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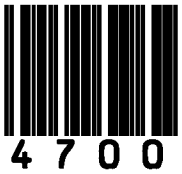

Application No. 12060856

This application is being forwarded to your office for further processing. A decision has been rendered on a petition filed in this application, as indicated below. For details of this decision, please see the document PET.OP.DEC filed on the same date as this document.

- [X] **GRANTED**
- [ ] **DISMISSED**
- [ ] **DENIED**

Office of Petitions: Decision Count Sheet

Mailing Month: 8

Application No.: 12060856

12060856

For US serial numbers: enter number only, no slashes or commas. Ex: 10123456
For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official: Debra Wyatt

Count (1) - Palm Credit 12060856

Decision: GRANT

FINANCE WORK NEEDED
☐ Select Check Box for YES

GRANT

Decision Type: 502 - 37 CFR 1.137(b) - REVIVAL BASED ON UNINTENTI

502

Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

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Printed on: 8/18/2017

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson		7469

109587 7590 09/20/2017

SPINAL KINETICS, Inc.
501 Mercury Drive
Sunnyvale, CA 94085

EXAMINER
BECCIA, CHRISTOPHER J

ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
09/20/2017	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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In re Application of	:	
Robinson, Janine	:	
Application No. 12/060,856	:	ON PETITION
Filed: April 1 , 2008	:	
For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES	:	

This is a decision on the petition under 37 CFR 1.137(a), filed April 3, 2017, to revive the above-identified application.

The petition is **GRANTED**.

This application became abandoned as a result of petitioner's failure to file an appeal brief within the time period provided in 37 CFR 41.37(a). As the required appeal brief was not filed within two (2) months of the Decision mailed November 4, 2015, and no extensions of time under the provisions of 37 CFR 1.136(a) were obtained, the appeal was dismissed and the proceedings as to the rejected claims were terminated. See 37 CFR 1.197(b). As no claim was allowed, the application became abandoned on January 5, 2016. *See* MPEP 1215.04.

The petition satisfies the conditions for revival pursuant to the provisions of 37 CFR 1.137(a) in that petitioner has supplied (1) the reply in the form of Appeal Brief, (2) the petition fee of $850.00, and (3) a proper statement of unintentional delay.

Telephone inquiries concerning this decision should be directed to the Debra Wyatt at (571) 272-3621.

This application is being referred to Technology Center AU 3775 for appropriate action by the Examiner in the normal course of business on the reply received April 3, 2017.

/JoAnne Burke/
JoAnne Burke
Paralegal Specialist
Office of Petitions

Doc Code: PET.OP

Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (12-13)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(a)

Docket Number (Optional): SK20025.00

First named inventor: Janine C. ROBINSON

Application No.: 12/060,856 Art Unit: 3775

Filed: April 1, 2006 Examiner: C.J. BECCIA

Title: Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact the Office of Petitions at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION.

NOTE: A grantable petition requires the following items:

(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee – required for all utility and plant applications filed before June 8, 1995, and for all design applications; and
(4) Statement that the entire delay was unintentional.

1. **Petition fee**

☑ Small entity fee $ 850 (37 CFR 1.17(m)). Applicant asserts small entity status. See 37 CFR 1.27.

☐ Undiscounted fee $ _____ (37.CFR.1.17(m)).

2. **Reply and/or fee**

A The reply and/or fee to the above-noted Office notice or action in the form of

Appeal Brief (identify the type of reply):

☐ has been filed previously on _____.

☑ is enclosed herewith.

B The issue fee and publication fee (if applicable) of $ _____

☐ has been paid previously on _____.

☐ is enclosed herewith.

04/04/2017 HVUONG1 00000038 12060856
01 FC:2453 850.00 OP

This collection of information is required by 37 CFR 1.137(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PET.OP
Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (12-13)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(a)

3. **Terminal disclaimer with disclaimer fee**

☑ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $ _____) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. **STATEMENT:** The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(a) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(a) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

E. Thomas Wheelock
Signature

March 22, 2017
Date

E. Thomas Wheelock
Typed or Printed Name

28,825
Registration Number, if applicable

Spinal Kinetics, 501 Mercury Dr.
Address

650-302-6286
Telephone Number

Sunnyvale, CA 94085
Address

Enclosures:

☑ Fee Payment
☑ Reply
☐ Terminal Disclaimer Form
☐ Additional sheet(s) containing statements establishing unintentional delay
☑ Other: transmittal form, return receipt postcard

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

☑ Deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

☐ Transmitted by EFS-Web or facsimile on the date shown below to the United States Patent and Trademark Office at (571) 273-8300.

March 22, 2017
Date

E. Thomas Wheelock
Signature

E. Thomas Wheelock
Typed or printed name of person signing certificate

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

THE PATENT TRIAL AND APPEAL BOARD

In the Application of JANINE C. ROBINSON

Serial No.: 12/060,856

Filed: April 1, 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

Examiner: C. J. Beccia

Art Unit: 3775

Confirmation No.: 7469

Docket No. SK20025.00

Customer No.: 109,587

APPEAL BRIEF

This Appeal Brief is filed in response to a final rejection of claims 1 and 3-9 dated March 14, 2013

Table of Contents

Appendices

I. REAL PARTY IN INTEREST

The real party in interest is Spinal Kinetics, Inc., a corporation of Delaware.

II. RELATED APPEALS AND INTERFERENCES

There are no prior or pending appeals, interferences, or judicial proceedings known to appellant, appellant's legal representatives, or assignee which may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

The status of the claims is:

Claims 1 and 3-9 are pending in this application. Claim 2 has been canceled.

Claims 1 and 3-9 stand rejected.

The claims being appealed are:

Claims 1 and 3-9.

IV. STATUS OF AMENDMENTS FILED SUBSEQUENT TO THE FINAL REJECTION

The Appellant has not amended the claims, specification, or drawings subsequent to the final Office Action (mailed on March 14, 2013).

V. SUMMARY OF CLAIMED SUBJECT MATTER

Background

The claimed invention is a medical device -- a prosthetic disc -- that replaces a diseased or injured disc in a human spine. Certain of the dependent claims are to kits of the inventive prosthetic disc. The prosthetic disc is placed between adjacent vertebrae to restore and to stabilize the spacing between those two vertebrae, to provide shock absorption abilities to the spine, and to permit axial rotation, motion in flexion-extension, and motion from side-to-side. In many instances, restoration and stabilization of that spacing will alleviate back pain caused by a so-called "slipped disc."

The human spine includes 23 discs, each disc located between a pair of adjacent vertebral bones in that spine. A normal human spine is able to bend front-and-back, to bend from side-to-side, and to move in a twisting motion. The spine absorbs pressure and shock applied along its axis, e.g., during a session of weightlifting. During each of these spinal motions and applications of force, one or more of the discs partakes of some portion of the spine's total motion or pressure. For instance, in bending over to pick up a child, each disc in a parent's spine bends forward at least a few degrees. In picking up the child, each disc (below the level of the shoulders) is compressed a bit in absorbing the pressure generated by the weight of the thusly-lifted child.

The structure of a natural human disc allows these small, but limited, bending and compressional displacements. Each natural disc includes two major components: the surrounding fibrous annulus or "*annulus fibrosus*" and the inner jelly-like nucleus or "*nucleus pulposus*." The *annulus* is made up of a collection of tough, but strong, collagenous fibers connecting the two adjacent vertebral bones and has the shape of a flattened donut. The *nucleus* is made up of a jelly-like proteinaceous material located in the open center of the donut-like *annulus*. The *annulus* allows the spine to bend and twist; the *nucleus* -- captured within the surrounding *annulus* -- maintains spacing between adjacent vertebral bones and absorbs pressure and shock applied to the spine.

A common disc-specific malady is the so-called "slipped disc" -- a misnomer typically used to describe a fissure or herniation in the annulus, the fissure perhaps allowing the *nucleus* to push

through the wall of the *annulus* and to press upon those proximal nerve bundles. The pressure on nerve bundles often causes significant pain. Although a "slipped disc" may result from a variety of causes, trauma is a common cause. Another common malady of the disc is simple disc degeneration, where the disc figuratively collapses lessening the distance between adjacent vertebrae.

Mapping of Claim 1 to the Written Support of the Original Specification

The application on appeal contains a single independent claim, which is claim 1.

Support for claim 1 will be cited generally with respect to original claim 1, Figs 2-3(c), and the text corresponding to these figures. Other locations will also be cited. However, it should be understood that these citations are not exhaustive and not all support has been cited herein.

Claim 1 recites "a prosthetic intervertebral disc." Support for this claim language may be found at, e.g.: Figs 2-3(c); page 2, paragraph [007]; and page 21, original claim 1.

Claim 1 also recites "a first end plate" and "a second end plate." Support for this claim language may be found at, e.g.: Figs 2-3(c); pages 2-3, paragraphs [007]-[008]; pages 8-10, paragraphs [030]-[032] and [035]; and page 21, original claim 1.

Claim 1 also recites "at least one compressible core member configured so that it may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second end plates." Support for this claim language may be found at, e.g.: Figs 2-3(c); pages 2-3, paragraphs [007]- [008]; pages 8-11, paragraphs [031]-[033] and [037]-[038]; pages 15-18, paragraphs [050]- [061]; and page 21, original claim 1.

Claim 1 also recites "at least one fiber extending between and engaged with said first and second end plates." Support for this claim language may be found at, e.g.: Figs 2-3(c); pages 2-3, paragraphs [007]-[008]; pages 8-10, paragraphs [031]-[032] and [036]; pages 14-15, paragraphs [047]-[049]; and page 21, original claim 1.

Claim 1 also recites "wherein said end plates and said core member are held together by said at least one fiber." Support for this claim language may be found at, e.g.: Figs 2-3(c); page 14, paragraph [047]; and page 21, original claim 1.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal are:

1. Whether claims 1 and 3-5 are properly rejected under 35 USC. §103(a) as being unpatentable over US Patent Publ. No 2007/0239279 to Francis in view of US Patent No. 7,153,325 to Kim et al.

2. Whether claims 6-9 are properly rejected under 35 USC. §103(a) as being unpatentable over US Patent Publ. No 2007/0239279 to Francis in view of US Patent No. 7,153,325 to Kim et al. and further in view of US Patent Publ. No. 2007/0270952 to Wistrom et al.

VII. ARGUMENTS

1. Whether claims 1 and 3-5 are properly rejected under 35 USC. §103(a) as being unpatentable over US Patent Publ. No 2007/0239279 to Francis in view of US Patent No. 7,153,325 to Kim et al.

The final rejection states in support of the rejection:

"As to Claim 1, Francis discloses a prosthetic intervertebral disc (100), comprising a first end plate (104A), a second end plate (1048), and at least one compressible core member (102) configured so that it may be introduced in a first lower profile and positioned between the first and second end plates and be rotated to a second higher profile while located between the first and second end plates [0037-0038]. Further, Francis teaches an elastic body (109) to support the core (102), and distribute load [0038].

"As to Claim 3, Francis discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (Fig. 1 A)

"As to Claim 4, Francis discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 1).

"As to Claim 5, Francis discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 1 A).

"As to Claims 1 and 3-5, Francis discloses the claimed invention except for at least one fiber extending between and engaged with the first and second end plates, and wherein the end plates and the core member are held together by the at least one fiber.

"Kim discloses a prosthetic disc implant (70, Fig. 7) including at least one fiber (73) extending between and engaged with the first (71 A) and second end plates (71 B), and wherein the end plates and the core member (76) are held together by the at least one fiber (Col. 9, Lines 4-11) in order to achieve similar mechanical properties of a healthy disc (Col. 5, Lines 44-54).

"It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the prosthetic disc implant of Francis with the fibrous reinforcement modification of Kim in order to achieve similar mechanical properties of a healthy disc."

In addition, the final rejection provides a "Response to Arguments" section:

"As to claim 1, Applicant argues that "Placing the Kim fibers (that hold the two Kim end plates together) into the Francis structure is to construct an implant that would be unsatisfactory for the purposes of Kim. The resulting structure would not have the natural-disc-like compressibility required of the Kim device because of the presence of

the Francis central stiffer rotating element," and that "Consequently, since the function of the annulus fibrosis remains during the intended use Francis device, adding the Kim fibers would be at least redundant in the functioning of the Francis device. In the absence of Applicant's disclosure, no technical, common-sense reason for combining the teachings is present."

"Examiner respectfully disagrees. [0016] of Francis discusses an elastic body surrounding a core support structure. [0017] describes that the rotatable core member can be constructed of an *elastic polymer,* indicating that the core is compressible. The elastic body of Francis allows for the implant to support natural compression of the spine, as described in [0038], with various compressive strengths, as described in [0049]. The fibers of Kim, as described in Col. 5, Lines 44-54, are compressible members designed to support, yet mimic the elastic properties of a natural disc. Examiner maintains that the combination of the rotatable, compressible core member of Francis, with the fibrous member of Kim would not destroy the functionality of the implant, as the motivation lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc.

"2. In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine,* 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones,* 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.,* 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Examiner maintains the rationale as explained above, as the motivation to combine the rotatable core of Francis with the fibrous member of Kim lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc."

ARGUMENTS

Placing Kim's fibers in the Francis device creates a redundant function in the Francis device

Appellant disagrees that the combination of Francis with Kim renders the claims unpatentable under 35 USC 103.

The final rejection states that Francis describes a nucleus replacement implant (100) made up of a first end plate (104A) and a second end plate (104B) and having a rotatable member (102) located between the end plates. Rotatable member (102) may be rotated from a first horizontal orientation to a second vertical orientation to change the spacing between the end plates. However,

the noted parts make up a subcomponent denominated by Francis as a "core support member." The "core support member" is necessarily surrounded by an "elastic body 109" forming the remainder of the implant. The "core support member" -- i.e., the rotatable member (102) and the two end plates (104A, 104B) -- are to be fabricated from "metal, a non-elastic biocompatible material, or an elastic polymer (of higher stiffness than the elastic body)." See, Para. [0035]. These compositional constraints mean that the center of the Francis implant is necessarily stiffer than the edges of the implant. If, as the final rejection argues, the purpose of the Francis device is to have a structure that approximates the compressibility of a natural disc, then it follows that the vast majority of the implant – "elastic body 109" -- must also have a compressibility similar to that of a natural disc. Since Francis itself places constraints on the materials making up the "rotatable member 102," the assembled and implanted Francis implant will rock or pivot about the Francis implant's center when so placed in a spine between two vertebrae interior to the surrounding fence-like *annulus fibrosus*.

Kim describes an intervertebral total disc replacement having a structure with end plates, a compressible core, and including fibers that hold the component end plates together. The Kim structure, in contrast to the Francis structure, is designed to emulate the motion of a natural disc, not just the *nucleus pulposus*:

> "The subject discs are characterized in that they include both an upper (or top) and lower (or bottom) endplate, where the upper and lower endplates are separated from each other by a fibrous compressible element, where the combination structure of the endplates and fibrous compressible element provides a prosthetic disc that functionally closely mimics real disc." Kim, Para. [0032]."

Placing the Kim fibers (that hold the two Kim end plates together) into the Francis structure is to construct an implant that would be unsatisfactory for the purposes of Kim. The resulting structure would not have the natural-disc-like compressibility required of the Kim device because of the presence of Francis' central stiffer rotating element.

As mentioned elsewhere several times, the two devices are designed for two different purposes: the Kim device is a replacement for a total disc and the Francis device is a replacement only for the *nucleus pulposus*. The Office Action proposes no practical, technology-based reason for including the Kim fibers in the Francis device. Francis clearly indicates that the natural *annulus*

fibrosus located between two vertebrae (see, No. 130 in Figs. 1 and 1A; No. 230 in Fig. 2; No. 330 in Fig. 3; and No. 430 in Fig.4) is to be left in place and the Francis device inserted within it. Consequently, since the function of the *annulus fibrosus* remains during the intended use of the Francis device, adding the Kim fibers would be at least redundant in the functioning of the Francis device. The Examiner has not provided any technical reason why one of ordinary skill in the art would place additional, perhaps bulky, components into the Francis device when the only apparent function of those added components is already supplied by the natural remaining ligaments of the unitary compressible core member.

In the absence of Appellant's disclosure, no technical, common-sense reason for combining the teachings is present.

Appellant requests that the rejection of claims 1 and 3-5 under 35 USC. §103(a) as being unpatentable over Francis in view of Kim et al be **REVERSED**.

The rationale stated in the final rejection for inserting the Kim fibers in the Francis device is conclusory and does not make engineering "common sense."

The Supreme Court in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007) disposed of the long-utilized and sometimes rigid requirement that rejections under 35 USC 103 combining the teachings of two prior art references must derive an impetus from the references themselves to make that combination. The Court acknowledged -- as the final rejection states -- that the rationale for making such a combination may be based in "common sense."

The rationale stated in the final rejection is conclusory. That statement in the final rejection does not provide a technological and logical basis for reaching the stated rationale.

Consider first that the Francis device is not designed to replace a whole disc in a human spine. It is instead designed only to replace a portion of the disc -- the *nucleus pulposus* – in that the tough ligaments of the natural *annulus fibrosus* remain largely in place after implantation of the Francis device. Note also that, as shown in Fig. 1A, the rotated "rotatable member 102" occupies

only an estimated ¼ of the diameter of the intervertebral diameter. [1]

The Kim device is a total disc replacement and therefore is wider than the Francis device. The fibers in the Kim device reside in the outer regions of the device and are positioned as far out on the artificial disc as is practically possible while still remaining within the confines of the intervertebral space.

The final rejection proposes placing the Kim fibers -- the Kim fibers that are normally placed at the widest possible radius from the center of the intervertebral space – at a very narrow radius around the Francis "rotatable member 102" near the very center of the intervertebral space between the two "vertebral support structures 104A, 104B." The rationale for such a placement is said to be "in order to achieve similar mechanical properties of a healthy disc" and "allowing for a strong load-bearing implant that remains compressible, mimicking the properties of a natural healthy disc." These are hollow rationale.

There is no explanation (in a cause and effect sense) why insertion of the disc-edge-residing-Kim fibers so near the center of Francis' replacement *nucleus pulposus* would cause the effect of providing "mechanical properties" so to mimic a "natural healthy disc." It is unlikely that surrounding the relatively stiff "rotatable member 102" with one or more fibers would have any more than a minimal effect on the implanted Francis disc.[2]

Appellant requests that the rejection of claims 1 and 3-5 under 35 USC. §103(a) as being unpatentable over Francis in view of Kim et al be **REVERSED**.

2. Whether claims 6-9 are properly rejected under 35 USC. §103(a) as being unpatentable over US Patent Publ. No 2007/0239279 to Francis in view of US Patent No. 7,153,325 to Kim et al. and further in view of US Patent Publ. No. 2007/0270952 to Wistrom et al.

