the claimed systems. The claimed systems comprise an "access tool" or "cannula" for establishing an access path through tissue and into bone; "a void forming tool" such as a balloon or cutting tool for forming a void in bone; a "nozzle" that is sized and configured to pass through the access path or cannula and that has an interior bore for delivery of a measured volume of the filling material; and an "auxiliary tool" such as a tamping instrument or stylet for urging the filling from the nozzle. (*See id.* at claims 1, 14.) As discussed further below, all of these items were known and used in the art as claimed as of August 1998. Claims 2-13 depend from claim 1 and claims 15-18 depend from claim 14. These dependent claims are generally directed to known characteristics of the various tools and the composition of the filling material used in the system.

Figure 33 discloses an embodiment of the system. The system has a

cannula 184, a nozzle 180, and a stylet 182, which is sized to pass through the interior bore of the nozzle 180. This embodiment also includes a conventional syringe 104 that holds the filling material. According to the patent, this syringe may be a manually actuated syringe with a push plunger or a LeVeen Inflation Syringe with a threaded plunger, which can be actuated manually or by mechanical means. (Ex. 1001 at 10:44-48.)

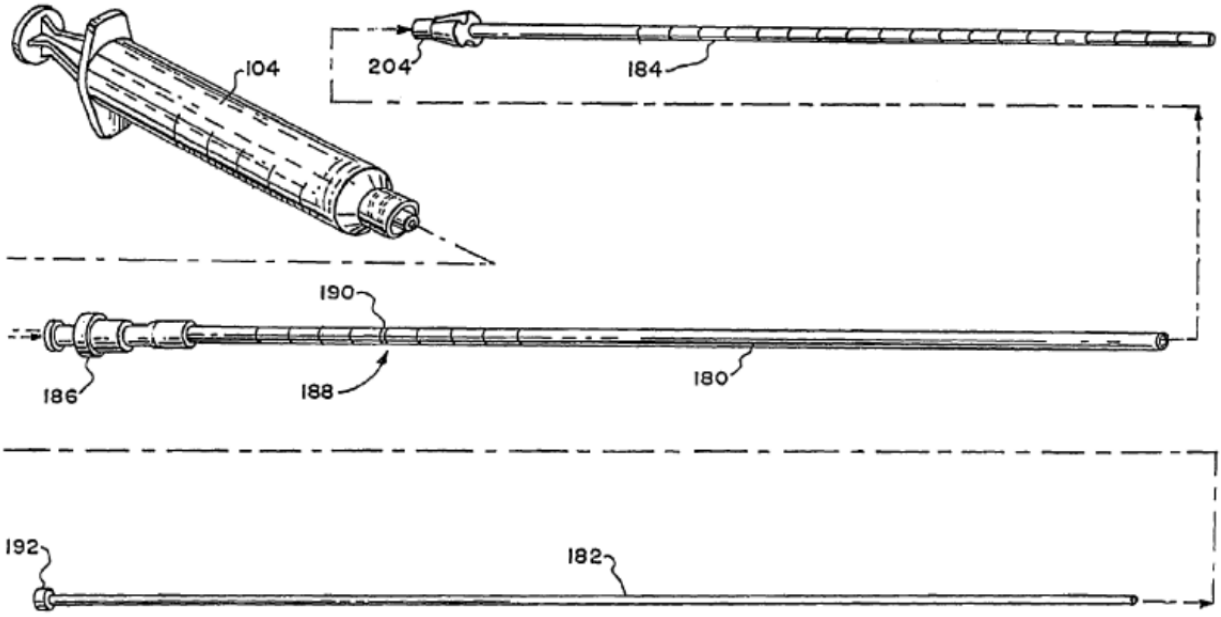

FIG. 33

According to the '307 patent, as is typical for both kyphoplasty and vertebroplasty, an access cannula is inserted into the bone to facilitate injection of bone filling material. For kyphoplasty applications, before injection, a void forming tool such as a balloon may first be inserted into the cannula to form a void within the bone. According to the alleged invention of the '307 patent,

instead of injecting the material using the nozzle of, e.g., a high pressure gun, which is inserted into the access cannula, the filling material is instead urged into the bone using an "auxiliary" injection tool such as a stylet (*Id.* at Fig. 33, item 182), which pushes material through the nozzle. Specifically, the nozzle is inserted through the access cannula 184 into the previously-formed cavity. The nozzle 180 may be coupled to "a receptacle" that holds filling material (such as syringe 104). (*Id.* at 16:7-15, 17:34-53.) If a syringe is used, the plunger in the syringe is then depressed to deliver material into the nozzle and into the cavity. The syringe is then uncoupled from the nozzle and the auxiliary tool 182 is inserted into the nozzle to push any filling material remaining in the nozzle into the cavity. (*Id.* at 20:17-19, 21:4-9.)

C. Prosecution Of The '307 Patent

During prosecution of the application resulting in the '307 patent, the applicant made clear that it was the "auxiliary tool" that made the invention patentable over the prior art.

Specifically, in the first rejection, the Examiner rejected the '307 application for obviousness-type double patenting in view of its parent application and found the claimed invention obvious in view of Reiley '404 with "Mikhail." (Ex. 1017 at 9.) Specifically, the Examiner stated that Reiley '404 discloses all of the claimed

elements except for "an auxiliary tool sized and configured to be received by the interior passage and urge filling material from the nozzle." (*Id*.) The Examiner found this missing element in "Mikhail," stating that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an auxiliary tool in the device of Scholten [Reiley '404] et al; as taught by Mikhail…." (*Id*.) The applicants did not contest that Reiley '404 contained all the elements except for the auxiliary tool or that it would be obvious to add an auxiliary tool to Reiley '404. (*Id.* at 16-17 (Response dated 1/18/05).) Instead, the applicants amended and cancelled claims (*id.* at 13-15) and argued that Mikhail was distinguishable because it disclosed a dispenser for injecting material into an open surgical cavity and that, unlike the nozzle of the claimed invention, the dispenser had an adjustable interior volume that varied depending on how the user adjusted an attached plunger. (*Id.* at 16-17.) The applicants also argued that the auxiliary tool of Mikhail "is integrated with the nozzle." (*Id.* at 17.)

The examiner issued another rejection in view of prior art, again noting that Reiley '404 disclosed everything but an auxiliary tool (even with amendments). (*Id.* at 29-30 (Office Action mailed 12/21/05).) The examiner stated that it would have been obvious to incorporate into Reiley '404 the auxiliary tool in another reference that disclosed an applicator for delivering flowable tissue implant

material, which the examiner stated disclosed "the use of an auxiliary tool sized to apply pressure to a measured implantable material through a cannula and deliver the material to a desired site." (*Id.* at 30.) The examiner also noted that all of the dependent claims were known in the art. (*Id.*) In response to this rejection, the applicants again did not contest that Reiley '404 disclosed all the elements except for the auxiliary tool or that it would be obvious to add an auxiliary tool to Reiley '404. (*Id.* at 36-37 (Response dated June 23, 2006).) Instead, they argued that the reference, an unpublished application, was not entitled to a priority date earlier than the 307 application for its teaching of an auxiliary tool. (*Id.*)

In light of these arguments and amendments, the '307 patent was allowed. (*Id.* at 39.) Thus, the applicants relied upon the auxiliary tool to distinguish the claimed invention over the prior art Reiley '404 patent.

V. CLAIM CONSTRUCTION

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. 37 C.F.R. § 42.100 (b); *see also In re Trans Texas Holding Corp.*, 498 F.3d 1290, 1298 (Fed. Cir. 2007) (citing *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984)). The broadest reasonable interpretation of the terms in the '307 patent are their plain

and ordinary meaning which is evident from the claims themselves.[1] To the extent that the Patent Owner proposes claim construction in the Patent Owner's Preliminary Response, Stryker clarifies the interpretation of the following claim terms.

Independent claims 1 and 14: ***"sized and configured to"*** means the claimed structure is of a size and configuration so as to be capable of performing the recited function. (Jensen Decl. at ¶ 48.) *See also, e.g., Ex Parte Coers*, 2013 WL 5402245, *3 (P.T.A.B. 2013) ("the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitations of that claimed") (citing *Ex Parte Masham*, 2 USPQ2d. 1647, 1648 (B.P.A.I. 1987)); *In re Schreiber*, 128 F.3d 1473, 1477-78 (Fed. Cir. 1997); *see also* MPEP (9th ed. Rev. 11, Mar. 2014) § 2114 ("While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.").

Independent Claims 1 and 14: "***a nozzle . . . including an interior bore defining a fixed interior volume to receive and deliver a measured volume of***

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

filling material into the void" means the interior bore of the nozzle defines an interior volume that is fixed (i.e., cannot be changed) to receive and deliver a specific or determined volume of filling material into the void. (Ex. 1017 at 14; Jensen Decl. at ¶ 49.) In other words, the nozzle has a known and defined volume, which is unchanging. (Jensen Decl. at ¶ 49.) The nozzle 180 shown in figure 33 is an example of such a nozzle (see also nozzle 106 in figure 5).

VI. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE 307 PATENT IS UNAPATENTABLE

Petitioner seeks *inter partes* review of claim 1-18 of the '307 patent. Claims 1 and 14 are independent claims. Claims 2-13 depend from claim 1 and claims 15-18 depend from claim 14.

A. Ground 1: Reiley II Anticipates Claims 1-7, 10, 13-15, and 18

Reiley II (WO 96/39970) discloses all of the elements of independent claims 1 and 14 as well as dependent claims 2-7, 10, 13, 15, and 18 and thus anticipates these claims.

Reiley II is a published patent application that focused on balloons of varying shapes and sizes that can be used to create voids in bone and also on balloons that can deliver therapeutic substances to bone. Reiley II, which is a follow on kyphoplasty application, discusses the original kyphoplasty patents (including the Reiley '404 patent) in the background section. (Ex. 1004, Reiley II at

2-3.) 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 a balloon (10, 21) that is sized to be advanced through the cannula; and then delivering bone cement into the cavity via the access cannula. (*Id.* at p. 24 l. 30 – p. 25 l. 23; Fig. 8.)

