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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. 6,440,138 to Reiley et al.
Appl. No. 09/055,805 filed April 6, 1998
Issued August 27, 2002

IPR Trial No. *TBD*

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,440,138 PURSUANT TO 35 U.S.C. § 312 AND 37 C.F.R. § 42.108

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EXHIBIT LIST

Exhibit No.	Description	Short Reference
1001	U.S. Patent No. 6,440,138	the '138 Patent
1002	U.S. Patent No. 5,015,255	*Kuslich*
1003	U.S. Patent No. 4,467,800	*Zytkovicz*
1004	U.S. Patent No. 5,669,926	*Aust*
1005	U.S. Patent No. 6,371,968	*Kogasaka*
1006	U.S. Patent No. 6,001,116	*Heisler*
1007	Declaration of Dr. Timothy Harrigan ("Dr. Harrigan")	Harrigan Declaration
1008	Curriculum Vitae of Dr. Harrigan	
1009	List of documents reviewed by Dr. Harrigan	
1010	U.S. Patent No. 4,751,922	*DiPietropolo*
1011	Amendment A filed April 13, 2001	Amendment A
1012	Amendment B filed October 29, 2001	Amendment B
1013	Evarts, McCollister C. (Ed.) *Surgery of the Musculoskeletal System*, 2nd Ed. Churchill Livingstone, 1990, ISBN 0-443-08516-1	*Evarts*
1014	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*
1015	Soni, Ram K "An Anterolateral Approach to the Hip Joint," *Acta Orthopedica Scandinavica* 68 (5), 1997	*Soni*
1016	Pai, V.S. "A Comparison Of Three Lateral Approaches In Primary Total Hip Replacement," *International Orthopaedics (SICOT)*, 1997	*Pai*
1017	Hulka, Jaroslav F. and Harry Reich, *Textbook of Laparoscopy*, (2nd ed) W. B. Saunders, 1994, ISBN 0-7216-3643-8	*Hulka*
1018	Johnson, Lanny L., *Arthroscopic Surgery, Principles & Practice*, C. V. Mosby, 1986, ISBN 0-8016-2591-2	*Johnson*
1019	Tilkian, Ara G. and Elaine Keiss Daly, *Cardiovascular Procedures,* C. V. Mosby,	*Tilkian*

	1986, ISBN 0-8016-4965-X	
1020	MacIsaac, Andrew I. et al., **"**High Speed Rotational Atherectomy: Outcome in Calcified and Noncalcified Coronary Artery Lesions", JACC 26(3), 1995	*MacIsaac*
1021	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*
1022	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*
1023	Norton, R.L.*, Machine Design, an Integrated Approach,* Chapter 2: Materials and Processes, Prentice-Hall (1996)	*Norton*
1024	Duerig,T.W., *Engineering Aspects of Shape Memory Alloys'*, Butterworth-Heineman, 1990	*Duerig*

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. 6,863,672, which is related to U.S. Patent No. 6,440,138 ("the '138 patent").

C. Counsel And Service Information

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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. 6,440,138 ("the '138 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 1-12 of the '138 patent (Ex. 1001) and requests that each challenged claim be canceled. The earliest priority date of the '138 patent is April 6, 1998.

A. Prior Art

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

U.S. Patent No. 5,015,255 to Kuslich ("*Kuslich*"; Ex. 1002), which was filed on May 10, 1989 and issued on May 14, 1991 and is prior art under 35 §§ 102(b) /103(a).

This reference was not before the Examiner during the prosecution of the '138 patent.

B. Grounds for Challenge

Wright Medical requests cancellation of Claims 1-12 ("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. 1007), accompanied by his Curriculum Vitae (Ex. 1008), and a list of documents he

considered (Ex. 1009). 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 '138 PATENT

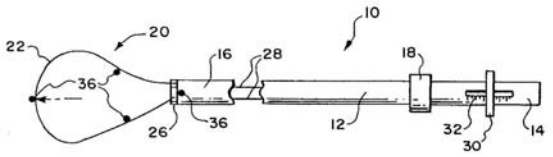
A. The '138 Patent Specification

The '138 patent is directed to systems and methods for treating bone, such as cancellous bone, wherein the systems and methods enable the formation of a cavity in a targeted treatment area. Ex. 1001 at Co1. 3:35-55. As admitted in the Background of the Invention section, various known systems existed in which 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 such that the cavity receives filling material therein. *Id*. at 1:18-21. The specification of the '138 patent acknowledges that there was a demand for alternative systems or methods that are capable of forming cavities in bone and other interior body regions in "safe and efficacious ways". *Id*. at 1:29-32.

The '138 patent describes a rotatable tool (10) for forming a cavity in a targeted treatment area. *Id*. at 3:49-50. FIG. 1 (shown here), shows the tool (10)

including a catheter tube (12) having a proximal and a distal end, (respectively 14 and 16). *Id*. at 3:50-52. The catheter tube (12) includes a handle (18) to aid in gripping and/or maneuvering the tube (12). *Id*. at 3:52-53. A cavity forming structure (20) is carried by the tube (12) at its distal end (16). *Id*. at 3:56-57.

FIG. 1

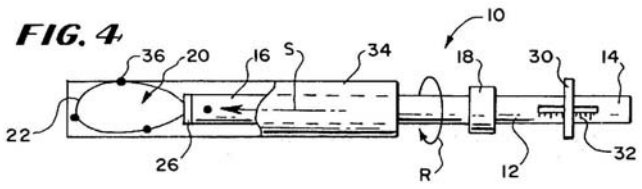


As shown in FIG 1, the structure (20) includes a filament (22) of resilient memory material, which is bent back upon itself and preformed to form a loop. *Id*. at 3:56-60. The materials for the catheter tube (12) are selected to facilitate advancement and rotation of the loop structure (20). *Id*. at 4:37-43.

The filament (22) can carry radiological markers (36). *Id*. at 4:48-51. A marker (36) can be placed at or near the distal extremity of the loop structure (20). Other markers can be spaced apart at 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.