Claims 6-9 are dependent ultimately upon claim 1 and are patentable for the same reasons as is claim 1. Wistrom et al does not add the elements missing from a proper rejection under 35

[1] The Appellant understands that patent drawings are not necessarily drawn to scale, but in this instance the diameter of an intervertebral space is well known and the relative size of the "rotatable member 102" is discussed in Francis at, e.g., Paragraphs [0033] to [0035].

[2] It should be noted that a natural disc does not contain a fibrous component near its central axis.

USC 103 of claim 1 over Francis in view of Kim et al.

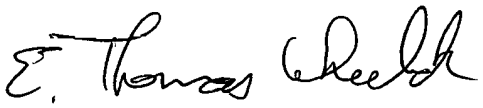
Claims 6-9 rise or fall with claim 1.

Appellant requests that the rejection of claims 6 to 9 under 35 USC. §103(a) be **REVERSED**.

VIII. SUMMARY

For the reasons stated above, the final rejection of claims 1 and 3-9 under 35 USC 103 is improper and should be **REVERSED**.

Respectfully submitted,



E. Thomas Wheelock
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650-302-6286

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Spinal Kinetics Inc.
501 Mercury Drive
Sunnyvale, California 94085

CLAIMS APPENDIX

1. A prosthetic intervertebral disc, comprising:

   a first end plate;

   a second end plate;

   at least one compressible core member configured so that it may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second end plates;

   at least one fiber extending between and engaged with said first and second end plates; and

   wherein said end plates and said core member are held together by said at least one fiber.

2. (Canceled)

3. The prosthetic intervertebral disc of claim 1 wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered.

4. The prosthetic intervertebral disc of claim 1 wherein the disc is bullet-shaped.

5. The prosthetic intervertebral disc of claim 1 wherein the disc is lozenge-shaped.

6. A kit for surgically replacing a disc in a spine with a posterior approach, comprising exactly two of the prosthetic discs of claim 1.

7. The kit of claim 6 further comprising at least one cannula suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs of claim 1.

8. The kit of claim 6 wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width.

9. The kit of claim 8 wherein the first and second end plates of the prosthetic discs have a length: width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1.

EVIDENCE APPENDIX

(None.)

RELATED PROCEEDINGS APPENDIX

(None.)

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	22

Application Number	12/060,856
Filing Date	April 1, 2008
First Named Inventor	Janine C. ROBINSON
Art Unit	3775
Examiner Name	C. J. BECCIA
Attorney Docket Number	SK20025.00

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☑ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☑ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  - Return receipt Postcard
  - Check for $850

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	SPINAL KINETICS INC.		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	3/23/2017	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	3/23/2017

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson		7469

109587 7590 07/13/2016

SPINAL KINETICS, Inc.
501 Mercury Drive
Sunnyvale, CA 94085

EXAMINER
BECCIA, CHRISTOPHER J

ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
07/13/2016	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Abandonment	Application No.	Applicant(s)
	12/060,856	ROBINSON, JANINE C.
	Examiner	Art Unit
	CHRISTOPHER BECCIA	3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *04 November 2015*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) if this is utility or plant application, a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. Note that RCEs are not permitted in design applications.)
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record or other party authorized under 37 CFR 1.33(b). See 37 CFR 1.138(b).

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☒ The reason(s) below:

No reply has been received within the 2 month period for filing an Appeal Brief, based on the Office of Petitions Decision of November 4, 2015.

	/CHRISTOPHER BECCIA/ Primary Examiner, Art Unit 3775

Petitions to revive under 37 CFR 1.137, or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

Office of Petitions: Routing Sheet

Application No. 12/060,856

This application is being forwarded to your office for further processing. A decision has been rendered on a petition filed in this application.

- [X] **GRANTED**
- [ ] **DISMISSED**
- [ ] **DENIED**

Office of Petitions: Decision Count Sheet

Mailing Month

Application No. 12060856

12060856

For US serial numbers: enter number only, no slashes or commas. Ex: 10123456
For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official: FAISON-BALL, PATRICIA

Count (1) - Palm Credit 12/060,856

Decision: GRANT

FINANCE WORK NEEDED
☐ Select Check Box for YES

GRANT

Decision Type: 502 - 37 CFR 1.137(b) - REVIVAL BASED ON UNINTENTIC

502

Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

If more than 3 decisions, attach 2nd count sheet & mark this box ☐

Printed on: *11/3/2015*

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson		7469

109587 7590 11/04/2015

SPINAL KINETICS, INC.
595 N. Pastoria Ave.
Sunnyvale, CA 94085

EXAMINER
BECCIA, CHRISTOPHER J

ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
11/04/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Application of
Janine C. Robinson
Application No. 12/060,856 ON PETITION
Filed: April 1, 2008
Attorney Docket No.: SK20025.00

This is a decision on the petition filed April 27, 2015 under 37 CFR 1.137(a)[1], to revive the above-identified application.

The petition is **GRANTED**.

This application became abandoned for failure to timely file a reply to the Final Office action mailed March 14, 2013, which set a three (3) month shortened statutory period for reply. Accordingly, a Notice of Abandonment was mailed September 24, 2013.

The Notice of Appeal filed September 27, 2013 and the Notice of Appeal fee filed with the instant petition have been entered and made of record. Accordingly, the two (2)-month period for filing the Appeal Brief, accompanied by the fee required by law, runs from the date of this decision.

All other requirements of 37 CFR 1.137(a) having now been met, this matter is being referred to Technology Center 3775 for processing of the Notice of Appeal.

Telephone inquiries concerning this matter should be directed to the undersigned Attorney at (571) 272-3212.

/Patricia Faison-Ball/

Patricia Faison-Ball
ATTORNEY ADVISOR
Office of Petitions

---

[1] Effective December 18, 2013, a grantable petition under 37 CFR 1.137(a) must be accompanied by: (1) the required reply, unless previously filed; (2) the petition fee as set forth in 37 CFR 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(a) was unintentional; and (4) any terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required by 37 CFR 1.137(d). Where there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137 was unintentional, the Director may require additional information. See MPEP 711.03(c)(II)(C) and (D).

Doc Code: PET.OP
Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (12-13)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(a)

Docket Number (Optional): SK20025.00

First named inventor: Janine C. ROBINSON

Application No.: 12/060,856 Art Unit: 3775

Filed: April 1, 2008 Examiner: Christopher J. BECCIA

Title: Prosthetic Intervertebral Discs Having Rotatable, Expandible Cores That Are Implantable Using Minimally Invasive Surgical Techniques

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact the Office of Petitions at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION.

NOTE: A grantable petition requires the following items:

(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee – required for all utility and plant applications filed before June 8, 1995, and for all design applications; and
(4) Statement that the entire delay was unintentional.

1. **Petition fee**

☑ Small entity fee $ 850 (37 CFR 1.17(m)). Applicant asserts small entity status. See 37 CFR 1.27.

☐ Undiscounted fee $ _____ (37.CFR.1.17(m)).

2. **Reply and/or fee**

A The reply and/or fee to the above-noted Office notice or action in the form of

Response to Office Action and Notice of Appeal (identify the type of reply):

☑ has been filed previously on September 16, 2013.

☐ is enclosed herewith.

B The issue fee and publication fee (if applicable) of $ _____

☐ has been paid previously on _____.

☐ is enclosed herewith.

This collection of information is required by 37 CFR 1.137(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

04/28/2015 EEKUBAY1 00000004 12060856

01 FC:2453 850.00 OP
02 FC:2401 400.00 OP

Doc Code: PET.OP
Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (12-13)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(a)

3. **Terminal disclaimer with disclaimer fee**

☑ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $ _____) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. **STATEMENT:** The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(a) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(a) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

E. Thomas Wheelock
Signature

4/22/2015
Date

E. Thomas Wheelock
Typed or Printed Name

28,825
Registration Number, if applicable

SPINAL KINETICS INC.
Address

650-302-6286
Telephone Number

595 N. Pastoria; Sunnyvale, CA 94085
Address

Enclosures:

☑ Fee Payment

☐ Reply

☐ Terminal Disclaimer Form

☐ Additional sheet(s) containing statements establishing unintentional delay

☑ Other: Check for payment of fee ($400) for Notice of Appeal

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

☑ Deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

☐ Transmitted by EFS-Web or facsimile on the date shown below to the United States Patent and Trademark Office at (571) 273-8300.

4/22/2015
Date

E. Thomas Wheelock
Signature

E. Thomas Wheelock
Typed or printed name of person signing certificate

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	3

Application Number	12/060,856
Filing Date	April 1, 2008
First Named Inventor	Janie C. Robinson
Art Unit	3775
Examiner Name	Christopher J.BECCIA
Attorney Docket Number	SK20025.00

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☑ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
- ☐ Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  - Check for $1250
  - Return Receipt Postcard

Remarks

Check is $850 for Petition to Revive and $400 for omitted Notice of Appeal fee

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	SPINAL KINETICS, INC.		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	4/22/2015	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	4/22/2015

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson		7469

109587 7590 12/18/2014

SPINAL KINETICS, INC.
595 N. Pastoria Ave.
Sunnyvale, CA 94085

EXAMINER
BECCIA, CHRISTOPHER J

ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
12/18/2014	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Application of :
Robinson et al. :
Application No. 12/060,856 : ON PETITION
Filed: April 1, 2008 :
Title: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES :

This is a decision on the petition, filed July 22, 2014, under 37 CFR 1.181, requesting withdrawal of the holding of abandonment in the above-identified application.

The petition is **DISMISSED**.

This application was held abandoned for failure to timely respond to the Office action of March 14, 2013, which set a three (3) month shortened statutory period for reply. Accordingly, a reply was due on or before June 14, 2013. A Notice of Abandonment was mailed September 24, 2013.

Petitioner states that a timely reply was submitted on September 16, 2013, which included the following papers: 1) Response and Amendment, 2) Petition for Extension of Time under 37 CFR 1.136(a), and 3) a Notice of Appeal. Petitioner has submitted a copy of the previously mailed correspondence.

Petitioner further states that with the three month extension of time, the above response was timely filed as September 14, 2013 was a Saturday. Therefore, the response was timely filed on the next business day, Monday, September 16, 2013.

Petitioner is correct in that response was timely received on September 16, 2013. However, it appears that only the $700.00 extension of time fee was received that day. The $400.00 Notice of Appeal fee, which Petitioner has listed on the Notice of Appeal form, was not and has not yet been received. If petitioner can show that payment of that fee was indeed made on September 16, 2013, petitioner is asked to provide it with a renewed petition.

Accordingly, absent the required evidence to establish the above, the petition requesting withdrawal of the holding of abandonment cannot be granted at this time.

If petitioner cannot supply the evidence necessary to withdraw the holding of abandonment, or simply does not wish to, petitioner should consider filing a petition under 37 CFR 1.137(a)

stating that the delay was unintentional. An "unintentional" petition under 37 CFR 1.137(a) must be accompanied by the $850.00 petition fee.

The filing of a petition under 37 CFR 1.137(a) cannot be intentionally delayed and therefore must be filed promptly. A person seeking revival due to unintentional delay cannot make a statement that the delay was unintentional unless the entire delay, including the date it was discovered that the application was abandoned until the filing of the petition to revive under 37 CFR 1.137(a), was unintentional. A statement that the delay was unintentional is not appropriate if petitioner intentionally delayed the filing of a petition for revival under 37 CFR 1.137(a).

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop PETITIONS
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

By hand: Customer Window located at:

U.S. Patent and Trademark Office
Customer Service Window Randolph Building
401 Dulany Street
Alexandria, VA 22314

By fax: (571) 273-8300
ATTN: Office of Petitions

Any questions concerning this matter may be directed to the undersigned at (571) 272-3206.

/Liana Walsh/
Liana Walsh
Petitions Paralegal Specialist
Office of Petitions

Office of Petitions: Decision Count Sheet

Mailing Month 12

Application No. 12060856

12060856

For US serial numbers: enter number only, no slashes or commas. Ex: 10123456
For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official: WALSH, LIANA

Count (1) - Palm Credit 12/060,856

Decision: DISMISSED

FINANCE WORK NEEDED ☐ Select Check Box for YES

DISMISSED

Decision Type: 525 - 37 CFR 1.181 for W/D HOLDING OF ABANDONMEI

525

Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED ☐ Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED ☐ Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

If more than 3 decisions, attach 2nd count sheet & mark this box ☐

Printed on: *12/18/2014*

Office of Petitions: Routing Sheet

Application No. 12/060,856

This application is being forwarded to your office for further processing. A decision has been rendered on a petition filed in this application.

- ☐ **GRANTED**
- ☒ **DISMISSED**
- ☐ **DENIED**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Janine C. ROBINSON

Application Ser. No.: 12/060,856

Filing Date: April 1, 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

Art Unit: 3775

Examiner: BECCIA, Christopher J.

Confirmation No. 7469

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Petition Under 37 CFR 1.181 to Withdraw Improper Holding of Abandonment

Dear Sir:

This is a Petition Under 37 CFR 1.181 to Withdraw a Holding of Abandonment. The application is not abandoned since a Response and Amendment and a Notice of Appeal were timely filed.

A Notice of Abandonment, a copy of which is included as Attachment 1, was mailed on September 24, 2013. The Notice of Abandonment erroneously indicated that Applicants had not filed a response to a final Office Action. That Office Action was mailed on Tuesday March 14, 2013. The six-month extended period for response to the Office Action expired on Saturday, September 14, 2013.

Applicants had filed a complete and timely response to the final Office Action on Monday, September 16, 2013, the final day of the period for response as extended for three months under 37 CFR 1.136(a). Since September 16th was a Saturday, the period for response

was extended by law until the following Monday. Applicants' response included a Response and Amendment, a Petition for Extension of Time Under 37 CFR 1.136(a) requesting a three-month extension, and a Notice of Appeal. The response also included a Transmittal Form. Copies of each of the listed documents are included as Attachment 2. Applicants' response was filed using first class mail under 37 CFR 1.8. The attached copies of the response are taken from the USPTO's public PAIR database and were received by the USPTO Mailroom on September 27, 2013. The Transmittal Form includes a Certificates of Mailing under 37 CFR 1.8 specifying September 16, 2013 as the mailing date.

The undersigned attorney, by his signature below, attests that he personally deposited the response with the United States Postal Service on September 16, 2013.

No fee is required for this Petition.

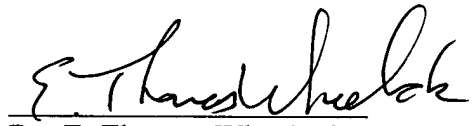
Applicants request that the USPTO withdraw the holding of abandonment as erroneous in this application.

SUMMARY

Applicants request withdrawal of the holding of abandonment in this application and its return to normal prosecution. Applicants further request allowance of the application as amended.

Should there be questions, Applicants' attorney; E. Thomas Wheelock (Reg. No. 28,825) may be reached at 650-302-6286.

Respectfully submitted,



Date: July 17, 2014

By: E. Thomas Wheelock
Attorney for Assignee
(Reg. No. 28,825)

650-302-6286
650-858-2131 (fax)

tom@etwheelocklaw.com
twheelock@spinalkinetics.com

Spinal Kinetics, Inc.
595 N. Pastoria Ave.
Sunnyvale, CA, 94085

Attachment 1: copy of September 24, 2013 Notice of Abandonment

Attachment 2: copy of papers filed on September 16, 2013 in response to the March 14, 2013 final Office Action

ATTACHMENT 1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson	S0134.0033	7469

91477 7590 09/24/2013

Dickstein Shapiro LLP
1633 Broadway
New York, NY 10019

EXAMINER	
BECCIA, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
09/24/2013	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Abandonment	Application No.	Applicant(s)
	12/060,856	ROBINSON, JANINE C.
	Examiner	Art Unit
	CHRISTOPHER BECCIA	3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *14 March 2013*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection. (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☒ The reason(s) below:

No reply has been received in six months since the mailing of the last Office Action on March 14, 2013. A telephone call was made to E. Thomas Wheelock on September 18, 2013 who confirmed the abandonment.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

ATTACHMENT 2

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson	S0134.0033	7469

91477 7590 03/14/2013

Dickstein Shapiro LLP
2049 Century Park East
Suite 700
Los Angeles, CA 90067

EXAMINER	
BECCIA, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
3775	
MAIL DATE	DELIVERY MODE
03/14/2013	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/060,856	ROBINSON, JANINE C.	
	Examiner	Art Unit	
	CHRISTOPHER BECCIA	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2013*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1 and 3-9* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1 and 3-9* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *01 December 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

4) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. As to claim 1, Applicant argues that "Placing the Kim fibers (that hold the two Kim end plates together) into the Francis structure is to construct an implant that would be unsatisfactory for the purposes of Kim. The resulting structure would not have the natural-disc-like compressibility required of the Kim device because of the presence of the Francis central stiffer rotating element," and that "Consequently, since the function of the annulus fibrosis remains during the intended use Francis device, adding the Kim fibers would be at least redundant in the functioning of the Francis device. In the absence of Applicant's disclosure, no technical, common-sense reason for combining the teachings is present."

Examiner respectfully disagrees. [0016] of Francis discusses an elastic body surrounding a core support structure. [0017] describes that the rotatable core member can be constructed of an *elastic polymer,* indicating that the core is compressible. The elastic body of Francis allows for the implant to support natural compression of the spine, as described in [0038], with various compressive strengths, as described in [0049]. The fibers of Kim, as described in Col. 5, Lines 44-54, are compressible members designed to support, yet mimic the elastic properties of a natural disc. Examiner maintains that the combination of the rotatable, compressible core member of Francis, with the fibrous member of Kim would not destroy the functionality of the implant, as the motivation lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc.

2. In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Examiner maintains the rationale as explained above, as the motivation to combine the rotatable core of Francis with the fibrous member of Kim lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 1 and 3-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2007/0239279 to *Francis* in view of U.S. Patent No. 7,153,325 to *Kim et al.*

As to **Claim 1,** *Francis* discloses a prosthetic intervertebral disc (100), comprising a first end plate (104A), a second end plate (104B), and at least one compressible core member (102) configured so that it may be introduced in a first lower profile and positioned between the first and second end plates and be rotated to a second higher profile while located between the first and second end plates [0037-0038]. Further, *Francis* teaches an elastic body (109) to support the core (102), and distribute load [0038].

As to **Claim 3,** *Francis* discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (Fig. 1A)

As to **Claim 4,** *Francis* discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 1).

As to **Claim 5,** *Francis* discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 1A).

As to **Claims 1 and 3-5,** *Francis* discloses the claimed invention except for at least one fiber extending between and engaged with the first and second end plates, and wherein the end plates and the core member are held together by the at least one fiber.