Reiley II also discloses how to manually deliver materials into a vertebral cavity via the cannula by using a "long pin" to push materials down "a tube" that has a diameter that is narrower than the cannula:

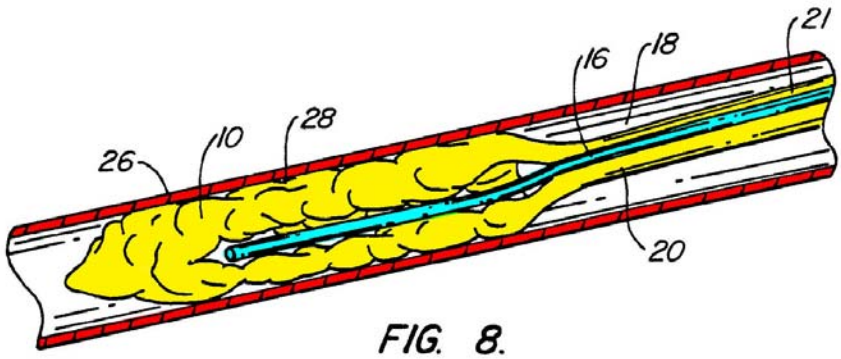

FIG. 8.

> 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 [nozzle] with a long pin [auxiliary tool] whose diameter is slightly more narrow than the inner diameter of the canula through procedures which the minimally-invasive procedure is taking place.

(*Id.* at p. 40 l. 32 – p. 41 l. 3 (emphasis added).) As described below, the "tube" is a nozzle and the "long pin" is the auxiliary tool as later claimed in the '307 patent.

As shown in the claim charts below (and Jensen Declaration at paragraphs

55-63), Reiley II discloses every element of independent claim 1 as well as dependent claims 2-7, 10 and 13 (which depend on claim 1):

'307 Patent	**Reiley II (Ex. 1004)**
1. A system comprising an access tool sized and configured to establish an access path through soft tissue to bone having an interior volume occupied, at least in part, by cancellous bone,	As seen in Figure 8, like the '307 patent, Reiley II discloses a system with an access tool (cannula 26, colored red above) for establishing a subcutaneous path through soft tissue into a vertebral body, which is occupied, at least in part, by cancellous bone. (*See* Ex. 1004 at p. 7, l. 27-30; p. 24, l. 20 - p. 25, l. 18; Fig. 8.)
a void forming tool sized and configured to be introduced through the access path to form a void in cancellous bone,	As seen in Figure 8 above, Reiley II discloses balloon 10 (colored yellow), sized and configured to be introduced through cannula 26, which establishes the access path. (*Id*. at p. 24, l. 24-35; p. 25, l. 19-29.) "The balloon is then inflated to compact the bone marrow and/or cancellous bone in the cavity." (*Id*. at p. 25, l. 19-20).
a nozzle sized and configured to pass through the access path and including an interior bore defining a fixed interior volume to receive and deliver a measured volume of filling material into the void, and	Reiley II discloses a "tube . . . whose diameter is slightly more narrow than the inner diameter of the canula through procedures which the minimally-invasive procedure is taking place." (*Id.* at p. 40, l. 32 - p. 41, ln. 3). The tube, which is the nozzle, is used "[t]o insert materials which do not flow into the balloon-made cavity, like hydroxyapatite granules or bone mineral matrix." (*Id*.) The tube has a fixed interior volume to receive and deliver a measured volume of the filling material. (*Id.*; Jensen Decl. at ¶ 55.)
an auxiliary tool sized and configured to be advanced through the interior bore and urge filling material from the nozzle.	The "long pin" is sized and configured to be advanced through the interior bore of the nozzle ("tube") and urge filling material from the nozzle. (Ex. 1004 at p. 40, l. 32 - p. 41, l. 3) ("the surgeon can push them [filling material] down a tube with a long pin….").

'307 Patent	Reiley II (Ex. 1004)
2. A system according to claim 1 wherein the access tool comprises a cannula.	See claim 1 above. As seen in Figure 8, Reiley II discloses a "cannula 26" (red), which is an access tool. (*Id*. at p. 24, l. 20-32.)

'307 Patent	Reiley II (Ex. 1004)
3. A system according to claim 1 wherein the void forming tool is carried by an elongate member sized and configured to pass through the access path.	See claim 1 above. As seen in Figure 8, the balloon is carried by an elongate catheter 21 (blue), which is sized and configured to pass through the cannula 26, which establishes the access path. (*Id.* at p. 24, l. 31-35) ("The balloon in canula 26 is deflated and is forced through the canula by exerting manual force on the catheter 21 which extends into a passage 28 extending into the interior of the bone.").

'307 Patent	Reiley II (Ex. 1004)
4. A system according to claim 3 wherein the elongate member comprises a catheter.	See claim 3 above. As discussed in claim 3, the elongate member is catheter 21. (*Id.* at p. 24, l. 31-35.)

'307 Patent	Reiley II (Ex. 1004)
5. A system according to claim 1 wherein the void forming tool comprises an expandable body.	See claim 1. Reiley II discloses that the void forming tool is an expandable body such as a balloon. (*id.* at p. 25, l. 19-20 ("The balloon is then inflated to compact the bone marrow and/or cancellous bone in the cavity . . . ."); Abstract; Fig. 8 (disclosing balloon 10).)

'307 Patent	Reiley II (Ex. 1004)
6. A system according to claim 5 wherein the expandable body, when expanded, assumes a non-	See claim 5. Reiley II discloses balloons of varying non-spherical shapes. (*See, e.g.*, *id.* at p. 24, l. 1-2 ("spherical outer surface 66 and has an outer periphery which is surrounded substantially by a

'307 Patent	Reiley II (Ex. 1004)
spherical shape.	ring shaped part 68"); p. 24, l. 16 ("doughnut-shaped as shown in Fig. 1"); p. 26, l. 20-21 ("modified doughnut shape"); p. 27, l. 30 - p. 28, l. 8) ("kidney shaped"); p. 30, l. 2 ("cylindrical"); p. 30, l. 26-27 ("pyramid" or "humpbacked banana" shape); p. 35, l. 23 ("boomerang").)

'307 Patent	Reiley II (Ex. 1004)
7. A system according to claim 1 wherein the nozzle comprises an elongate tube.	See claim 1. The nozzle is an elongate "tube" used with "a long pin." (*Id.* at p. 40, l. 32 - p. 41, l. 3; Jensen Decl. at ¶ 61.)

'307 Patent	Reiley II (Ex. 1004)
10. A system according to claim 1 wherein the auxiliary tool comprises an elongate body.	See claim 1. The auxiliary tool in Reiley II is a "long pin," which is an elongate body. (Ex. 1004 at p. 40, l. 32 – p. 41, ln. 3; Jensen Decl. at ¶ 62.)

'307 Patent	Reiley II (Ex. 1004)
13. A system according to claim 1 wherein the filling material comprises at least one of a flowable material that hardens to a rigid state, a bone cement, autograft material, allograft material, calcium carbonate, demineralized bone matrix material, and calcium phosphate.	See claim 1. Reiley II discloses inserting "hydroxyapatite granules or bone mineral matrix" using the long pin/tube system which are calcium phosphates. (*Id.* at p. 40, l. 32 - p. 41, l. 3; Jensen Decl. at ¶ 63.) Reiley also discloses using "acrylic bone cement or biocompatible bone substitute," "hydroxyapatite granules or bone mineral matrix," "bone graft," "bone substitutes," "biocompatible filling material, such as methylmethacrylate cement of a synthetic bone substitute." (*Id.* at p. 39, ln. 31; p. 1, l. 29-31; p. 3, l. 24-28.)

Independent claim 14 generally has the same limitations as independent claim 1; however, it expressly requires that access tool be a cannula and that the

nozzle "can be manipulated independent of the cannula" and is "sized and configured to pass through the cannula" as well as a few additional limitations. As shown in the claim chart below (and Jensen Declaration at paragraph 64), Reiley II discloses every element of independent claim 14.

'307 Patent	**Reiley II (Ex. 1004)**
14. A system comprising a cannula sized and configured to establish an access path through soft tissue to bone having an interior volume occupied, at least in part, by cancellous bone,	See claim 1. As seen in Figure 8, Reiley II discloses a system including a cannula 26 (red) for establishing an access path through soft tissue into bone.
a void forming tool sized and configured to be introduced through the cannula to form a void in cancellous bone,	See claim 1. As seen in Figure 8, Reiley II discloses balloon 10, which is sized and configured to be introduced through the cannula 26 to form a void in cancellous bone.
a nozzle that can be manipulated independent of the cannula and that is sized and configured to pass through the cannula, the nozzle including an interior bore to receive and deliver a measured volume of filling material into the void, and	Reiley discloses a nozzle ("tube") as explained in claim 1. Reiley II explains that the "tube" can be manipulated independent of the access cannula and is sized and configured to pass through that cannula given that it has a "diameter [that] is slightly more narrow than the inner diameter of the canula through…which the minimally-invasive procedure is taking place." (*Id.* at p. 40, l. 32 - p. 41, l. 3). As discussed in claim 1, the "tube" necessarily includes an interior bore to receive and deliver a measured volume of filling material into the void. (*Id.*; Jensen Decl. at ¶ 64.)
an auxiliary tool that can be manipulated independently of the nozzle and the cannula and that is sized and	As discussed in claim 1, the auxiliary tool is the "long pin," which is separate from and configured to be advanced through the interior of the tube such that it can be manipulated independently of both the

'307 Patent	Reiley II (Ex. 1004)
configured to be advanced through the interior bore and urge filling material from the nozzle, the auxiliary tool, when fully advanced, substantially fully occupying the entire interior bore of the nozzle.	tube and cannula. (Ex. 1004 at p. 40, l. 32 - p. 41, l. 3.) The physician uses the long pin to push materials down the tube (nozzle). (*Id*.) The long pin substantially fully occupies the entire interior bore of the nozzle when fully advanced. (*Id.*; Jensen Decl. at ¶ 64.)

Dependent claims 15 and 18 contain the same requirements as dependent claims 13 and 5 (relating to the filling material and the void forming tool being an expandable body) but depend on independent claim 14 instead of independent claim 1. Reiley II discloses all the elements of claim 14 and, for the same reasons as discussed with dependent claims 13 and 5, anticipates dependent claims 15 and 18. (See Jensen Decl. ¶¶ 65-66.)

