Filed on behalf of Petitioner, Wright Medical Technology, Inc.
By: Samuel W. Apicelli
Steven E. Koffs
DUANE MORRIS LLP
30 South 17th Street
Philadelphia, PA 19103
Tel.: (215) 979-1000
Email: swapicelli@duanemorris.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Wright Medical Technology, Inc.,

Petitioner

v.

Owner of
U.S. Patent No. 6,863,672 to Reiley et al.
Appl. No. 10/208,391 filed July 30, 2002
Issued March 8, 2005
Division of Appl. No. 09/055,805, filed on April 6, 1998, now U.S. Patent No. 6,440,138
Issued August 27, 2002

IPR Trial No. *TBD*

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,863,672 PURSUANT TO 35 U.S.C. § 312 AND 37 C.F.R. § 42.108

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

EXHIBIT LIST

Exhibit No.	Description	Short Reference
1001	U.S. Patent No. 6,863,672	the '672 patent
1002	U.S. Patent No. 5,439,464	*Shapiro*
1003	U.S. Patent No. 6,371,968	*Kogasaka*
1004	U.S. Patent No. 4,467,800	*Zytkovicz*
1005	Declaration of Dr. Timothy Harrigan ("Dr. Harrigan")	Harrigan Declaration
1006	Curriculum Vitae of Dr. Harrigan	
1007	List of documents reviewed by Dr. Harrigan	
1008	Amendment A filed January 28, 2004	Amendment A
1009	Amendment B filed June 7, 2004	Amendment B
1010	Evarts, McCollister C. (Ed.) *Surgery of the Musculoskeletal System*, 2nd Ed. Churchill Livingstone, 1990, ISBN 0-443-08516-1	*Evarts*
1011	Bridwell, Keith H. and Ronald L. DeWald (Eds.)*, The Textbook of Spinal Surgery* 2nd Ed., Volume 2, Lippincott-Raven, 1997, ISBN 0-397-51800-5	*Bridwell*
1012	Soni, Ram K "An Anterolateral Approach to the Hip Joint," *Acta Orthopedica Scandinavica* 68 (5), 1997	*Soni*
1013	Pai, V.S. "A Comparison Of Three Lateral Approaches In Primary Total Hip Replacement," *International Orthopaedics (SICOT)*, 1997	*Pai*
1014	Hulka, Jaroslav F. and Harry Reich, *Textbook of Laparoscopy*, (2nd ed) W. B. Saunders, 1994, ISBN 0-7216-3643-8	*Hulka*
1015	Johnson, Lanny L., *Arthroscopic Surgery, Principles & Practice*, C. V. Mosby, 1986, ISBN 0-8016-2591-2	*Johnson*
1016	U.S. Patent No. 5,601,564	*Gustilo*
1017	Tilkian, Ara G. and Elaine Keiss Daly, *Cardiovascular Procedures,* C. V. Mosby, 1986, ISBN 0-8016-4965-X	*Tilkian*

1018	MacIsaac, Andrew I. et al., **"**High Speed Rotational Atherectomy: Outcome in Calcified and Noncalcified Coronary Artery Lesions", JACC 26(3), 1995	*MacIsaac*
1019	Masura, Jozef et al., "Transcatheter Closure of Secundum Atrial Septal Defects Using the New Self-Centering Amplatzer Septal Occluder: Initial Human Experience," *Catheterization and Cardiovascular Diagnosis* 42, 1997	*Masura*
1020	Legeros, Racquel, "Materials for Bone Repair, Augmentation, and Implant Coatings", *Biomechanics in Orthopedics*, S. Niwa, S.M. Perren, T. Hattori (Eds.), Springer-Verlag p. 147 (1992)	*Legeros*
1021	European Patent Application 0607688	*Neubardt*
1022	U.S. Patent No. 5,820,629	*Cox*
1023	U.S. Patent No. 5,470,352	*Rappaport*
1024	Leu Hansjoerg F. et al, "Lumbar Percutaneous Interbody Fusion", *Clinical Orthopedics and Relater Research*, No. 337, 1997	*Leu*
1025	U.S. Patent No. 3,175,554	*Stewart*
1026	Canale, Terry S. (Ed.), *Campbell's Operative Orthopaedics*, 9th Ed., Vol. 2, 1998	*Canale*
1027	U.S. Patent No. 4,881,547	*Danforth*
1028	Gray, Henry, *Anatomy of the Human Body*, 1918, *available at* http://www.barteby.com/107	*Gray*

I. MANDATORY NOTICES

A. Real Party-In-Interest

Wright Medical Technology, Inc. is the real party-in-interest. Wright Medical Technology, Inc., is a wholly-owned subsidiary of Wright Medical Group, Inc.

B. Related Matters

Other matters that may affect or be affected by a decision in this proceeding include: *Orthophoenix, LLC v. Wright Medical Technology, Inc.*, Civil Action No. 13-10007-LPS (D. Del.). Wright is also filing an additional Petition for *inter partes* review in U.S. Patent No. 6,440,138, which is related to U.S. Patent No. 6,863,672.

C. Counsel And Service Information

Lead Counsel	Back-up Counsel
Samuel W. Apicelli Registration No. 36,427 swapicelli@duanemorris.com	Steven E. Koffs Registration No. 37,163 sekoffs@duanemorris.com
Duane Morris LLP 30 South 17th St. Philadelphia, PA 19103 Telephone: (215) 979-1255 Fax: (215) 689-0827	Duane Morris LLP 30 South 17th St. Philadelphia, PA 19103 Telephone: (215) 979-1250 Fax: (215) 689-2744

II. CERTIFICATION OF GROUNDS FOR STANDING

Pursuant to 37 C.F.R. § 42.104(a), Wright Medical Technology, Inc. ("Wright Medical") certifies that U.S. Patent No. 6,863,672 ("the '672 patent") is

available for *inter partes* review and that Wright Medical is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition.

III. OVERVIEW OF THE CHALLENGE AND RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.22(a)(1) and 42.104(b)(1)-(2), Wright Medical challenges Claims 1-26 of the '672 patent (Ex. 1001) and requests that each challenged claim be canceled. The earliest priority date of the '672 patent is April 6, 1998.

A. Prior Art

Wright Medical relies upon the following patents, published patent applications, and/or published non-patent literature:

1. U.S. Patent No. 5,439,464 to Shapiro ("*Shapiro*"; Ex. 1002), which was filed on March 9, 1993 and issued on August 8, 1995 and is prior art under 35 §§ 102(b) / 103(a).

2. U.S. Patent No. 6,371,968 to Kogasaka et al. ("*Kogasaka*"; Ex. 1003), which was filed on May 8, 1997 and issued on April 16, 2002 and is prior art under 35 §§ 102(e) / 103(a).

None of these references was before the Examiner during the prosecution of the '672 patent.

B. Grounds for Challenge

Wright Medical requests cancellation of Claims 1-26 ("Challenged Claims") as unpatentable under 35 U.S.C. § 103(a). This petition is supported by the attached declaration of Dr. Timothy Harrigan ("Harrigan Declaration"; Ex. 1005), accompanied by his Curriculum Vitae (Ex. 1006), and a list of documents the considered (Ex. 1007). The Harrigan Declaration supports the grounds in this petition showing that there is a reasonable likelihood that Wright Medical will prevail with respect to at least one challenged claim and that each challenged claim is not patentable.

IV. OVERVIEW OF THE '672 PATENT

A. The '672 Patent Specification

The '672 patent is directed to systems and methods for treating bone, such as cancellous bone, including formation of a cavity in a treatment area. Ex. 1001 at Col. 3:35-55. As admitted in the Background, in various known systems, an expandable body could be deployed to form a cavity in cancellous bone tissue, as part of a therapeutic procedure. *Id*. at 1:10-18. Such a procedure can be performed for treating, for example, fractures or other abnormal bone conditions. *Id*. The expandable body compresses the cancellous bone to form an interior cavity, and the cavity is then backfilled. *Id*. at 1:18-21. The specification acknowledges that

there was a demand for systems or methods capable of forming cavities in bone and other interior body regions in "safe and efficacious ways". *Id*. at 1:29-32.

The '672 patent specification describes embodiments of tools using a linear movement during cavity formation. For example, FIGs. 20 (at right) and 21 (at right) illustrate a linear movement tool (66) capable of forming a cavity in a targeted treatment area. *Id*. at 7:59-60. The tool (66) also includes a catheter tube (68) having a handle (70) on its proximal end (72) to facilitate gripping and maneuvering of the tube (68). *Id*. at 7:60-63.

FIG. 20

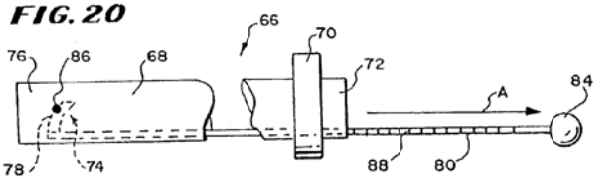
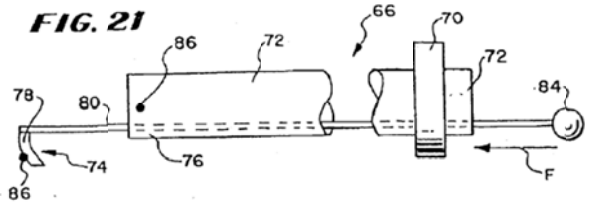
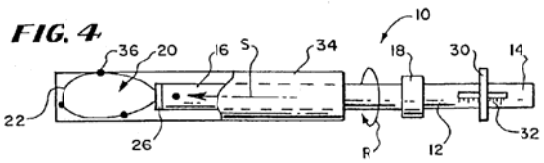


FIG. 21

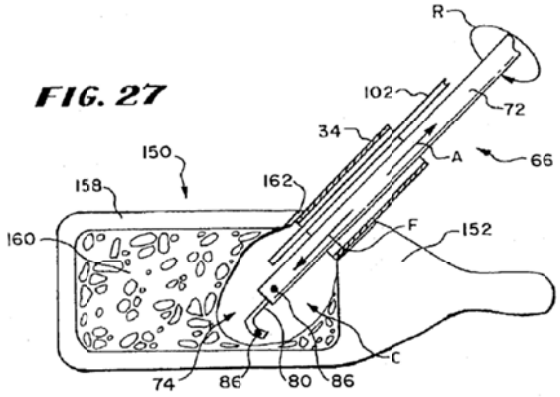


The catheter tube (68) carries a linear movement cavity forming structure (74) at its distal end (76). *Id*. at 7:64-65. The structure (74) includes a rigid blade (78), which projects at a side angle from the distal end (76). *Id*. at 7:65-66 and 8:1. In one embodiment, a stylet (80) is carried by an interior track (82) within the catheter tube (68). *Id*. at 8:3-4; *see also* FIGs. 18 and 19. The track (82) extends along the axis of the catheter tube (68) and the stylet is free to move within the track (82). *Id*. at 8:5-7. The stylet (80) is also free to rotate within the track (82). *Id*. at 8:7-9; *see also* FIG. 17(arrow R).