Kim discloses a prosthetic disc implant (70, Fig. 7) including at least one fiber (73) extending between and engaged with the first (71A) and second end plates (71B), and wherein the end plates and the core member (76) are held together by the at least

one fiber (Col. 9, Lines 4-11) in order to achieve similar mechanical properties of a healthy disc (Col. 5, Lines 44-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the prosthetic disc implant of *Francis* with the fibrous reinforcement modification of *Kim* in order to achieve similar mechanical properties of a healthy disc.

3. **Claims 6-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2007/0239279 to *Francis* in view of U.S. Patent No. 7,153,325 to *Kim et al.* in further view of U.S. Patent Pub. No. 2007/0270952 to *Wistrom et al.*

As to **Claim 8,** *Francis* discloses a kit wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width [0035-0036].

As to **Claim 9,** *Francis* discloses a kit wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1 [0036 and 0038].

As to **Claims 6-9,** *Francis* and *Kim* disclose the claimed invention except for a kit comprising exactly two of the prosthetic disc, and at least one cannula suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs.

Wistrom discloses a kit (100) comprising exactly two prosthetic discs (100), and at least one cannula (700) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs [0011 and 0027] in order to facilitate delivery of multiple implants using a minimally invasive procedure [0011 and 0027].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of *Francis* and *Kim* with the delivery cannula modifications of *Wistrom* in order to facilitate delivery of multiple implants using a minimally invasive procedure.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Beccia whose telephone number is

(571)270-7391. The examiner can normally be reached on Mon-Fri from 9:00am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Kevin Truong, at (571) 272-4705***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Kevin T Truong/
Supervisory Patent Examiner, Art Unit 3775

Doc Code: TRAN.LET Best Available Copy

Document Description: Transmittal Letter

AF

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	10

Application Number	12/080,856
Filing Date	April 1, 2013
First Named Inventor	Janine C. Robinson
Art Unit	3775
Examiner Name	Christopher J. BECCIA
Attorney Docket Number	SK20025.00

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☑ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  - Check for $700
  - Return receipt postcard

Remarks

Appeal fee was paid previously

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Spinal Kinetics, Inc. attn.: E.T. Wheelock		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	September 16, 2013	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	September 16, 2013

PTO/SB/22 (03-13)
Approved for use through 3/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): SK20025.00

Application Number: 12/060,856

Filed: April 1, 2008

For: Prosthetic Intervertebral Discs having Rotatable, Expandible etc.

Art Unit: 3775

Examiner: Christopher J. BECCIA

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$
☐ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☑ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$ 700
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☑ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☑ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number _____.

☐ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).

☐ attorney or agent of record. Registration number _____.

☑ attorney or agent acting under 37 CFR 1.34. Registration number 28,825.

E. Thomas Wheelock — Signature

September 16, 2013 — Date

E. Thomas Wheelock — Typed or printed name

650-302-6286 — Telephone Number

09/30/2013 LJUHAR1 00000003 12060856
01 FC:2253 700.00 OP

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

PTO/SB/31 (09-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

NOTICE OF APPEAL FROM THE EXAMINER TO THE PATENT TRIAL AND APPEAL BOARD

Docket Number (Optional): SK20025.00

I hereby certify that this correspondence is being facsimile transmitted to the USPTO EFS-Web transmitted to the USPTO, or or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on September 16, 2013

Signature E. Thomas Wheelock

Typed or printed name E. Thomas Wheelock

In re Application of: Janine C. ROBINSON

Application Number	Filed
12/060,856	April 1, 2008

For: Prosthetic Intervertebral Discs etc.

Art Unit	Examiner
3775	Christopher J. BECCIA

Applicant hereby **appeals** to the Patent Trial and Appeal Board from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 800

☑ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ 400

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____.

☑ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☐ attorney or agent of record. Registration number _____.

☑ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. 28,825

E. Thomas Wheelock
Signature

E.Thomas Wheelock
Typed or printed name

650-302-6286
Telephone number

September 16, 2013
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Janine C. ROBINSON

Application No.: 12/060,856

Filing Date: 01 April 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

Confirmation No.: 7469

Examiner: BECCIA, Christopher J.
Art Unit: 3775

RESPONSE TO FINAL OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action mailed March 14, 2013 in which claims 1 and 3-5 were finally rejected under 35 USC 103. This is the second Office Action since the re-opening of prosecution after Applicant filed an Appeal Brief.

Applicant has not amended, cancelled, nor added claims. Consequently, claims 1 and 3-9 are under consideration. Allowance is requested.

A **REMARKS** section begins on the following page.

A **SUMMARY** section is on page 7.

REMARKS

REJECTION of CLAIMS 1 AND 3-5

Claims 1 and 3-5 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent Pub. No. 2007/0239279 to Francis in view of U.S. Patent No. 7,153,325 to Kim et al. In support of the rejection, the Examiner states:

> "As to Claim 1, Francis discloses a prosthetic intervertebral disc (100), comprising a first end plate (104A), a second end plate (104B), and at least one compressible core member (102) configured so that it may be introduced in a first lower profile and positioned between the first and second end plates and be rotated to a second higher profile while located between the first and second end plates [0037-0038]. Further, Francis teaches an elastic body (109) to support the core (102), and distribute load [0038].
>
> "As to Claim 3, Francis discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (Fig. 1A)
>
> "As to Claim 4, Francis discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 1).
>
> "As to Claim 5, Francis discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 1A).
>
> "As to Claims 1 and 3-5, Francis discloses the claimed invention except for at least one fiber extending between and engaged with the first and second end plates, and wherein the end plates and the core member are held together by the at least one fiber.
>
> "*Kim* discloses a prosthetic disc implant (70, Fig. 7) including at least one fiber (73) extending between and engaged with the first (71 A) and second end plates (71 B), and wherein the end plates and the core member (76) are held together by the at least one fiber (Col. 9, Lines 4-11) in order to achieve similar mechanical properties of a healthy disc (Col. 5, Lines 44-54).
>
> "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the prosthetic disc implant of *Francis* with the fibrous reinforcement modification of *Kim* in order to achieve similar mechanical properties of a healthy disc."

Applicant disagrees that the combination of *Francis* with *Kim* renders the claims unpatentable under 35 USC 103.

As the Examiner notes, *Francis* describes a nucleus replacement implant (100) made up of a first end plate (104A) and a second end plate (104B) and having a rotatable member (102) located between the end plates. Member (102) may be rotated from a first horizontal orientation to a second vertical orientation to change the spacing between the end plates. However, the

noted parts make up a subcomponent denominated by Francis as a "core support member." The "core support member" is necessarily surrounded by an "elastic body 109" forming the remainder of the implant. The "core support member" -- i.e., the rotatable member (102) and the two end plates (104A, 104B) -- may only be fabricated from "metal, a non-elastic biocompatible material, or an elastic polymer (of higher stiffness than the elastic body)." See, Para. [0035]. These compositional requirements mean that the center of the *Francis* implant is necessarily stiffer than the edges of the implant. It is clear that such a structure does not have the compressibility of the natural disc and will rock or pivot about the *Francis* implant's center when placed in a spine between two vertebrae.

The *Kim* device shows an intervertebral total disc replacement having a structure with end plates, a compressible core, and includes fibers that hold the component end plates together. The *Kim* structure, in contrast to the *Francis* structure, is designed to emulate the motion of a natural disc:

> "The subject discs are characterized in that they include both an upper (or top) and lower (or bottom) endplate, where the upper and lower endplates are separated from each other by a fibrous compressible element, where the combination structure of the endplates and fibrous compressible element provides a prosthetic disc that functionally closely mimics real disc." Kim, Para. [0032].

Placing the *Kim* fibers (that hold the two *Kim* end plates together) into the *Francis* structure is to construct an implant that would be unsatisfactory for the purposes of *Kim.* The resulting structure would not have the natural-disc-like compressibility required of the *Kim* device because of the presence of the *Francis* central stiffer rotating element.

Additionally, the two devices are designed for two different purposes: the *Kim* device is a replacement for a total disc and the *Francis* device is a replacement only for the *nucleus pulposus.* The Office Action proposes no practical, technology-based reason for including the *Kim* fibers in the *Francis* device. The *Francis* disclosure clearly indicates that the *annulus fibrosus* located between two vertebrae (see, No. 130 in Figs. 1and 1A; No. 230 in Fig. 2; No. 330 in Fig. 3; and No. 430 in Fig.4) is to be left in place and the *Francis* device inserted within it. Consequently, since the function of the *annulus fibrosus* remains during the intended use *Francis* device, adding the Kim fibers would be at least redundant in the functioning of the *Francis* device. In the absence of Applicant's disclosure, no technical, common-sense reason for

combining the teachings is present.

Withdrawal of the rejection is requested.

REJECTION of CLAIMS 6-9

Claims 6-9 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent Pub. No. 2007/0239279 to Francis in view of U.S. Patent No. 7,153,325 to Kim et al and further in view of U.S. Patent Pub. No. 2007/0270952 to Wistrom et al. In support of the rejection, the Examiner states:

> "As to Claim 8, Francis discloses a kit wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width [0035-0036].
>
> "As to Claim 9, Francis discloses a kit wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1 [0036 and 0038].
>
> "As to Claims 6-9, Francis and Kim disclose the claimed invention except for a kit comprising exactly two of the prosthetic disc, and at least one cannula suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs.
>
> "Wistrom discloses a kit (100) comprising exactly two prosthetic discs (100), and at least one cannula (700) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs [0011 and 0027] in order to facilitate delivery of multiple implants using a minimally invasive procedure [0011 and 0027].
>
> "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of Francis and Kim with the delivery cannula modifications of Wistrom in order to facilitate delivery of multiple implants using a minimally invasive procedure."

Applicant disagrees. Claims 6-9 depend from claim 1 or rely upon claim 1 for content. As discussed above, the combination of *Francis* and *Kim* does not show the device required by claim 1. The *Wistrom* disclosure does not remedy those shortcomings.

Withdrawal of the rejection is requested.

The Examiner argues in a section entitled **RESPONSE TO ARGUMENTS:**

"As to claim 1, Applicant argues that 'Placing the Kim fibers (that hold the two Kim end plates together) into the Francis structure is to construct an implant that would be unsatisfactory for the purposes of Kim. The resulting structure would not have the natural-disc-like compressibility required of the Kim device because of the presence of the Francis central stiffer rotating element,' and that 'Consequently, since the function of the annulus fibrosis remains during the intended use Francis device, adding the Kim fibers would be at least redundant in the functioning of the Francis device. In the absence of Applicant's disclosure, no technical, common-sense reason for combining the teachings is present.'

"Examiner respectfully disagrees. [0016] of Francis discusses an elastic body surrounding a core support structure. [0017] describes that the rotatable core member can be constructed of an *elastic polymer*, indicating that the core is compressible. The elastic body of Francis allows for the implant to support natural compression of the spine, as described in [0038], with various compressive strengths, as described in [0049]. The fibers of Kim, as described in Col. 5, Lines 44-54, are compressible members designed to support, yet mimic the elastic properties of a natural disc. Examiner maintains that the combination of the rotatable, compressible core member of Francis, with the fibrous member of Kim would not destroy the functionality of the implant, as the motivation lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International* Co. *v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Examiner maintains the rationale as explained above, as the motivation to combine the rotatable core of Francis with the fibrous member of Kim lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc."

Applicant again disagrees that the combination of Kim and Francis renders the claims unpatentable under 35 USC 103. The purported technical explanation providing motivation to introduce the fibrous member of Kim into the Francis structure lacks a reasonable scientific, medical basis.

In addition to ignoring the functions of the Kim components (as discussed above and in the Response to the prior Office Action), the combination of components urged in the Office Action, e.g., placing the Kim fibers between the Francis vertebral support structures (e.g., 204A and 204B) and around the rather portly Francis elastic body 209 ignores the both the function of that elastic body by constraining its elastic movement and compressibility and the function of the Kim fibers in mimicking the actions of a natural *annulus fibrosis*.

The Examiner relies only upon hindsight arguments based upon Applicant's specification for the combination structure recited in the Office Action. Applicant requests withdrawal of the rejection and allowance of the pending claims.

Doc Code: TRAN.LET
Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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OPAP JUL 22 2014 PATENT & TRADEMARK OFFICE

TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	12/060856
		Filing Date	April 1, 2008
		First Named Inventor	Janine C. ROBINSON
		Art Unit	3775
		Examiner Name	Christopher J. BECCIA
Total Number of Pages in This Submission	26	Attorney Docket Number	SK20025.00

ENCLOSURES (*Check all that apply*)

- [ ] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [x] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) ______
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC (**Appeal Notice, Brief, Reply Brief**)
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):
  – Return receipt post card

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	SPINAL KINETICS INC.: attn. E.T. Wheelock		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	July 17, 2014	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	July 17, 2014

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	

CONFIRMATION NO. 7469

POA ACCEPTANCE LETTER

109587
SPINAL KINETICS, INC.
595 N. Pastoria Ave.
Sunnyvale, CA 94085

OC000000066554238

Date Mailed: 02/10/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/22/2014.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/rmturner myles/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	S0134.0033

CONFIRMATION NO. 7469

POWER OF ATTORNEY NOTICE

91477
Dickstein Shapiro LLP
1633 Broadway
New York, NY 10019

OC000000066554191

Date Mailed: 02/10/2014

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/22/2014.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/rmturner myles/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/SB/80 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

☑ Practitioners associated with the Customer Number: 109587

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

☑ The address associated with Customer Number: 109587

OR

☐ Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

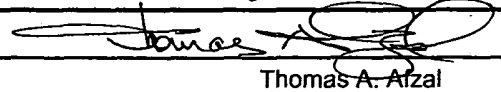
Assignee Name and Address:

Spinal Kinetics inc.
595 N. Pastoria Avenue
Sunnyvale, CA 94085

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	1/14/13
Name	Thomas A. Afzal	Telephone	408-636-2500
Title	President and CEO		

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: TRAN.LET

Document Description: Transmittal Letter

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	3

Application Number	12/060,856
Filing Date	April 1, 2008
First Named Inventor	Janine C. ROBINSON
Art Unit	3775
Examiner Name	Christopher J. BECCIA
Attorney Docket Number	SK20025.00

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
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  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
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- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  - copy of 3.73 Statement
  - Return Receipt Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Spinal Kinetics Inc.		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	January 15, 2014	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

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Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	January 15, 2014

G

PTO/SB/96 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Spinal Kinetics Inc.

Application No./Patent No.: 12/060,856 Filed/Issue Date: April 1, 2008

Titled: Prosthetic Intervertebral Discs having Rotatable, Expandable Cores that are Implantable Using Minimally Invasive Surgical Techniques

Spinal Kinetics Inc. , a corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.

states that it is:

1. [X] the assignee of the entire right, title, and interest in;

2. [ ] an assignee of less than the entire right, title, and interest in
(The extent (by percentage) of its ownership interest is _____ %); or

3. [ ] the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

A. [X] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 022125, Frame 0768, or for which a copy therefore is attached.

OR

B. [ ] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet(s).

[X] As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

E. Thomas Wheelock — January 15, 2014
Signature — Date

E. Thomas Wheelock — Attorney for Assignee
Printed or Typed Name — Title

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Janine C. ROBINSON

Application No.: 12/060,856

Filing Date: 01 April 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

Confirmation No.: 7469

Examiner: BECCIA, Christopher J.
Art Unit: 3775

RESPONSE TO FINAL OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action mailed March 14, 2013 in which claims 1 and 3-5 were finally rejected under 35 USC 103. This is the second Office Action since the re-opening of prosecution after Applicant filed an Appeal Brief.

Applicant has not amended, cancelled, nor added claims. Consequently, claims 1 and 3-9 are under consideration. Allowance is requested.

A **REMARKS** section begins on the following page.

A **SUMMARY** section is on page 7.

REMARKS

REJECTION of CLAIMS 1 AND 3-5

Claims 1 and 3-5 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent Pub. No. 2007/0239279 to Francis in view of U.S. Patent No. 7,153,325 to Kim et al. In support of the rejection, the Examiner states:

> "As to Claim 1, Francis discloses a prosthetic intervertebral disc (100), comprising a first end plate (104A), a second end plate (104B), and at least one compressible core member (102) configured so that it may be introduced in a first lower profile and positioned between the first and second end plates and be rotated to a second higher profile while located between the first and second end plates [0037-0038]. Further, Francis teaches an elastic body (109) to support the core (102), and distribute load [0038].
>
> "As to Claim 3, Francis discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (Fig. 1A)
>
> "As to Claim 4, Francis discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 1).
>
> "As to Claim 5, Francis discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 1A).
>
> "As to Claims 1 and 3-5, Francis discloses the claimed invention except for at least one fiber extending between and engaged with the first and second end plates, and wherein the end plates and the core member are held together by the at least one fiber.
>
> "*Kim* discloses a prosthetic disc implant (70, Fig. 7) including at least one fiber (73) extending between and engaged with the first (71 A) and second end plates (71 B), and wherein the end plates and the core member (76) are held together by the at least one fiber (Col. 9, Lines 4-11) in order to achieve similar mechanical properties of a healthy disc (Col. 5, Lines 44-54).
>
> "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the prosthetic disc implant of *Francis* with the fibrous reinforcement modification of *Kim* in order to achieve similar mechanical properties of a healthy disc."

Applicant disagrees that the combination of *Francis* with *Kim* renders the claims unpatentable under 35 USC 103.

As the Examiner notes, *Francis* describes a nucleus replacement implant (100) made up of a first end plate (104A) and a second end plate (104B) and having a rotatable member (102) located between the end plates. Member (102) may be rotated from a first horizontal orientation to a second vertical orientation to change the spacing between the end plates. However, the

noted parts make up a subcomponent denominated by Francis as a "core support member." The "core support member" is necessarily surrounded by an "elastic body 109" forming the remainder of the implant. The "core support member" -- i.e., the rotatable member (102) and the two end plates (104A, 104B) -- may only be fabricated from "metal, a non-elastic biocompatible material, or an elastic polymer (of higher stiffness than the elastic body)." See, Para. [0035]. These compositional requirements mean that the center of the *Francis* implant is necessarily stiffer than the edges of the implant. It is clear that such a structure does not have the compressibility of the natural disc and will rock or pivot about the *Francis* implant's center when placed in a spine between two vertebrae.

The *Kim* device shows an intervertebral total disc replacement having a structure with end plates, a compressible core, and includes fibers that hold the component end plates together. The *Kim* structure, in contrast to the *Francis* structure, is designed to emulate the motion of a natural disc:

> "The subject discs are characterized in that they include both an upper (or top) and lower (or bottom) endplate, where the upper and lower endplates are separated from each other by a fibrous compressible element, where the combination structure of the endplates and fibrous compressible element provides a prosthetic disc that functionally closely mimics real disc." Kim, Para. [0032].