As illustrated in FIG. 4 (shown here), the catheter tube (12) is carried for "axial" and "rotational" movement within a guide sheath or cannula (34). *Id*. at 4:20-22. A

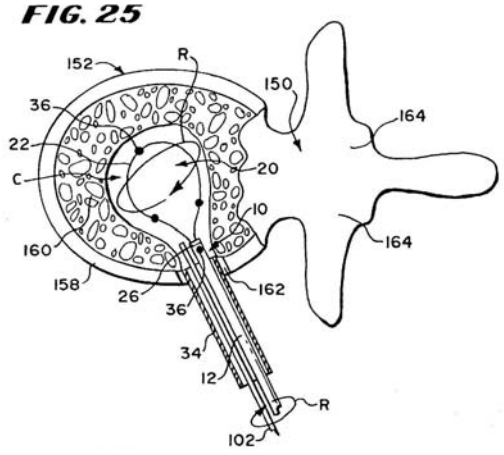
FIG. 4



user, such as a physician, can slide the catheter tube (12) "axially" within the guide sheath (34) (arrow S in FIG. 4). *Id*. at 4:22-24. When fully confined by the guide sheath (34), the loop structure (20) is collapsed by the surrounding sheath (34). *Id*. at 4:23-27. When free of the guide sheath (34), the loop structure (20) springs open to assume its normal dimension. *Id*. at 4:27-28. The physician can operate the controller (30) to alter the dimension of the loop structure (20). *Id*. at 4:29-30. When free of the guide sheath (34), the physician can rotate the deployed loop structure (20) by rotating the catheter tube (12) within the guide sheath (34) (arrow R in FIG. 4). *Id*. at 4:31-34. The rotation of the loop structure (20) slices or cuts through surrounding tissue mass. *Id*. at 4:34-36.

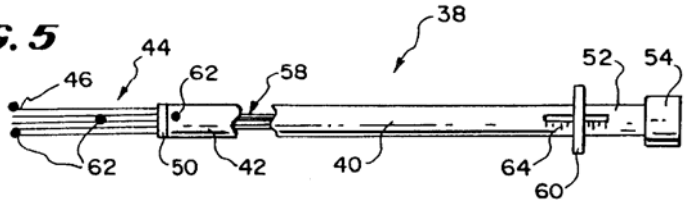
FIG. 25 (right) shows rotation and operation of the controller (30) to enlarge the dimensions of the loop structure (20), enabling the physician to create a cavity of the desired dimension. *Id*. at 9:44-47. The dimension of the loop structure (20) can be gauged by radiologic monitoring using the markers (36). *Id*. at 9:30-34. The physician manually rotates the loop structure (20) through surrounding cancellous bone (160) (as indicated by arrows R in FIG. 25). *Id*. at 9:34-37. The rotating loop structure (20) cuts bone (160) to form the cavity (C). *Id*. at 9:37-38.

FIG. 25



The '138 patent also describes alternative embodiments of rotatable tools that have similar functions, and can be used in place of the rotatable tool (10). For example, as illustrated in FIG. 5 (below), a rotatable tool (38) can form a cavity in a targeted treatment area. *Id*. at 4:62-64. The tool (38) includes a drive shaft (40).

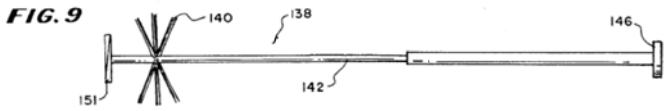
FIG. 5



Id. at 4:64-67. The distal end (42) of the drive shaft carries a cavity forming structure (44), which includes an array of filaments forming bristles (46). *Id*. at 5:1-3. The drive shaft (40) is carried for "axial" and "rotational" movement within the guide sheath or cannula (34), in the same manner shown for the tool (10) in FIG., 4. *Id*. at 5:35-40.

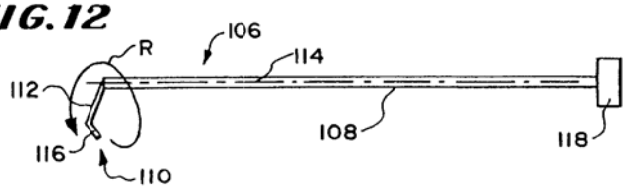
The '138 patent also describes an embodiment in FIG. 9 (at right) of a rotatable tool (138) having an array of filament forming bristles (140), which is capable of forming a cavity in a targeted treatment area. *Id*. at 5:6-9.

FIG. 9



The '138 patent, in FIG. 12 (right), illustrates a rotatable tool (106), for forming a cavity. *Id*. at

FIG. 12



6:19-21. The tool (106) includes a stiff drive shaft (108) . *Id*. at 6:21-24. The distal end of the drive shaft (108) carries a cavity forming structure (110), which includes a cutting blade (110) that can take various shapes. *Id*. at 6:25-27.

B. Prosecution History

During prosecution, the Applicant attempted to distinguish the claims based on the recitation that the cavity forming structure directly "contacts and shears" cancellous bone from several references describing electrical and ablation tools. *See* Amendment A filed April 13, 2001, paragraph bridging pp. 8-9 ("Amendment A"; Ex. 1011):

> Kordis is a basket structure carrying sensing electrodes for mappinq electrical activity in the heart. Fearnot, Chia, and Monroe are tissue ablation tools. None teaches or suggests a structure deployed in bone having a surface that directly contacts and shears cancellous bone to form a cavity, as defined in the amended apparatus and method claims. Furthermore, none teaches or suggests a structure deployed in bone having a surface that directly contacts and shears cancellous bone to form a cavity without coupling to a source of electrical energy, as defined in new apparatus claims 41 to 44.

The Applicant also attempted to distinguish the claims based on the recitation that the shaft is adapted to be deployed or is introduced by "movement within and along the axis" of the cannula. For example, in Amendment B filed October 29, 2001 ("Amendment B"; Ex. 1012), the Applicant argued that the references U.S. Patent No. 5,957,884 ("Hooven '884") and U.S. Patent No. 5,814,044 ("Hooven '044") that had been cited against the application disclose tissue morselating devices having a stationary outer tube (22) and an inner tube (24) rotatably received within the outer tube, wherein the inner tube (24) is either permanently attached or attached in a rotationally locked engagement with an inner body sleeve (34). Ex. 1012 at p. 6. The Applicant argued that:

> Neither Hooven '844 nor Hooven '044 teach or disclose a system for treating bone that comprises a cannula and a shaft adapted to be deployed inside bone by movement within and along the axis of the cannula….

Id.

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 '138 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. 1007 at ¶ 47. 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 '138 patent was such that use of surgical tools for bone treatment was known. 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*. at ¶¶ 21-39. As the '138 patent acknowledges, various known systems existed in which an expandable body can be deployed to form a cavity in cancellous bone tissue, as part of a therapeutic procedure for fixing, for example, fractures or other abnormal bone conditions. Ex. 1001 at 1:11-21.

D. The '138 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 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). Any such amendment would only be permissible if the proposed amended claims comply with 35 U.S.C. § 112.

[1] It is noted that this interpretation is only applicable 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.