The catheter tube (68) is carried for sliding and rotation within the guide sheath or cannula (34), as shown in FIG. 4 (right). *Id*. at 8:23-25. The catheter tube (68) slides freely, "axially" within the guide sheath (34) to deploy the tool 66 in the treatment site. *Id*. at 8:25-27. At the site, the physician deploys the blade (78) outside the catheter tube (68) and slides the blade (78) along the tissue in a linear path. *Id*. at 8:27-30. Linear movement of the blade (78) along the tissue cuts the tissue. *Id*. at 8:30-31. The blade (78) can carry one or more radiological markers (86) for monitoring the tool during surgery. *Id*. at 8:36-38.

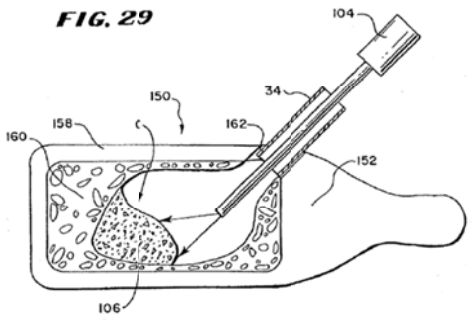


Referring to FIG. 27 (right), when using the blade tool (66), the physician moves the stylet (80) forward (arrow F) and aft (arrow A) to move the blade (78) in a linear path through cancellous bone (160). *Id*. at 10:45-48. The blade (78) scrapes loose and cuts cancellous bone (160) along its path, which the suction tube (102) removes. *Id*. at 10:48-49. A cavity (C) is formed. *Id*. at 10:50. Rotation (arrow R) and linear movement (arrows F and A)

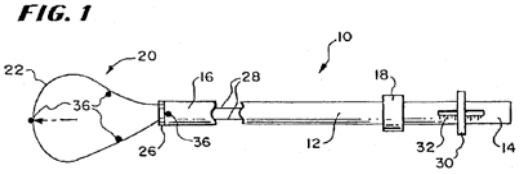


of the blade (78) allow the physician to create a cavity (C) having a desired dimension. *Id*. at 10:50-53.

As shown in FIG. 29 (right), after the cavity is formed, a second tool (104) can be used to perform a therapeutic procedure. *Id*. at 11:3-12. For example, material (106) can be dispensed into the cavity (C), such as bone cement, allograft material, synthetic bone substitute, a medication, or a flowable material. *Id*.



As shown in FIG 1 (below), an embodiment of the structure (20) includes a filament (22) that can carry a radiological marker (36), made from radiopaque materials. *Id*. at 4:48-51. A marker (36) can be placed at or near the distal end of the loop structure (20), while other markers can be placed at spaced apart locations on the loop structure (20). *Id*. at 4:51-54. The distal end (16) of the catheter tube (12) can also carry markers. The markers (36) permit radiologic visualization of the loop structure (20) and of the catheter tube (12) within the targeted treatment area. *Id*. at 4:54-57.



B. Prosecution History

During prosecution, the Applicant distinguished the claims from several cited prior art references based on the recitations that the cavity forming structure carried by the shaft is "adapted to extend beyond the distal end of the cannula" and that the cavity is formed "in the cancellous bone". *See* Amendment A filed January 28, 2004, Remarks Section at ¶ 3 ("Amendment A"; Ex. 1008). In distinguishing the claims from U.S. Patent No. 5,540,693 to Fisher ("*Fisher*"), Applicant argued that the *Fisher* "device does not extend beyond the distal end of the cannula" and merely "protrudes from an apical aperture". *Id*. The Applicant further argued that *Fisher* merely discloses a method in which inert gas is delivered to a treatment site but does not "teach or suggest the formation of a cavity in cancellous bone." *Id*.

The Applicant also distinguished Claims 52 and 57 (which issued as Claims 19 and 23) from U.S. Patent No. 5,015,255 to Kuslich ("*Kuslich*"), which discloses a device for removing material from the intervertebral disc and adjacent vertebra on either side of the disc to enable fusion of the adjacent vertebrae. *See* Amendment B filed June 7, 2004, p. 12, lines 6-12 ("Amendment B"; Ex. 1009). The patentee argued that "wholly within the vertebral body" means that the intervertebral disc is not affected by the claimed treatment. *Id*. at p. 11, lines 20-22.

C. Person of Ordinary Skill in the Art ("POSA") And State of the Art

A POSA is a hypothetical person who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. As of April 6, 1998, the effective filing date of the '672 patent, a POSA would have at least a bachelor's degree in the field of mechanical engineering, biomedical engineering, or a related discipline and at least 3-5 years of practical work experience in the field of surgical tools used for bone treatment, including the design, construction, and implantation of surgical tools in bones and tissue, such as cancellous bone. Ex. 1005 at ¶ 48. Alternatively, a POSA could have an advanced degree such as a Masters, Ph.D., M.D., or D.O. in one of the above disciplines and 1-2 years of experience in one of the above fields. *Id*. A POSA would have had familiarity with the extant literature on the use of surgical tools to achieve the formation of a cavity within the bone, such as cancellous bone, and/or within the surrounding tissue for treatment therein. *Id*. As of April 6, 1998, the state of the art pertinent to the '672 patent was such that use of surgical tools for bone treatment was known. *Id*. at ¶¶ 21-39. Surgical tools used for the treatment of bone generally included a shaft and a cavity forming structure coupled to the shaft, and the shaft could be inserted within a target treatment area using a cannula. *Id*. As the '672 patent admits, in various known systems, an expandable body can be deployed to form a cavity in cancellous bone tissue, as part of a

therapeutic procedure for fixing, e.g., fractures or other abnormal bone conditions. Ex. 1001 at 1:11-21.

D. The '672 Patent Claims and Claim Construction

In an *inter partes* review, claim terms are interpreted according to their broadest reasonable construction[1] in light of the patent specification. 37 C.F.R. § 42.100(b). The following discussion proposes constructions of terms in the Challenged Claims under the broadest reasonable construction standard. Any claim terms not included in the following discussion are to be given their broadest reasonable interpretation in light of the specification as commonly understood by those of ordinary skill in the art. (M.P.E.P. § 2111.01(I)). Should the patent owner, in order to avoid the prior art, contend that the claims have a construction different from their broadest reasonable interpretation, the appropriate course is for

[1] This interpretation only applies to the *inter partes* review sought herein and should not be construed as constituting, in whole or in part, the Petitioner's own interpretation of any claims for any other purposes, including any litigation. Accordingly, Petitioner expressly reserves the right to present an interpretation of a claim term in other proceedings, which is different, in whole or in part, of that presented in this Petition.

the patent owner to seek to amend the claims to expressly correspond to its contentions in this proceeding. *See* 77 Fed. Reg. 48764 (Aug. 14, 2012).

"Movement within and along the axis of the cannula"

Each of the claims require a shaft that is introduced by "movement within and along the axis of the cannula" to deploy a cavity forming structure inside bone or cancellous bone. Based on the description provided in the '672 patent specification, this term means that the shaft is being moved within the cannula in the direction of the axis of the cannula.

As explained in the specification, the catheter tube (12) is carried for "***axial***" and rotational movement ***within*** a guide sheath or cannula (34). Ex. 1001 at 4:20-22 (emphasis added); *see also* FIG. 4. The specification describes that the physician is able to freely slide the catheter tube (12) "***axially within***" the guide sheath (34) (arrow S in FIG. 4). *Id*. at 4:22-24 (emphasis added). Similarly, in explaining the alternative tool (66), the catheter tube (68) of the tool (66) is described as also being carried for "sliding" and "rotation" within the guide sheath or cannula (34), in the same manner shown in FIG. 4. *Id*. at 8:23-25. For example, the physician is able to move the catheter tube (68) "axially" within the guide sheath (34) to deploy the tool (66) in the targeted treatment site. *Id*. at 8:25-27.

Thus, under the broadest reasonable construction, this term means that the shaft is being moved within the cannula in the direction of the axis of the cannula.

V. OVERVIEW OF THE PRIMARY PRIOR ART REFERENCES

As explained in detail below, limitation by limitation, there is nothing new or non-obvious in the challenged claims of the '672 patent. Ex. 1005 at ¶¶ 21-40 and 55-141. Before 1998 the traditional method for orthopedic surgery was known as an "open" procedure where incisions were made in the skin, and, as described in Evarts, *Surgery of the Musculoskeletal System*, which was published in 1990, dissection of the tissues under the skin was undertaken (muscles, nerves, blood vessels, organs, etc.) in order to expose the bone structures which were to be surgically altered. *Id.* at ¶ 21. Such surgical procedures enabled adequate exposure such that the surgery on the bone could be accurately performed and damage to intervening tissues during dissection could be inhibited. *Id*.