Placing the *Kim* fibers (that hold the two *Kim* end plates together) into the *Francis* structure is to construct an implant that would be unsatisfactory for the purposes of *Kim.* The resulting structure would not have the natural-disc-like compressibility required of the *Kim* device because of the presence of the *Francis* central stiffer rotating element.

Additionally, the two devices are designed for two different purposes: the *Kim* device is a replacement for a total disc and the *Francis* device is a replacement only for the *nucleus pulposus.* The Office Action proposes no practical, technology-based reason for including the *Kim* fibers in the *Francis* device. The *Francis* disclosure clearly indicates that the *annulus fibrosus* located between two vertebrae (see, No. 130 in Figs. 1and 1A; No. 230 in Fig. 2; No. 330 in Fig. 3; and No. 430 in Fig.4) is to be left in place and the *Francis* device inserted within it. Consequently, since the function of the *annulus fibrosus* remains during the intended use *Francis* device, adding the Kim fibers would be at least redundant in the functioning of the *Francis* device. In the absence of Applicant's disclosure, no technical, common-sense reason for

combining the teachings is present.

Withdrawal of the rejection is requested.

REJECTION of CLAIMS 6-9

Claims 6-9 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent Pub. No. 2007/0239279 to Francis in view of U.S. Patent No. 7,153,325 to Kim et al and further in view of U.S. Patent Pub. No. 2007/0270952 to Wistrom et al. In support of the rejection, the Examiner states:

> "As to Claim 8, Francis discloses a kit wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width [0035-0036].
>
> "As to Claim 9, Francis discloses a kit wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1 [0036 and 0038].
>
> "As to Claims 6-9, Francis and Kim disclose the claimed invention except for a kit comprising exactly two of the prosthetic disc, and at least one cannula suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs.
>
> "Wistrom discloses a kit (100) comprising exactly two prosthetic discs (100), and at least one cannula (700) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs [0011 and 0027] in order to facilitate delivery of multiple implants using a minimally invasive procedure [0011 and 0027].
>
> "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of Francis and Kim with the delivery cannula modifications of Wistrom in order to facilitate delivery of multiple implants using a minimally invasive procedure."

Applicant disagrees. Claims 6-9 depend from claim 1 or rely upon claim 1 for content. As discussed above, the combination of *Francis* and *Kim* does not show the device required by claim 1. The *Wistrom* disclosure does not remedy those shortcomings.

Withdrawal of the rejection is requested.

The Examiner argues in a section entitled **RESPONSE TO ARGUMENTS:**

"As to claim 1, Applicant argues that 'Placing the Kim fibers (that hold the two Kim end plates together) into the Francis structure is to construct an implant that would be unsatisfactory for the purposes of Kim. The resulting structure would not have the natural-disc-like compressibility required of the Kim device because of the presence of the Francis central stiffer rotating element,' and that 'Consequently, since the function of the annulus fibrosis remains during the intended use Francis device, adding the Kim fibers would be at least redundant in the functioning of the Francis device. In the absence of Applicant's disclosure, no technical, common-sense reason for combining the teachings is present.'

"Examiner respectfully disagrees. [0016] of Francis discusses an elastic body surrounding a core support structure. [0017] describes that the rotatable core member can be constructed of an *elastic polymer*, indicating that the core is compressible. The elastic body of Francis allows for the implant to support natural compression of the spine, as described in [0038], with various compressive strengths, as described in [0049]. The fibers of Kim, as described in Col. 5, Lines 44-54, are compressible members designed to support, yet mimic the elastic properties of a natural disc. Examiner maintains that the combination of the rotatable, compressible core member of Francis, with the fibrous member of Kim would not destroy the functionality of the implant, as the motivation lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International* Co. *v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Examiner maintains the rationale as explained above, as the motivation to combine the rotatable core of Francis with the fibrous member of Kim lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc."

Applicant again disagrees that the combination of Kim and Francis renders the claims unpatentable under 35 USC 103. The purported technical explanation providing motivation to introduce the fibrous member of Kim into the Francis structure lacks a reasonable scientific, medical basis.

In addition to ignoring the functions of the Kim components (as discussed above and in the Response to the prior Office Action), the combination of components urged in the Office Action, e.g., placing the Kim fibers between the Francis vertebral support structures (e.g., 204A and 204B) and around the rather portly Francis elastic body 209 ignores the both the function of that elastic body by constraining its elastic movement and compressibility and the function of the Kim fibers in mimicking the actions of a natural *annulus fibrosis*.

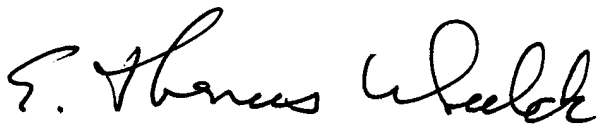
The Examiner relies only upon hindsight arguments based upon Applicant's specification for the combination structure recited in the Office Action. Applicant requests withdrawal of the rejection and allowance of the pending claims.

SUMMARY

Applicant has responded to each matter of substance in the Office Action and requests allowance of the application.

Should the Examiner have any questions or believe that a telephonic interview would be beneficial, he is urged and invited to call Applicant's attorney, E. Thomas Wheelock (Reg. No. 28,825), at 650-302-6286.

Respectfully submitted,



E. Thomas Wheelock
(Reg. No. 28,825)

650-302-6286
650-858-2131 (fax)

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Doc Code: TRAN.LET Best Available Copy

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	10

Application Number	12/060,856
Filing Date	April 1, 2013
First Named Inventor	Janine C. Robinson
Art Unit	3775
Examiner Name	Christopher J. BECCIA
Attorney Docket Number	SK20025.00

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☑ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  - Check for $700
  - Return receipt postcard

Remarks

Appeal fee was paid previously

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Spinal Kinetics, Inc. attn.: E.T. Wheelock		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	September 16, 2013	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	September 16, 2013

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Best Available Copy

PTO/SB/22 (03-13)
Approved for use through 3/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): SK20025.00

Application Number: 12/060,856

Filed: April 1, 2008

For: Prosthetic Intervertebral Discs having Rotatable, Expandible etc.

Art Unit: 3775

Examiner: Christopher J. BECCIA

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$
☐ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☑ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$ 700
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☑ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☑ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number _____.

☐ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).

☐ attorney or agent of record. Registration number _____.

☑ attorney or agent acting under 37 CFR 1.34. Registration number 28,825.

E. Thomas Wheelock — Signature

September 16, 2013 — Date

E. Thomas Wheelock — Typed or printed name

650-302-6286 — Telephone Number

09/30/2013 ZJUHAR1 00000003 12060856
01 FC:2253 700.00 OP

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

PTO/SB/31 (09-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

NOTICE OF APPEAL FROM THE EXAMINER TO THE PATENT TRIAL AND APPEAL BOARD

Docket Number (Optional): SK20025.00

I hereby certify that this correspondence is being facsimile transmitted to the USPTO EFS-Web transmitted to the USPTO, or or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on September 16, 2013

Signature E. Thomas Wheelock

Typed or printed name E. Thomas Wheelock

In re Application of: Janine C. ROBINSON

Application Number	Filed
12/060,856	April 1, 2008

For: Prosthetic Intervertebral Discs etc.

Art Unit	Examiner
3775	Christopher J. BECCIA

Applicant hereby **appeals** to the Patent Trial and Appeal Board from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 800

☑ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ 400

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____ .

☑ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☐ attorney or agent of record. Registration number _____ .

☑ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. 28,825

E. Thomas Wheelock
Signature

E.Thomas Wheelock
Typed or printed name

650-302-6286
Telephone number

September 16, 2013
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson	S0134.0033	7469

91477 7590 09/24/2013

Dickstein Shapiro LLP
1633 Broadway
New York, NY 10019

EXAMINER	
BECCIA, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
09/24/2013	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Abandonment	Application No.	Applicant(s)
	12/060,856	ROBINSON, JANINE C.
	Examiner	Art Unit
	CHRISTOPHER BECCIA	3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *14 March 2013*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☒ The reason(s) below:

No reply has been received in six months since the mailing of the last Office Action on March 14, 2013. A telephone call was made to E. Thomas Wheelock on September 18, 2013 who confirmed the abandonment.

	/CHRISTOPHER BECCIA/ Examiner, Art Unit 3775

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson	S0134.0033	7469

91477 7590 03/14/2013

Dickstein Shapiro LLP
2049 Century Park East
Suite 700
Los Angeles, CA 90067

EXAMINER	
BECCIA, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
03/14/2013	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/060,856	ROBINSON, JANINE C.	
	Examiner	Art Unit	
	CHRISTOPHER BECCIA	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2013*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1 and 3-9* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1 and 3-9* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *01 December 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. As to claim 1, Applicant argues that "Placing the Kim fibers (that hold the two Kim end plates together) into the Francis structure is to construct an implant that would be unsatisfactory for the purposes of Kim. The resulting structure would not have the natural-disc-like compressibility required of the Kim device because of the presence of the Francis central stiffer rotating element," and that "Consequently, since the function of the annulus fibrosis remains during the intended use Francis device, adding the Kim fibers would be at least redundant in the functioning of the Francis device. In the absence of Applicant's disclosure, no technical, common-sense reason for combining the teachings is present."

Examiner respectfully disagrees. [0016] of Francis discusses an elastic body surrounding a core support structure. [0017] describes that the rotatable core member can be constructed of an *elastic polymer,* indicating that the core is compressible. The elastic body of Francis allows for the implant to support natural compression of the spine, as described in [0038], with various compressive strengths, as described in [0049]. The fibers of Kim, as described in Col. 5, Lines 44-54, are compressible members designed to support, yet mimic the elastic properties of a natural disc. Examiner maintains that the combination of the rotatable, compressible core member of Francis, with the fibrous member of Kim would not destroy the functionality of the implant, as the motivation lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc.

2. In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Examiner maintains the rationale as explained above, as the motivation to combine the rotatable core of Francis with the fibrous member of Kim lies in allowing for a strong, load bearing implant that remains compressible, mimicking the mechanical properties of a natural, healthy disc.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 1 and 3-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2007/0239279 to *Francis* in view of U.S. Patent No. 7,153,325 to *Kim et al.*

As to **Claim 1,** *Francis* discloses a prosthetic intervertebral disc (100), comprising a first end plate (104A), a second end plate (104B), and at least one compressible core member (102) configured so that it may be introduced in a first lower profile and positioned between the first and second end plates and be rotated to a second higher profile while located between the first and second end plates [0037-0038]. Further, *Francis* teaches an elastic body (109) to support the core (102), and distribute load [0038].

As to **Claim 3,** *Francis* discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (Fig. 1A)

As to **Claim 4,** *Francis* discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 1).

As to **Claim 5,** *Francis* discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 1A).

As to **Claims 1 and 3-5,** *Francis* discloses the claimed invention except for at least one fiber extending between and engaged with the first and second end plates, and wherein the end plates and the core member are held together by the at least one fiber.

Kim discloses a prosthetic disc implant (70, Fig. 7) including at least one fiber (73) extending between and engaged with the first (71A) and second end plates (71B), and wherein the end plates and the core member (76) are held together by the at least

one fiber (Col. 9, Lines 4-11) in order to achieve similar mechanical properties of a healthy disc (Col. 5, Lines 44-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the prosthetic disc implant of *Francis* with the fibrous reinforcement modification of *Kim* in order to achieve similar mechanical properties of a healthy disc.

3. **Claims 6-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2007/0239279 to *Francis* in view of U.S. Patent No. 7,153,325 to *Kim et al.* in further view of U.S. Patent Pub. No. 2007/0270952 to *Wistrom et al.*

As to **Claim 8,** *Francis* discloses a kit wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width [0035-0036].

As to **Claim 9,** *Francis* discloses a kit wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1 [0036 and 0038].

As to **Claims 6-9,** *Francis* and *Kim* disclose the claimed invention except for a kit comprising exactly two of the prosthetic disc, and at least one cannula suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs.

Wistrom discloses a kit (100) comprising exactly two prosthetic discs (100), and at least one cannula (700) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs [0011 and 0027] in order to facilitate delivery of multiple implants using a minimally invasive procedure [0011 and 0027].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of *Francis* and *Kim* with the delivery cannula modifications of *Wistrom* in order to facilitate delivery of multiple implants using a minimally invasive procedure.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Beccia whose telephone number is

(571)270-7391. The examiner can normally be reached on Mon-Fri from 9:00am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Kevin Truong, at* (571) 272-4705**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Kevin T Truong/
Supervisory Patent Examiner, Art Unit 3775

Notice of References Cited	Application/Control No. 12/060,856	Applicant(s)/Patent Under Reexamination ROBINSON, JANINE C.	
	Examiner CHRISTOPHER BECCIA	Art Unit 3775	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,911,718 A	03-1990	Lee et al.	623/17.15
*	B	US-5,658,336 A	08-1997	Pisharodi, Madhavan	623/17.16
*	C	US-5,888,224 A	03-1999	Beckers et al.	623/17.16
*	D	US-2002/0151976 A1	10-2002	Foley et al.	623/17.11
*	E	US-2004/0093082 A1	05-2004	Ferree, Bret A.	623/017.11
*	F	US-2004/0106999 A1	06-2004	Mathews, Hallett H.	623/017.16
*	G	US-2005/0043796 A1	02-2005	Grant et al.	623/017.11
*	H	US-2005/0216088 A1	09-2005	McKinley et al.	623/017.16
*	I	US-7,153,325 B2	12-2006	Kim et al.	623/17.15
*	J	US-2007/0239279 A1	10-2007	Francis, Thomas J.	623/017.16
*	K	US-2007/0270952 A1	11-2007	Wistrom et al.	623/017.11
*	L	US-7,655,046 B2	02-2010	Dryer et al.	623/17.15
*	M	US-7,776,094 B2	08-2010	McKinley et al.	623/17.16

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	"12060856"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:24
S2	38	robinson-janine-c.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:25
S3	4708	623/17.11-17.16.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:25
S5	654	S3 and rotatable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:32
S6	30	S3 and (rotatable with insert)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:33
S7	6	US-5658336-$.DID. OR US-5159244-$.DID. OR US-5962608-$.DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:50
S8	92	("3334624" | "3486505" | "4349921" | "4657550" | "4696290" | "4711232" | "4759769" | "4834757" | "4863476" | "4932975" | "5015247" | "5059193" | "5129899" | "5171278" | "5306309" | "5324292" | "5401269" | "5443514" | "5505732").PN. OR ("5658336").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/10/26 14:50
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S19	112	S14 and (disc with rotatable)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2012/07/30 16:04
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EAST Search History (Interference)

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12060856	ROBINSON, JANINE C.
	Examiner	**Art Unit**
	CHRISTOPHER BECCIA	3775

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/26/2010	07/06/2011	07/31/2012	03/08/2013					
	1	✓	✓	✓	✓					
	2	✓	✓	-	-					
	3	✓	✓	✓	✓					
	4	✓	✓	✓	✓					
	5	✓	✓	✓	✓					
	6	✓	✓	✓	✓					
	7	✓	✓	✓	✓					
	8	✓	✓	✓	✓					
	9	✓	✓	✓	✓					

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12060856	ROBINSON, JANINE C.
	Examiner	Art Unit
	CHRISTOPHER BECCIA	3775

CPC- SEARCHED		
Symbol	Date	Examiner

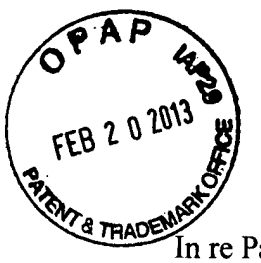
CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	10/26/2010	CJB
606	60, 246-279, 86A	7/31/2012	CJB

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search Attached	10/26/2010	CJB
Inventor Search	10/26/2010	CJB
EAST Search Attached	7/6/2011	CJB
EAST Search Attached	7/31/2012	CJB
EAST Search Attached	3/8/2013	CJB

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/CHRISTOPHER BECCIA/ Examiner.Art Unit 3775	



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Janine C. ROBINSON

Application No.: 12/060,856

Filing Date: 01 April 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

Confirmation No.: 7469

Examiner: BECCIA, Christopher J.
Art Unit: 3775

RESPONSE TO NON-FINAL OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action mailed August 9, 2012 in which claims 1 and 3-5 were rejected under 35 USC 103.

Applicant has not amended, cancelled, nor added claims. Consequently, claims 1 and 3-9 are under consideration. Allowance is requested.

A **REMARKS** section begins on the following page.

A **SUMMARY** section is on page 5.

REMARKS

Applicant acknowledges that after the conclusion of prosecution, including the filing of an Appeal Brief to the Board of Patent Appeals and Interferences (an administrative board that is no longer in existence) that prosecution on the merits has been reopened. As a preliminary formal matter, Applicant exercises the option of filing this Response under 37 CFR 1.111.

Applicant further acknowledges that the formerly extant rejection under 35 USC 103 has now been withdrawn.

REJECTION of CLAIMS 1 AND 3-5

Claims 1 and 3-5 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent Pub. No. 2007/0239279 to Francis in view of U.S. Patent No. 7,153,325 to Kim et al. In support of the rejection, the Examiner states:

> "As to Claim 1, Francis discloses a prosthetic intervertebral disc (100), comprising a first end plate (104A), a second end plate (104B), and at least one compressible core member (102) configured so that it may be introduced in a first lower profile and positioned between the first and second end plates and be rotated to a second higher profile while located between the first and second end plates [0037-0038]. Further, Francis teaches an elastic body (109) to support the core (102), and distribute load [0038].
>
> "As to Claim 3, Francis discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (Fig. 1A)
>
> "As to Claim 4, Francis discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 1).
>
> "As to Claim 5, Francis discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 1A).
>
> "As to Claims 1 and 3-5, Francis discloses the claimed invention except for at least one fiber extending between and engaged with the first and second end plates, and wherein the end plates and the core member are held together by the at least one fiber.
>
> "*Kim* discloses a prosthetic disc implant (70, Fig. 7) including at least one fiber (73) extending between and engaged with the first (71 A) and second end plates (71 B), and wherein the end plates and the core member (76) are held together by the at least one fiber (Col. 9, Lines 4-11) in order to achieve similar mechanical properties of a healthy disc (Col. 5, Lines 44-54).
>
> "It would have been obvious to one having ordinary skill in the art at the time the invention

> was made to modify the prosthetic disc implant of *Francis* with the fibrous reinforcement modification of *Kim* in order to achieve similar mechanical properties of a healthy disc."

Applicant disagrees that the combination of *Francis* with *Kim* renders the claims unpatentable under 35 USC 103.