1. "Movement within and along the axis"

Each of the claims require a shaft that is adapted to be deployed and/or introduced inside bone by "movement within and along the axis" of the cannula. Based on the description provided in the '138 patent specification, this term means that the shaft is configured to be deployed (claims 1-10), and/or is deployed (claims 11-12), inside bone by being moved in the cannula (i.e., within the cannula) on, or in the direction of, the axis that is defined within 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). When the catheter tube (12) is in the cannula (34), the catheter tube (12) is not permanently locked to the cannula (34) nor is the catheter tube (12) attached in a rotationally locked engagement, as such mechanical couplings identified in the prior art were distinguished by the Applicant during prosecution with the recitation to the claims of "movement within and along the axis". Ex. 1012 at p. 6.

Thus, under the broadest reasonable construction, this term means that the shaft is configured to be deployed (claims 1-10), and/or is deployed (claims 11-

12), inside bone by being moved in the cannula (i.e., within the cannula) on, or in the direction of, the axis that is defined within the cannula.

2. "Within and About the Axis of the Cannula"

Each of the claims require that the shaft is rotated "within and about the axis of the cannula." Based on the description provided in the '138 patent specification, this term means that the shaft is rotated while the shaft is inside (i.e., within) the cannula, and the rotation is about the axis that is defined within the cannula. The catheter tube (12) (i.e., the shaft) is carried within the cannula for axial and rotational movement (34). *Id*. at 4:20-22. As illustrated in FIG. 4 above, at least a portion of the catheter tube (12) is positioned within the cannula (34) as the physician is able to slide the catheter tube 12 axially within the guide sheath 34 (arrow S in FIG. 4). *Id*. at 4:22-24. The catheter tube (12) is rotated within the guide sheath (34) (arrow R in FIG. 4) about the axis defined therein, which enables the rotation of the loop structure (20). *Id*. at 4:31-34.

Thus, under the broadest reasonable construction, this term means the shaft is rotated while the shaft is inside (i.e., within) the cannula, and the rotation is about the axis that is defined within the cannula.

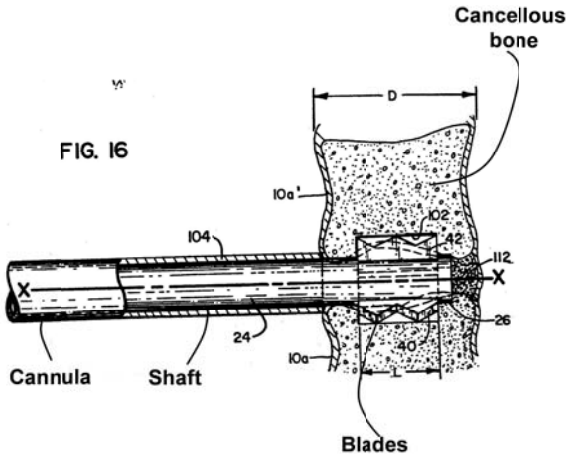
V. OVERVIEW OF THE PRIMARY PRIOR ART REFERENCE

As explained in detail below, limitation by limitation, there is nothing new or non-obvious in the challenged claims of the '138 patent. Ex. 1007 at ¶¶ 21-39 and 54-140. In 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*, Ex. 1013 at p. 1846, 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. Ex. 1007 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. The technology that existed in 1998 for spinal fusion or treatment of spine pain is directly analogous to the technology described in the patent at issue. *Id*. at ¶ 28. For example, the primary reference cited herein, *Kuslich*, is directly applicable to the technology of the '138 patent.

FIG. 16 of *Kuslich* (copied below and annotated by Petitioner for clarity) shows a tool (22) for forming a bore extending into adjacent vertebra for a spinal fusion treatment. The tool (22) has a cannula (locating cylinder (104)) that has an axis X-X establishing a percutaneous path leading to inside a bone (10a, 10a'). Ex 1002 at 5:18-35. A shaft (24) is adapted to be deployed inside the bone (10, 10a') through the cannula (104). *Id*. at 8:28-47. The shaft (24) is deployed at the area to be treated by moving the shaft (24) within the cannula (104). The



movement is along the axis of the cannula (104). *Id*. at 8:28-42. The shaft (24) carries a cavity forming structure including metal blades (40, 42). When the distal end (26) of the shaft (24) is inside the bore (100), the blades (40, 42) extend radially from within the shaft. *Id*. at 7:51-60; *see also* FIGS. 11 and 12. The cavity forming structure (40, 42) directly contacts and shears cancellous bone in response to rotating the shaft (24) in the cannula (104). The rotation is about the axis X-X of the cannula (104). *Id*. The surgeon incrementally rotates a handle (60) to progressively increase the amount of extension of the blades (40, 42). At each incremental extension, the surgeon rotates the handle (30) completely about axis X-X. *Id*.

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. 1007), show in detail the prior art disclosures that render the challenged claims unpatentable.

A. The Challenged Claims are Unpatentable Over *Kuslich* in view of the Knowledge of a POSA

Pursuant to Rule 42.104(b)(4)-(5), the section below, as well as the accompanying Harrigan Declaration (Ex. 1007), demonstrate in detail where each of the claimed features is disclosed by the cited prior art, and how each claim would have been unpatentable over *Kuslich* taken alone or in view of the knowledge of a POSA.

1. Independent Claims 1 and 11 would have been obvious in view of *Kuslich*

Kuslich expressly discloses or suggests all of the claimed features of Claims 1 and 11. Ex. 1007 at ¶¶ 56-95. To whatever extent that *Kuslich* does not expressly disclose each feature of any of the challenged claims, then *Kuslich* in combination with the knowledge of one of ordinary skill in the art would have rendered obvious each of such features. *Id*. As set forth in the Harrigan Declaration, all of the features of the Claims 1 and 11 were within the knowledge of one of ordinary skill in the art prior to the priority date of the '138 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 Claim 1

Claim 1 is rendered obvious by *Kuslich*. Ex. 1007 at ¶ 56. For example, Claim 1 recites:

> Claim 1
>
> A system for treating bone comprising

Kuslich discloses a system and method for fusing contiguous vertebra. For example, *Kuslich* teaches a system that uses a surgical tool that is inserted "into the bore . . . [and] operation of the tool reams an enlarged cavity on the interior of the opposing vertebra bodies and removes the degenerative disc material…." Ex. 1002 at 2:68 and 3:1-8; *see e.g.*, FIGs. 5-15. *Kuslich* further describes the cavity as being "filled with a graft medium which grafts with the opposing vertebra to form a suitable fusion." *Id*. A POSA would have understood that a system for treating bone includes systems that are used for fusing bone, such as the fusing of vertebra disclosed in *Kuslich*. Ex. 1007 at ¶ 57.