While complex bone resection and surgical modification continued to be practiced using open procedures, a subset of orthopedic procedures were amenable to less invasive surgical techniques. *Id*. at ¶ 24. For example, in the 1980s and 1990s, a wide array of general surgical procedures were developed and performed using laparoscopes. *Id*. at ¶ 25. These techniques were common knowledge to designers of surgical equipment, and tools to perform surgical treatment through laparoscopes and arthroscopes were common in the 1990s. *Id*.

Surgical tools, such as scissors, graspers, and side-cutting tools, were designed to fit through a cannula being used and to then be deployed for use. For

example, these procedures were operated on soft tissue (cartilage, meniscus, and tendon) and bone cutting was accomplished through an arthroscope using rotating tools. *Id*. at ¶ 26. Laparoscopic procedures for bone disorders in the spine were in existence in 1998, and were generally focused on methods for anterior fusion of the spine. *Id*. at ¶ 27. Cutting tools for bone that operate via linear motion were also widely known in orthopedics. *Id*. The technology that existed in 1998 for spinal fusion or the treatment of the spine is directly relavant to the technology described in the patent at issue. *Id*. at ¶ 28. For example, the primary references cited herein, *Shapiro* and *Kogasaka*, are directly applicable to the technology of the '672 patent.

A. Overview of *Shapiro*

Shapiro describes a method and instruments that can be used for arthroscopically accessing a predetermined area of a patient's spinal column and for subsequently performing desired surgical procedures thereon. Ex. 1002 at 1:53-56. The method uses a laminectomy tool adapted for cutting ligaments and/or bone. *Id*. at 5:43-48.

Shapiro, discloses with respect to FIG. 9 (shown below and annotated by Petitioner for clarity) and FIG. 10 (below), a cannula having a body (10) which is cylindrical in form and the body (10) has an internal cylindrical passageway (12) to accommodate a viewing scope and the fluid necessary for proper utilization of the

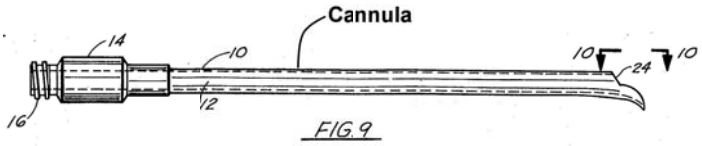


FIG. 9

scope. *Id*. at 3:31-36. The cannula has an interior end (18) which is inserted into the patient's body in the desired location. *Id*. at 3:39-41.

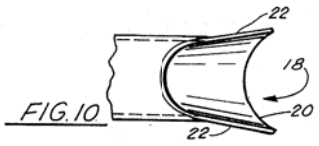


FIG. 10

A cutting edge (20) performs tissue movement, as opposed to tissue cutting or dissection. *Id*. at 3:41-44. The edge (20) extends both radially from and axially along the body (10). *Id*. at 3:44-45.

Shapiro also discloses a tool that can be used with the cannula to form a cavity within a bone, such as in cancellous bone. For example, FIG. 5 (at right and annotated by Petitioner for clarity) illustrates a known Kerison rongeur instrument that is sized and shaped to pass through a cannula. *Id*. at 3:60-68 and 4:1. The instrument has a body (30) which has a suction connection (32) at one end and a cutting tip (34) at the opposite end. *Id*. at 4:8-10. The body (30), which is cylindrical, has an axially extending passage (36) which connects to the suction attachment. *Id*. at 4:10-15.

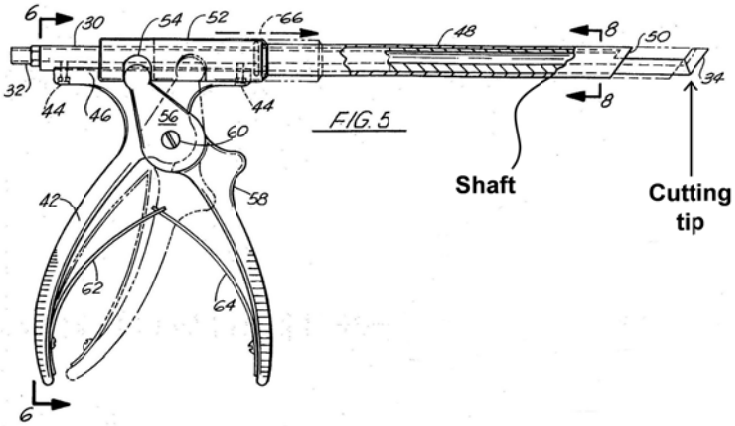
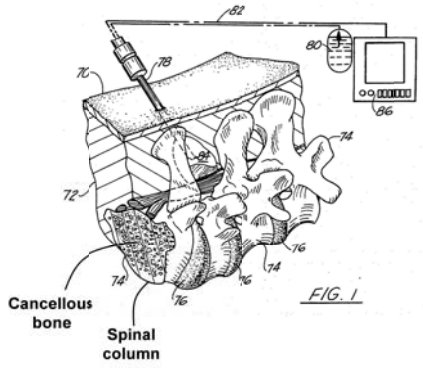
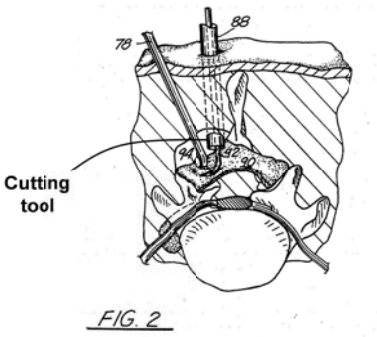


FIG. 5

A movable sleeve (48), coaxially mounted on body (30), has a cutting edge (50) at one end. Cutting edge (50) cooperates with the cutting edge (34) to sever pieces of tissue and/or bone upon coaxial movement of the sleeve (48) relative to the body. *Id*. at 4:23-27. When the handles (42, 58) are squeezed together, sleeve (48) slides to the right, in the direction of arrow (66), so that the cutting edges (50) and (34) are brought together for cutting. *Id*. at 4:40-43. As shown in FIGs. 1 and 2 (both shown below and are annotated by Petitioner for clarity), a cannula (78) is inserted through the outer skin (70) and muscle (72) in a posterolateral direction relative to the spinal column (74). *Id*. at 5:5-8. A surgeon manipulates a cutting or tissue moving end of the cannula to create the working space (84). *Id*. at 5:14-17. Once the space (84) is created, a second cannula (88) is inserted between the cannula (78) and the midline of the spinal column (74) as shown in FIG. 2. *Id*. at 5:25-29. The surgeon inserts a cutting tool (92) through the working cannula (88). *Id*. at 5:29-34. The cutting element or curette (92) incises the ligamentum





flavum. Then, the Kerison rongeur suction punch (95) can be inserted through cannula 88, (FIG. 3, at right), to remove sufficient portions of the ligamentum flavum to expose the bone beneath it. *Id*. at 5:37-43. In some instances, the Kerison rongeur suction punch removes portions of bone to expose the spinal nerves 96. *Id*. at 5:43-48.

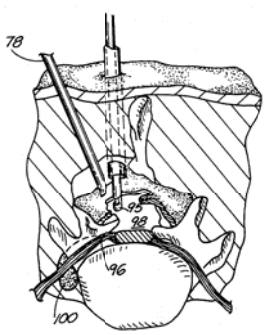


FIG. 3

B. Overview of *Kogasaka*

Kogasaka discloses a cavity-retaining tool for bone surgery. Ex. 1003 abstract, lines 1-3. As shown in FIG. 2A (right, annotated by Petitioner for clarity), a cavity-retaining sheath (1) is configured to be introduced into a body, and the sheath (1) is provided with a number of channels. One of the channels is a treatment channel (11), through which treatment tools pass. *Id*. at 10:19-48. The treatment channel (11) is a straight passage in the cavity of sheath (1). A central axis of a scope channel (12) is apart from a central axis of the treatment channel (11). *Id*. at 10:19-48.

FIG.2A

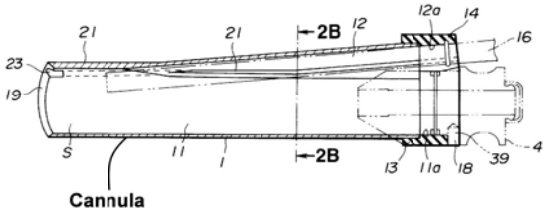


FIG.5

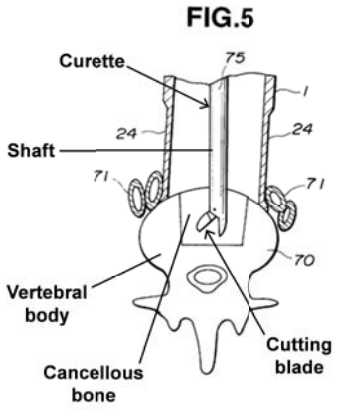
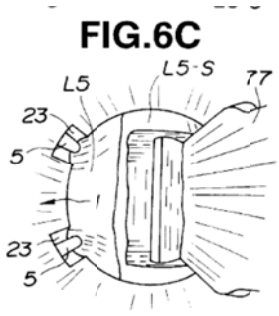


FIG.6C



A tool, such as a lancet (76), can be inserted through the treatment channel (11). *Id*. at 16: 17-25. FIG. 5 (above, annotated by Petitioner for clarity) shows the curette (75) cutting wholly within the vertebral body (70). Although not labeled as such, the curette (75) is cutting cancellous bone. Ex. 1005 at ¶ 33. Then, the medullar nucleus and disc are removed with, for example, the curette (75). Ex. 1001 at 16: 17-25. The L5 and S1 bones can be removed with a chisel (77) as in FIG. 6C (above). *Id*. The cavity within the sheath 1 forms a straight channel, to allow the operator to impose "a linear, intense strength" to those tools which is necessary for this type of surgery. *Id*.

As shown in FIGs. 3C and 3D (right), tissue (62), such as vessels, organs, and muscles, can be pushed aside, and the sheath (1) can be stabilized against a vertebral body (70) such that its front end securely rests against the vertebral body. *Id*. at 15:7-24. The sheath (1) has a tip shaped like a concave arch so the tip corresponds with the perimeter of the vertebral body (70).