As the Examiner notes, *Francis* describes a nucleus replacement implant (100) made up of a first end plate (104A) and a second end plate (104B) and having a rotatable member (102) located between the end plates. Member (102) may be rotated from a first horizontal orientation to a second vertical orientation to change the spacing between the end plates. However, the noted parts make up a subcomponent denominated by Francis as a "core support member." The "core support member" is necessarily surrounded by an "elastic body 109" forming the remainder of the implant. The "core support member" -- i.e., the rotatable member (102) and the two end plates (104A, 104B) -- may only be fabricated from "metal, a non-elastic biocompatible material, or an elastic polymer (of higher stiffness than the elastic body)." See, Para. [0035]. These compositional requirements mean that the center of the *Francis* implant is necessarily stiffer than the edges of the implant. It is clear that such a structure does not have the compressibility of the natural disc and will rock or pivot about the *Francis* implant's center when placed in a spine between two vertebrae.

The *Kim* device shows an intervertebral total disc replacement having a structure with end plates, a compressible core, and includes fibers that hold the component end plates together. The *Kim* structure, in contrast to the *Francis* structure, is designed to emulate the motion of a natural disc:

> "The subject discs are characterized in that they include both an upper (or top) and lower (or bottom) endplate, where the upper and lower endplates are separated from each other by a fibrous compressible element, where the combination structure of the endplates and fibrous compressible element provides a prosthetic disc that functionally closely mimics real disc." Kim, Para. [0032].

Placing the *Kim* fibers (that hold the two *Kim* end plates together) into the *Francis* structure is to construct an implant that would be unsatisfactory for the purposes of *Kim.* The resulting structure would not have the natural-disc-like compressibility required of the *Kim* device because of the presence of the *Francis* central stiffer rotating element.

Additionally, the two devices are designed for two different purposes: the *Kim* device is a replacement for a total disc and the *Francis* device is a replacement only for the *nucleus pulposus.* The Office Action proposes no practical, technology-based reason for including the *Kim* fibers in the *Francis* device. The *Francis* disclosure clearly indicates that the *annulus fibrosus* located between two vertebrae (see, No. 130 in Figs. 1and 1A; No. 230 in Fig. 2; No. 330 in Fig. 3; and No. 430 in Fig.4) is to be left in place and the *Francis* device inserted within it. Consequently, since the function of the *annulus fibrosus* remains during the intended use *Francis* device, adding the Kim fibers would be at least redundant in the functioning of the *Francis* device. In the absence of Applicant's disclosure, no technical, common-sense reason for combining the teachings is present.

Withdrawal of the rejection is requested.

REJECTION of CLAIMS 6-9

Claims 6-9 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent Pub. No. 2007/0239279 to Francis in view of U.S. Patent No. 7,153,325 to Kim et al and further in view of U.S. Patent Pub. No. 2007/0270952 to Wistrom et al. In support of the rejection, the Examiner states:

> "As to Claim 8, Francis discloses a kit wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width [0035-0036].
>
> "As to Claim 9, Francis discloses a kit wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1 [0036 and 0038].
>
> "As to Claims 6-9, Francis and Kim disclose the claimed invention except for a kit comprising exactly two of the prosthetic disc, and at least one cannula suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs.
>
> "Wistrom discloses a kit (100) comprising exactly two prosthetic discs (100), and at least one cannula (700) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs [0011 and 0027] in order to facilitate delivery of multiple implants using a minimally invasive procedure [0011 and 0027].

> "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of Francis and Kim with the delivery cannula modifications of Wistrom in order to facilitate delivery of multiple implants using a minimally invasive procedure."

Applicant disagrees. Claims 6-9 depend from claim 1 or rely upon claim 1 for content. As discussed above, the combination of *Francis* and *Kim* does not show the device required by claim 1. The *Wistrom* disclosure does not remedy those shortcomings.

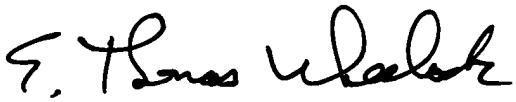
Withdrawal of the rejection is requested.

SUMMARY

Applicant has responded to each matter of substance in the Office Action and requests allowance of the application.

Should the Examiner have any questions or believe that a telephonic interview would be beneficial, he is urged and invited to call Applicant's attorney, E. Thomas Wheelock (Reg. No. 28,825), at 650-302-6286.

Respectfully submitted,



E. Thomas Wheelock
(Reg. No. 28,825)
(signed under 37 CFR 1.34)

650-302-6286
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Doc Code: TRAN.LET
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	8

Application Number	12/060,856
Filing Date	01 April 2008
First Named Inventor	Janine C. ROBINSON
Art Unit	3775
Examiner Name	BECCIA, Christopher J.
Attorney Docket Number	SK20025.00

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  --- check for $645
  --- return receipt postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Spinal Kinetics Inc.; attn.: E. Thomas Wheelock		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	February 11, 2013	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	February 11, 2013

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/22 (10-12)
Approved for use through 1/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): SK20025.00

Application Number	Filed
12/060,856	01 April 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

Art Unit	Examiner
3775	BECCIA, Christopher J.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$150	$75	$
☐ Two months (37 CFR 1.17(a)(2))	$570	$285	$
■ Three months (37 CFR 1.17(a)(3))	$1,290	$645	$ 645
☐ Four months (37 CFR 1.17(a)(4))	$2,010	$1,005	$
☐ Five months (37 CFR 1.17(a)(5))	$2,730	$1,365	$

■ Applicant claims small entity status. See 37 CFR 1.27.

■ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number _____.

☐ Payment made via EFS-Web.

02/20/2013 ZJUHAR1 00000071 12060856
01 FC:2253 645.00 OP

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).

☐ attorney or agent of record. Registration number _____.

■ attorney or agent acting under 37 CFR 1.34. Registration number 28,825.

E. Thomas Wheelock
Signature

February 11, 2013
Date

E. Thomas Wheelock
Typed or printed name

650-302-6286
Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

■ * Total of 1 forms are submitted.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/060,856	Filing Date 04/01/2008	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	02/20/2013	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 9	Minus	** 20	= 0	X $31 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $125 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/GOIGA DUCKETT/

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson	S0134.0033	7469

91477 7590 08/09/2012

Dickstein Shapiro LLP
2049 Century Park East
Suite 700
Los Angeles, CA 90067

EXAMINER	
BECCIA, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
08/09/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/060,856	ROBINSON, JANINE C.	
	Examiner	Art Unit	
	CHRISTOPHER BECCIA	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1 and 3-9* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1, 3-9* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *01 December 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. In view of the Appeal Brief filed on July 17, 2012, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Kevin T Truong/

Supervisory Patent Examiner, Art Unit 3775.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 1 and 3-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2007/0239279 to *Francis* in view of U.S. Patent No. 7,153,325 to *Kim et al.*

As to **Claim 1,** *Francis* discloses a prosthetic intervertebral disc (100), comprising a first end plate (104A), a second end plate (104B), and at least one compressible core member (102) configured so that it may be introduced in a first lower profile and positioned between the first and second end plates and be rotated to a second higher profile while located between the first and second end plates [0037-0038]. Further, *Francis* teaches an elastic body (109) to support the core (102), and distribute load [0038].

As to **Claim 3,** *Francis* discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (Fig. 1A)

As to **Claim 4,** *Francis* discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 1).

As to **Claim 5,** *Francis* discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 1A).

As to **Claims 1 and 3-5,** *Francis* discloses the claimed invention except for at least one fiber extending between and engaged with the first and second end plates, and wherein the end plates and the core member are held together by the at least one fiber.

Kim discloses a prosthetic disc implant (70, Fig. 7) including at least one fiber (73) extending between and engaged with the first (71A) and second end plates (71B), and wherein the end plates and the core member (76) are held together by the at least one fiber (Col. 9, Lines 4-11) in order to achieve similar mechanical properties of a healthy disc (Col. 5, Lines 44-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the prosthetic disc implant of *Francis* with the fibrous reinforcement modification of *Kim* in order to achieve similar mechanical properties of a healthy disc.

3. **Claims 6-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2007/0239279 to *Francis* in view of U.S. Patent No. 7,153,325 to *Kim et al.* in further view of U.S. Patent Pub. No. 2007/0270952 to *Wistrom et al.*

As to **Claim 8,** *Francis* discloses a kit wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width [0035-0036].

As to **Claim 9,** *Francis* discloses a kit wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1 [0036 and 0038].

As to **Claims 6-9,** *Francis* and *Kim* disclose the claimed invention except for a kit comprising exactly two of the prosthetic disc, and at least one cannula suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal

cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs.

Wistrom discloses a kit (100) comprising exactly two prosthetic discs (100), and at least one cannula (700) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs [0011 and 0027] in order to facilitate delivery of multiple implants using a minimally invasive procedure [0011 and 0027].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of *Francis* and *Kim* with the delivery cannula modifications of *Wistrom* in order to facilitate delivery of multiple implants using a minimally invasive procedure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Beccia whose telephone number is (571)270-7391. The examiner can normally be reached on Mon-Fri from 9:00am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Kevin Truong, at* (571) 272-4705**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Kevin T Truong/
Supervisory Patent Examiner, Art Unit 3775

Notice of References Cited	Application/Control No. 12/060,856	Applicant(s)/Patent Under Reexamination ROBINSON, JANINE C.	
	Examiner CHRISTOPHER BECCIA	Art Unit 3775	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,911,718 A	03-1990	Lee et al.	623/17.15
*	B	US-5,658,336 A	08-1997	Pisharodi, Madhavan	623/17.16
*	C	US-5,888,224 A	03-1999	Beckers et al.	623/17.16
*	D	US-2002/0151976 A1	10-2002	Foley et al.	623/17.11
*	E	US-2004/0093082 A1	05-2004	Ferree, Bret A.	623/017.11
*	F	US-2004/0106999 A1	06-2004	Mathews, Hallett H.	623/017.16
*	G	US-2005/0043796 A1	02-2005	Grant et al.	623/017.11
*	H	US-2005/0216088 A1	09-2005	McKinley et al.	623/017.16
*	I	US-7,153,325 B2	12-2006	Kim et al.	623/17.15
*	J	US-2007/0239279 A1	10-2007	Francis, Thomas J.	623/017.16
*	K	US-2007/0270952 A1	11-2007	Wistrom et al.	623/017.11
*	L	US-7,655,046 B2	02-2010	Dryer et al.	623/17.15
*	M	US-7,776,094 B2	08-2010	McKinley et al.	623/17.16

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12060856	ROBINSON, JANINE C.
	Examiner	Art Unit
	CHRISTOPHER BECCIA	3775

SEARCHED

Class	Subclass	Date	Examiner
623	17.11-17.16	10/26/2010	CJB
606	60, 246-279, 86A	7/31/2012	CJB

SEARCH NOTES

Search Notes	Date	Examiner
EAST Search Attached	10/26/2010	CJB
Inventor Search	10/26/2010	CJB
EAST Search Attached	7/6/2011	CJB
EAST Search Attached	7/31/2012	CJB

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

/CHRISTOPHER BECCIA/ Examiner.Art Unit 3775	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12060856	ROBINSON, JANINE C.
	Examiner	**Art Unit**
	CHRISTOPHER BECCIA	3775

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/26/2010	07/06/2011	07/31/2012						
	1	✓	✓	✓						
	2	✓	✓	-						
	3	✓	✓	✓						
	4	✓	✓	✓						
	5	✓	✓	✓						
	6	✓	✓	✓						
	7	✓	✓	✓						
	8	✓	✓	✓						
	9	✓	✓	✓						

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	"12060856"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:24
S2	38	robinson-janine-c.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:25
S3	4708	623/17.11-17.16.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:25
S5	654	S3 and rotatable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:32
S6	30	S3 and (rotatable with insert)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:33
S7	6	US-5658336-$.DID. OR US-5159244-$.DID. OR US-5962608-$.DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:50
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S10	162	("20020058950" | "20030105528" |	US-PGPUB;	ADJ	ON	2010/10/26

		"3486505" | "3518993" | "3604487" | "3745995" | "3848601" | "4026304" | "4026305" | "4646738" | "4657550" | "4743256" | "4781591" | "4834757" | "4877020" | "4878915" | "4932975" | "4961740" | "4962766" | "5026373" | "5055104" | "5062845" | "5092572" | "5133717" | "5133755" | "5171278" | "5192327" | "5217497" | "5269785" | "5284153" | "5290494" | "5300076" | "5304210" | "5306307" | "5306309" | "5322505" | "5334205" | "5336223" | "5364400" | "5395372" | "5397363" | "5405391" | "5413602" | "5425772" | "5431658" | "5443514" | "5443515" | "5445639" | "5454811" | "5458638" | "5484403" | "5489308" | "5505732" | "5522879" | "5522899" | "5524624" | "5527312" | "5534029" | "5534030" | "5540688" | "5545222" | "5562736" | "5565005" | "5571190" | "5571192" | "5593409" | "5609636" | "5611800" | "5611810" | "5632747" | "5645598" | "5653761" | "5653762" | "5658336" | "5658337" | "5662710" | "5665122" | "5669909" | "5676703" | "5683394" | "5683400" | "5683464" | "5690629" | "5700264" | "5700291" | "5700292" | "5702449" | "5702451" | "5702453" | "5702454" | "5702455" | "5703451" | "5707373" | "5711957" | "5716415" | "5720748" | "5720751" | "5723013" | "5741261" | "5755797" | "5766252" | "5772661" | "5775331" | "5779642" | "5782830" | "5782919" | "5785710" | "5797909" | "5800549" | "5800550" | "5814084" | "5851208" | "5865845" | "5865847" | "5865848" | "5885299" | "5888219" | "5888224" | "5893890" | "5904719" | "5910315" | "5954769" | "5961554" | "5968098").PN. OR ("5993474" | "6004326" | "6015436" | "6033405" | "6039761" | "6042582" | "6045580" | "6048342" | "6059790" | "6063088" | "6083225" | "6096080" | "6102948" | "6120506" | "6132472" | "6159211" | "6159215" | "6193756" | "6200347" | "6224607" | "6224631" | "6241769" | "6241771" | "6251140" | "6258125" | "6277149" | "6319257" | "6371989" | "6440142" | "6442814" | "6454806" | "6527773" | "6595998" | "6635086" | "6648895" | "6887248").PN. OR ("7776094").URPN.	USPAT; USOCR			16:06
S11	53	S3 and ((mesh or fiber) with insert)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 16:34
S12	3	"20050216088"	US-PGPUB; USPAT; USOCR;	ADJ	ON	2010/10/26 17:06

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S13	7	("4911718" | "5192327" | "5211664" | "5429863" | "5906616" | "5968098" | "6224631").PN. OR ("7341600").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/10/26 17:29
S14	5947	623/17.11-17.16.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2012/07/30 15:50
S15	860	S14 and rotatable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2012/07/30 15:50
S16	298	S15 and fiber	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2012/07/30 15:50
S17	32	US-20050216088-$.DID. OR US-2301716-$.DID. OR US-5916267-$.DID. OR US-6231711-$.DID. OR US-20050027364-$.DID. OR US-2301713-$.DID. OR US-20050159814-$.DID. OR US-6344057-$.DID. OR US-6086613-$.DID. OR US-6231716-$.DID. OR US-20060265075-$.DID. OR US-5458641-$.DID. OR US-5702455-$.DID. OR US-6231715-$.DID. OR US-6190413-$.DID. OR US-5879385-$.DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/07/30 15:52
S18	3	"20050027364"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/07/30 15:53
S19	112	S14 and (disc with rotatable)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2012/07/30 16:04
S20	25	("20020026244" | "20020111686" | "20020128715" | "20020177897" | "20030074074" | "20030199983" | "20030199984" | "20040093082" | "20040117019" | "20040236425" | "20050043796" | "20050187632" | "20050228500" | "20050256576" | "3867728" | "4932969" | "6620196" |	US-PGPUB; USPAT; USOCR	OR	OFF	2012/07/30 16:11

		"6960232" | "7008453" | "7018415").PN. OR ("7766967").URPN.				
S21	252	("3486505" | "4349921" | "4599086" | "4772287" | "4834757" | "4863476" | "4878915" | "5015247" | "5092893" | "5171278" | "5192327" | "5306307" | "5425772" | "5443514" | "5458638" | "5489308" | "5658337").PN. OR ("5888224").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/07/30 22:57
S22	5954	623/17.11-17.16.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2012/07/31 15:14
S23	124	S22 and (cannula with (delivery and two))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2012/07/31 15:14
S24	0	S22 and (cannula with (delivery and second implant))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2012/07/31 15:23
S25	154	S22 and (cannula with (delivery and second))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2012/07/31 15:23

EAST Search History (Interference)

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7/31/2012 5:18:14 PM
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Docket No.: S0134.0033
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE USPTO BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Janine C. Robinson

Application No.: 12/060,856 | Confirmation No.: 7469

Filed: 04/01/2008 | Art Unit: 3775

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USIING MINIMALLY INVASIVE SURGICAL TECHNIQUES | Examiner: C. J. Beccia

APPEAL BRIEF

EFS Web
Commissioner for Patents

Dear Sir:

Pursuant to 37 C.F.R. 41.37, Appellant states as follows:

REAL PARTY IN INTEREST

The real party in interest is Spinal Kinetics, Inc.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 1 and 3-9 are pending in this application. Claims 1-9 have been rejected. Claim 2 has been canceled. No claims have been allowed or withdrawn.

The rejection of claims 1 and 3-9 is appealed.

STATUS OF AMENDMENTS

No claim amendments were made prior to the final rejection. Claim 2 has been canceled in this appeal brief. The canceling of claim 2 has necessitated no amendments to the dependencies of the remaining dependent claims 3-9.

SUMMARY OF CLAIMED SUBJECT MATTER

The spinal disc is an area of soft and compressible tissue positioned between the hard and rigid vertebral bones of the spinal column. The spinal disc may be displaced or damaged due to injury or disease, at which point the nucleus pulposus (the inner jelly-like material of the disc) may protrude from between the harder opposing vertebral bones into the vertebral canal or intervertebral foramen. Such deformation is known as a herniated or slipped disc.

The present application is directed to spinal implants that may be surgically implanted into the spine to replace these (and other) types of damaged or diseased discs, preferably using a posterior approach. The spinal implants include a first end plate, a second end plate, at least one compressible core member, and at least one fiber.

Mapping of Claim 1 to the Written Support of the Original Specification

The application on appeal contains a single independent claim, which is claim 1. Support for claim 1 will be cited generally with respect to original claim 1, FIGs. 2-3(c), and the text corresponding to these figures. Other locations will also be cited. However, it should be understood that these citations are not exhaustive and not all support has been cited herein.

Claim 1 recites "a prosthetic intervertebral disc." Support for this claim language can be found at, e.g.: FIGs. 2-3(c); page 2, paragraph [007]; and page 21, original claim 1.