Claim 1 further recites:

> Claim 1
>
> a cannula having an axis establishing a percutaneous path leading to inside a bone,

Kuslich, in FIG. 16 (shown above in Section V), teaches the use of a cannula that has an axis establishing a percutaneous path leading to inside a bone. *Kuslich* explains that in "a percutaneous method", "a small incision is formed" and "a guide tube is placed against the desired location of tissue 12." Ex. 1002 at 4:40-44. *Kuslich* describes the cannula as "a locating cylinder 104" that "is placed over the sheath." *Id*. at 8:31-37. An axis X-X of the shaft 24 is shown in FIG. 16, above.

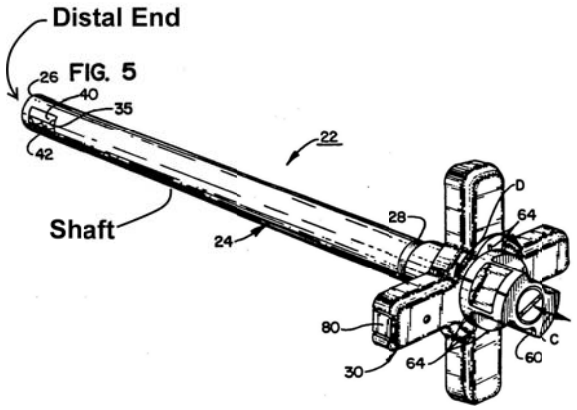
FIG. 16 also shows the cannula 104 arranged symmetrically about the axis X-X, and the end view of FIG. 22 shows the distal end 26 of the shaft 24 arranged concentric with the cannula 104. It would have been obvious to one of ordinary skill that the axis of the cannula 104 coincides with the axis X-X of the shaft 24. Ex. 1007 at ¶61. Thus, when the shaft 24 rotates about its own axis X-X, it also rotates about the axis of the cannula. *Id*. "[A] drill bit (not shown) is passed through cylinder 104 and a hole sized to receive the distal end 26 is drilled into the intervertebral space." Ex. 1002 at 8:31-37. *Kuslich* further explains that forming a bore by drilling through a locating cylinder is known in the art. *Id*.; *see also* Ex. 1007 at ¶62.

Claim 1 further recites:

> Claim 1
> a shaft adapted to be deployed inside
> bone by movement within and along the
> axis of the cannula,

As illustrated in, for example, FIG. 5 (shown below and annotated by Petitioner for clarity), *Kuslich* teaches a "tool 22" that "includes an elongate cylindrical shaft 24 having a distal end 26 and an operator engaging end 28", wherein the diameter of the shaft (24) at the distal end (26) is configured and sized such that the shaft (24) can be inserted into a patient's body with the distal end (26)

placed against a diseased disc without shaft (24) having undue interference with "other anatomical organs." Ex. 1002 at 5:20-27.



With referecnce to FIG. 10A (shown at right and annotated by Petitioner for clarity), *Kuslich* further teaches an "interior rod 32" that is "coaxially disposed within shaft 24 and mounted therein" to enable "rotational movement about axis X-X." *Id*. at 5:29-32; *see also* FIG. 7-10.

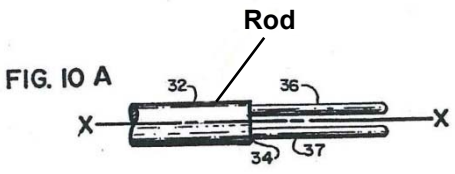


FIG. 16 illustrates the shaft (24) as being deployed inside the locating cylinder (104) by movment within and along the axis of the cannula. For example, *Kuslich* teaches that the shaft (22) is "being guided by a locating cylinder 104", wherein the tool 22 is used to produce an enlarged chamber (102) within the disc (12) and surrounding bone (10a, 10a'). *Id*. at 8:39-44.

One of ordinary skill in the art would also have understood that the shaft (24) is being deployed inside the cylinder (104) by movement within and along the axis of the cannula. For example, a POSA would have understood that for the

shaft (24) to be deployed inside the bone, the shaft (24) would need to be inserted within the cannula (104) and the shaft (24) would need to move along the axis of the cannula (104) to reach the position in the bone where the tool will be used. Ex. 1007 at ¶ 66. For example, a POSA would have understood that the cannula provides a safe path for insertion of a sharp cutting tool to travel past the organs in the intervening space, and it steers the cutting tool to the area where the cavity can be formed in the proper orientation. *Id*. Axis X-X is the only axis identified by *Kuslich*, and it would have been obvious to move the shaft (22) along the longitudinal axis of the cannula, since that is the only axis identified by *Kuslich*. *Id*.

Claim 1 further recites:

> Claim 1
> a cavity forming structure carried by the shaft comprising a surface which directly contacts and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula.

Kuslich teaches a cavity forming structure having a surface that is carried by the shaft. For example, *Kuslich* describes the "distal end 26" of the shaft (24) as having "a slot 35 extending therethrough" and received within the slot (35) are

cutting blades (40 and 42), wherein each of the blades "is provided with a blade body 41,43." Ex. 1002 at 5:43-46. Blades (40,42) are sized and configured such that, when received in slot (35), blades (40, 42) are "slidable relative to one another with surface 51 engaging surface 52 in sliding engagement." *Id*. at 5:60-63. The blades (40, 42) are the cavity forming structure. *Kuslich* explains how the blades form a chamber (cavity). Ex. 1002 at 7:51-64. A POSA knew that such blades or analgous structures were used frequently to form a cavity in bone. Ex. 1007 at ¶ 69. *Kuslich* also shows the chamber 102 extending into cancellous bone in FIG. 16. *Id*.

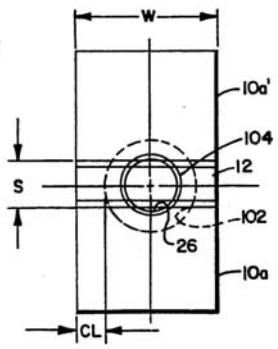
In the prosecution history, as described above in Section IV (B), the Patentee distinguished the term "directly contacts and shears" from non-contact methods (e.g., ablating). Ex. 1011 at ¶ bridging pp. 8-9. A POSA would have understood that the surface of *Kuslich's* cavity forming structure directly contacts and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula, and teaches the alleged distinguishing features. Ex. 1007 at ¶ 70.