FIG.3C

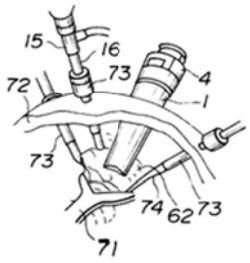
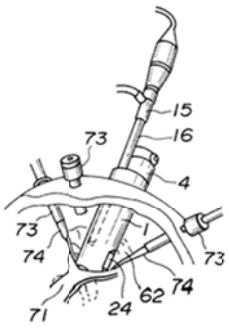


FIG.3D



VI. THE CHALLENGED CLAIMS WOULD HAVE BEEN OBVIOUS

Pursuant to 37 C.F.R. § 42.104(b)(4)-(5), specific grounds identified below and discussed in the Harrigan Declaration (Ex. 1005), show in detail the prior art disclosures that render the challenged claims unpatentable.

A. The Challenged Claims are Unpatentable Over *Shapiro* in View of a POSA or Over *Kogasaka* in in View of *Shapiro or a POSA*

Pursuant to Rule 42.104(b)(4)-(5), the section below, as well as the accompanying Harrigan Declaration (Ex. 1005), demonstrate in detail where each of the claimed features is disclosed by the cited prior art, and how each Challenged Claim would have been unpatentable over *Shapiro* taken alone or in view of the knowledge of a POSA, in the combinations identified below. The section below also demonstrates how each Challenged Claim would have been unpatentable over *Kogasaka* taken alone or in view of *Shapiro* or the knowledge of a POSA, in the combinations identified below.

1. Independent Claims 1, 6, 11, 15, 19, and 23 would have been obvious in view of *Shapiro* or in view of *Kogasaka*

Shapiro and *Kogasaka* each expressly disclose or suggest all of the claimed features of Claims 1, 6, 11, 15, and 23. Ex. 1005 at ¶¶ 55-141. *Shapiro* discloses the claimed methods using a laminectomy tool suitable for cutting bone, and is available as prior art under § 102(b)/103. *Kogasaka* discloses the claimed method using a variety of bone surgery tool embodiments, and is available as prior art under § 102(e)/103. To whatever extent that *Shapiro* or *Kogasaka* do not

expressly disclose each feature of any of the Challenged Claims, then *Shapiro* or *Kogasaka* in combination with the knowledge of a POSA would have rendered obvious each of such features. *Id*. As set forth in the Harrigan Declaration, all of the features of the Claims 1, 6, 11, 15, and 23 were within the knowledge of one of ordinary skill in the art prior to the priority date of the '672 patent. *Id*.

The test for obviousness is "expansive and flexible," such that a patent challenger need "not seek out precise teachings directed to the specific subject matter of the challenged claim." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007); *see also Plasmart, Inc. v. Kappos*, 482 Fed. Appx. 568, 572 (Fed. Cir. May 22, 2012) (unpublished) ("minor distinctions" do not preclude a finding of obviousness).

a. Independent Claims 1 and 6

Claims 1 and 6 are rendered obvious by *Shapiro* or *Kogasaka*. *See* Ex. 1005 at ¶ 57. For example, Claims 1 and 6 recite:

Claim 1	Claim 6
A method for creating a cavity in cancellous bone comprising	A method for treating bone comprising

Shapiro discloses a laminectomy method that can also include treating bone and a method for creating a cavity in bone. For example, *Shapiro* teaches a method and instruments that can be used for arthroscopically accessing a

predetermined area of a patient's spinal column and for subsequently performing desired surgical procedures thereon. Ex. 1002 at 1:53-56. *Shapiro* explains that, in some circumstances, it can be necessary to remove portions of bone to a sufficient extent to expose the spinal nerves. *Id*. at 5:43-48. *Shapiro* also discloses insertion of bone particles and/or bone segments for a fusion type procedure. *Id*. at 6:35-39. A POSA would have known that a fusion type procedure typically involves removal of bone tissue at the ends of the bones to be fused. Ex. 1005 at ¶ 58. The tool described in *Shapiro* functions in a manner that is similar to the device disclosed in the '672 patent. *Id*. at ¶ 59. It would have been obvious to a POSA to use *Shapiro's* tool to form a cavity in cancellous bone because when the outer cylinder (48) is retracted back along the axis of the shaft and the cutting edge (34) is extended, the tool shown in *Shapiro* would contact cancellous bone and cause the formation of a cavity. *Id*. When the outer sleeve (48) is extended, the cutting edge on the sleeve (50) would enable focused material removal that is similar to a rongeur. *Id*. Such a motion would facilitate the removal of dense cancellous bone to form a cavity. *Id*..

Kogasaka discloses a different method for treating bone and a method for creating a cavity in cancellous bone. For example, *Kogasaka* teaches a cavity-retaining tool that can be used for bone surgery. Ex. 1003 at abstract, lines 1-3. *Kogasaka* explains that the air-tight core cylinder (4) is removed from the sheath

(1), and tools for vertebral treatment are inserted through the treatment channel (11) to treat the vertebra as shown in FIG. 5. *Id*. at 16:13-16.

Claims 1 and 6 further recite:

Claim 1	Claim 6
providing a cannula having an axis that establishes a percutaneous path leading into bone,	providing a cannula having a distal end and an axis that establishes a percutaneous path leading into the bone,

Shapiro and *Kogasaka* each teach providing a cannula as is recited in Claims 1 and 6. For example, *Shapiro* discloses, with respect to FIGS. 9 and 10, a cannula having a body (10) which is cylindrical in form, and the body (10) has an internal cylindrical passageway (12) to accommodate a viewing scope and the fluid necessary for proper utilization of the scope. Ex. 1002 at 3:31-36. The cannula has an interior end (18) which is inserted into the patient's body. *Id*. at 3:39-41. As shown in FIGS. 1 and 2, a cannula (78) is inserted through the outer skin (70) and muscle (72) in a posterolateral direction relative to the spinal column (74). *Id*. at 5:5-8. A second cannula (88) is inserted between the cannula (78) and the midline of the spinal column (74) as shown in FIG. 2. *Id*. at 5:25-29.

Kogasaka discloses a different embodiment of a cannula described as a cavity-retaining sheath (1) in FIG. 2A. The sheath (1) is configured to be introduced into a body and the sheath (1) is provided with a number of channels,

wherein one of the channels is a treatment channel (11) through which treatment tools pass. Ex. 1003 at 10:19-48. The treatment channel (11) is a straight passage formed in the cavity of the sheath (1) and has a central axis. As shown in FIGs. 3C and 3D, the tip of the sheath (1) can be safely stabilized against a vertebral body (70), and then, under endoscopic monitoring, the sheath (1) can be pushed in until its front end securely rests against the vertebral body. *Id*. at 15:7-24.

Claims 1 and 6 further recite:

Claim 1	Claim 6
providing a shaft having an axis and a distal end portion adapted to be deployed inside the bone through the cannula, said distal end portion having a cavity forming structure comprising a surface which directly contacts cancellous bone in response to linear movement of the shaft along the axis of the cannula,	providing a shaft having an axis and adapted to be deployed inside bone through the cannula including a cavity forming structure carried by the shaft adapted to extend beyond the distal end of the cannula and comprising a surface which directly contacts cancellous bone in response to linear movement of the shaft along the axis of the cannula,

Shapiro and *Kogasaka* each teach providing a shaft as is recited in Claims 1 and 6. For example, *Shapiro* disloses a well known Kerison rongeur instrument that is sized and shaped to pass through or be deployed inside the bone through a

cannula. Ex. 1002 at 3:60-68 and 4:1; *see also* Ex. 1005 at ¶ 65-66. The instrument has a body (30) which has a suction connection (32) at one end thereof and a cavity forming structure or a cutting tip (34) at the opposite end or distal end. Ex. 1002 at 4:8-10; *see also* FIG. 5. Coaxially mounted on the body (30) is a movable sleeve (48) which has a cutting edge (50) at one end that cooperates with the cutting edge (34) to sever pieces of tissue and/or bone upon coaxial movement of the sleeve (48) relative to the body. Ex. 1002 at 4:23-27.

Shapiro explains that "it may be necessary to use the Kerison rongeur suction punch to actually remove portions of bone, as what is required is that the ligamentum flavum ***and/or*** bone be removed to a sufficient extent to expose the spinal nerves." *Id*. at 5:44-48 (emphasis added). A POSA would have recognized that the use of the term "and/or" indicates "either one or both," and that the tool could be used to remove bone without removing the ligamentum flavum. Ex. 1005 at ¶ 65. A POSA would have also understood that such tools can be deployed inside the bone through the use of the cannula. *Id*.

During use, the instrument can be inserted through the cannula (88), as shown in FIG. 3, to remove sufficient portions of the ligamentum flavum to expose the bone beneath it. *Id*. at 5:37-43. In some instances, the instrument is used to remove portions of bone. *Id*. at 5:43-48. The cutting edges (50) and (34) are sharp, and bringing these edges together severs whatever is positioned between

them. *Id*. at 4:45.47. It would have been obvious to a POSA that the cutting edge (34) and/or the cutting edge (50) extends beyond the distal end of the cannula during use. Ex. 1005 at ¶ 67. For example, the instrument would only be able to cut bone or tissue when the edges extend beyond the distal end, and are brought together and directly touch the site that needs to be cut. *Id*. The edges would also need to extend beyond the distal end of the cannula to move together for cutting the targeted area. *Id*.

It would have been obvious to a POSA to use the instrument in *Shapiro* to contact and cut cancellous bone. 1005 at ¶ 68. For example, the instrument in *Shapiro* can be used as a side-cutting rongeur, where the tip of the device contacts and penetrates into cancellous bone tissue. *Id*. This function is similar to the function of the devices shown in FIGs. 12 to 21 in the '672 patent. *Id*. Given the depression that is caused by penetrating cancellous bone with the tip of the device, the action of the sleeve (48) and the cutting edge of the sleeve (50) would be able to remove cancellous bone in a precise manner to, for example, form a cavity. *Id*.