Claim 1 also recites "a first end plate" and "a second end plate." Support for this claim language can be found at, e.g.: FIGs. 2-3(c); pages 2-3, paragraphs [007]-[008]; pages 8-10, paragraphs [030]-[032] and [035]; and page 21, original claim 1.

Claim 1 also recites "at least one compressible core member configured so that it may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second end plates." Support for this claim language can be found at, e.g.: FIGs. 2-3(c); pages 2-3, paragraphs [007]-[008]; pages 8-11, paragraphs [031]-[033] and [037]-[038]; pages 15-18, paragraphs [050]-[061]; and page 21, original claim 1.

Claim 1 also recites "at least one fiber extending between and engaged with said first and second end plates." Support for this claim language can be found at, e.g.: FIGs. 2-3(c);

pages 2-3, paragraphs [007]-[008]; pages 8-10, paragraphs [031]-[032] and [036]; pages 14-15, paragraphs [047]-[049]; and page 21, original claim 1.

Claim 1 also recites "wherein said end plates and said core member are held together by said at least one fiber." Support for this claim language can be found at, e.g.: FIGs. 2-3(c); page 14, paragraph [047]; and page 21, original claim 1.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pending claims 1 and 3-9 have been rejected under 35 USC. §103(a) as being unpatentable over U.S. Publ. No. 2005/0216088 ("McKinley") in view of U.S. Patent No. 4,911,718 ("Lee"). The appellant requests withdrawal of the rejections.

ARGUMENT

I. The Primary Reference in the Obviousness Combination (McKinley) Fails to Disclose a Compressible Core Member and End Plates

McKinley does not disclose the claimed "compressible core member" as the office action suggests. McKinley discloses a "bone block" made of human tissue that is inserted directly between two opposing vertebral bones in the human spine. See McKinley at ¶¶ 7-9 and 22. The "bone block" is seated such that it promotes "fusion," which is expressly defined by McKinley as "complete ingrowth of bone tissue between adjacent vertebrae." *Id*. at ¶ 9 and 67.

In other words, McKinley is replacing the spinal disc with a block of bone that fuses to the adjacent vertebrae, essentially creating a continuous span of bone where the space for the natural spinal disc used to be.

Claims are to be given their broadest reasonable interpretation consistent with the specification. MPEP §2111. The present specification and claims distinguish between prosthetic discs having a "compressible core member" and approaches like McKinley that rely on fusion. The background recognizes that "spinal fusion" causes "increased stiffness of the fused segment" and changes the mechanics of motion of the spine. See application at ¶ 5. This "increased stiffness" means that the adjacent discs must bear more load that causes those discs to degenerate. *Id*. Artificial disc replacement is given as the alternative to fusion, specifically with artificial discs that have "a compressible core member disposed between the two end plates," the compressible nature of the core member helping to provide "a prosthetic disc that functionally approaches or closely mimics a natural disc." *Id*. at ¶¶ 6 and 30. Thus, fusion-based approaches like McKinley do not have a "compressible core member" as that term is used in the claims and specification.

Furthermore, the "bone block" of McKinley is not at the "core" of any device. The bone blocks are themselves the entire implant of McKinley – there is no larger implant that the "bone block" is the "core" of. This is yet another reason why McKinley's bone block(s) cannot be a "compressible core member."

In this regard, the office action misrepresents McKinley as disclosing the claimed first and second end plates, presumably based on the extremely oversimplified representations of the vertebral bones (50 and 52) of the spine in, e.g., FIGs. 8-11B. McKinley does not disclose any "end plate," nor anything that can be interpreted as such. McKinley clearly states that reference numerals 50 and 52 are "adjacent vertebrae" to the bone block. See McKinley at ¶ 79. They are not end plates of an implantable device.[1] On these grounds alone the rejection set forth in the office action must fail.

II. Any Combination of McKinley with Lee Renders McKinley's Implant Unsatisfactory for Its Intended Purpose

The office action relies on McKinley, as a primary reference, in combination with Lee as a secondary reference. The office action incorrectly interprets McKinley as disclosing end plates, and uses Lee only for his disclosure of the alleged "at least one fiber." The failure of McKinley to disclose end plates is indicative of the impropriety of the rejection as formulated. However, should the Examiner reformulate the rejection such that the McKinley device is redesigned to also include the end plates of Lee, then this must fail as well.

Inclusion of the end plates from Lee in the device of McKinley would render McKinley inoperable and unsatisfactory for its intended purpose. As already discussed, McKinley's implant is a bone block that is intended "to promote bone fusion between the adjacent vertebrae." McKinley at ¶ 9. McKinley defines "fusion" as "***complete ingrowth of bone tissue between adjacent vertebrae***" (emphasis added). To accomplish this, McKinley teaches that the bone block must be positioned against and in contact with the vertebral bodies such that complete ingrowth between adjacent vertebrae can occur. *Id.* at ¶ 83 (e.g., "vertebral contact surfaces" of the bone block).

Without complete ingrowth, fusion does not occur according to McKinley. But the endplates of Lee are not bone tissue, and interposition of Lee's end plates between the bone block and the vertebral bodies of McKinley would prevent complete ingrowth of bone tissue

[1] The "first end plate" and "second end plate" are consistently described in the specification as components of the manmade prosthetic disc.

between adjacent vertebrae in the manner that McKinley describes. As such, McKinley's device would be unable to fuse the adjacent vertebral bodies, rendering it both inoperable and unsatisfactory for its intended purpose. See MPEP §2143.01 ("If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.").

III. Reforumlating the Rejection Such That Lee Is the Primary Reference Also Fails

Should the Examiner consider reformulating the rejection such that Lee is treated as the primary reference and McKinley's bone block is substituted for the alleged core member of Lee, then the appellant submits that this too will fail.

A. Use of McKinley's Bone Block with Lee's Artificial Disc Would Render Lee Unsatisfactory for Its Intended Purpose

Lee clearly states that the object of his invention is to provide an intervertebral disc "that is both strong and ***elastically comparable*** to the natural structure [i.e., disc]." Lee at col. 2, ll. 61-65. The natural human disc does not contain bone tissue. The bone is present in the vertebral bodies located on either side of the disc.

No one of skill in the art would use the bone tissue block of McKinley to construct an intervertebral disc that is "elastically comparable" to the natural disc. To propose such a combination is to fundamentally confuse the function and capabilities of the human vertebral bone body with those of the human intervertebral disc. Any device resulting from such a combination would not be elastically comparable to the natural disc, and would render Lee inoperable for its intended purpose. See MPEP § 2143.01.

B. Lee Teaches Away from a Combination with the Fusion Device of McKinley

As already discussed, McKinley's bone block is a fusion device and the present application explicitly teaches away from fusion-based solutions, primarily for the negative limitations that fusion has on the mobility of the spinal segments. Lee teaches away from the use of fusion-based devices for similar reasons:

> The fusion procedure is an excellent method of eliminating symptoms and yet maintaining joint stability, ***but at the expense of total loss of motion of the fused vertebral joint.*** The adjacent discs will have increased motion and stress due to the increased majority of the fused segment. In the long term, this change in mechanics of the motion of the spine causes these adjacent discs to ***degenerate***. *Id.* at col. 1, line 68 – col. 2, line 7 (emphasis added).

Lee instead teaches the use of a prosthetic intervertebral disc spacer that is "elastically comparable" to the natural [disc] structure and has "similar properties to that of a natural spinal disc in compression and torsion testing."

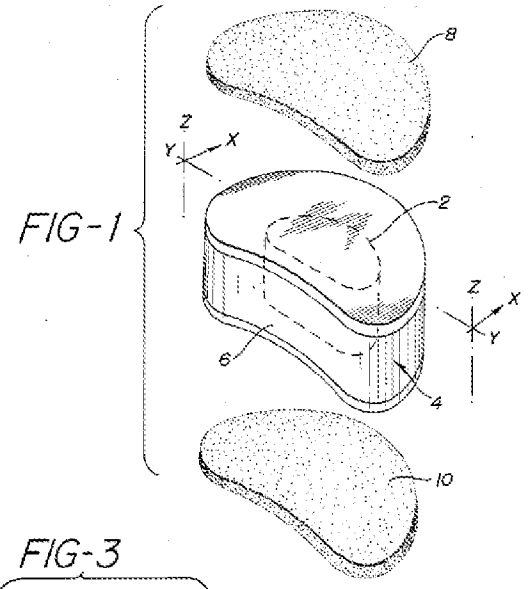
> It is the object of the present invention to provide a novel intervertebral disc spacer which can be used to replace a damaged or diseased disc with a device that is both strong and ***elastically comparable*** to the natural structure. *Id.* at col. 2, ll. 61-65 (emphasis added).
>
> . . .
>
> For instance, a disc spacer utilizing Biomer® as the elastomer, aluminum endplates, and having a wrapping configuration of 3 layers each of 0, +45, -45 degree fiber strips has been found ***to possess similar properties to that of a natural spinal disc in compression and torsion testing***. *Id.* at col. 6, ll. 61-66 (emphasis added).

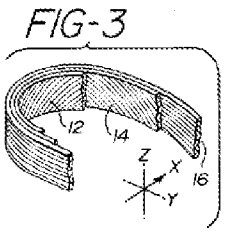
Thus, Lee explicitly recognizes the undesirability of the stiff and rigid fusion-based implants like McKinley and teaches those of ordinary skill in the art to use the more elastic and compressible artificial disc replacements instead. Because Lee teaches away from McKinley, no one of ordinary skill in the art would not seek to combine Lee with McKinley, and the rejection must fail. See MPEP § 2145 ("References Cannot Be Combined Where Reference Teaches Away from Their Combination").

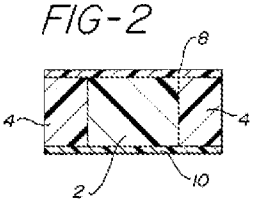
C. There Is No Motivation to Combine Lee and McKinley

Lee cannot be treated as the primary reference because there is no teaching or suggestion, in Lee or McKinley, as to how to combine the bone block of McKinley with Lee's device such that the bone block of McKinley "may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second plates" as recited in claim 1.

McKinley requires an elongate insertion tool (see e.g., reference 20 in FIG. 2) that mates with the bone block and rotates the bone block to the desired orientation within the intervertebral space. Lee's device comprises "a central core 2 of biocompatible elastomer," "laminae 4 wrapping said central core," and "endplates 8 and 10." Lee, col. 3, ll. 51-64. As shown in the figures reproduced below, there is no opening in the laminae (construed in the office action as containing the claimed "at least one fiber") that permits the passage of the insertion tool 20.







The laminae are shown most clearly in FIG. 3. They are a series of layered strips 12, 14, and 16 that surround the "central core 2" and are bonded to the end plates with elastomer or during a bonding or curing process. Lee at col. 6, ll. 16-23 and 49-66. There is no gap through which an insertion tool could be routed. This is in stark contradiction to the disclosure in McKinley, where there is no laminae surrounding the bone block and the insertion tool has unobstructed access to the bone block to permit rotation.

A combination of Lee and McKinley, such that Lee's "central core 2" is replaced with McKinley's bone block, is therefore non-sensical. The presence of the layered and continuous laminae of Lee prevents access by McKinley's insertion tool into the core region of Lee's disc. Thus, there can be no motivation to combine McKinley with Lee for the purpose of introducing a rotatable bone block into the interior of the Lee device, if that bone block cannot be rotated once in place within Lee's implant.

IV. Dependent Claims

Claim 3 requires that the at least one cylindrical compressible core member includes edges that have been radiused or chamfered. The Examiner identified McKinley's surfaces 72 and 74 as discussed in Para. [0088] as edges of the core member. Surfaces 72 and 74 shown in Figure 27 are not surfaces of the bone block or core member. Those surfaces are on the inserter tool, cannula 70.

Claim 4 requires the disc to be "bullet-shaped." The Examiner identifies McKinley Figure 27 as showing a disc that is "bullet-shaped." Figure 27 however does not show a bullet-shaped disc, nor a disc at all. McKinley does not describe any device having endplates and consequently does not show a disc, bullet-shaped or not. In any case, Para [0088] and Figure 27 shows bone block 10. Bone block 10 has a rectangular form with a chisel end. The round device shown in Figure 27 is a cannula 70 and is used to insert the bone block 10.

Claim 5 requires the disc to be "lozenge-shaped." The Examiner identifies McKinley Figure 25 as showing a disc that is "lozenge-shaped." Figure 25 however does not show a "lozenge-shaped" disc. McKinley does not describe any device having end plates and consequently does not show a disc, whether lozenge-shaped or not. As is the case with the rejections discussed just above, the Examiner includes the bone-block delivery device (cannula 20) with the angular -- but not lozenge-shaped -- bone block 10b, but ignores the absence of any endplates, in alleging that Figure 25 shows a disc implant.

Claim 6 requires a "kit" including exactly two of the discs of claim 1. The Examiner identifies Para. [0071, 0089] as showing a kit comprising exactly two of the prosthetic discs of claim 1. However, Para. [0071, 0089] do not describe such a kit but instead discuss procedures

for implanting two or more bone blocks in an intervertebral space, but, in the absence of any description of device endplates, do not show a kit of two discs.

Claims 7, 8, and 9 depend from claim 6 and are patentable for the reasons discussed above with relation to that claim.

In sum, the USPTO has not provided adequate technical support for modifying the references in the way proposed in the Office Action nor even properly identified the components shown in the two references. The applicant requests withdrawal of the rejection.

SUMMARY

It is respectfully submitted that each of the rejections of record is in error and should be reversed.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1073.

Dated: July 17, 2012

Respectfully submitted,

Electronic signature: /Mark Stirrat/
Mark Stirrat
Registration No.: 50,756
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CLAIMS APPENDIX

1. A prosthetic intervertebral disc, comprising:

a first end plate;

a second end plate;

at least one compressible core member configured so that it may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second end plates;

at least one fiber extending between and engaged with said first and second end plates; and

wherein said end plates and said core member are held together by said at least one fiber.

2. (Canceled)

3. The prosthetic intervertebral disc of claim 1 wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered.

4. The prosthetic intervertebral disc of claim 1 wherein the disc is bullet-shaped.

5. The prosthetic intervertebral disc of claim 1 wherein the disc is lozenge-shaped.

6. A kit for surgically replacing a discs in a spine with a posterior approach, comprising exactly two of the prosthetic discs of claim 1.

7. The kit of claim 6 further comprising at least one cannula suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs of claim 1.

8. The kit of claim 6 wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width.

9. The kit of claim 8 wherein the first and second end plates of the prosthetic discs have a length:width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

Electronic Patent Application Fee Transmittal

Application Number:	12060856
Filing Date:	01-Apr-2008
Title of Invention:	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques
First Named Inventor/Applicant Name:	Janine C. Robinson
Filer:	Mark Andrew Stirrat/Karen Johnson
Attorney Docket Number:	S0134.0033

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Filing a brief in support of an appeal	2402	1	310	310
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 5 months with $0 paid	2255	1	1345	1345
Miscellaneous:				
			Total in USD ($)	**1655**

Electronic Acknowledgement Receipt

EFS ID:	13275537
Application Number:	12060856
International Application Number:	
Confirmation Number:	7469
Title of Invention:	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques
First Named Inventor/Applicant Name:	Janine C. Robinson
Customer Number:	91477
Filer:	Mark Andrew Stirrat/Karen Johnson
Filer Authorized By:	Mark Andrew Stirrat
Attorney Docket Number:	S0134.0033
Receipt Date:	17-JUL-2012
Filing Date:	01-APR-2008
Time Stamp:	18:18:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1655
RAM confirmation Number	5472
Deposit Account	041073
Authorized User	STIRRAT,MARK

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Appeal Brief Filed	S0134_0033_APPEAL_BRF.pdf	196756 840f54fe326f4389f5bd18487b0fbec031c739c2	no	20
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32226 11752e258312901843b18520ba285b19c4ba56a0	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	228982		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

CONFIRMATION NO. 7469

POA ACCEPTANCE LETTER

91477
Dickstein Shapiro LLP
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OC00000052651515

Date Mailed: 02/21/2012

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/10/2012.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/fstephanos/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

CONFIRMATION NO. 7469

POWER OF ATTORNEY NOTICE

34313
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IP PROSECUTION DEPARTMENT
2050 Main Street, Suite 1100
IRVINE, CA 92614

OC000000052651499

Date Mailed: 02/21/2012

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/10/2012.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/fstephanos/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/SB/80 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

[X] Practitioners associated with the Customer Number: 91477

OR

[ ] Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

[X] The address associated with Customer Number: 91477

OR

[ ] Firm or Individual Name					
Address					
City		State		Zip	
Country		Telephone		Email	

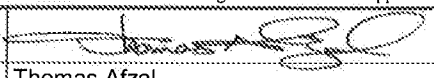
Assignee Name and Address:

SPINAL KINETICS, INC.
595 NORTH PASTORIA AVENUE
SUNNYVALE, CA 94085

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	10/1/11
Name	Thomas Afzal	Telephone	(650) 533-6388
Title	President and CEO		

PTO/SB/96 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Janine C. Robinson

Application No./Patent No.: 12/060856 Filed/Issue Date: April 1, 2008

Titled: Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores that Are Implantable Using Minimally Invasive Surgical Techniques

Spinal Kinetics, Inc. (Name of Assignee) , a corporation (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. [X] the assignee of the entire right, title, and interest in;

2. [ ] an assignee of less than the entire right, title, and interest in
(The extent (by percentage) of its ownership interest is _____ %); or

3. [ ] an assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made) the patent application/patent identified above by virtue of either:

A. [X] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 022125 , Frame 0768

OR

B. [ ] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____ , Frame _____ , or for which a copy thereof is attached.

2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____ , Frame _____ , or for which a copy thereof is attached.

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____ , Frame _____ , or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet(s).