Kuslich teaches that the surface of the blades directly contacts and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula. For example, *Kuslich* explains that with "the bore formed, the distal end is inserted within the bore " and "with distal end 26 completely received within bore, the surgeon incrementally rotates handle 60 to progressively increase the

amount of extension of blades 40, 42." Ex. 1002. at 7:52-60. "At each incremental extension, the surgeon rotates the handle 30 completely about axis X-X so that the blades cut out a large chamber 102." *Id*. When "shaft 34 is rotated counterclockwise (when viewed in FIG. 11), pins 36, 37 rotate within bores 49 and 50" and the cooperation of the eccentric pins and the bores "translates rotational movement of shaft 32 into lateral movement of blade 40, 42 in the direction of the arrows A and B" such that a "45° rotation of the shaft fully extends the blades to the position shown in FIG. 12." *Id*. at 6:7-15. "To retract the extended blades, shaft 32 is rotated clockwise (when viewed in FIG. 12)." *Id*.

Kuslich's drawings show that the the end (26) of th eshaft (24) is within the cannula (104), and the axis X-X of the shaft (24) coincides with the axis of the cannula (104). Ex. 1002 at FIG. 16. FIG. 16 (shown above in Section V) illustrates that the shaft (24) and the cannula (104) are both aligned parallel to, and symetrically about, the axis X-X. FIG. 22 (right) illustrates the distal end 26 of shaft 24 as being arranged concentrically with the cannula 104.

FIG. 22



Although not expressly recited in the specification, it would have been obvious to a POSA that rotation of the shaft 24 in *Kuslich* should be within and about the axis X-X of the cannula 104. Ex. 1007 at ¶72. The axis X-X is the only

axis identified by Kuslich, and it would have been obvious to rotate the shaft about the axis of rotational symmetry of the shaft, which is also the only axis identified by Kuslich. *Id*.

As each of the features of Claim 1 are disclosed in *Kuslich* and was within the knowledge and skill of a POSA, Claim 1 is not patentable and should be canceled. *Id*. ¶ 77.

b. Independent Claim 11

Claim 11 is rendered obvious by *Kuslich*. *Id*. ¶75. For example, Claim 11 recites:

> Claim 11
>
> A method for treating bone comprising
>
> the steps of

Kuslich teaches a method for treating bone, as *Kuslich* discloses a "method of the present invention" as involving "the use of the novel apparatus 22 to form a chamber in a spine for receiving a graft medium" and "[t]he present invention can be used in both open and percutaneous surgical methods." *See, e.g.,* Ex. 1002 at 7: 28-32.

Claim 11 further requires:

> Claim 11
>
> providing a cannula having an axis that establishes a percutaneous path leading to inside bone,

Kuslich discloses a cannula as recited in Claim 11. As demonstrated above with respect to Claim 1, *Kuslich*, in FIG. 16, teaches the use of a cannula that has an axis establishing a percutaneous path leading to inside a bone. *Kuslich* explains that in a percutaneous method, "a small incision is formed and a guide tube is placed against the desired location of tissue 12." *Id*. at 4:40-44. *Kuslich* describes the cannula as "a locating cylinder 104" that "is placed over the sheath." *Id*. at 8:31-37. In addition, "a drill bit (not shown) is passed through cylinder 104 and a hole sized to receive the distal end 26 is drilled into the intervertebral space." *Id*. *Kuslich* further explains that forming a bore by drilling through a locating cylinder is known in the art. *Id*.; *see also* Ex. 1007 at ¶¶ 77-79.

Claim 11 also recites:

> Claim 11
>
> providing a shaft adapted to be deployed inside bone through the cannula including a cavity forming structure carried by the shaft comprising a surface which directly contacts and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula.

As demonstrated above, with respect to Claim 1, *Kuslich*, as shown in FIG. 5, teaches a "tool 22" that "includes an elongate cylindrical shaft 24 having a distal end 26 and an operator engaging end 28" and the diameter of the shaft (24) at the distal end (26) is configured and sized such that the shaft (24) can be inserted into a patient's body with the distal end (26) placed against a diseased disc without the shaft (24) having undue interference with other "anatomical organs." Ex. 1002 at 5:20-27. With referecnce to FIG. 10A, *Kuslich* teaches an "interior rod 32" that is "coaxially disposed within shaft 24 and mounted therein" to enable "rotational movement about axis X-X." *Id*. at 5:29-32; *see also* FIG. 7-10a. *Kuslich* teaches that the shaft (22) is "being guided by a locating cylinder 104 . . . [and] [t]he tool

22 is used . . . to produce an enlarged chamber 102 within disc 12 and surrounding bone 10a, 10a'." *Id*. at 8:39-44. *Kuslich* also teaches a cavity forming structure having a surface that is carried by the shaft. As demonstrated above with respect to Claim 1, *Kuslich* describes the "distal end 26" of the shaft (24) as having "a slot 35 extending therethrough" and received within the slot (35) are cutting blades (40 and 42), wherein each of the blades "is provided with a blade body 41,43." Ex. 1002 at 5:43-46. Blades (40, 42) are sized such that when received in slot (35), blades (40, 42) are "slidable relative to one another with surface 51 engaging surface 52 in sliding engagement." *Id*. at 5:60-63.

As demonstrated above, with respect to Claim 1, a POSA would have understood that the surface of *Kuslich's* cavity forming structure directly contacts and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula. Ex. 1007 at ¶ 84. Kuslich teaches the feature by which the patentee attempted to distinguish his invention from prior art electrical and ablation tools. *Id*.

Here, *Kuslich* also teaches the surface of the blades directly contacts and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula. For example, *Kuslich* explains that with "the bore formed, the distal end is inserted within the bore" and "with distal end 26 completely received within bore", the surgeon incrementally rotates the handle (60) to progressively increase

the amount of the extension of the blades (40, 42). *Id*. at 7:52-60. "At each incremental extension, the surgeon rotates the handle 30 completely about axis X-X so that the blades cut out a large chamber 102." *Id*. When "shaft 34 is rotated counterclockwise (when viewed in FIG. 11)", the pins (36, 37) rotate within bores 49 and 50. *Id*. The cooperation of the eccentric pins and the bores translates rotational movement of the shaft (32) into lateral movement of the blades (40, 42) "in the direction of the arrows A and B" such that a "45° rotation of the shaft fully extends the blades to the position shown in FIG. 12." *Id*. at 6:7-15. "To retract the extended blades, shaft 32 is rotated clockwise (when viewed in FIG. 12)." *Id*.

Kuslich's drawings show that the shaft (24) is within the cannula (104), and the axis X-X of the shaft (24) coincides with the axis of the cannula 104. *See, e.g.*, Ex. 1002 at FIG. 16. As demonsrated above with respect to Claim 1, FIG. 16 shows that the shaft (24) and the cannula (104) are both aligned parallel to, and symetrically about, the axis X-X. FIG. 22 shows the distal end 26 of shaft 24 arranged concentrically with the cannula 104. Although not expressly recited in the specification, it would have been obvious to a POSA that the shaft (24) rotates within the cannula (104), and about the axis X-X of the cannula 104. Ex. 1007 ¶86. The axis X-X is the only axis identified by *Kuslich*, and it would have been obvious to rotate the shaft about the axis of rotational symmetry of the shaft, which

is the only axis identified by *Kuslich* and appears to also be the axis of the cannula. *Id*.