B. Ground 2: Reiley II Renders Obvious Claims 8, 9, 11, 12, And 14-18 In View of the Knowledge of the Ordinary Skilled Artisan

Reiley renders obvious claims 8, 9, 11, 12, and 14-18 in light of the knowledge and experience of a person of ordinary skill in the art. A person of ordinary skill in the art relating to the subject matter of the '307 patent would be a physician or a biomedical engineer with a number of years of experience, e.g., three to five years, in the field of orthopedic technology or minimally-invasive surgery and, in particular, minimally invasive radiological procedures. This person would be experienced in performing, and/or designing devices for performing,

minimally invasive procedures such as vertebroplasty. (Jensen Decl. at ¶ 13.)

Under the Supreme Court's decision in *KSR Int'l Co. v. Teleflex, Inc.*, a "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." 550 U.S. 398, 416 (2007). "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. Dependent claim 8 – Receptacle for filling material

Dependent claim 8 requires that the system of claim 1 further include "a receptacle for holding a volume of filling material, and wherein the nozzle includes a connector to couple the nozzle to the receptacle." As shown in Figure 25, the '307 patent discloses "conventional syringe 104" as the receptacle for holding a volume of filling material and depicts the threaded connector 114 that allows the syringe to couple to the nozzle. (Ex. 1001 at Figs. 25, 27, 10:43; Jensen Decl. at ¶ 68.) The patent also explains that filling material may be loaded using a funnel, e.g., into the cannula. (*Id.* at 17:34-45.)

As explained by Dr. Jensen, an ordinary skilled artisan would understand that physicians performing any type of material delivery know, as a basic principle

of injection, that gaps in the injection system are to be avoided so that the materials do not leak or fall out. (Jensen Decl. at ¶ 71.) Thus, conventional injection systems at the time of the invention provided a coupling system for components in the system, e.g., luer-lock syringes, to ensure flow of materials through the delivery tube or nozzle without leakage. (*Id.*) Dr. Jensen identifies several references that demonstrate this common knowledge. (*Id.* at ¶ 72.)

As Dr. Jensen explains, while Reiley II does not mention the expressly mention the receptacle for delivering the filling materials for the tube/long pin system, "long tubes" or nozzles at the time of the invention would have already been provided with threading for coupling to a device such as a luer-lock syringe. (*Id.* at ¶ 71-73.) Moreover, Reiley II does mention the use of such a receptacle for delivering a therapeutic substance to the expandable balloon using an applicator with "a reservoir of the therapeutic substance and a nozzle for dispensing a gel formulation" on the balloon. (*See, e.g.,* Ex. 1004 at claim 14.)

Using a receptacle to deliver filling material to a nozzle and coupling the receptacle to the nozzle with a connector to prevent leakage was "conventional" as the '307 patent itself recognizes (Ex. 1001 at 10:42-44). There are no unexpected results from adding such a conventional receptacle to the system or from including a connector to couple that receptacle to the nozzle. Thus, a

person of ordinary skill would have had reason, basis, or motivation and found it obvious to select such off-the-shelf components when delivering filling materials to bone, e.g., to avoid leaks, and, in particular, to select such components for the long pin/tube system of Reiley II. (Jensen Decl. at ¶ 74.) Thus, dependent claim 8 would have been obvious.

2. Dependent claim 9 - Calibration markings

Dependent claim 9 requires that the nozzle of claim 1 has calibration markings, i.e., "has a length and includes measured markings along the length." As explained by Dr. Jensen, such calibration markings were well known in the art at the time of the invention (including on nozzles) and she identifies several references that demonstrate this common knowledge. (Jensen Decl. at ¶ 76-77; *see, e.g.,* Ex. 1013 at 6:58-64 ("Calibrations may be provided on the rod and/or tube to provide an indication of the amount of agent dispensed and the rate of dispensing."; Ex. 1012 at 3:67-4:3 ("[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.")

Because such markings were conventional in the art as of August 1998, a person of ordinary skill would have been motivated and found it obvious to include such markings on the nozzle for the very reasons known in the art, e.g., to

gauge depth of the device within the cannula, if desired, and there are no unexpected results from adding these markings. (Jensen Decl. at ¶ 78.) As explained by Dr. Jensen, the inclusion of such markings along the length of the nozzle assists in ensuring proper device positioning and would have been a known, desirable design choice. (*Id.*) Thus, dependent claim 9 would have been obvious in view of Reiley II and the knowledge of the ordinary skilled artisan.

3. Dependent claims 11, 12, 16, and 17 – Flexible and rigid materials

Dependent claims 11 and 16 require that the nozzle in the system of independent claims 1 and 14 "is made from a generally flexible material." ***Dependent claims 12 and 17*** require the nozzle is "made from a generally rigid material." The '307 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." (Ex. 1001 at 10:56-58.) The patent further states that, "[a]lternatively, the nozzle 106 can be made from a generally rigid plastic or metal material." (Ex. 1001 at 10:58-60.)[2]

[2] The patent also provides some examples of generally flexible and generally rigid materials for the catheter tube. For example, "The catheter tube 78 can be constructed, for example, using standard flexible, medical grade plastic materials,

Dr. Jensen explains that 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 minimally invasive surgery: instruments made from flexible materials or instruments made from rigid materials. (Jensen Decl. at ¶ 81.) As Dr. Jensen explains, 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 ¶ 82; *see also* Ex. 1006 at 3:3-13 (disclosing, e.g., "stainless steel or similar alloys commonly used to fabricate surgical instruments" and the use of "polymeric materials such as, for example, . . . polyethylene"); Ex. 1013 at 5:16-25; Ex. 1016 at 3:25-65.) The '307 patent claimed both of the known design choices.

Selecting a nozzle 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, physician preference, and enhanced patient

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like vinyl, nylon, polyethylenes, ionomer, polyurethane, and polyethylene tetraphthalate (PET)." (8:49-52.) "The catheter tube 78 can also include more rigid materials to impart greater stiffness and thereby aid in its manipulation. More rigid materials that can be used for this purpose include stainless steel, nickel-titanium alloys (Nitinol™ material), and other metal alloys." (8:52-56.)

safety. (Jensen Decl. at ¶¶ 82, 86.) Dr. Jensen provides examples of when the design choice of selecting a nozzle made from flexible material would have been preferred and when a nozzle made from rigid materials would have been preferred. (*Id.* at ¶ 82, 84-85.) While the Reiley II reference does not specify whether the "tube" or nozzle for delivering the "materials which do not flow into the balloon-made cavity" is made from generally flexible or generally rigid materials, a person of ordinary skill in the art reviewing Reiley II would understand that either design option would have been appropriate depending on the physician's application and clinical situation. (*Id.* at ¶ 83.) For example, Reiley II discloses using a generally flexible material for another tool in the system – the elongate member / catheter that is sized and configured to be introduced into the cannula. (Ex. 1004 at p. 24, l. 30 - p. 25, l. 4.) It would be obvious to use a similar generally flexible material for another tool in the system that has the same requirements. (Jensen Decl. at ¶ 84.)

Thus, dependent claims 11, 12, 16 and 17 would have been obvious in view of Reiley II and the knowledge of the ordinary skilled artisan.

4. Independent claim 14 – Auxiliary tool substantially fully occupying nozzle

Independent claim 14 requires that the "auxiliary tool, when fully advanced, substantially fully occupying the entire interior bore of the nozzle." As

shown in the claim chart above (and Jensen Declaration ¶ 87), a person of ordinary skill in the art would understand that the auxiliary tool in Reiley II inherently substantially fully occupies the "tube" in order for the long pin to push out the materials in the tube. This was the conventional design of stylet/cannula systems at the time. (Jensen Decl. at ¶ 87.) Nonetheless, to the extent that this limitation is not inherently disclosed in Reiley II, a person of ordinary skill would have been motivated to ensure that the long pin was designed so that it could operate properly. As explained by Dr. Jensen, a person of ordinary skill in the art would have known to select a long pin of such construction to urge materials down the tube; in fact, that would have been the only reasonable selection. (*Id.*) To effectively urge materials down the tube, the long pin should substantially fully occupy the entire bore of the tube, which is why conventional stylet/cannula systems were designed this way. (*Id.*) If the long pin was too short or too skinny materials would remain in the tube or extrude backwards from the nozzle, defeating the purpose of the tool. (*Id.*) Thus, independent claim 14 would have been obvious in view of Reiley II and the knowledge of the ordinary skilled artisan. Anticipated claims 15 and 18, which depend on claim 14, would similarly be obvious for the reasons discussed in Section A above.

C. Ground 3: Reiley '404 Renders Obvious Claims 1-18 In View Of Muller and the Knowledge of a Person of Ordinary Skill in the Art

Reiley '404 (Ex. 1003) combined with Muller (Ex. 1005) and the knowledge of one of ordinary skill in the art renders obvious claims 1-18 of the '307 patent.

As the Examiner acknowledged during prosecution (and applicants did not dispute), Reiley '404 discloses all the limitations of independent claims 1 and 14 with the exception of the auxiliary tool used to urge filling material from a nozzle. (*See* Section IV.C. supra.) As the Examiner also acknowledged (and applicants did not dispute), it would have been obvious to use the claimed auxiliary tool in the Reiley '404 system. (*Id.*) While the Examiner did not identify any such prior art during prosecution, an auxiliary tool to urge filling material from a nozzle was indeed a known element in the prior art and a person of ordinary skill in the art would have had reason, basis, or motivation to use an auxiliary tool if they were seeking to deliver filling material in a controlled manner.

Reiley '404, which is a precursor to Reiley II, teaches performing balloon-assisted vertebroplasty by using an access cannula to create an access path into the bone, creating a void in the bone with an expandable balloon, and thereafter delivering bone cement into the cavity using an injection gun with a nozzle.

As required by ***Claims 1 and 14***, Reiley '404 discloses an access tool (cannula 30) "sized and configured to establish an access path through soft tissue to bone." (Ex. 1003 at 6:7-46.) Reiley '404 specifically discloses that the bone has "an interior volume occupied, at least in part, by cancellous bone." (*Id*. at 7:27-35.)