[X] As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Mark Stirrat/	February 10, 2012
Signature	Date
Mark Stirrat	Attorney/Agent for Assignee
Printed or Typed Name	Title

Electronic Acknowledgement Receipt

EFS ID:	12051155
Application Number:	12060856
International Application Number:	
Confirmation Number:	7469
Title of Invention:	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques
First Named Inventor/Applicant Name:	Janine C. Robinson
Customer Number:	34313
Filer:	Mark Andrew Stirrat/Lynne Fulmer
Filer Authorized By:	Mark Andrew Stirrat
Attorney Docket Number:	145912002500
Receipt Date:	10-FEB-2012
Filing Date:	01-APR-2008
Time Stamp:	15:31:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	SKPOA.pdf	112908 981c0ff6176a8f88dd032af1e31a6f550b430a2e	no	1

Warnings:	
Information:	

2	Assignee showing of ownership per 37 CFR 3.73(b).	373BStatementS01340033.pdf	108732 4e62af778f36b3f1b53585522f8f33cd666a0b1e	no	1

Warnings:	
Information:	
Total Files Size (in bytes):	221640

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson	145912002500	7469

34313 7590 02/02/2012

ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
2050 Main Street, Suite 1100
IRVINE, CA 92614

EXAMINER	
BECCIA, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
3775	

NOTIFICATION DATE	DELIVERY MODE
02/02/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPPROSECUTION@ORRICK.COM
vsantos@orrick.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 12/060,856	**Applicant(s)** ROBINSON, JANINE C.	
	Examiner CHRISTOPHER BECCIA	**Art Unit** 3775	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 January 2012 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: As to Applicant's arguments regarding the combination of McKinley and Lee, Examiner maintains arguments put forth in the Final Rejection, as to the modification of the disc prosthesis of McKinely with the compressible core of Lee.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Janine C. ROBINSON

Application No.: 12/060,856

Filing Date: 01 April 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

Confirmation No.: 7469

Examiner: BECCIA, Christopher J.
Art Unit: 3775

RESPONSE TO FINAL OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action mailed July 19, 2011 in which claims 1-9 were finally rejcted under 35 USC 103.

Applicant has not amended, cancelled, nor added claims. Consequently, claims 1-9 are under consideration. Allowance is requested.

A **REMARKS** section begins on the following page.

A **SUMMARY** section is on page 9.

REMARKS

Claims 1-9 stand finally rejected under 35 U.S.C. 103 over U.S. Pub. No. 2005/0216088 (to McKinley et al) in view of U.S. Pat. No. 4,911,718 (to Lee et al). In support of the rejection, the Examiner argues:

"As to Claim 1, McKinley discloses a prosthetic intervertebral disc (Fig. 8), comprising:

a first end plate (50);

a second end plate (52); and

at least one compressible core member (10) configured so that it may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second end plates [0072, 0080].

"As to Claim 2, McKinley discloses a prosthetic intervertebral disc wherein the at least one compressible core member is substantially cylindrical (Fig. 27).

"As to Claim 3, McKinley discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (surfaces 72 and 74, [0088])

"As to Claim 4, McKinley discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 27).

"As to Claim 5, McKinley discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 25).

"As to Claim 6, McKinley discloses a kit for surgically replacing a [sic] discs in a spine with a posterior approach, comprising exactly two of the prosthetic discs of claim 1 (two implants of [0071, 0089]).

"As to Claim 7, McKinley discloses a kit further comprising at least one cannula (40a and 40b) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs of claim 1 [0090, 0091].

"As to Claims 1-9, McKinley discloses the claimed invention except for wherein at least one fiber extending between and engaged with said first and second end plates; and wherein said end plates and said core member are held together by said at least one fiber; wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width; and wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1.

"Lee discloses an insert for a prosthetic disc implant including first and second endplates (8, 10) wherein at least one fiber (4) extending between and engaged with said first and second end plates (Col. 3, Lines 50-64); and wherein said end plates and said core member are held together by said at least one fiber (Col. 3, Lines 65-69 - Col. 4, Lines 1-

11); wherein the first and second end plates of each of the prosthetic discs have a length and a width (Fig. 1), and wherein the length is greater than the width; and wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1 (Fig. 1. show approximate 1.5:1 ratio) in order to provide end plates and a spacer with biomechanical properties similar to a normal disc (Col. 3, Lines 10-16).

"It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of McKinley with the fiber and end plate modifications of Lee in order to provide end plates and a spacer with biomechanical properties similar to a normal disc."

In addition, the Examiner has provided a "Response to Arguments" section:

"As to Claims 1-9, Applicant argues that "The two devices described, respectively,in McKinley and in Lee are devices intended to provides two very different functions: McKinley shows a device that immobilizes two vertebrae with respect to each other; Lee shows a device that is flexible and is intended to provide a flexible joint between two adjacent vertebrae. The teachings of one reference are not applicable to the devices of the other." Examiner respectfully disagrees.

"In response to applicant's argument that the teachings of Lee are not applicable to McKinley, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both McKinley and Lee are directed towards intervertebral disc prostheses for reestablishing normal spacing in degenerative discs.

"In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Examiner stresses the structural similarities between McKinley and Lee regarding two endplates, and a central core member. McKinley is relied upon to teach a rotatable core member capable of increasing the distance between the discs. Lee is relied upon to teach a core member with elastomeric fibers. There is motivation to modify the rotatable spacer member of McKinley with the fibrous core of Lee to mimic the properties of a healthy disc."

Applicant again disagrees with the rejection. The combination of Mckinley and Lee does not render obvious Applicant's claims 1-9.

Applicant understands from the rejection that as to claim 1, the Examiner suggests an intervertebral device made up of the McKinley "end plates," McKinley rotatable, compressible core member capable of "increasing the distance between the discs [sic -- endplates? -- vertebrae?]", and the Lee "at least one fiber."

McKinley -- Compressible Core Member

First, Applicant reiterates the statement that McKinley does not teach nor suggest a compressible core member. The specified element "10" of McKinley is said to be a bone block comprised of "any suitable bone material including autologous, allographic, xenographic, or other osteoinductive and osteoproliferative elements." See Paragraph [0022]. Bone, particularly bone used to separate, stabilize, or fuse vertebral elements is not considered in this art to be "compressible."

The Examiner did not comment specifically on Applicant's argument that McKinley's "bone block 10" is not considered to be compressible in this art.

Applicant would point to various patents, published patent applications, and journal articles, e.g., showing that certain materials in this art are considered to be "incompressible" and that fusion devices themselves such as that shown in McKinley are considered to be "incompressible." See, for instance, "History and Evolution of Disc Replacement" Bono et al, The Spine Journal 4 (2004) 145S-150S. (copy attached).

If the Examiner is arguing that the Lee polymeric core be introduced into the McKinley device in place of the McKinley bone block, Applicant would point out that the compressible Lee core is not "capable of increasing the distance between the discs [sic -- endplates? -- vertebrae?]." See the compression tests in Lee's Figure 6. The resultant Silicone deformation values portrayed in that Figure show deformation for all of the applied axial compression values. Said another way: placement of a Silicone into an intervertebral space will not "increase the distance" between the endplates.

McKinley -- End Plates

Contrary to the Examiner's statement, McKinley does not show a device having two end plates. As is noted in the discussion relating to Figure 8, Nos 50 and 52 are vertebral bones, not components of the McKinley device.

Despite the Examiner's comments in the "Response to Arguments," there is little, if any, similarity between the structures disclosed in McKinley and in Lee. The intervertebral body shown in McKinley is solely a relatively rigid block of bone shaped according to the teachings in McKinley. The intervertebral body shown in Lee, in contrast, does include endplates -- often formed of metal -- and a central elastomeric core surrounded by laminae.

McKinley -- bone block

Required in the description of the device described in McKinley is the concept that the bone block itself have the physical parameters and capabilities, once "cammed" into position between two vertebral bones by the cooperating inserter tool, "to promote bone fusion between the adjacent vertebrae." The physical parameters and capabilities must include adequate strength and size to prevent substantial movement of the bone block after implantation. The goal of the McKinley device is to fuse two adjacent vertebrae -- See Paragraph [0004].

As will be discussed below, Lee does not utilize materials promoting overall fusion of the implant between the vertebrae. Somehow adding "at least one fiber" to directly engage the two vertebrae and to hold the two vertebrae together does not promote the McKinley-required fusion between the two endplates.

Further, because the McKinley bone block does not have the compressibility of the Lee polyurethane core, it is very highly unlikely that the "spacer" proposed by the Examiner will have "biomechanical properties similar to a normal disc..."

Combination of References McKinley and Lee

Applicant urges that no cogent reason has been presented for combination of the technology shown in the references in the way proposed by the Examiner. Although Applicant agrees with the Examiner that the two references are in a general sense in the same area of endeavor as Applicant's and would further agree that Lee is somewhat pertinent to Applicant's general problem -- providing an intervertebral disc replacement that simulates the motions of a

natural disc and may be inserted posteriorly or laterally. Applicant woud not agree that McKinley is at all pertinent to the problem that Applicant wishes to solve. In any event, even if the references and /or problems to be solved meet broad criteria discussed in the caselaw cited by the Examiner, that case law also requires that Office Actions provide some technology-based reasoning for making the modifications to the cited art urged in an Office Action.

Applicant would disagree that the Examiner's synthesis of the direction of both the Lee and McKinley disclosures -- "directed towards intervertebral disc prostheses for reestablishing normal spacing in degenerative discs" -- is appropriate or correct. Although the McKinley reference shows a device used only to provide such an interevertebral spacing -- albeit by fusing portions of the spine into a total lack of intervertebral motion between the two fused discs, the Lee device has a much more sophisticated usage -- trying to make a prosthetic disc that "has mechanical properties akin to those of the normal disc and will preserve normal functions of the spinal motion segment." See the Abstract. Merging the McKinley and Lee disclosures only on the simplistic basis that they both provide appropriate intervertebral spacing is similar to urging that a common brick and 6 Apple iPhones piled on each other are both directed to spacers for closing an open space in a brick wall. That the Lee device provides an appropriate intervertebral spacing is minimal in the overall scope of its utility in a spine.

The Examiner has urged that teaching, suggestion, or motivation to combine two disclosures may be found in the references themselves or from knowledge generally available to one of ordinary skill in the art. However, the Examiner has provided no technical or engineering-based reasoning for modifying the references in the manner specified in the Office Actions.

Finally, as noted above, the Examiner has argued that the McKinley and Lee devices are structurally similar -- each allegedly having endplates and core members -- apparently to provide a basis for substituting the fibrous core of Lee for the bone block of McKinley to mimic the properties of a healthy disc. Again, the two devices are not similar; the McKinley reference does not show a device having endplates. The alleged components identified as endplates of the device are, in fact, vertebrae. The rotatable bone block (10) is implanted directly upon the surfaces of the vertebrae adjacent the intervertebral space cleared for such an implantation. McKinley does not mention the use of independent device-type endplates associated with the McKinley's bone block.

Miscellaneous

As to claim 2: claim 2 requires the core member to be "substantially cylindrical." The Examiner identifies McKinley Figure 27 as showing a core member having such shape. Figure 27 however does not show a cylindrical bone block. As discussed in Para [0088], the bone block in that fifure is component 10; it has a rectangular form with a chisel end. The round portion shown in the Figure is instead a cannula 70 and is used to insert the bone block 10.

As to cliam 3: claim 3 requires that the at least one cylindrical compressible core member includes edges that have been radiused or chamfered. The Examiner identified surfaces 72 and 74 as discussed in Para. [0088] as edges of the core member. As discussed just above, surfaces 72 and 74 shown in Figure 27 are not surfaces of the bone block or core member. Those surfaces are on the inserter tool, cannula 70.

As to claim 4: claim 4 requires the disc to be "bullet-shaped." The Examiner identifies McKinley Figure 27 as showing a disc that is "bullet-shaped." Figure 27 however does not show a bullet-shaped disc. Figure 27 does not show a disc at all. McKinley does not describe any device having endplates and consequently does not show a disc, bullet-shaped or not. In any case, Para [0088] and Figure 27 shows bone block 10. Bone block 10 has a rectangular form with a chisel end. The round device shown in Figure 27 is a cannula 70 and is used to insert the bone block 10.

As to claim 5: claim 5 requires the disc to be "lozenge-shaped." The Examiner identifies McKinley Figure 25 as showing a disc that is "lozenge-shaped." Figure 25 however does not show a "lozenge-shaped" disc. McKinley does not describe any device having endplates and consequently does not show a disc, whether lozenge-shaped or not. As is the case with the rejections discussed just above, the Examiner includes the bone-block delivery device (cannula 20) with the angular -- but not lozenge-shaped -- bone block 10b, but ignores the absence of any endplates, in alleging that Figure 25 shows a disc implant.

As to claim 6: claim 6 requires a "kit" including exactly two of the discs of claim 1. The Examiner identifies Para. [0071, 0089] as showing a kit comprising exactly two of the prosthetic discs of claim 1. However, Para. [0071, 0089] do not describe such a kit but instead discuss procedures for implanting two or more bone blocks in an intervertebral space, but, in the absence of any description of device endplates, do not show a kit of two discs.

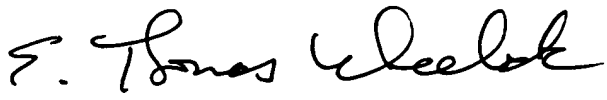
As to claims 7, 8, and 9: Claims 7, 8, and 9 depend from claim 6 and are patentable for the reasons discussed above with relation to that claim.

In sum, the USPTO has not provided adequate technical support for modifying the references in the way proposed in the Office Action nor even properly identified the components shown in the two references. Applicant requests withdrawal of the rejection.

SUMMARY

Applicant has responded to each matter of substance in the Office Action and requests allowance of the claims. Should the Examiner wish to have a telephonic interview to hasten conclusion of this examination, he is invited to contact Applicant's associate attorney, Thomas Wheelock, at 650-302-6286.

Respectfully submitted,



E. Thomas Wheelock
(Reg. No. 28,825)
filed under 37 CFR 1.34

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650-302-6286
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P.O. Box 61168
Palo Alto, California 94306

Attachment

ATTACHMENT

ELSEVIER

The Spine Journal 4 (2004) 145S–150S

THE SPINE JOURNAL

History and evolution of disc replacement

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Abstract Total joint replacement has revolutionized the treatment of limb arthritides. Spinal arthroplasty is emerging as a treatment for spinal disc degeneration. The purpose of this review is to highlight the evolution of artificial interventions for nucleus and total disc replacement. This review will provide the foundation for the understanding of present and future technologies in the field.

Keywords: Disc replacement; Constraint; Disc degeneration

Introduction

Total joint replacement has had an enormous impact on the way surgeons treat a variety of clinical disorders. Total hip replacement has been rated highest in terms of patient satisfaction of all operations, with total knee arthroplasty among the highest of all musculoskeletal procedures. Notwithstanding the treatment of arthritides, joint replacement technology has also had a profound influence on the options for limb reconstruction after tumor resection and deformity correction.

Spinal arthroplasty has lagged behind other anatomic regions, both temporally and technologically. Or has it? A rudimentary lumbar disc replacement consisting of a single metallic ball was first implanted in the late 1950s [1], which was approximately at the same time that initial reports of Charnley's total hip prosthesis emerged. Also in the 1950s, Nachemson began preliminary cadaveric work injecting a silicone rubber device into discs. From these simple origins came more complicated and sophisticated designs and, since 1973, an almost yearly acquisition of a new disc replacement patent [2] has occurred, of which only a small number have witnessed clinical fruition.

The disparity between disc and other joint replacements is not rooted in a lack of ideas, ingenuity or effort. More likely it is a reflection of a number of other factors, including biomaterial design, introduction of amenable surgical approaches and patient selection. As disc replacement becomes a reality, an understanding of its origins, history and evolution can help one gain a perspective on its role in the treatment of spinal disorders.

Origins of back pain: motion and emotion

Although applications for deformity and trauma may be introduced in the future, discogenic back and neck pain from degenerative disc disease is the current clinical focus of disc replacement surgery. This focus was not a random selection, as it reflects ideological changes in the thoughts and understanding of low back pain that have occurred in recent years. In brief, this was a shift from assigning culpability purely from abnormal intervertebral motion to implicating neurochemical pathomechanisms of the degenerating/degenerative disc in pain generation.

During the 1970s, Kirkaldy-Willis et al. [3] outlined the stages of the degenerative cascade. Abnormal and excessive motion was considered to be an intrinsic factor leading from one stage to the next. A myriad of biomechanical and clinical studies demonstrating the influence of disc degeneration on spinal mechanics amalgamated degenerative disc disease (DDD) and abnormal motion. These ideas were reflected in the popular, and persistent, term, mechanical low back pain, which became synonymous with DDD.

DePalma and Rothman [4] were among the first to advocate lumbar fusion for back pain. The goal of eliminating

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motion ideologically addressed the presumed pathology: abnormal motion. The procedure, however, was disparagingly unsuccessful in many cases despite surgically confirmed solid arthrodesis [5,6]. This led some to consider that imperceptible micromotion across the disc space, allowed by the inherent (albeit minimal) elasticity of the posterolateral fusion mass, was responsible.

Others turned to the disc itself, postulating that pain could arise from chemical factors, emanating from the degenerated nucleus, stimulating nociceptive nerve endings within the annulus fibrosis and/or the dorsal root ganglion. The reportedly improved clinical success of interbody fusion techniques, which obligatorily involve nucleus excision, appeared to support such a pathomechanism [7,8]. Improvements in patient selection, with recognition of various pyschosocial risk factors for poor outcome, were also a likely factor.

How this applies to total disc replacement is of current interest. The expected theoretical mechanism of pain relief after total disc replacement is based on a blending of both mechanical and chemical pathomechanisms. Two crucial components are (1) complete excision of the nucleus and (2) restoration or improvement of normal intervertebral mechanics.

Early attempts

Inelastic devices

Fernström's steel balls seem barbaric at first glance, but with more careful contemplation, they had a thoughtful premise (Fig. 1). In addition to nuclear excision, the ball was intended to maintain disc space height as well as motion. It placed the sagittal axis of rotation within the junction of the middle and posterior thirds of the disc space. This is similar to most contemporary designs, which produce sagittal angular motion arcs by using a ball-joint type articulation.

Good short-term results had been reported, but long-term failure of the device was attributed to excessive compressive load concentration with subsidence over the ball [1]. To help explain this, one can consider the interaction of a perfectly flat surface with a perfect sphere. The contact footprint would be at an infinitesimally small, single point. While lumbar end plates are not perfectly flat, stress would be concentrated within a small region in contact with the ball, worsened by the fact that these devices were placed in the central softer part of the end plate. With time the bone could succumb and the steel balls subside. Intervertebral height restoration was lost in about 88% of cases at 4- to 7-year follow-up. Furthermore, intervertebral motion necessarily produced shear forces at the metal–bone interface that could also have been a contributing factor.

Fig. 1. One of the first disc replacement devices, Fernström's steel balls failed by subsidence into the vertebral body end plates.

Elastic devices

In addition to stress concentration, the failure of metal ball implants could also be from a biomechanical modulus mismatch between the metal and the bone. Addressing these failure mechanisms, Fassio designed the first clinically implanted elastic disc replacement. The central portion resembled Fernström's steel ball, except it was made of silastic, an inherently compressible material with shock-absorbing properties. In addition, the silastic ball was bordered by, and contiguous with, a horseshoe-shaped, flat, noncompressible plateau. This was presumably intended to prevent subsidence. The device was implanted into three patients. At 4-year follow-up the device had subsided and migrated into the vertebral body in all patients [9]. In retrospect, the overall surface of the implant, although greater than that of Fernström's metal ball, covered only a small percentage of the end plate. Also, articulation still relied, at least partly, on shear forces between the silastic implant and bone. No further implantations were undertaken, or reported.