Kogasaka discloses a different embodiment for a shaft having a cavity forming structure. For example, in FIG. 5, *Kogasaka* illustrates a curette (75) having a shaft with a cavity forming structure on the distal end of the shaft. The medullar nucleus and disc can be removed with the curette (75). Ex. 1003 at 16:

17-25. It was well known in the art that the curette (75) can be used to cut bone, such as cancellous bone. Ex. 1005 at ¶ 69.

As shown in FIG. 5, the curette (75) can be deployed inside bone through a cannula or sheath (1). FIG. 5 of *Kogasaka* also shows the curette (75) cutting in a location occupied by cancellous bone. *Id*. at ¶ 70. As also shown in FIG. 5, the cavity forming structure of the curette (75) extends beyond the distal end of the sheath (1). *Id*. For the curette (75) to be in direct contact with and to cut the bone, such as cancellous bone, the shaft of the curette (75) needs to move in a linear motion. For example, *Kogasaka* explains that as the cavity within the sheath (1) forms a straight channel, it allows the operator to impose "***a linear, intense strength***" to those tools (i.e., the curette (75)) which is necessary for this type of surgery. Ex. 1003 at 16:22-25 (emphasis added).

Claims 1 and 6 further recite:

Claim 1	Claim 6
deploying the cannula percutaneously to establish a path leading to inside bone,	deploying the cannula percutaneously to establish a path leading to inside bone,

Shapiro and *Kogasaka* each teach deploying the cannula as is recited in Claims 1 and 6. For example, as demonstrated above, *Shapiro* discloses, with respect to FIGS. 9 and 10, the cannula with a distal or an interior end (18) which is inserted into the patient's body. Ex. 1002 at 3:31-41. As shown in FIGS. 1 and 2,

the cannula (78) is inserted through the outer skin (70) and muscle (72) in a posterolateral direction relative to the spinal column (74). *Id*. at 5:5-8. A second cannula (88) is inserted between the cannula (78) and the midline of the spinal column (74) as shown in FIG. 2. *Id*. at 5:25-29. Both the cannulas (78, 88) are thus deployed percutaneously to establish a path leading to inside the bone. Ex. 1005 at ¶ 72.

Kogasaka discloses a different embodiment of a cannula described as a cavity-retaining sheath (1) in FIG. 2A. The sheath (1) is configured to be introduced into a body, and the sheath (1) is provided with a number of channels. Ex. 1003 at 10:19-48. One of the channels is a treatment channel (11) through which treatment tools pass. *Id*. The treatment channel (11) is a straight passage formed in the cavity of sheath (1) and has a central axis. *Id*. As shown in FIGs. 3C and 3D, the tip of the sheath (1) can be safely stabilized against a vertebral body (70), and then, under endoscopic monitoring, the sheath (1) can be pushed in until its front end securely rests against the vertebral body. *Id*. at 15:7-24.

Claims 1 and 6 also recite:

Claim 1	Claim 6
introducing the shaft by movement within and along the axis of the cannula to deploy the cavity forming structure	introducing the shaft by movement within and along the axis of the cannula to deploy the cavity forming structure

inside the cancellous bone, inside bone,

Shapiro and *Kogasaka* each teach introducing the shaft as is recited in Claims 1 and 6. For example, *Shapiro* disloses a Kerison rongeur instrument and explains that it is sized and shaped to pass through or be deployed inside the bone through a cannula. Ex. 1002 at 3:60-68 and 4:1; *see also* Ex. 1005 at ¶ 75. The instrument is inserted through the cannula (88) (i.e., within and along the axis of the cannula (88)), as shown in FIG. 3. For example, as shown in FIG. 5, the Kerison rongeur is described as having a cylindrical shaft or body (30), wherein the body (30) has an axially extending passage (36). When the rongeur is positioned within the cannula (88), as shown in FIG. 3, a POSA would know that the body (30) of the rongeur is arranged concentric with the cannula and, as such, the axis of the cannula (88) coincides with the axis of the body (30) such that the rongeur moves within and along the axis of the cannula (88). *Id*. In some instances, it may be necessary to use the Kerison rongeur to remove portions of bone, as the ligamentum flavum and/or bone needs to be removed to a sufficient extent to expose the spinal nerves. *Id*. at 5:37-48.

Kogasaka discloses a different embodiment for a shaft having a cavity forming structure. The shaft is introduced by movement within and along the axis of the cannula to deploy the cavity forming structure inside bone . For example, in FIG. 5, *Kogasaka* shows a curette (75) having a shaft with a cavity forming

structure on its distal end. As shown in FIG. 5, the curette (75) can be deployed inside cancellous bone through a cannula or sheath (1).

Claims 1 and 6 futher recite:

Claim 1	Claim 6
moving the shaft linearly along, and not rotatingly about the axis of the cannula to cause the surface to form a cavity in the cancellous bone.	and moving the shaft linearly along, and not rotatingly about the axis of the cannula to cause the surface to contact cancellous bone to form a cavity.

Shapiro and *Kogasaka* each teach moving the shaft as is recited in Claims 1 and 6. For example, as demonstrated above, when using the Kerison rongeur instrument described in *Shapiro*, the instrument can be inserted through the cannula (88), as shown in FIG. 3, to remove sufficient portions of the ligamentum flavum and bone to expose the spinal nerves. *Id*. at 5:37-48. The cutting edge (34) and/or cutting edge (50) are intended to contact bone, such as cancellous bone, in response to linear movement of the shaft along the axis of the cannula. For example, when the handles (42, 58) are squeezed together, the sleeve (48) will "slide to the right, . . . , so that" the cutting edges (50) and (34) are brought together. *Id*. at 4:40-43. This action severs whatever is positioned between them. *Id*. at 4:45.47.

It would have been obvious to a POSA to use the instrument in *Shapiro* to contact and cut cancellous bone to form a cavity therein. Ex. 1005 at ¶ 79. For example, the instrument in *Shapiro* can be used as a side-cutting rongeur, where the tip of the device contacts and penetrates into cancellous bone tissue. *Id*. This function is similar to the function of the devices shown in FIGs. 12 to 21 in the '672 patent. *Id*. Given the depression that is caused by penetrating cancellous bone with the tip of the device, the action of the sleeve (48) and the cutting edge of the sleeve (50) would be able to remove cancellous bone in a precise manner to form a cavity. *Id*.

Also, *Kogasaka* describes the curette (75) as being deployed inside bone through a cannula or sheath (1). For the curette (75) to be in direct contact with and to cut the bone, such as cancellous bone, the shaft of the curette (75) moves in a linear motion. For example, *Kogasaka* explains that as the cavity within the sheath (1) forms a straight channel, it allows the operator to impose "***a linear, intense strength***" to those tools (i.e., the curette (75)) which is necessary for this type of surgery. Ex. 1003 at 16:22-25 (emphasis added).

It would have been obvious to a POSA to use the curette in *Kogasaka* to contact and cut cancellous bone to form a cavity therein. Ex. 1005 at ¶ 81. For example, gauges, chisels, and punches are used in revision total hip surgery to cut into bone and bone cement. *Id*.

As each of the features of Claims 1 and 6 are disclosed in *Shapiro* and *Kogasaka* and was within the knowledge and skill of a POSA, Claims 1 and 6 are not patentable and should be canceled. *Id*. at ¶ 82

b. Independent Claims 11, 15, 19, and 23

Claims 11, 15, 19, and 23 are rendered obvious by *Shapiro* or *Kogasaka*. *See* Ex. 1005 at ¶ 85. For example, Claims 11, 15, 19, and 23 recite:

Claim 11	Claim 15
A method for, treating a vertebral body by creating a cavity, wholly within the vertebral body in cancellous bone comprising	A method for treating a vertebral body by creating a cavity wholly within the vertebral body comprising
Claim 19	**Claim 23**
A method for treating a vertebral body by creating a cavity wholly inside the vertebral body in cancellous bone comprising	A method for treating a vertebral body by creating a cavity wholly within the vertebral body in cancellous bone comprising

As demonstrated above with respect to Claims 1 and 6, *Shapiro* teaches a method and instruments for arthroscopically accessing a patient's spinal column and for performing surgical procedures thereon. Ex. 1002 at 1:53-56. *Shapiro* explains that, it can be necessary to remove portions of bone to a sufficient extent

to expose the spinal nerves. *Id*. at 5:43-48. *Shapiro* also discusses the use of a Kerison rongeur instrument. *Shapiro* states that "what is required is that the ligamentum flavum ***and/or*** bone be removed." *Id*. (emphasis added). Because *Shapiro* uses the term "or", a POSA would have been motivated to use the instrument for only removing bone to avoid surgically induced damage to other tissue, and to reduce recovery time. Ex. 1005 at ¶ 65. It would have been obvious to a POSA to use the methodology disclosed in *Shapiro* and the Kerison rongeur instrument to create a cavity wholly within a vertebral body in cancellous bone. *Id*. at ¶ 84. For example, a POSA would see the need to avoid the nervous tissue whenever possible. *Id*. When a cavity is needed in a vertebral body, the requirement that adjacent tissues are not damaged will likely be met if the cavity is created entirely within cancellous bone. *Id*.

Kogasaka discloses a different method for treating bone and a method for creating a cavity wholly within a vertebral body in cancellous bone. For example, *Kogasaka* teaches a cavity-retaining tool that can be used for bone surgery. *See* Ex. 1003 at abstract, lines 1-3. *Kogasaka* explains that the tools for vertebral treatment are inserted through the treatment channel 11 to treat the vertebra as shown in FIG. 5. *Id*. at 16:13-16. FIG. 5 shows the tool cutting wholly within bone.