Claim 11 further recites:

> Claim 11
>
> deploying the cannula percutaneously to
>
> establish a path leading to inside bone,

Kuslich teaches the use of a percutaneous technique that describes this recitation of Claim 11. For example, *Kuslich* explains that

> the method of the present invention with use of the novel tool of the present invention may be used with a percutaneous surgical technique . . . [wherein] the patient is placed in a lateral position similar to that used during a chymopapain installation.

Ex. 1002 at 8:15-22.

As demonstrated above with respect to Claim 1, *Kuslich*, in FIG. 16, teaches the use of a cannula that has an axis establishing a percutaneous path leading to inside a bone. *Kuslich* explains that, in "a percutaneous method", "a small incision is formed" and "a guide tube is placed against the desired location of tissue 12." *Id*. at 4:40-44. *Kuslich* describes the cannula as "a locating cylinder 104" that "is placed over the sheath." *Id*. at 8:31-37. "[A] drill bit (not shown) is passed through cylinder 104 and a hole sized to receive the distal end 26 is drilled into the

intervertebral space." *Id*. *Kuslich* further explains that forming a bore by drilling through a locating cylinder is known in the art. *Id*.; *see also* Ex. 1007 at ¶ 89.

Claim 11 further requires:

> Claim 11
>
> introducing the shaft by movement
>
> within and along the axis of the cannula
>
> to deploy the cavity forming structure
>
> inside bone, and

As demonstrated above, with respect to Claim 1, *Kuslich*, in FIG. 16, teaches that in order to deploy the cavity forming structure inside bone, the shaft (24) is introduced by movement inside and along the axis of the locating cylinder (104). As explained above with respect to Claim 1, *Kuslich* teaches that the shaft (22) is "being guided by a locating cylinder 104", wherein the tool (22) is used to produce an enlarged chamber (102) within the disc (12) and surrounding bone (10a, 10a'). Ex. 1002 at 8:39-44. One of ordinary skill in the art would also have understood that for the shaft (24) to be introduced with respect to the cannula such that the cavity forming structure (i.e., blades (40,42)) is deployed inside the bone, the shaft (24) would need to be inserted within the cannula (104) and the shaft (24) would need to move along the axis of the cannula. Ex. 1007 at ¶ 91. As also explained above, axis X-X is the only axis identified by *Kuslich*, and it would have been

obvious to move the shaft along the longitudinal axis of the cannula, since that is the only axis identified by *Kuslich*. *Id*.

Claim 11 further requires:

Claim 11
rotating the shaft within and about the axis of the cannula to cause the surface to shear cancellous bone and form a cavity.

As demonstrated above with respect to Claim 1, *Kuslich* teaches that the surface of the blades directly contacts and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula to form a cavity (Ex. 1002 at chamber 102; *see also* FIGS. 16-18, 22). For example, *Kuslich* explains that with "the bore formed, the distal end is inserted within the bore" and "with distal end 26 completely received within bore, the surgeon incrementally rotates handle 60 to progressively increase the amount of extension of blades 40, 42." *Id*. at 7:52-60. "At each incremental extension, the surgeon rotates the handle 30 completely about axis X-X so that the blades cut out a large chamber 102." *Id*. When "shaft 34 is rotated counterclockwise (when viewed in FIG. 11), pins 36, 37 rotate within bores 49 and 50" and the cooperation of the eccentric pins and the bores "translates rotational movement of shaft 32 into lateral movement of blade

40, 42 in the direction of the arrows A and B" such that a "45° rotation of the shaft fully extends the blades to the position shown in FIG. 12." *Id*. at 6:7-15. "To retract the extended blades, shaft 32 is rotated clockwise (when viewed in FIG. 12)." *Id*.

For the same reason discussed above with respect to the step of "providing a shaft …" in Claim 1, it would have been obvious to one of ordinary skill in the art to rotate the shaft within and about the axis of the cannula in Kuslich. Ex. 1007 at ¶ 94.

As each of the features of Claim 11 are disclosed in *Kuslich* and was within the knowledge and skill of a POSA, Claim 11 is not patentable and should be cancelled. *Id*. at ¶ 96.

2. The Dependent Claims Recite Additional Features That are not Patentable Over *Kuslich* in view of the knowledge of a POSA

The dependent claims recite additional features of the system for treating bone (dependent Claims 2-10), and the method for treating bone of claim 11 (dependent claim 12). As discussed below, *Kuslich* in view of *the knowledge of a POSA* renders obvious all of the additional features of dependent claims 2-10 and 12. *See* Ex. 1007 at ¶¶ 96-140.

a. Dependent Claim 2

Claim 2 depends from independent Claim 1, which as discussed *above* is unpatentable over *Kuslich*. Claim 2 further limits Claim 1 by reciting:

Claim 2

wherein the shaft is flexible.

In *Kuslich*, the tool (33) has an "***elongate*** cylindrical shaft 24 having a distal end 26 and an operator engaging end 28" and "shaft is hollow". Ex. 1002 at 5:20-29 (emphasis added).

It would have been obvious to one of ordinary skill in the art to make the shaft (24) described in *Kuslich* flexible. Ex. 1007 at ¶ 99. One of ordinary skill in the art would understand that flexibility in a shaft would enable the cavity forming end of the shaft to take up different angular orientations, *Id*. at ¶ 100. Changes in such orientations can enable the cannula and the shaft from binding against the sides of the cavity while the shaft is being rotated to create the cavity. *Id*. Having a flexible shaft in *Kuslich*, for example, would enable the end of the shaft to be inserted between two vertebral bodies without requiring that the port on the skin (through which the cannula is inserted) be located in the plane of the intervertebral disk. *Id*. This could enable the cannula and the shaft to avoid certain organs more effectively than if both structures were rigid. *Id*. Therefore, Claim 2 is unpatentable over *Kuslich* in view of a POSA. *Id*. at ¶ 100.

b. Dependent Claim 3

Claim 3 depends from independent Claim 1, which as discussed *above* is unpatentable over *Kuslich*. Claim 3 further limits Claim 1 by reciting:

Claim 3

wherein the surface carries at least one marker to aid visualizing the cavity forming structure inside bone.