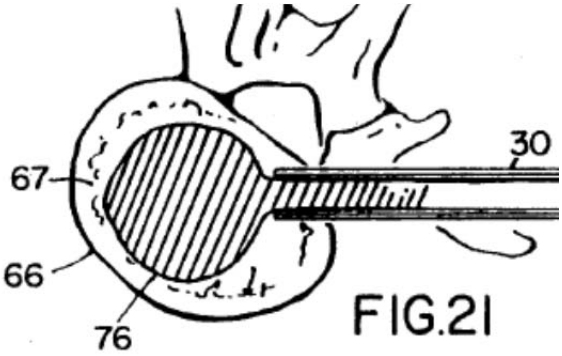


FIG.21

Reiley '404 further discloses a void forming tool (e.g., balloon 76) sized and configured to be "introduced through the access path" established by the access tool "to form a void in cancellous bone." (*Id.* at 7:27-31.) "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." *Id.* The balloon is sized and configured to be introduced through the cannula and into the interior of the vertebral body 66. (*Id.* at 6:67-7:3.)

Reiley '404 discloses an "injection gun nozzle" for delivering bone material into the void. (*Id.* at Fig. 25, 7:47-50.) This injection device comprises a "material delivery tube 80" which is a nozzle. As shown in Fig. 25, the nozzle 80 is sized and configured to pass through the cannula 30 after withdrawal of the balloon. Also

shown in Figure 25, the nozzle 80 comprises an interior bore for receiving and delivering a measured volume of filling material into the void. (Jensen Decl. at ¶ 93.) "The volume of injection ranges between 3 and 5 cc's." (*Id*. at 7:56.) The nozzle can be manipulated independent of the cannula as required by Claim 14. (*Id.* at Figs. 25, 26, 7:42-51.)

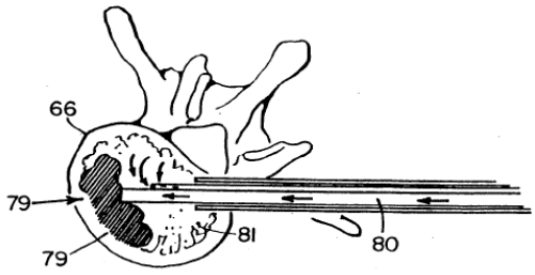
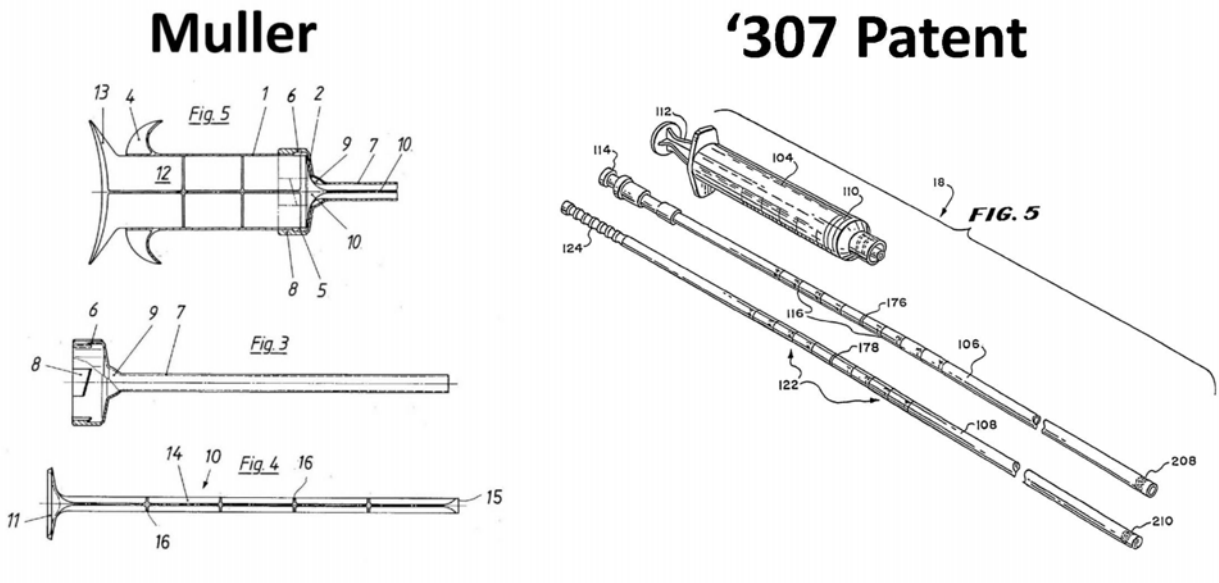


FIG.25

Reiley '404 discloses every element of independent claims 1 and 14 of the '307 patent except for the "auxiliary tool." (Jensen Decl. at ¶¶ 92-94.) However, an auxiliary tool sized and configured to be advanced through the interior bore and urge filling material from the nozzle, and that can be manipulated independently of the nozzle, was a known alternative to using an injection gun for cement delivery and an obvious design choice. (*Id.* at 94.) Dr. Jensen explains that, as evidenced by numerous prior art references, it was well known in the art at the time of the invention that a physician could deliver filling material to a vertebral body using hand-actuation of such "an auxiliary tool" (e.g., manually pushing material with a tool such as a pin through a tube rather than using an injection gun). (*Id.*) Physicians routinely selected hand-actuation devices or guns based on personal preference and comfort level. (*Id*. at ¶ 100.)

U.S. Patent No. 4,576,152 to Muller (Ex. 1005), entitled "Injector for Bone Cement," teaches using an auxiliary tool to urge filling material such as bone cement out of a nozzle. 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 that allows the user to deliver high-volume flow through a syringe-like cylinder tube or low-volume flow by attaching a narrower nozzle to the tube. As part of its teaching, Muller describes an auxiliary tool to manually push materials through a nozzle as claimed in the '307 patent. (*Id.* at 1:28-46.)



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

1:40-43.) Cement is loaded into a syringe-like cylinder tube (shown in figure 5) that is connected to a "nozzle 7" (shown separately in figure 3) and delivered from the cylinder tube by depressing the piston. The ram, shown in figure 4, is an auxiliary tool for urging filling material from the nozzle, just as claimed in the '307 patent.

For independent claim 1, as discussed above, Reiley '404 discloses every limitation except for "an auxiliary tool sized and configured to be advanced through the interior bore and urge filling material from the nozzle." However, Muller discloses this missing element. As shown in the figures, just like the '307 patent, Muller discloses a "nozzle tube" 7 that includes an interior bore defining a fixed interior volume to receive and deliver a measured volume of filling material. (Ex. 1005 at Fig. 3, 1:40-46, 3:46-60.) Muller also discloses an auxiliary tool (ram 10) that is sized and configured to be advanced through the interior bore of nozzle 7 to urge filling material from the nozzle. (*Id.* at Figs. 4, 3 & 6, 1:4-7 (use of nozzle 7 and ram 10 "for injecting expandable bone cement into a surgically prepared bone cavity").) Specifically, "[t]he ram serves to eject the bone cement from the filled nozzle tube." (*Id.* at 1:66-67.)

For independent claim 14, the claim requires "an auxiliary tool that can be manipulated independently of the nozzle and the cannula and that is sized and

configured to be advanced through the interior bore and urge filling material from the nozzle, the auxiliary tool, when fully advanced, substantially fully occupying the entire interior bore of the nozzle." As described above, Muller discloses an auxiliary tool that is configured to be advanced through the interior bore and urge filling material from the nozzle. Muller also discloses the additional limitations that the tool "can be manipulated independently of the nozzle and the cannula" and that the tool "when fully advanced, substantially fully occupying the entire interior bore of the nozzle." Specifically, as shown in Muller figure 4, ram 10 (auxiliary tool) is configured to be manipulated independently of the nozzle and cannula. "The ram is movably mounted in the nozzle tube to eject bone cement therefrom. In this respect, the ram is displaceable in the manner of a piston in the nozzle tube." (*Id.* at 1:54-56, 3:34-37.) Moreover, as shown in figure 5, the ram when fully advanced through the nozzle fully occupies the entire interior bore of the nozzle. Muller explains that "[s]ince 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 cement to be expelled." (*Id.* at 3:51-56.)

As Dr. Jensen explains, a person of ordinary skill in the art interested in varying the delivery pressure would have known to replace the injection gun of Reiley '404 with the delivery system of Muller, particularly since Muller

specifically addresses the issue of "high pressure" / "low pressure" cement delivery into bone cavities suggesting the very use later claimed in the '307 patent. (Jensen Decl. at ¶¶ 100-101.) A person of ordinary skill in the art would have understood that the gun system in Reiley '404 would be cumbersome in certain circumstances and would have been motivated to select a syringe-like device such as that disclosed in Muller as it allows for greater control of delivery (as was the standard practice in vertebroplasty and as Muller teaches). (*Id.*) An auxiliary tool, such as the ram disclosed in Muller, to manually push cement through the interior bore of the nozzle into bone was a known, predictable, and obvious alternative to the injection gun system disclosed in Reiley '404. *Id.* Thus, Reiley '404 in combination with Muller renders claims 1 and 14 obvious in view of the ordinary skill in the art.

The limitations of ***dependent claims 2-6, 13, 15, and 18,*** which address specifics of the access tool, void forming tool, and filling materials, were also known in the art and disclosed in Reiley '404. (*See* Jensen Decl. at ¶¶ 104-110.) Thus, these additional claims would also have been obvious in view of Reiley '404 and Muller.

With regard to **claim 2**, Reiley '404 discloses an access tool that is a cannula. (Ex. 1003 at 6:38-39.)

With regard to ***claims 3 and 4***, Reiley '404 discloses that the balloon is carried by a catheter, which is an elongate member sized and configured to pass through the access path. (*Id.* at Figs. 21, 22, 23, 6:60-64, 7:15-26.)

With regard to ***claims 5 and 18***, the void forming tool in Reiley '404 is an expandable balloon. (*Id.* at 2:13-15, 7:26-31.)

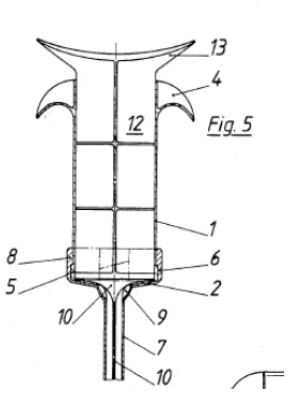
With regard to ***claim 6***, Reiley '404 discloses balloons that assume a non-spherical shape. (*Id.* at 6:67-7:3 ("After the elliptical balloon 65 is deflated and removed, checker-shaped or cylindrically shaped device or balloon is inserted into the cannula…").)