With reference to FIG. 38, in one embodiment, a drill (207) can be inserted into the treatment channel (201a) of the outer sheath (201). *Id*. at 28:27-29. While the drill (207) is being pressed against the vertebral body (70), the handle (207a) is turned to make a hole (218) that is sized and configured to receive an implant (213) for the intervertebral disc (216) and when a hole (218) is opened to a desired depth, the flange (207d) placed around the stem (207b) of the drill (207) hits against the rear end of the outer sheath (201). *Id*. at 28:30-41. As such, there will be no risk involved in the drill operation of making "***a too deep hole 218 in the vertebral body***". *Id*. at 28:41-43 (emphasis added). A POSA would have understood that due to the concern of the depth of the hole (218), the hole should be made wholly within the vertebral body. Ex. 1005 at ¶ 87. A POSA would have also known that the tool described in *Kogasaka* is fully capable of cutting bone and creating a cavity wholly within the vertebral body would inhibit collateral damage to surrounding tissue. *Id*.

Claims 11, 15, 19, and 23 further recite:

Claim 11	Claim 15
providing a cannula having an axis that establishes a percutaneous path leading into bone,	providing a cannula having a distal end and an axis that establishes a percutaneous path leading into the bone
Claim 19	Claim 23

providing a cannula having an axis that establishes a percutaneous path leading into bone,	providing a cannula having a distal end an axis that establishes a percutaneous path leading into bone,

As demonstrated above with respect to Claims 1 and 6, *Shapiro* discloses, with respect to FIGS. 9 and 10, a cannula having a body (10) which is cylindrical in form and the body (10) has an internal cylindrical passageway (12) to accommodate a viewing scope and the fluid necessary for proper utilization of the scope. Ex. 1002 at 3:31-36. The cannula has a distal end (18) which is inserted into the patient's body. *Id*. at 3:39-41. As shown in FIGS. 1 and 2, a cannula (78) is inserted through the outer skin (70) and muscle (72) in a posterolateral direction relative to the spinal column (74). *Id*. at 5:5-8. A second cannula (88) is inserted between the cannula (78) and the midline of the spinal column (74) as shown in FIG. 2. *Id*. at 5:25-29.

Kogasaka discloses a different embodiment of a cannula described as a cavity-retaining sheath (1) in FIG. 2A. The sheath (1) is configured to be introduced into a body and the sheath (1) is provided with a number of channels. Ex. 1003 at 10:19-48. One of the channels is a treatment channel (11) through which treatment tools pass. *Id*. The treatment channel (11) is a straight passage formed in the cavity of the sheath (1) and has a central axis. *Id*. As shown in

FIGs. 3C and 3D, the sheath (1) can be pushed in until its front end securely rests against the vertebral body. *Id*. at 15:7-24.

Claims 11, 15, 19, and 23 further recite:

Claim 11	Claim 15
providing a shaft having an axis and a distal end portion adapted to be deployed inside the bone through the cannula, said distal end portion having a cavity forming structure adapted to be extended in situ radially from the shaft and comprising a surface which directly contacts cancellous bone in response to linear movement of the shaft along the axis of the cannula,	providing a shaft having an axis and adapted to be deployed inside bone through the cannula including a cavity forming structure carried by the shaft adapted to extend beyond the distal end of the cannula and be extended in situ radially from the shaft and comprising a surface which directly contacts cancellous bone in response to linear movement of the shaft along the axis of the cannula,
Claim 19	**Claim 23**
providing a shaft having an axis and a distal end portion adapted to be deployed inside the bone through the cannula, said distal end portion having a cavity forming structure adapted to be	providing a shaft having an axis and adapted to be deployed inside bone through the cannula including a cavity forming structure carried by the shaft adapted to extend beyond the distal end of

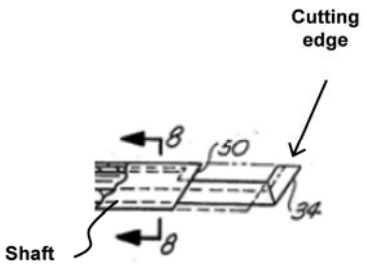
extended in situ radially from the shaft and comprising a surface which directly contacts the cancellous bone in response to movement of the shaft	the cannula and, be extended in situ radially from the shaft and comprising a surface which directly contacts the cancellous bone in response to movement of the shaft,

As demonstrated above with respect to Claims 1 and 6, *Shapiro* disloses a Kerison rongeur instrument that is sized and shaped to pass through or be deployed inside the bone through a cannula. Ex. 1002 at 3:60-68 and 4:1; *see also* Ex. 1005 at ¶ 93. A POSA would be familiar with the use of a rongeur or similar tools within a cannula as such use is common for arthroscopy procedures used in orthopedics. *Id*. The instrument has a body (30) which has a suction connection (32) at one end thereof and a cavity forming structure or a cutting tip (34) at the opposite end or distal end. Ex. 1002 at 4:8-10; *see also* FIG. 5. Coaxially mounted on body (30) is a movable sleeve (48) which has a cutting edge (50) at one end that cooperates with the cutting edge (34) to sever pieces of tissue and/or bone upon coaxial movement of the sleeve (48) relative to the body. *Id*. at 4:23-27.

The instrument can be inserted through a cannula (88) (FIG. 3), to remove sufficient portions of the ligamentum flavum to expose the bone beneath it. *Id*. at 5:37-43. In some instances, it may be necessary to use the instrument to remove

portions of bone. *Id*. at 5:43-48. It would have been obvious to a POSA that the cutting edge (34) and/or the cutting edge (50) needs to extend beyond the distal end of the cannula during use. Ex. 1005 at ¶ 93. For example, in order to engage a volume of bone between the cutting edges (50 and 34), both cutting edges, at a minimum, must be able to contact bone. *Id*. In order to contact the bone, both cutting edges must be extended out of the cannula. *Id*. Such an extension is more than just a mere protrusion, making the cavity forming structure in *Shapiro* analogous to the cavity forming structure in the '672 patent, as the patentee had distinguished such an extension from a mere protrusion during prosecution. *Id*.; *see also* Ex. 1008, Remarks Section at ¶ 3.

With reference to FIG. 5 (a portion of which is shown at right for clarity and annotated by Petitioner for clarity), not only would the cutting edge (34) extend beyond the distal end of the cannula, but the cutting edge (34) also extends radially outwardly from the shaft.

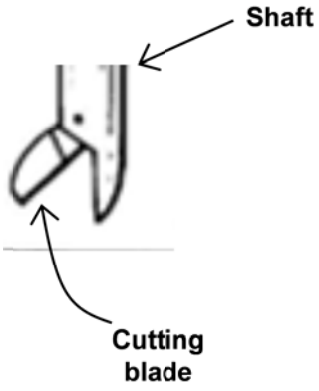


The cutting edge (34) and/or cutting edge (50) are intended to contact bone, such as cancellous bone, in response to linear movement of the shaft along the axis of the cannula. For example, when the handles (42, 58) are squeezed together, the sleeve (48) will slide to the right, "***in***

the direction of arrow 66" (i.e., linear movement), so that the cutting edges (50) and (34) are brought together. Ex. 1002 at 4:40-43 (emphasis added).

It would have been obvious to a POSA to use the instrument in *Shapiro* to contact and cut cancellous bone. For example, a POSA would have understood that the instrument in *Shapiro* can be used as a side-cutting rongeur that is capable of removing bone between the cutting edges in a controlled fashion. Ex. 1005 at ¶ 96.

Kogasaka discloses a different embodiment for a shaft having a cavity forming structure. For example, in FIG. 5, *Kogasaka* illustrates a curette (75) having a shaft with a cavity forming structure on the distal end of the shaft. Ex. 1003 at 16: 17-25. It is well known in the art that the curette (75) can be used to cut bone, such as cancellous bone. Ex. 1005 at ¶ 97. For example, well known tools, such as gauges, chisels, and punches are used in revision total hip surgery to cut into bone. *Id*.



As shown in FIG. 5, the curette (75) can be deployed inside bone through a cannula or sheath (1). As demonsrated above, with respect to Claims 1 and 6, during use, the cavity forming structure of the curette (75) extends beyond the distal end of the sheath (1) . With reference to FIG. 5 (a portion of which is shown above for clarity and annotated by Petitioner for clarity),

the cavity forming blade on the curette extends radially outwardly from the distal end of the shaft of the curette. During operation, for the curette (75) to be in direct contact with and to cut the bone, such as cancellous bone, the shaft of the curette (75) needs to move in a linear motion. For example, *Kogasaka* explains that as the cavity within the sheath (1) forms a straight channel, it allows the operator to impose "***a linear, intense strength***" to those tools (i.e., the curette (75)) which is necessary for this type of surgery. *Id*. at 16:22-25 (emphasis added).

Kogasaka teaches other embodiments having a cavity forming structure with a radial member. For example, as shown in FIG. 111A (below) and 111B (below), the external surface of the treatment segment (442) is covered with a mesh (443), and, in its interior, is an elastic member (444) which takes a nearly cylindrical form made of silicone or a spring material. *Id*. at 57:11-20.

FIG.111A

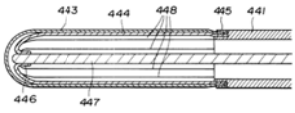
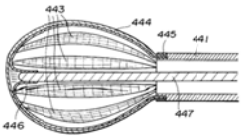


FIG.111B



As shown in FIGS. 111A or 112A (below), before insertion, it is allowed to take a cylindrical form which has a similar outer diameter to that of the insert (441), and as the folded part (446) moves towards the base, the interstices between slits (448) increasingly widen until the elastic member (444) "***is expanded in a radial***

FIG.112A

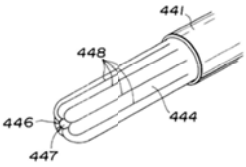
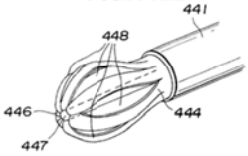


FIG.112B



direction", to become spherical, which makes blunt stripping possible as shown in FIGS. 111B and 112B (above). *Id*. at 58:25-48 (emphasis added).