Kuslich explains that "under bi-plane fluoroscopic control, a smooth guide pin (not shown) (preferably 2.5 millimeters in diameter) is carefully positioned to line up with the diseased disc." Ex. 1002 at 8:26-29. By using a fluoroscopic control, the positioning can be monitored by an X-ray and, therefore, a POSA would have understood that either the guide pin or the instrument inserting the guide pin would need to have markers, such as radiopaque markers. Ex. 1007 at ¶ 103.

It would have been obvious to include a marker, such as a radiopaque insert or a radiopaque marker, with the tool shown in *Kuslich*. *Id*. at ¶104. It would be advantageous for the surgeon to monitor the location of a surgical tool by fluoroscopy during a procedure to improve the accuracy of material removal. *Id*. The use of a radiopaque marker was a known technique and still is a common technique to permit the monitoring of the location of the tool by fluoroscopy during surgery. *Id*. For example, if a multi-part apparatus for bone removal is used or contemplated, then a part, such as the cavity forming end piece of the

apparatus, may become loose and/or can get lost during the procedure . *Id*. A radiopaque marker on the part of the apparatus can aid in its retrieval. *Id*.

Therefore, Claim 3 is unpatentable over *Kuslich* in view ofof a POSA. *Id*. at ¶ 105.

c. Dependent Claim 4

Claim 4 depends from independent Claim 3, which as discussed *above* is unpatentable over *Kuslich*. Claim 4 further limits Claim 3 by reciting:

> Claim 4
>
> wherein the marker is made from a
>
> radiopaque material.

As demonstrated above with respect to Claim 3, it would have been obvious to apply a marker, such as one that is made from a radiopaque material, to the cavity forming structure of *Kuslich*. For example, it would have been obvious to a POSA to include a marker, such as a radiopaque insert or a radiopaque marker, with the tool shown in *Kuslich* to permit the surgeon to monitor the location of the tool by fluoroscopy during a surgical procedure. *Id*. at ¶ 107**.** A POSA would also know that radiopaque markers can also be used to monitor the configuration as well as the position of surgical tools, to ensure that a surgeon has proper control over the instrument being used. *Id*.

Therefore, Claim 4 is unpatentable over *Kuslich* in view of the knowledge of a POSA. *Id*. at ¶ 108.

d. Dependent Claim 5

Claim 5 depends from independent Claim 1, which as discussed above is unpatentable over *Kuslich* in view of the knowledge of a POSA. Claim 5 further limits Claim 1 by reciting:

> Claim 5
>
> wherein the cavity forming structure
>
> comprises a resilient material.

As demonstrated above with respect to Claim 1, *Kuslich* discloses cutting blades (40) and (42) that are each provided with a blade body (41 and 43 respectively). Ex. 1002 at 5:43-48.

It would have been obvious to a POSA to have a cavity forming structure, such as blades, as including a resilient material. Ex. 1007 at ¶ 111. It would have been obvious to one of ordinary skill in the art to use a resilient cutter in *Kuslich's* design because allowing the cutter to deform and return to its original shape allows the user to deploy a tool through the cannula, to cut a bore wider than the cannula, and then to remove the tool through the cannula. *Id*. A POSA would also know that a deformable cutter would enable the cutting blades to be oriented so that certain anatomical structures can be cut safely while avoiding others. *Id*. For

example, the chance of mistakenly cutting important nerve or blood vessels can be inhibited. *Id*. A deployable resilient cutter can also enable better control over the tissue removal process. *Id*.

It would have also been obvious to A POSA to use a known elastic member in *Kuslich's* design. *Id*. at ¶¶ 112-114. *Kuslich* discloses straight cutting blades that can cut the cortical bone on the surface of a vertebral body. *Id*. It would have been obvious to a POSA to make the blades resilient with an elastic member such that the blades are curved, as such a design would likely not cut hard cortical bone. *Id*. Therefore, the goal of forming a cavity entirely within the bone can be met. *Id*.

Therefore, Claim 5 is unpatentable over *Kuslich* in view of a POSA. *Id*. at ¶ 115.

e. Dependent Claim 6

Claim 6 depends from Claim 5, which as discussed *above* is unpatentable over *Kuslich* in view of the knowledge of a POSA. Claim 6 further limits Claim 5 by reciting:

> Claim 6
>
> wherein the resilient material is metal.

It would have been obvious to a POSA that the cutting blades (40 and 42) disclosed in *Kuslich* can be metal, as metal cutting blades are notoriously well known. *Id*. at ¶¶ 116-117. It would have been obvious to one of ordinary skill in

the art to make *Kuslich's* blades of metal for strength and durability, and for the ability to reach farther into the bone as needed. *Id*.

Therefore, Claim 6 is unpatentable over *Kuslich* in view of a POSA. *Id*. ¶ 118.

f. Dependent Claim 7

Claim 7 depends from Claim 5, which as discussed *above* is unpatentable over *Kuslich* in view of the knowledge of a POSA. Claim 7 further limits Claim 5 by reciting:

> Claim 7
>
> wherein the resilient material is plastic.

It would have been obvious to a POSA that the cutting blades (40 and 42) disclosed in *Kuslich* could be plastic. The use of plastic as a resilient material is very common in engineering. Ex. 1007 at ¶ 120. The properties of plastics are well-known to engineers, tool designers, and surgeons. *Id*. Plastic, or any of the many available grades of plastic, would have been obvious to try as a resilient material. *Id*. A POSA would render the tool disclosed in *Kulisch* as a "one-use device", which would have enhanced flexibility, and the plastic used for the device could be chosen to cut cancellous bone. *Id*. The single-use aspect of the tool would enhance infection control, and the compliance of plastics could render the tool as flexible. *Id*.

Therefore, Claim 7 is unpatentable over *Kuslich* in view of a POSA. *Id*. at ¶ 121.

g. Dependent Claim 8

Claim 8 depends from independent Claim 1, which as discussed *above* is unpatentable over *Kuslich* . Claim 8 further limits Claim 1 by reciting:

> Claim 8
>
> wherein the cavity forming structure
>
> comprises a shape memory material.

Kuslich teaches that the cutting edges (47, 48) described therein can have various different embodiments. For example, *Kuslich* explains that "[i]t will be appreciated by those skilled in the art that the cutting edges 47,48 ***can be adapted***…." Ex. 1002 at 7:20-22. It would have been obvious to a POSA to include a cavity forming device including a shape memory material because it would be desirable to be able to return the cavity forming device to its original shape after it has been deformed. Ex. 1007 at ¶ 123. Shape memory materials have been commonly known in engineering for decades, and they have been used in medical devices in certain applications. *Id*. The key characteristic of these materials is a recoverable plastic deformation enabling the material to deform, yet recover to its initial shape. *Id*. Nitinol is the most common of these materials. *Id*. It would have been obvious a POSA to use the shape-memory property of Nitinol

to deploy the cutting blades in *Kuslich* by directly changing the temperature of a spring-like apparatus at the tip of the shaft. Alternatively, the shaft itself could be pre-deformed in torsion, so it would unwind (and rotate) when the temperature rises. *Id*.