With regard to ***claims 13 and 15***, Reiley '404 discloses that the "cavity is injected with…methyl methacrylate cement or a liquid artificial bone substitute," which is a flowable material that hardens into a rigid state as claimed. (*Id.* at 9:14-18; Jensen Decl. at ¶ 110.)

The additional elements of ***dependent claims 7–12, 16 and 17***, which address characteristics of the nozzle and auxiliary tool, were also known in the art as addressed below. (See also Jensen Decl. at ¶¶ 112-116.) Thus, these additional claims would also have been obvious in view of Reiley '404 and Muller.

With regard to ***claim 7***, Muller discloses that the nozzle is an elongate tube, referring to the nozzle as "an elongated nozzle tube 7." (Ex. 1005 at 3:3-19.)

With regard to ***claim 8***, which claims "a receptacle for holding a volume of filling material, and wherein the nozzle includes a connector to couple the nozzle to the receptacle," Muller discloses a "cylinder tube [1] for receiving the bone cement." (*Id.* at 1:40-45.) A bayonet connection secures "nozzle element 6 in a releasable manner to the cylinder tube 1 as indicated in FIG. 5." (*Id.* at 3:7-10.) Such systems were known in the art as discussed in Section B.1. above.



With regard to ***claim 9***, calibration markings were known in the art as discussed in Section B.2. above. For the same reasons as discussed, a person of ordinary skill would have found it obvious to include measured markings along the length of the Muller nozzle. (Jensen Decl. at ¶ 114.)

With regard to ***claim 10***, as shown in figure 4 of Muller, the auxiliary tool in (ram 10) is an elongate body that fits within the "elongated nozzle tube." (*Id.* at Fig. 4, 3:25-29.)

With regard to ***dependent claims 11, 12, 16 and 17*****,** Muller states that "the injector may consist of a plastic which is common for such injectors, for example polymethyl pentene (TPX)," which is generally rigid. (*Id.* at 2:25-30.) However, as discussed in Section B.3., it was well known at the time of the invention (and the

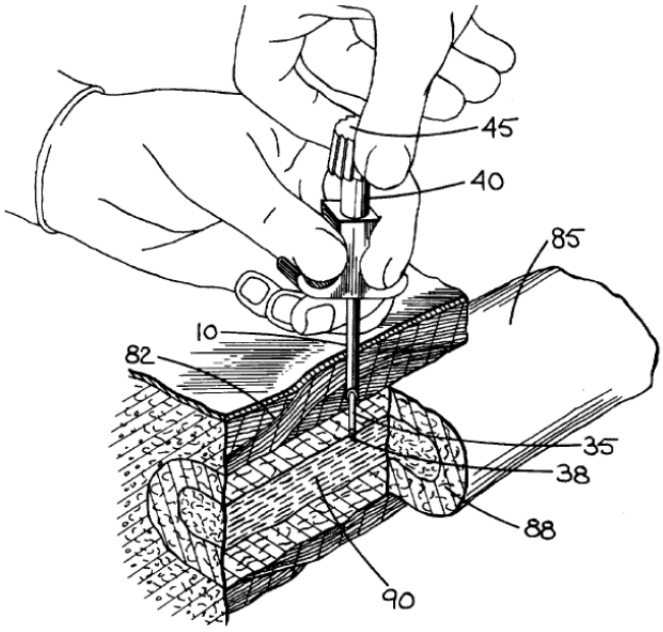
time of the Muller patent) that plastics that were common for components of such injectors included plastics made from generally rigid and generally flexible materials and that one could select a nozzle made from generally flexible or generally rigid materials depending on the intended clinical use. (Jensen Decl. at ¶ 116.) 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 either generally flexible and generally rigid materials – the two known design options – depending on the application. (*Id.*)

In sum, as mentioned above, the '307 patent addresses the purported problem of delivering filling material into bone using an auxiliary tool for more controlled delivery. However, Muller already disclosed the use of an auxiliary tool to address the issue of controlled delivery of bone cement into a surgically prepared bone cavity before the '307 patent. (Ex. 1005 at 1:28-35.) One of ordinary skill in the art would have therefore been motivated to consider the teaching of Muller to address such considerations. (Jensen Decl. at ¶ 117.) Muller's disclosure of injection devices for the delivery of bone cement into a surgically prepared bone cavity would have motivated one having ordinary skill in the art to use the ram 10 of Muller to urge filling material from the nozzle 6 in the system of Reiley '404. (*Id.*) Accordingly, Reiley '404 in view of Muller and the

knowledge of a person of ordinary skill in the art renders obvious claims 1-18.

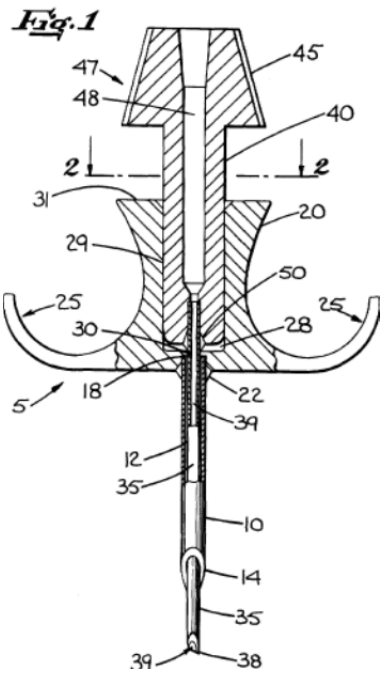
D. Ground 4: Hofsess Anticipates Claims 1-3, 7 and 10-17

Hofsess (Ex. 1006) discloses all of the elements of independent claims 1 and 14 as well as dependent claims 2, 3, 7, 10-13, and 15-17 and thus anticipates these claims.



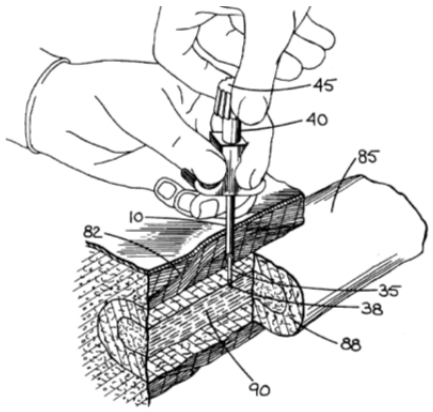
Hofsess teaches an instrument for gaining access to inner bone that includes an alignment needle with a cannula 10 that penetrates soft tissue 82 to access to bone 85. (Ex. 1006 at Figs. 1-12, 2:35-64, 3:19-21.)

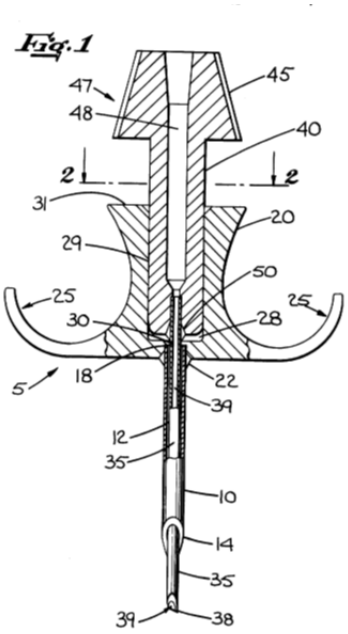
Hofsess further discloses a bone cutting instrument (with a bone penetrating and indenting point 38) that is inserted within the cannula to create a void in the bone. (*Id.* at 3:41-49.) As shown in figure 1, the bone cutting instrument optionally includes a conduit 48 with a lumen 39 "giving a continuous passage traversing the entire bone cutting component



47." (*Id.* at 3:66-4:3.) The conduit provides a means of passing a stylet to clear out bone chips, allowing the instrument to serve as a nozzle for delivery of materials. (*Id.* at 4:3-4:6.) Moreover, a conventional hypodermic needle or blunt point cannula can be inserted through the access cannula (the alignment needle) to remove tissue samples from the bone, e.g., for a bone biopsy. (*Id.* at 6:1-11.)

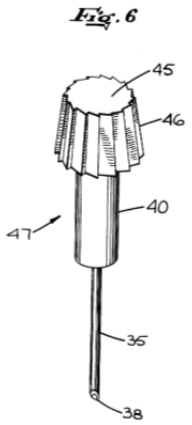
As shown in the claim charts below (and Jensen Declaration at paragraphs 120-127), Hofsess discloses every element of independent claim 1 as well as dependent claims 2, 3, 7, and 10-13 (which depend on claim 1):

'307 Patent	**Hofsess (Ex. 1006)**
1. A system comprising an access tool sized and configured to establish an access path through soft tissue to bone having an interior volume occupied, at least in part, by cancellous bone,	Hofsess discloses an access tool (alignment needle that comprises cannula 10) which is sized and configured to establish an access path through soft tissue to bone as shown in figure 12 below. (*See also* Figs. 3, 4, 5, 11.) Hofsess describes the purpose of the needle as follows: "there is an alignment needle 5 having a cannula body 10 defining a lumen 12 and a soft tissue penetrating and bone indenting point 14. Cannula 10 is preferably of from 14 to 18 gauge tubular stock and has a length just sufficient to reach the surface of the bone." (Ex. 1006 at 3:17 - 25.) 

'307 Patent	Hofsess (Ex. 1006)
a void forming tool sized and configured to be introduced through the access path to form a void in cancellous bone,	The bone cutting assembly, shown in figure 6, is a void forming tool that is sized and configured to be introduced through the access path to form a void in cancellous bone: "As shown in FIG. 1, bone cutting assembly 47 is emplaced within the axial passage 12, 28 of alignment needle 5 [access tool] so that bone cutting cannula 35 is moveable linearly and axially in lumen 12 and extends from bore 28 beyond penetration point 14 of alignment needle. . . . The length of cannula 35 exceeds the length of cannula 10 a distance sufficient to penetrate the average bone cortex." (*Id.* at Fig. 12, 3:41-46, 5:57-61 ("FIG. 12 shows . . . penetration of the bone cortex 88 into medullary cavity 90 by cutting point 38 of bone cutting cannula 35.").) 
a nozzle sized and configured to pass through the access path and including an interior bore defining a fixed interior volume to receive and deliver a measured volume of filling material into the void, and	Hofsess discloses an optional conduit 48 and lumen 39 that traverses the bone cutting component. Specifically, "conduit 48 provides a means of passing a stylet to clear out bone chips which accumulate in lumen 39 during use." (*Id.* at 4:4-8.) The nozzle (the bone cutting component which includes a conduit lumen) is sized and configured to pass through the access path as indicated above and includes an interior bore as claimed. (See Jensen Decl. at ¶ 120.)