Claims 11, 15, 19, and 23 further recite:

Claim 11	Claim 15
deploying the cannula percutaneously to establish a path leading to inside bone,	deploying the cannula percutaneously to establish a path leading to inside bone,
Claim 19	**Claim 23**
deploying the cannula percutaneously to establish a path leading to inside bone,	deploying the cannula percutaneously to establish a path leading to inside bone,

Shapiro, discloses, with respect to FIGS. 9 and 10, the cannula with a distal end (18) which is inserted into the patient's body. Ex. 1002 at 3:31-41. As shown in FIGS. 1 and 2, the cannula (78) is inserted through the outer skin (70) and muscle (72) in a posterolateral direction relative to the spinal column (74). *Id*. at 5:5-8. A second cannula (88) is inserted between the cannula (78) and the midline of the spinal column (74) as shown in FIG. 2. *Id*. at 5:25-29. Both the cannulas (78, 88) are deployed percutaneously to establish a path leading to inside the bone.

Kogasaka discloses a different embodiment of a cannula described as a cavity-retaining sheath (1) in FIG. 2A. The sheath (1) is configured to be introduced into a body and the sheath (1) is provided with a treatment channel (11) through which treatment tools pass. Ex. 1003 at 10:19-48. The treatment channel

(11) is a straight passage formed in the cavity of sheath (1) and has a central axis. As shown in FIGs. 3C and 3D, the sheath (1) can be pushed in until its front end securely rests against the vertebral body. *Id*. at 15:7-24.

Claims 11, 15, 19, and 23 further recite:

Claim 11	Claim 15
introducing the shaft by movement within and along the axis of the cannula to deploy the cavity forming structure inside the cancellous bone,	introducing the shaft by movement within and along the axis of the cannula to deploy the cavity forming structure inside cancellous bone,
Claim 19	**Claim 23**
introducing the shaft by movement within and along the axis of the cannula to deploy the cavity forming structure inside the cancellous bone,	introducing the shaft by movement within and along the axis of the cannula to deploy the cavity forming structure inside the cancellous bone,

As demonstrated above with respect to Claims 1 and 6, *Shapiro* disloses a Kerison rongeur instrument that is sized and shaped to pass through or be deployed inside the bone through a cannula. Ex. 1002 at 3:60-68 and 4:1; *see also* Ex. 1005 at ¶ 105. A POSA would have known that bone cutting or bone removal tools can be deployed through such a cannula. There are advantages to using a cannula in that the sharp edges of the tools are kept from damaging the tissue, blood vessels,

and nerves. *Id*. The instrument can be inserted through the cannula (88) (i.e., within and along the axis of the cannula (88)), as shown in FIG. 3, to remove sufficient portions of the ligamentum flavum and bone to expose the spinal nerves. *Id*. at 5:37-48.

Kogasaka describes a shaft introduced by movement within and along the axis of the cannula to deploy the cavity forming structure inside bone . For example, in FIG. 5, *Kogasaka* illustrates a curette (75) having a shaft with a cavity forming structure on the distal end of the shaft. The curette (75) can be deployed inside bone, such as cancellous bone, through a cannula or sheath (1).

Claims 11, 15, 19, and 23 further recite:

Claim 11	Claim 15
extending the cavity forming structure in situ radially from the shaft,	extending the cavity forming structure in situ radially from the shaft,
Claim 19	**Claim 23**
extending the cavity forming structure in situ radially from the shaft,	extending the cavity forming structure in situ radially from the shaft,

As demonstrated above, *Shapiro*, with reference to FIG. 5, discloses that the cutting edge (34) extends beyond the distal end of the cannula, and also discloses that the cutting edge (34) extends radially outwardly from the shaft. Also demonstrated above, with reference to FIG. 5, *Kogasaka* discloses a cavity forming

blade on a curette that extends radially outwardly from the distal end of the shaft of the curette.

It would have been obvious to a POSA to have a cavity forming structure that is adapted to be extended and/or extends in situ radially from the shaft, as many surgical tools provide this geometry and are used by surgeons for scraping or abrasion of tissue. Ex. 1005 at ¶ 109. As demonstrated above, *Kogasaka* teaches other embodiments having such a geometry for the cavity forming structure.

Claims 11, 15, 19, and 23 further recite:

Claim 11	Claim 15
and moving the shaft linearly along the axis of the cannula to cause the surface to form a cavity, wholly within the vertebral body in the cancellous bone.	and moving the shaft linearly along the axis of the cannula to cause the surface to contact cancellous bone to from a cavity wholly within the vertebral body in the cancellous bone.
Claim 19	**Claim 23**
and moving the shaft to cause the surface to form a cavity wholly within the vertebral body in the cancellous bone.	and moving the shaft to cause the surface to contact cancellous bone to form a cavity wholly within the vertebral body in the cancellous bone.

As demonstrated above with respect to Claims 1 and 6, when using the Kerison rongeur instrument described in *Shapiro*, the instrument can be inserted through the cannula (88), as shown in FIG. 3, to remove sufficient portions of the ligamentum flavum and/or bone to expose spinal nerves. Ex. 1002 at 5:37-48. The cutting edge (34) and/or cutting edge (50) are intended to contact bone, such as cancellous bone, in response to movement, such as linear movement, of the shaft along the axis of the cannula. For example, when the handles (42, 58) are squeezed together, the sleeve (48) will slide to the right, "***in the direction of arrow 66***" (i.e., linear movement), so that the cutting edges (50) and (34) are brought together. *Id*. at 4:40-43 (emphasis added).

It would have been obvious to a POSA to use the instrument in *Shapiro* to contact and cut cancellous bone to form a cavity wholly within the vertebral body. Ex. 1005 at ¶ ¶ 84 and112. For example, the device in *Shapiro* can be used as a side-cutting rongeurs, which can carefully remove cancellous bone by punching a depression into the surface and cutting away a small region between the cutting edges. *Id*. ¶114.

As also demonstrated above, *Kogasaka* describes the curette (75) as being deployed inside bone through a cannula or sheath (1). Ex. 1003 at 15:7-28. During operation, for the curette (75) to be in direct contact with and to cut the bone, such as cancellous bone, the shaft of the curette (75) needs to move or be in

motion, such as a linear motion. For example, *Kogasaka* explains that as the cavity within the sheath (1) forms a straight channel, it allows the operator to impose "***a linear, intense strength***" to those tools (i.e., the curette (75)) which is necessary for this type of surgery. Ex. 1003 at 16:22-25 (emphasis added).

It would have been obvious to a POSA to use the curette in *Kogasaka* to contact and cut cancellous bone to form a cavity wholly within the vertebral body. Ex. 1005 at ¶ 114. For example, a POSA would know that tools, such as gauges, chisels, and punches are used in revision total hip surgery to cut into bone and bone cement. *Id*.

It also would have been obvious to a POSA to use the instrument in *Shapiro* or the curette in *Kogasaka* to form the cavity wholly within the vertebral body such that the cavity is within cancellous bone and does not extend to the cortical shell. *Id*. ¶ 115. Anatomically, a vertebral body is made up of cancellous bone surrounded by a cortex and vertebral end-plates. *Id*. The ends of the long bones near the joints are similarly made up of cancellous bone surrounded by a fairly thin cortical shell. *Id*. In these regions, a POSA would know that the cavity should not extend into the cortical bone for various reasons. *Id*. For example, the cortical bone is thin, and any cavity forming operation could break through it and damage adjacent tissues. *Id*. A POSA would know that the purpose of forming most cavities is to subsequently fill the cavity with material, and if a cavity forming

operation breaks through the cortical shell, the cavity filling material could not be confined to stay within the bone. *Id*. The cortical shell also provides structural stability for the bone under load and, therefore, a POSA would know that the cavity forming operation should not make the surrounding cortical bone thinner or cause a defect in the cortical shell. *Id*.

As each of the features of Claims 11, 15, 19, and 23 are disclosed in *Shapiro* and *Kogasaka* and was within the knowledge and skill of a POSA, Claims 11, 15, 19, and 23 are not patentable and should be canceled. *Id*. at ¶ 116.

2. None of the additional features of the dependent claims render them patentable over *Shapiro* or over *Kogasaka* in view of *Shapiro*

The dependent claims recite additional features of the method Claim 1 (dependent Claims 2-5), the method of Claim 6 (dependent Claims 7-10), the method of Claim 11 (dependent Claims 12-14), the method of Claim 15 (dependent Claims 16-18), the method of Claim 19 (dependent Claims 20-22), and the method of Claim 23 (dependent Claims 24-26). As discussed below, *Shapiro* in view of the knowledge of a POSA, or *Kogasaka* in view of *Shapiro* or the knowledge of a POSA renders obvious all of the additional features of dependent Claims 2-5, 7-10, 12-14, 16-18, 20-22, and 24-26.

a. Dependent Claims 2, 7, 12, 16, 20, and 24

Claims 2, 7, 12, 16, 20, and 24 respectively depend from independent claims 1, 6, 11, 15, 19, and 23, which are unpatentable over *Shapiro* or *Kogasaka,* as

discussed above. Claims 2, 7, 12, 16, 20, and 24 further recite that the method includes "the step of filling the cavity with a filling material."

Shapiro and *Kogasaka* both teach the step of filling a cavity with a filling material. For example, *Shapiro* states that once the area of the bone is exposed, bone particles and/or bone segments for a fusion may also be inserted through a cannula and properly positioned. Ex. 1002 at 6:36-39. It would have been obvious to a POSA to use *Shapiro's* device to create a cavity wholly within the vertebral body (as discussed with respect to the independent claims) and to fill the cavity as taught by *Shapiro*. Ex. 1005 at ¶ 119. *Shapiro's* device is known to create a cavity or defect in the bone of the posterior spine, and to augment that defect or cavity with bone grafting or similar material. *Id*. The procedure of Lumbar Percutaneous Interbody fusion was and continues to be commonly known. *Id*. A POSA would understand that in this procedure, a defect is made in the posterior elements of two spinal levels, such as wholly within the vertebral body. *Id*. Bone grafting or augmentation material is then applied, and the bones are stabilized until a bony bridge is formed between the two spinal levels. *Id*. As such, it would have been obvious to a POSA to understand that following cavity formation, appropriate materials, such as bone particles or segments, can be inserted until the cavity is filled with filling material. *Id*. *Shapiro* expressly describes forming and filling a cavity during a laminectomy or fusion. A POSA would also have recognized the

desirability of creating a cavity wholly within bone, and filling the cavity in a similar manner to that described by *Shapiro*, to treat an individual vertebral body in the case where fusion of two vertebrae is not required. *Id*.