Therefore, Claim 8 is unpatentable over *Kuslich* in view of POSA. *Id*. ¶ 124.

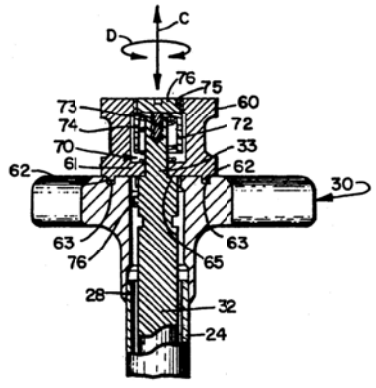
h. Dependent Claim 9

Claim 9 depends from independent Claim 1, which as discussed *above* is unpatentable over *Kuslich*. Claim 9 further limits Claim 1 by reciting:

> Claim 9
>
> and further including an element to
>
> adjust extension of the cavity forming
>
> structure beyond the shaft.

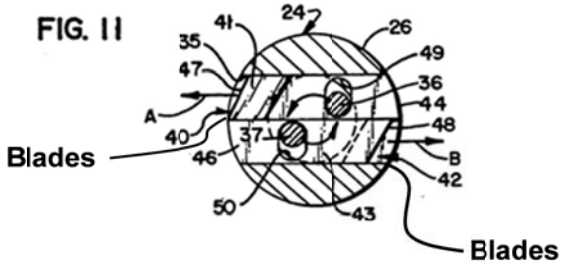
Kuslich teaches a control mechanism that controls the amount of extension of the blades (40,42) such that the blades can be held in a desired extended position. Ex. 1002 at 6:17-30. For example, in one embodiment (FIG. 7, right), *Kuslich* describes the control mechanism as including an adjustment grip (60) that is

FIG. 7

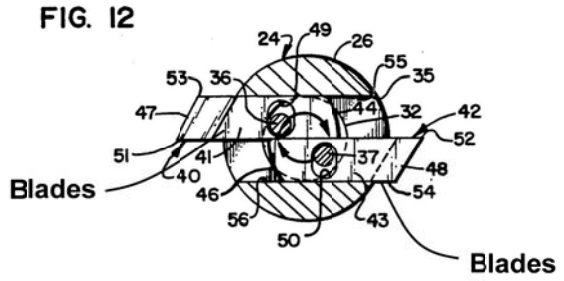


carried on an exposed end (33) of a rod (32). *Id*. As further shown in FIG. 7 (above), the grip (60) includes a pair of pins (62) that oppose the handle (30), wherein the pins (62) are sized to be received within any of a plurality of circumferentially spaced holes (63) formed on the surface of handle (30). *Id*.

The holes (63) correspond with positioning of blades (40, 42) such that when the pins (62) are received within holes (63a), the blades (40, 42) are fully received within the distal end (26) as shown in FIG. 11 (shown below and annotated by Petitioner for clarity). *Id*.



With the pins (62) received within the holes (63b), the blades (40, 42) are fully extended as shown in FIG. 12(shown below and annotated by Petitioner for clarity). *Id*.



Thus, *Kuslich* teaches an element that adjusts the extension of the cavity forming structure as is recited in Claim 9. *See* Ex. 1007 at ¶ 129. Accordingly, Claim 9 is unpatentable over *Kuslich*. *Id*. at ¶ 130.

i. Dependent Claim 10

Claim 10 depends from independent Claim 1, which as discussed *above* is unpatentable over *Kuslich*. Claim 10 further limits Claim 1 by reciting:

> Claim 10
>
> wherein the surface comprises a loop.

Kuslich teaches that the cavity forming structure can have a surface that includes a loop. For example, *Kuslich* explains that "the cutting edges 47, 48 ***can be adapted such that a wide variety of geometries can be given to a final hole to be cut by the blades***." Ex. 1002 at 7:20-25 (emphasis added). *Kuslich* further discloses that the "cutting edges 47, 48 could be arcuate (rather than generally linearly) to form a generally spherical hole." *Id*.

It would have been obvious to a POSA that the arcuate cutting edges for forming a generally sperical hole in *Kuslich* could include a loop, because a loop structure is known to cut the spherical hole described by *Kuslich* when it is rotated. Ex. 1007 at ¶ 134. It also would have been obvious to a POSA to adapt the cavity forming structure in *Kuslich* to include a loop so that the diameter of the shaft does not limit the size of the cavity that can be formed. Ex. 1007 at ¶ 133. A POSA

would have understood that with *Kuslich*, only a small amount of material could be removed because the extension of the material for the removal blade is limited and a large amount of material removal can be contemplated while keeping the hole in the cortical bone small. *Id.* When liquid bone cement or other filling material is used in the cavity, containment of the material is key to minimizing damage to adjacent tissues**.** *Id.*

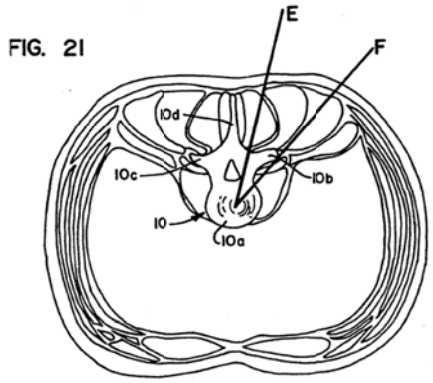
Therefore, Claim 10 is unpatentable over *Kuslich* in view of a POSA. *Id.* ¶ 136.

j. Dependent Claim 12

Claim 12 depends from independent Claim 11, which as discussed above is unpatentable over *Kuslich*. Claim 12 further limits Claim 11 by reciting:

> Claim 12
> further including the step of filling the
> cavity with a material

Kuslich teaches the step of filling a cavity with a material. For example, as illustrated in FIG. 21 (shown below), after the chamber (102) is formed and the surgical tool (22) is removed, "the chamber 102 is filled with any suitable graft medium 103", such as finely chopped cortical or cancellous bone chips. Ex. 1002 at 8:8-13.



Therefore, Claim 12 is unpatentable over *Kuslich*.

VII. CONCLUSION

Based on the foregoing, Wright Medical submits that Claims 1-12 of the '138 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,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,440,138 PURSUANT TO 35 U.S.C. § 312 AND 37 C.F.R. § 42.108, WITH EXHIBITS 1001 to 1024,** 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:

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