'307 Patent	Hofsess (Ex. 1006)
	Hofsess also discloses using a conventional hypodermic needle within the alignment needle for withdrawing a sample. (Ex. 1006 at 6:1-5.) This needle includes a nozzle that sized and configured to pass through the access path as well as an interior bore capable of receiving and delivering filling material as claimed. Hofsess further discloses using a blunt point cannula, a tissue cutting cannula, or a Silverman type inner cannula (Becton-Dickenson, Rutherford, N.J. Catalogue No. 1420) in place of the hypodermic needle for removal of a sample of marrow tissue. (*Id.* at 6:6-11; Jensen Decl. at ¶ 120.)
an auxiliary tool sized and configured to be advanced through the interior bore and urge filling material from the nozzle.	The "stylet," which is passed through the conduit and lumen in the bone cutting assembly nozzle, "clear[s] out bone chips which accumulate in lumen 39 during use." (Ex. 1006 at 4:4-6.)

'307 Patent	Hofsess (Ex. 1006)
2. A system according to claim 1 wherein the access tool comprises a cannula.	See claim 1. As seen in figures 1, 11, and 12, Hofsess discloses an alignment needle 5 that comprises a "cannula 10." (Ex. 1006 at 3:17-25.)

'307 Patent	Hofsess (Ex. 1006)
3. A system according to claim 1 wherein the void forming tool is carried by an elongate member sized and configured to pass through the access path.	See claim 1. The bone cutting assembly 47 includes a bone cutting point 38 and is carried by a cutting cannula 35 sized and configured to pass through the access path. "The length of cannula 35 exceeds the length of cannula 10 a distance sufficient to penetrate the average bone cortex." (Ex. 1006 at 3:45-50; Jensen Decl. at ¶ 122.) 

'307 Patent	Hofsess (Ex. 1006)
7. A system according to claim 1 wherein the nozzle comprises an elongate tube.	See claim 1. The bone cutting assembly that includes conduit 38 and lumen 39. (*See* Ex. 1006 at Fig. 1; Jensen Decl. at ¶ 123.)

'307 Patent	Hofsess (Ex. 1006)
10. A system according to claim 1 wherein the auxiliary tool comprises an elongate body.	See claim 1. Hofsess discloses a "stylet" for the lumen. (Ex. 1006 at Fig. 1, 4:4-6; Jensen Decl. at ¶ 124.)

'307 Patent	Hofsess (Ex. 1006)
11. A system according to claim 1 wherein the nozzle is made from a generally flexible material.	See claim 1. "Alternatively, the cutting and penetration points may be fabricated from surgical steel while the remainder of the apparatus is fashioned from polymeric materials such as, for example, polymethacrylate, polyurethane, polyethylene, polystyrene, polycarbonate and like polymeric materials." (*See* Ex. 1006 at 3:3-13.)[3]

'307 Patent	Hofsess (Ex. 1006)
12. A system according to claim 1 wherein the nozzle is made from a generally rigid material.	See claim 1. "For example, the apparatus of the invention may be fabricated from stainless steel or similar alloys commonly used to fabricate surgical instruments." (*Id.*)

'307 Patent	Hofsess (Ex. 1006)
13. A system according to claim 1 wherein the filling	See claim 1. "Bone chips" are autograft material. (Ex. 1006 at 4:4-6; Jensen Decl. at ¶ 127.)

[3] Polyethylene is specifically identified in the '307 patent as an example of a flexible material. (Ex. 1001 at 10:58.)

'307 Patent	Hofsess (Ex. 1006)
material comprises at least one of a flowable material that hardens to a rigid state, a bone cement, autograft material, allograft material, calcium carbonate, demineralized bone matrix material, and calcium phosphate.	

As shown in the claim chart below (and Jensen Declaration at paragraph 128), Hofsess discloses every element of independent claim 14.

'307 Patent	Hofsess (Ex. 1006)
14. A system comprising a cannula sized and configured to establish an access path through soft tissue to bone having an interior volume occupied, at least in part, by cancellous bone,	Hofsess discloses using an alignment needle with a cannula to access bone. See claim 1.
a void forming tool sized and configured to be introduced through the cannula to form a void in cancellous bone,	Hofsess discloses a bone cutting assembly that has a bone cutting point, which is the claimed void forming tool. See claim 1.
a nozzle that can be manipulated independent of the cannula and that is sized and configured to pass through the cannula, the nozzle including an interior bore to receive and deliver a measured volume of filling material into the void, and	The bone cutting assembly can also be used as a nozzle for delivering materials. See claim 1. The bone cutting tool can be manipulated independently of the alignment needle (cannula): "bone cutting assembly is emplaced within the axial passage 12, 28 of alignment needle 5 so that bone cutting cannula 35 is moveable linearly and axially in lumen 12." (Ex. 1006 at 3:41-44.) As shown in the figure, the nozzle has an interior bore to receive and

'307 Patent	Hofsess (Ex. 1006)
	deliver a measured volume of filing material into the void just like the nozzle of the '307 patent. (Jensen Decl. at ¶ 128.)
an auxiliary tool that can be manipulated independently of the nozzle and the cannula and that is sized and configured to be advanced through the interior bore and urge filling material from the nozzle, the auxiliary tool, when fully advanced, substantially fully occupying the entire interior bore of the nozzle.	See claim 1. Hofsess discloses using "a stylet to clear out bone chips which accumulate in lumen 39 during use." (Ex. 1006 at 4:4-6; Jensen Decl. at ¶ 128.)

Dependent claims 15, 16, and 17 contain the same limitations, respectively, as dependent claims 13, 11, and 12 (relating to the filling material and the flexible/rigid materials) but depend on independent claim 14 instead of independent claim 1. Hofsess discloses all the elements of claim 14 and, for the same reasons as discussed with dependent claims 11, 12, and 13, anticipates dependent claims 15, 16 and 17. (See Jensen Decl. ¶¶ 129 and 130.)

E. Ground 5: Hofsess In Combination With the Knowledge Of One Skilled In The Art Renders Obvious Claims 8 and 9

As discussed above, ***dependent claim 8*** requires that the system of claim 1 further includes "a receptacle for holding a volume of filling material, and wherein the nozzle includes a connector to couple the nozzle to the receptacle." As

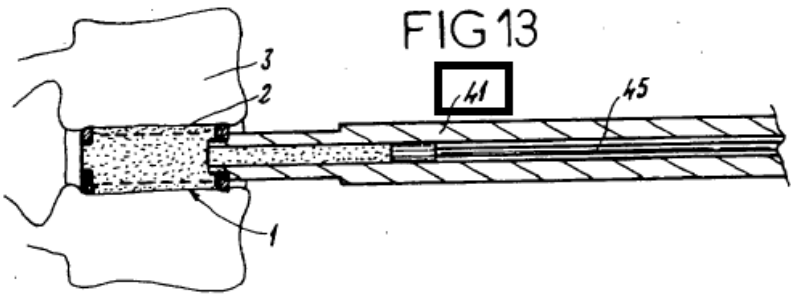
discussed above in Section B.1., using a receptacle to deliver filling material to a nozzle and coupling the receptacle to the nozzle with a connector to prevent leakage was "conventional" as the '307 patent itself recognizes. (Ex. 1001 at 10:43-44.) There are no unexpected results from adding such a conventional receptacle to the system, or from including a connector to couple that receptacle to the nozzle, and thus would be obvious as explained above. Moreover, Hofsess already envisions the use of such receptacles. Hofsess discloses a "hypodermic needle is inserted into the medullary cavity by passage through the axial passage 12, 28 of alignment needle 5." (Ex. 1006 at 6:1-5.) Hypodermic needles necessarily are proximally fit to a syringe and a vacuum syringe is typically connected to the nozzle hub to facilitate collection of tissue. (*Id.* at 6:5-6; Jensen Decl. at ¶ 133.)

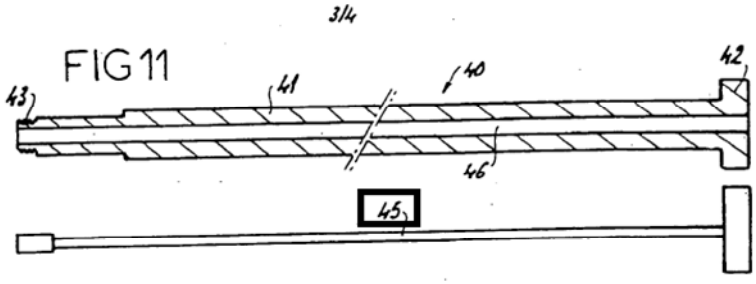
Dependent claim 9 requires that the nozzle of claim 1 "has a length and includes measured markings along the length." As explained in Section B.2., such calibration markings on such instruments were well known and conventional as of August 1998. For the same reasons as discussed above, it would have been obvious to the ordinary skilled artisan to provide the same type of conventional markings on the bone cutting assembly or nozzle of Hofsess if markings were not already included to gauge the insertion depth. (Jensen Decl. at ¶ 134.)

F. Ground 6: Grosse Anticipates Claims 1-3, 7, 10, and 13

Grosse (Ex. 1007) discloses all of the elements of independent claim 1 as well as dependent claims 2-3, 7, 10, and 13 (which depend on claim 1) and thus anticipates these claims.

Grosse discloses implantation of an intervertebral implant that includes the injection of cancellous bone chips through the interior bore of a "tubular body 41" that is suitable for advancement through an access path or cannula. (Ex. 1007 at p. 9, Fig. 13.) This tubular body comprises an "interior bore 46" and "cancellous bone chips can be injected into the interior of cavity 10 by exerting pressure on the piston 45, as shown in Figure 13, to ensure perfect filling of the cavity 10." (*Id.* at p. 9, Figs. 11, 13.).