Kogasaka describes implants (213) which are inserted in the space between vertebral bodies to be fused. The internal cavity of the implant (213) is filled with a bone graft sampled from the patient himself, or a bone prosthesis made of .beta.-TCP (calcium phosphate). It would have been obvious to a POSA to fill a cavity within the bone to backfill the surgically created cavity and strengthen the bone, as both bone derived materials and synthetic materials were commonly used. *Id*. ¶ 120.

It would have been obvious to a POSA to modify *Kogasaka* to form the cavity wholly in the vertebral body (as discussed with respect to the independent claims), and to fill the cavity as taught by *Kogasaka,* to backfill the surgically created defect. *Id*. ¶ 122. For example, *Kogasaka* explains that "this invention can be applied for every possible operation requiring an approach towards a vertebral body, not to mention of the fixation of the vertebral body." Ex. 1003 16:38-40. *Kogasaka* also suggests a cavity within a vertebral body. *Id*. at 4:17-19 . ("FIG. 6D gives a view after a bone graft has been implanted into the cavity prepared in the vertebral body…"). A POSA would have understood this to mean that the device in *Kogasaka* is capable of forming a cavity inside the vertebral body. Ex.

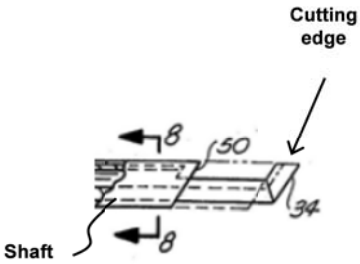
1005 at ¶ 121. After the cavity is formed, bone grafting or augmentation material would then need to be applied such that the bones can be stabilized until a bony bridge is formed between the two spinal levels. *Id*.

Therefore, Claims 2, 7, 12, 16, 20, and 24 are unpatentable over *Shapiro* in view of a POSA or *Kogasaka* taken alone or in view of a POSA . *Id*. at ¶ 123.

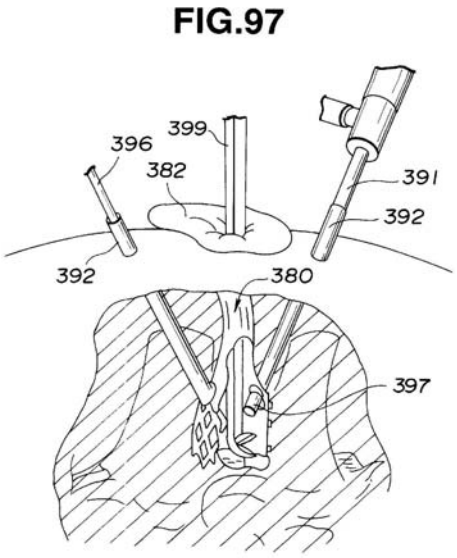
b. <u>Dependent Claims 3, 8, 13, 17, 21, and 25</u>

Claims 3, 8, 13, 17, 21, and 25 respectively depend from independent claims 1, 6, 11, 15, 19, and 23, which, as discussed above, are unpatentable over *Shapiro* or *Kogasaka*. Claims 3, 8, 13, 17, 21, and 25 further recite that the cavity forming structure is adapted to be "deployed at an axis that transverses the axis of the shaft."

Shapiro teaches a cavity forming structure that is adapted to be "deployed at an axis that transverses the axis of the shaft". For example, as demonstrated above with respect to Claims 11 and 15, *Shapiro*, in FIG. 5 (a portion of which is shown here for clarity and annotated by Petitioner for clarity), illustrates a cutting edge (34) that is substantially L-shaped and extends beyond the distal end of the cannula during use. Since the cutting



edge (34) is substantially L-shaped when it is deployed, as shown in FIG. 5, a portion of the cutting edge (34) will transverse the axis of the shaft at an angle. Ex. 1005 at ¶ 124.



Kogasaka illustrates a different embodiment in which a cavity forming structure in. FIG. 97 (right) shows a scope (391) or a treatment tool (396) that is introduced through the port (392), and a specially formed tool (399) which cannot pass through the port (392) is introduced into the sheath (380) for surgery because the sheath forms a soft port. Ex. 1003 at 53:17-24. In FIG. 97, the tool (399) appears to have a shaft and a cavity forming structure that extends from an end portion of the shaft. The cavity forming structure appears to be substantially v-shaped such that when the tool (399) is deployed and is being used, as shown in FIG. 97, a portion of the cavity forming structure would likely cross the axis of the shaft at an angle. Ex. 1005 at ¶ 126.

Even if the tool (399) is not transverse to the axis of the shaft, it would have been obvious to a POSA to modify the tool (399) in *Kogasaka* with the cutting edge (34) of *Shapiro*. *Id*. at ¶127. A POSA would recognize that the tool (399) in *Kogasaka* is a side-oriented rongeurs. *Id*. Having an L-shaped structure to the

side-oriented rongeurs would enable more efficient material removal for the cavity formation. *Id*. Also, having an L-shaped structure, as opposed to the opposing jaw structure in the tool (399), would enable the tool to undercut a cavity more effectively. *Id*. at ¶128.

Therefore, Claims 3, 8, 13, 17, 21, and 25 are unpatentable over *Shapiro* and *Kogasaka* in view of *Shapiro*.

c. Dependent Claims 4 and 9

Claims 4 and 9 respectively depend from Claims 1 and 6, which are unpatentable over *Shapiro* or *Kogasaka,* discussed above. Claims 4 and 9 further specify "extending the cavity forming structure, in situ radially from the shaft."

In *Shapiro*, with reference to FIG. 5, the cutting edge (34) extends beyond the distal end of the cannula and also extends radially outwardly from the shaft. Also, with reference to FIG. 5 in *Kogasaka*, the cavity forming blade on the curette (75) extends radially outwardly from the distal end of the shaft of the curette.

It also would have been obvious to a POSA to have a cavity forming structure that is adapted to be extended and/or extends in situ radially from the shaft, as many surgical tools provide this geometry. Ex. 1005 at ¶ 131. Such a geometry can be beneficial. *Id*. For example, such a geometry can faciliate a removal of tissue from a space that has a larger diameter than the insertion site for

the tool. *Id*. As demonstrated above, *Kogasaka* teaches other embodiments having such a geometry for the cavity forming structure.

Therefore, Claims 4 and 9 are unpatentable over *Shapiro* and *Kogasaka*. *Id*. at ¶ 133.

d. Dependent Claims 5, 10, 14, 18, 22, and 26

Claims 5, 10, 14, 18, 22, and 26 respectively depend from independent Claims 1, 6, 11, 15, 19, and 23, which are unpatentable over *Shapiro* or *Kogasaka* in view of the knowledge of a POSA. Claims 5, 10, 14, 18, 22, and 26 further specify that the surface of the cavity forming structure carries "at least one marker to aid in visualizing the cavity forming structure inside bone, further including observing the marker to visualize the cavity forming structure inside bone."

Shapiro teaches the use of a viewing scope to enable a surgeon to view the procedure. For example, *Shapiro* explains that a viewing scope can be passed through the cannula such that the surgeon may utilize a viewing screen (86) to have a full picture of the area in which the interior end of the cannula is working. Ex. 1002 at 5: 9-12.

Kogasaka teaches the use of a laparoscope (15) for viewing. For example, *Kogasaka* explains that treatment of the vertebral body (70) can be directly performed by way of the sheath (1) while the visual images supplied by the

laparoscope (15) inserted through the sheath 1 are being monitored." Ex. 1003 at 15:66-67 and 16:1-2.

Thus, *Shapiro* and *Kogasaka* both teach monitoring the cavity forming procedure, but do not expressly discuss using a radiopaque marker for visualizing the cavity forming structure inside bone.

A POSA would have been familiar with the use of radiopaque markers for monitoring surgical procedures. Ex. 1005 at ¶ 138. It would have been obvious to a POSA to include a marker, such as radiopaque markers or inserts, with the tool shown in *Shapiro* or *Kogasaka* to permit the surgeon to conveniently monitor the location of the tool by fluoroscopy during a surgical procedure. By having such a marker on the tool itself, an additional device, such as the viewing scope or the laparoscope, does not need to be inserted within the cannula. *Id*. There are various other benefits to using the marker, which would have been known by a POSA. *Id*.

Therefore, Claims 5, 10, 14, 18, 22, and 26 are unpatentable over *Shapiro* and *Kogasaka*, and further in view of the knowledge of a POSA. *Id*. at ¶ 140.

VII. CONCLUSION

Based on the foregoing, Wright Medical submits that Claims 1-26 of the '672 patent are unpatentable as being obvious over the prior art. Wright Medical therefore requests that the Board institute an *inter partes* review to cancel these claims.

Please charge any fees or credit overpayment to Deposit Account No. 08933.

Respectfully submitted,

DUANE MORRIS, LLP

Dated: June 6, 2014 By: */Samuel W. Apicelli/*
Samuel W. Apicelli
Registration No. 36,427
Customer No. 08933
Attorney for Petitioner
Wright Medical Technology, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,440,672, WITH EXHIBITS 1001 TO 1028, PURSUANT TO 35 U.S.C. § 312 AND 37 C.F.R. § 42.108** was served on June 6, 2014, via **Express Mail** service to the correspondence address of record for the subject patent pursuant to 37 C.F.R. § 42.105:

Ascenda Law Group, PC
84 W. Santa Clara St.
Suite 550
San Jose, CA 95113

DUANE MORRIS, LLP

Dated: June 6, 2014 By: /Samuel W. Apicelli/
Samuel W. Apicelli
Registration No. 36,427
Customer No. 08933
Attorney for Petitioner
Wright Medical Technology, Inc.

DM2\4959453.1