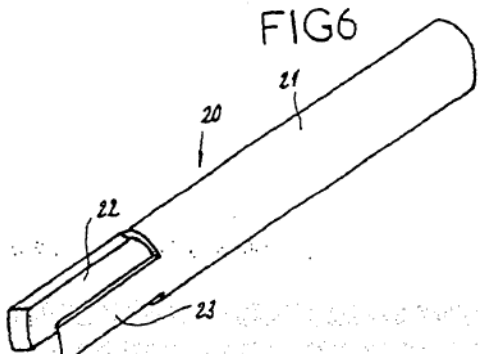
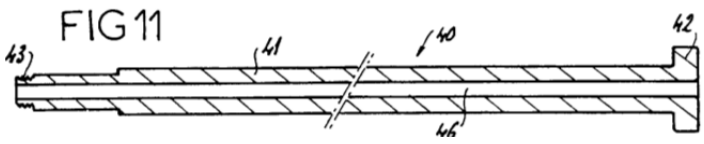
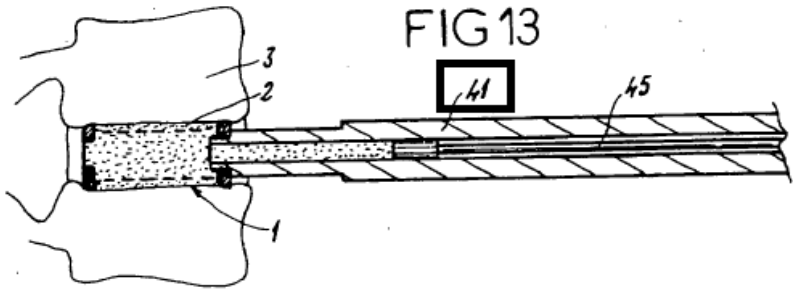


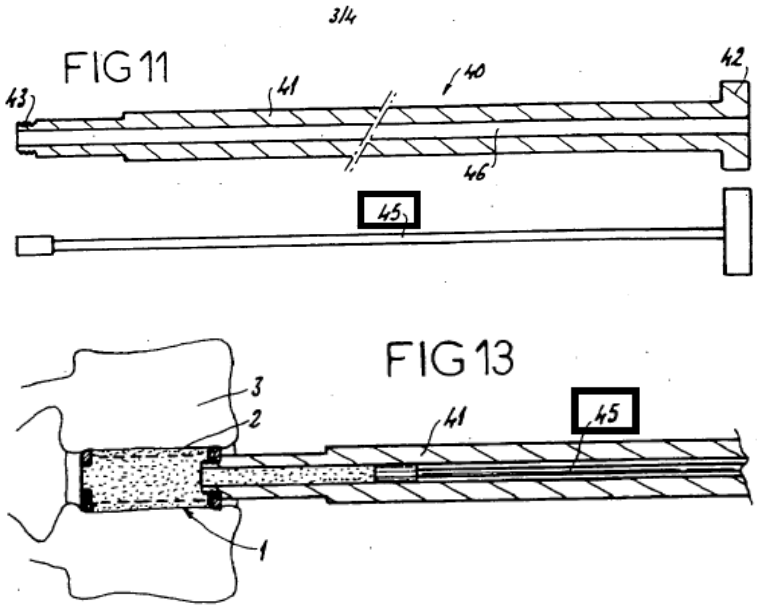
Before delivering the chips, a drill guide is used to establish a percutaneous access path through soft tissue into the human vertebral body including the intervertebral space so that one can gain access to the implantation area.

Specifically, Grosse discloses a "drilling jig 20" that "has a tubular portion 21, which is used to guide a drill bit." (*Id.* at p. 8, Fig 6.) This drill guide is a cannula for establishing a subcutaneous access path through soft tissue into the human vertebral body as claimed in the '307 patent. That is because the implant is "intended to come in contact with the cancellous bone of vertebral plates when the implant is [installed]." (*Id.* at p. 12, claim 1.) Moreover, the drill bit that is guided through this drill guide 20 is a void forming tool sized and configured to be introduced through the access path. (Id. at p. 8.)

Provided below is a table showing how each limitation of Claims 1-3, 7, 10 and 13 are met by Grosse (see also Jensen Declaration ¶¶ 138-143):

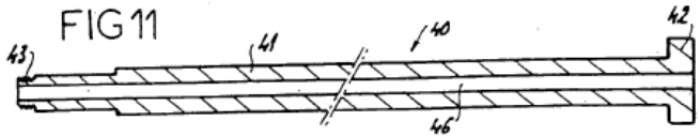
'307 Patent	**Grosse (Ex. 1007)**
1. A system comprising an access tool sized and configured to establish an access path through soft tissue to bone having an interior volume occupied, at least in part, by cancellous bone,	As seen in Figure 6, Grosse discloses a system including a "drilling jig 20" that is inserted into bone with a tubular portion 21 designed to guide a drill bit. (Ex. 1007 at pp. 6, 8.) "The blades are intended to be inserted into the disc before the receptacle that is designed to receive the implant body has been drilled." (*Id.* at p. 6.) The implant is "intended to come in contact with the cancellous bone of vertebral plates when the implant is installed." (Id. at p. 12, claim 1) See also Jensen Decl. at ¶ 138.

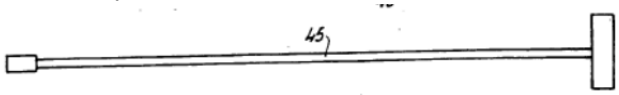
'307 Patent	Grosse (Ex. 1007)
	
a void forming tool sized and configured to be introduced through the access path to form a void in cancellous bone,	Grosse discloses a "drill bit." (Ex. 1007 at 8; Jensen Decl. at ¶ 138.) Grosse discloses that "a cavity has to be formed not only in the disc 4, but also in the subchondral bone of the vertebral plates 3a, providing access to the cancellous bone." (Ex. 1007 at p. 8.)
a nozzle sized and configured to pass through the access path and including an interior bore defining a fixed interior volume to receive and deliver a measured volume of filling material into the void, and	As shown in figures 11 and 13, "The instrument 40 tubular body 41" with an "interior bore 46." (*Id.* at p. 9.) Once the implant is in place, "cancellous bone chips can be injected into the interior of the cavity 10 by exerting pressure on the piston 45, as shown in figure 13, to ensure the perfect filling of the cavity." (*Id;* see also Fig. 12; Jensen Decl. at ¶ 138.)  

‘307 Patent	Grosse (Ex. 1007)
an auxiliary tool sized and configured to be advanced through the interior bore and urge filling material from the nozzle.	Figures 11 and 13 depict “piston rod 45,” which passes through the interior bore 46 of the tubular body 41 to inject cancellous chips into the cavity. (Ex. 1007 at p. 9.) 

‘307 Patent	Grosse (Ex. 1007)
2. A system according to claim 1 wherein the access tool comprises a cannula.	See claim 1. The access tool in Grosse is a cannula with a slot at the end, i.e., “drilling jig 20” that has “a tubular portion 21, which is used to guide a drill bit.” (Ex. 1007 at p. 8; Jensen Decl. at ¶ 139.)

‘307 Patent	Grosse (Ex. 1007)
3. A system according to claim 1 wherein the void forming tool is carried by an elongate member sized and configured to pass through the access path.	See claim 1. The “drill bit” is guided through the tubular portion 21 of the drilling jig 20. (Ex. 1007 at p. 8; Jensen Decl. at ¶ 140.)

'307 Patent	Grosse (Ex. 1007)
7. A system according to claim 1 wherein the nozzle comprises an elongate tube.	See claim 1. Figure 11 depicts "tubular body 41." (Ex. 1007 at p. 9, Fig. 11; Jensen Decl. at ¶ 141.) 

'307 Patent	Grosse (Ex. 1007)
10. A system according to claim 1 wherein the auxiliary tool comprises an elongate body.	See claim 1. Figure 11 depicts "a piston rod 45 that defines a piston slidable in the interior bore 46 of the body 41." (Ex. 1007 at p. 9, Fig 11; Jensen Decl. at ¶ 142.) 

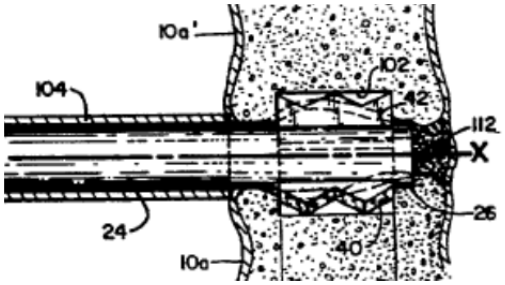
'307 Patent	Grosse (Ex. 1007)
13. A system according to claim 1 wherein the filling material comprises at least one of a flowable material that hardens to a rigid state, a bone cement, autograft material, allograft material, calcium carbonate, demineralized bone matrix material, and calcium phosphate.	Grosse discloses injection of "cancellous bone chips," which is an autograft material. (Ex. 1007 at p. 10; Jensen Decl. at ¶ 143.)

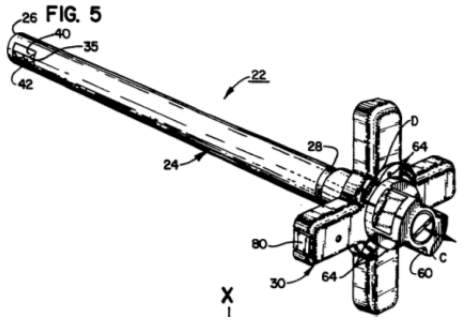
G. Ground 7: Kuslich Renders Obvious Claims 1-3 and 5-18 In View Of Grosse And The Knowledge Of The Ordinary Skilled Artisan

Kuslich (Ex. 1008) in view of Grosse (Ex. 1007) and the knowledge of the

ordinary skilled artisan renders obvious claims 1-3 and 5-18 of the '307 patent. Like Grosse, Kuslich relates to methods and systems for treating vertebral conditions particularly those affecting the intervertebral disk. (*See, e.g.*, Ex. 1008 at 1:19-22, 3:6-15.) Therefore a person of ordinary skill in the art would be motivated to consider Kuslich and Grosse in combination. (Jensen Decl. at ¶ 151.)

With regard to independent claims 1 and 14, Kuslich focuses on a tool that can be used in both open and percutaneous surgery to create an enlarged chamber or void in an intervertebral space for insertion of an implant and other filling materials. (Ex. 1008 at 7:30-9:11.) In the context of percutaneous surgery, Kuslich teaches using an "access tool," which is a "cannula" (locating cylinder 104), to establish an access path through soft tissue to a vertebral body as claimed in the '307 patent. (*Id.* at Fig. 16, 8:25-40.) "The bores 16 are made as large as possible so that they also cut into the bone of the body portions 10a and 10a'." (*Id.* at 4:43-45.) A drill bit is then "passed through cylinder 104 and a hole sized to receive the distal end 26 is drilled into the intervertebral space."

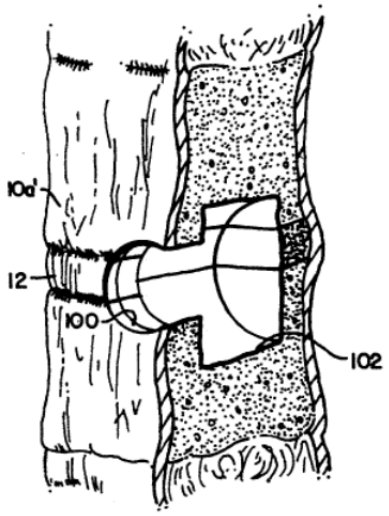




(*Id.* at 8:34-36.) Kuslich notes that "forming a bore by drilling through a locating cylinder as described is known in the art." (*Id.* at 8:36-39.)

Kuslich also discloses a "void forming tool sized and configured to be introduced through the access path to form a void in cancellous bone" as claimed. Specifically, once the access path is formed, the Kuslich tool, e.g., shaft 22 shown in Figure 5, which includes retractable blades, is introduced through the access path established by the locating cylinder 104 to form an enlarged chamber 102 or void in the disk and surrounding bone 10a and 10a'. (*Id.* at Figs. 16-20, 8:4-8, 8:40-46, 9:44-51.) The tool 22 is sized and configured to pass through the access path to form a void in cancellous bone: "With the access bore 100 so formed, the distal end 26 is guided through the cylinder 104 into the bore. FIG. 16 shows shaft 22 being guided by a locating cylinder 104." (*Id.* at 8:41-44; see also Jensen Decl. at ¶ 147.)

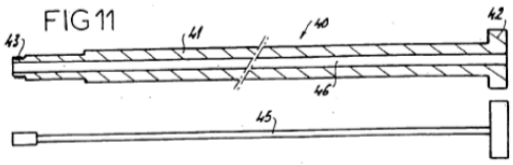
FIG. 17



After this void in the bone has been created, Kuslich teaches that "additional procedures may be done at this time depending upon the needs of the patient" including filling the cavity "with finely chopped cortical or cancellous bone chips impacting the chip to provide some mechanical stability." (Ex. 1008 at

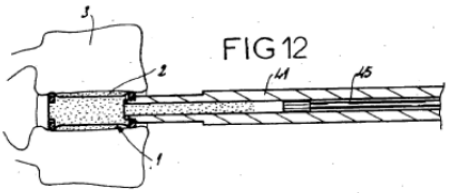
8:50-62.) Kuslich discloses filling its void 102 with bone graft material and thereby inherently discloses some type of tool for performing this function. (*Id.*; Jensen Decl. at ¶ 149.) A person of ordinary skill in the art would have reason to combine Kuslich with the Grosse reference to find one of the well-known methods of injecting bone filling, i.e., manually injecting the materials using a nozzle and an auxiliary tool. (Jensen Decl. at ¶ 149.)

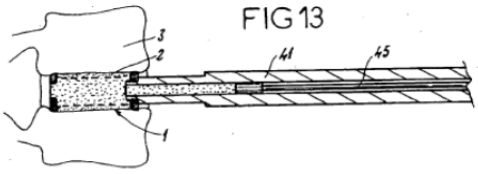
As discussed above in Section F, Grosse (Ex. 1007) discloses a nozzle 41 that is sized and configured to pass through an access path into bone and includes an interior bore 46 defining a fixed interior volume to receive and deliver a measured volume of filling material into the void. The



nozzle 41, shown in Figure 11 of Grosse, is specifically disclosed as a nozzle for delivering filling material, such as bone graft material, into the void. (Ex. 1007 at p. 10.) A person of ordinary skill in the art would be motivated to select an access cannula (cylinder 104) of Kuslich such that it could appropriately receive the nozzle 41 of Grosse. (Jensen Decl. at ¶ 150.) Accordingly, the nozzle "can be manipulated independent of the cannula" and "is sized and configured to pass through the cannula" as required by claim 14. (*Id.* at ¶ 154.)

Also as discussed above in Section F, Grosse discloses an auxiliary tool 45 sized and configured to be advanced through the interior bore 46 of the nozzle 41. The auxiliary tool 45 is used to inject "cancellous bone chips into [the] cavity" formed in the vertebral space. (Ex. 1007 at p. 10.) Kuslich likewise discloses filling the "cavity . . . with finely chopped cortical or cancellous bone chips" and thereby inherently discloses some type of tool for performing this function. (Ex. 1008 at 8:56-62.) As further required by Claim 14, Grosse further discloses that "the auxiliary can be manipulated independently of the nozzle." (Ex. 1007 at p. 9 ("instrument 40 has a piston rod 45 that defines a piston slidable in the interior bore 46 of the body 41.").)





Grosse further discloses that "the auxiliary tool, when fully advanced substantially fully occupying the entire interior bore of the nozzle" as can be seen in figures 12 and 13 of Grosse.

Combining the teachings of the nozzle instrument 41 and auxiliary instrument 45 for performing this manual injection process would not only be obvious to one having ordinary skill in the art, but would provide the information needed to complete the process described in Kuslich. (Jensen Decl. at ¶ 151.)

Accordingly, the combination of Kuslich in view of Grosse renders obvious claims 1 and 14 of the 307. (*Id.* at ¶¶ 153-155.)

The limitations of ***dependent claims 2, 3, 5-13, 15-18,*** which depend on claims 1 and 14 and address specifics of the access tool, void forming tool, and filling materials, were also known in the art as discussed below. (*See* Jensen Decl. at ¶¶ 153-165.) Thus, these additional claims would also have been obvious in view of Kuslich and Grosse.

With regard to ***claim 2***, the locating cylinder 104 of Kuslich is a cannula. (Ex. 1008 at 8:26-44; Jensen Decl. at ¶ 156.)

With regard to ***claim 3***, the void forming tool of Kuslich is carried by an elongate member sized and configured to pass through the access path. Kuslich teaches that "Tool 22 includes an elongate cylindrical shaft 24 having a distal end 26 and an operator engaging end 28." (Ex. 1008 at 5:24-26.) As discussed with claim 1 above, the tool 22 is configured to pass through the access path. (*Id.* at 8:41-44; Jensen Decl. at ¶ 157.)

With regard to ***claims 5 and 18***, the void forming tool in Kuslich comprises an expandable body. Tool 22 includes retractable blades that expand, once inside the vertebral space, to create a void. "When in the retracted position, the blades are completely received within the external dimensions of the distal end 26." (Ex.

1008 at 6:1-9.) "[R]otation of the shaft fully extends the blades to the position shown in FIG. 12." (*Id.* at 6:15-16; Jensen Decl. at ¶ 158.) With regard to ***claim 6***, as shown in Figure 12, the expanded blades in Kuslich are not spherical.

FIG. 11

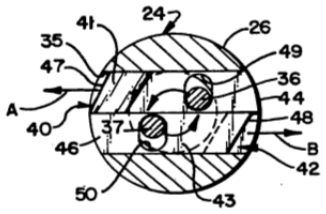
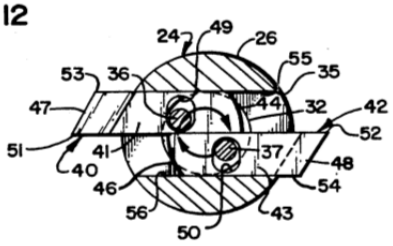


FIG. 12



With regard to ***claim 7***, the Grosse nozzle is an elongate tube as discussed in Section F above.

With regard to ***claims 8 and 9***, which requires a receptacle coupled to the nozzle and markings on the nozzle, as explained in Sections B.1. and B.2, using such a receptacle and including such markings were known in the art and an obvious design choice. (See also Jensen Decl. at ¶¶ 161, 162) With regard to ***claim 10***, as discussed in Section F, the auxiliary tool in Grosse comprises an elongate body. (See Jensen Decl. at ¶ 163.)

With regard to ***claims 11, 12, 16 and 17,*** as explained in Section B.3, it was well known at the time of the invention that selecting a nozzle made from either flexible or rigid materials (the two available design choices) was a matter of physician preference and clinical application. Thus, as discussed, a person of ordinary skill would have had reason and found it obvious to construct the nozzle

out of both materials. (See also Jensen Decl. at ¶ 164.)

With regard to ***claims 13 and 15***, which require the filling material to be one of a number of items including autograft or allograft material, Grosse discloses the use of autograft materials as discussed above in Section F and Kuslich discloses the use of bone chips (Ex. 1008 at 4:4-6), which are autograft material or allograft material. (See Jensen Decl. at ¶ 165.)

In sum, as mentioned above, Kuslich addresses a tool for creating a void in vertebral space when performing a surgery for placing an intervertebral implant such as the one proposed by Grosse. Both Grosse and Kuslich recognize that it is desirable to deliver bone chips into the cavity in such a procedure and Grosse describes the tools to do so. Accordingly, Kuslich in view of Grosse and the knowledge of a person of ordinary skill in the art renders claims 1-3 and 5-18 obvious. (See Jensen Decl. ¶ 166.)

VII. SECONDARY CONSIDERATIONS

Stryker is not aware of any secondary considerations that would tend to show non-obviousness (e.g., commercial success, copying, long-felt but unresolved need, failure of others, etc.) that would have a nexus with the claimed inventions. (Jensen Decl. at ¶¶ 167-168.)

VIII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *inter partes* review of claims 1-18 of the '307 patent.

Respectfully submitted,

Dated: September 3, 2014

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IPR2014-01434

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: December 26, 2006

Application No. 10/617,976

U.S. Patent No. 7,153,307

Filing Date: July 11, 2003

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. 7,153,307 and Exhibits 1001-1017 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:

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