Other devices have progressed to animal testing but were never clinically implanted. Kostuik [10] developed a total disc replacement that rotated around an articulating hinge within the posterior third of the disc space (Fig. 2). A spring,

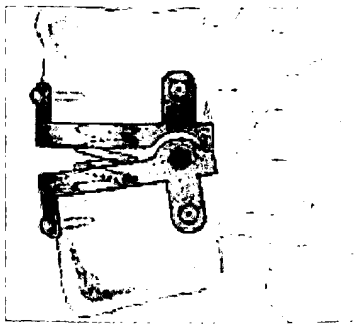

Fig. 2. Kostuik's design relied on a posterior hinge within the disc space to recreate an axis of rotation. A spring interposed between the metal implants attempted to provide axial shock absorption.

interposed between the two metallic end plates anterior to the hinge, was intended to produce some shock-absorption properties. Although it performed well during cyclical in vitro testing [10], the device failed with animal implantation. Clinical use has not been subsequently reported.

Lee and associates [11–13] developed an elastomeric intervertebral disc spacer that had hydroxyapatite-coated surfaces to encourage ingrowth (Fig. 3). It performed well in in vitro tests, but core migration was common with canine implantation (5 of 12 cases). Despite this, work has continued and several modifications have been made both in materials and structural design. To date, no human implantation has been reported.

Lessons learned

The lessons learned from the failure of Fernström's balls and Fassio's silastic device can be summarized. First, the area of contact between the implant and host bone should be maximized to minimize the chance for subsidence. Second, a synthetic-on-synthetic, instead of synthetic-on-bone, articulating surface should be employed. Third, the material that is in contact with the bone should have as close a modulus of elasticity to the bone as possible. Another feature that was common to both implants, but was not clearly a contributing factor to failure, was a fixed axis of rotation within the posterior third of the disc space.

Articulating nonelastic devices

The next most significant reported step in total disc replacement appears to have been the development of devices with synthetic-on-synthetic articulating surfaces. This concept was born in the 1980s, initially with development of the SB Charité (DePuy Spine, Raynham, MA) and the ProDisc Artificial Total Lumbar Disc Replacement (Synthes, Inc., Paoli, PA). Although a significant evolutionary step, this advancement addressed only one of the three potential sources of failure detailed above. In particular, with the SB Charité, some of the other lessons would be painfully learned again.

Polyethylene on metal

Using concepts derived from total hip and knee prostheses, articulating disc replacement designs began to emerge in the early 1980s. Among the first implants introduced was the SB Charité, designed by Shellnack and Büttner-Janz. The device consisted of a sliding core of ultra high molecular weight polyethylene (UHMWPE) interposed between metallic end plates.

Development of an unconstrained device

The SB Charité's main design focus was a sliding, unconstrained polyethylene (PE) core. With this, the instantaneous axis of rotation could translate anterior and posterior to the mid-point of the disc during extension and flexion, respectively (Fig. 4). Its advocates thought that this more closely parallels normal motion. However, it must be noted that the axis, whether in flexion or extension, is more anterior than normal, which may detract from the presumed advantages. The shape, which consisted of a round troughlike border with a shallow hemispherical center, articulated with the conformed polished metallic end plates to prevent extrusion.

The initial device (SB Charité I) had small, shelllike end plates made of steel that were actually smaller in diameter than the PE core itself (Fig. 5, a). Over time, stress concentrations along this minimal surface area led to migration and settling into the vertebral body in a number of patients implanted with the device. (The lesson of relationship of surface area to subsidence had apparently not been learned from initial disc replacement failures.) The second-generation implant (SB Charité II) featured flat extensions on the left and right sides of the metal end plates. Although settling had been reduced, fatigue fractures of the steel end plates were common and led to early failures.

The third and current version (SB Charité III, DePuy Spine, Raynham, MA), developed in 1987, features broadened, flat end plates (Fig. 5, b). This feature appeared to have minimized end plate subsidence in clinical trials. The

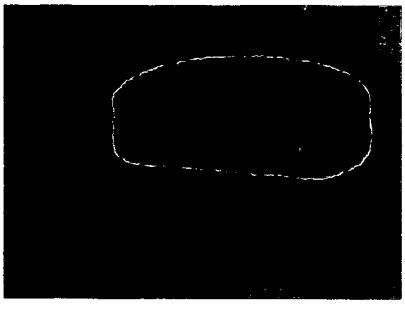

Fig. 3. Lee and Langrana's elastomeric intervertebral disc spacer has been extensively studied. Despite some failures in animal trials, modifications to the design and work toward human implantation has continued (personal communication, Casey K. Lee, MD, April, 2004).

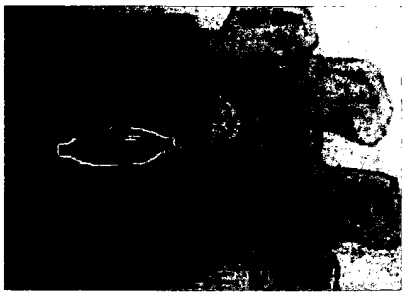

Fig. 4. The SB Charité III represents the third and current version of a total disc replacement design that relies on a "floating", unconstrained polyethylene core. This feature allows the axis of rotation to translate slightly posterior with flexion, and anterior with extension.

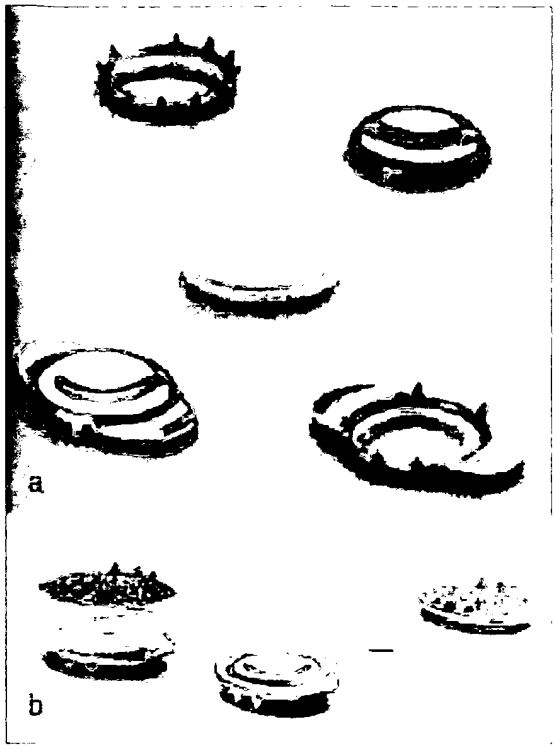

Fig. 5. (a) Components of the (top) SB Charité I and (bottom) SB Charité II total disc replacement system comparing the different end plate designs and the common, unrestrained polyethylene core. (b) Assembled and component views of the current SB Charité III disc replacement device.

end plate was manufactured from a cobalt-chromium-molybdenum (CoCrMo) alloy, a material that was found to result in less PE wear debris in total hip and knee replacements. However, to maximize osseous integration, the end plates were porous coated with titanium, and a layer of calcium phosphate was applied.

Early and medium-term clinical results using the SB Charité III have been encouraging. The design improvements of the current model appear to successfully address issues of implant subsidence and fatigue fracture. Analyses of revision cases have demonstrated little, if any, polyethylene debris, and excellent bony ingrowth [14]. Core extrusion has been reported, although the frequency of this complication appears to be low. It is a complication that one would believe to be inherently greater with an unconstrained versus a semi- or fully constrained device.

A contemporary semiconstrained disc replacement

Marnay developed a total disc replacement in the late 1980s currently called the ProDisc. The implant relied on a single semiconstrained articulating interface between the polyethylene core (or bearing) fixed to the inferior end plate and a polished superior metallic end plate. This is in contrast to the free-floating core of the SB Charité III that articulates at both its superior and inferior surfaces (ie, four articulating surfaces). A single midline sagittal fin is used to improve immediate bony fixation of the metallic end plates, as opposed to the six small teeth of the Charité.

In assigning the ProDisc's position on the evolutionary scale of total disc replacements, a number of observations can be made. Its design appears to be an improvement in terms of maximizing end plate coverage to avoid subsidence. The use of PE paralleled other total joint implants as well as its contemporary counterpart, the SB Charité. However, its fixed axis of rotation does not parallel anatomic motion patterns. In fact, there is an obligatory amount of translation that is produced with flexion and extension, a product of a rotational axis that lies within the anterosuperior aspect of the lower vertebral body. This could produce abnormal forces along the facet joints and dimensional changes of the neuroforamina during motion.

Notwithstanding material and specific design differences, the motion-producing mechanisms of the SB Charité, ProDisc, MAVERICK Artificial Disc (Medtronic Sofamor Danek, Inc., Memphis, TN) and the Prestige (Medtronic Sofamor Danek) discs (to be discussed below) are essentially a ball-joint that is quite analagous to the "archaic" Fernström metal balls. Other features of the normal intervertebral disc, such as elastic shock-absorption properties, are not approximated with any of these designs.

Metal on metal

The production of PE wear debris particles has been considered to be a major cause of periprosthetic bone resorption, loosening and failure of hip and knee arthroplasties. Alternative non-PE bearing surfaces have been advocated in recent years to address this issue. Metal and ceramic bearing implants have demonstrated comparable short- and medium-term results to standard PE bearing designs. The importance of these implants rests on the presumption that metallic and ceramic micro-debris would have less profound effects on the surrounding bone and soft tissue.

Although PE particulate-stimulated bone resorption does not appear to be a substantial cause of failure of total disc replacement, metal-on-metal total disc replacements have been advocated to remedy this problem—before it happens. To date, these are semiconstrained designs. The Maverick total disc replacement, developed by Mathews and associates, used cobalt-chrome end plates. A central sagittal fin, similar to that of the ProDisc, was included to enhance immediate fixation. The inferior articulating surface is a dome-shaped protrusion from the end plate. The superior articulating surface is a matched (but shallower) dome-shaped concavity built into the end plate component. By design, it offers a similar degree of constraint as the ProDisc. Biomechanical shock absorption abilities are nearly identical between the ProDisc and Maverick [15].

Gill and associates [16] developed a metal-on-metal, stainless steel cervical disc replacement, called the Prestige

total disc replacement. To provide immediate stability, screws are placed through a platelike extension that lies on the anterior vertebral body. A preliminary report indicates good clinical results in 20 patients [16].

An artificial joint capsule

As a preemptive solution to PE wear debris osteolysis, the Bryan Total Cervical Disc (Medtronic Sofamor Danek) was developed in the latter part of the 1990s. It featured a flexible rubber membrane that spanned between the metallic end plates to seal the articulating surfaces from surrounding tissues. Saline "joint fluid" contained inside the membrane served as a lubricant.

Like the ProDisc and SB Charité, the Bryan Total Cervical Disc also had an articulating core. However, it was made of polyurethane rather than PE. Presumably, polyurethane has greater shock-absorbing capability. This might be considered a small forward step on the evolutionary scale of total disc replacements.

Although it was not the first cervical disc replacement conceived, it was among the first to be implanted into humans. A number of clinical series have been published using this implant, including one reporting its use to reconstruct the cervical spine after anterior discectomy for myelopathy [17].

Increasing complexity: elastic (shock-absorbing) discs

Fassio's silastic disc was the first, and for some time the only, elastic disc replacement that had been implanted into patients. After its failure, a number of patents were obtained for designs during the 1980s. These included mechanisms that would enable axial load dissipation using silicon cushions, fluid-filled inflatable bladders, bioceramic fabric, elastic polymer, springs or coils. The most complex of designs was patented by Buttermann [18]. In a DaVinci-esque drawing, it called for eight tiny pistons supporting two end plates between which a series of springs were interposed. It has never clinically been reported.

Despite the continuing wealth of design types, it was not until 1993 that the next clinical trial of an elastic disc implant was published. Enker et al. [19] reported experience with the AcroFlex (DePuy Spine) disc designed by Steffee. This device consisted of a rubber core interposed between, and vulcanized to, porous coated titanium end plates. Satisfactory results in four of six patients were observed at an average of 3.4 years. Use of the implant was subsequently discontinued because of possible carcinogenicity of benzene-based solvents used during the vulcanization process.

Convinced of the merits of an inherently flexible device, Steffee collaborated with Fraser, Lowery and Ross to develop a similar implant that used a silicon elastomer. Unfortunately, early failure of the elastomer was noted by computed tomography in the first 40 devices at 1- to 2-year follow-up, resulting in a halt of implantation. Recent animal studies have also demonstrated poor maintenance of sagittal and lateral flexion ranges of motion [20]. Despite the failure of the AcroFlex device, it represented a forward step in the thinking of total disc replacements by its attempt to restore motion and shock absorption between the vertebrae.

Nucleus replacements

The development of prosthetic nuclear devices has grown from similar roots as total disc replacement. In considering Fernström balls, one might be hard-pressed to describe them as either a total disc or a nucleus replacement. With emerging technology comes the need to classify devices.

Classification distinction should be based on conceptual design differences. For the current discussion, total disc replacements are those that contain an artificial end plate as well as a simulated nuclear core; in distinction, nucleus replacements lack an end plate component. With this classification, one might conclude that Fernström's balls are more of a nuclear, than a total disc, replacement.

With both devices likely to be available within the next couple of years, one is challenged to distinguish which patients are candidates for nucleus replacement versus total disc arthroplasty; the distilled question being why would one device be preferred over another? Some have considered advanced disc space collapse (less than 5 mm residual height), end plate defects and obesity (body mass index over 30) to be contraindications to nucleus replacement [21].

To the authors' knowledge, there are only two devices of this kind that have been implanted into humans. Ray [21] designed the original prosthetic disc-nucleus (PDN), as well as several subsequent modified versions. The major design challenge was preventing expulsion from the disc space. The essential component is a hydrophobic gel pillow that absorbs water and expands once implanted. The gel is contained by a polyethylene-mesh "pillow cover" to prevent overexpansion. Two pillows are placed transversely within the disc space while preserving the annulus as much as possible. In distinction to total disc replacements, the PDN was placed through a posterior laminotomy and standard discectomy approach. Encouraging clinical results at 1-year follow-up have been reported [22]. However, migrations have occurred. This has led to a change in technique of implantation such that the implant is placed from a lateral approach leaving the annulus posteriorly intact.

Issues of implant migration with the PDN stimulated another group to design a coiled, spiral implant [23]. Notwithstanding various other differences, this was not the first spiral disc device proposed. Stubstad and associates [24] patented a helicoid disc implant in 1975 based on their experience in implanting them into chimpanzees [25]. Human implantation has not been reported.

The Memory Coiling Spiral (Centerpulse, Sulzer Spine-Tech Inc., Minneapolis, MN) [23] was designed to be implanted in a precompressed, coiled state to minimize the size of the annulotomy. It was composed of a polycarbonate urethane (a material that was probably not available in 1975). Once in place, it can "uncoil" to increase its surface contact footprint with the bony end plates. Early results in five patients with an average of 2 years of follow-up were recently published. No devices had migrated [26].

Biomaterials: evolving or revolving?

With a historical "bird's eye" view of the development of total disc replacements, interesting trends can be noted, particularly when comparing it with the history of peripheral joint arthroplasty design.

Take, for example, the SB Charité. In its first form, it was stainless steel. With involvement of the LINK Company, a leader in joint replacement technology, the end plates were changed to CoCrMo. This reflected experience with hip replacements, in which cobalt-PE articulating surfaces demonstrated better wear rates. At the same time LINK also added a porous coated titanium surface and a layer of calcium phosphate, technology borrowed from peripheral joint experience. In the current authors' view, this represents recycling of known technology, rather than evolution based on experience specific to total disc replacement.

In a discussion of "criteria for biomaterials optimization of total disc replacement design," Hallab et al. [27] stated that there are "three basic types of movements that occur between articular surfaces in the normal movement of most joints: spinning (rotation), sliding, and rolling." Although true for peripheral joint replacements, this list conveniently does not include axial compressive movements, which is a crucial part of normal intervertebral function, but not reproduced in currently available total disc replacements.

Conclusions

To maximize the clinical benefit, understanding of the origins of back and neck pain must also evolve as a necessary companion to the rapid advancements in disc replacement technology. Without this, there will emerge a new clinical entity: the failed disc replacement in which unimproved back pain continues despite a technically perfect operation with maintenance of some motion. The solution to this problem will not be a more physiological, long-lasting or biocompatible prosthesis. It will be improved diagnosis, patient stratification and outcome prediction, tasks that are still unclear after more than 30 years of clinical experience with fusion for low back pain and development of artificial discs.

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AP DFW

PTO/SB/31 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Docket Number (Optional): SK20025.00

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on December 17, 2012

Signature _____

Typed or printed name E. Thomas Wheelock

In re Application of: Janine C. ROBINSON

Application Number	Filed
12/060,856	01 April 2008

For PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE

Art Unit	Examiner
3775	BECCIA, Christopher J.

Applicant hereby **appeals** to the Board of Patent Appeals and Interferences from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 620

☑ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ 310

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____ .

☐ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

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☐ attorney or agent of record. Registration number _____ .

☑ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____

E. Thomas Wheelock
Signature

E. Thomas Wheelock
Typed or printed name

650-302-6286
Telephone number

December 17, 2012
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

PTO/SB/22 (09-11)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) SK20025.00
Application Number 12/060,856	Filed April 01, 2008
For PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT	
Art Unit 3775	Examiner BECCIA, Christopher J

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$150	$75	$_____
☐ Two months (37 CFR 1.17(a)(2))	$560	$280	$_____
☑ Three months (37 CFR 1.17(a)(3))	$1270	$635	$635
☐ Four months (37 CFR 1.17(a)(4))	$1980	$990	$_____
☐ Five months (37 CFR 1.17(a)(5))	$2690	$1345	$_____

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number _____.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☐ attorney or agent of record. Registration Number _____

☑ attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 28,825

E. Thomas Wheelock — Signature

December 17, 2012 — Date

E. Thomas Wheelock — Typed or printed name

650-302-6286 — Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of 1 forms are submitted.

Unsuccessful Authorization

Date: 01-19-2012

User ID: ZJUHAR1

Processing Center Response

Do not honor

Local Response

The card has been declined, the transaction will not be processed.

Retry | Dial | New Card | Cancel | Print Screen

10:05

Document Code: IMIS

Notice of Fee Due

Date: 1-19-12

Application Number: 12/260886

A fee is due for the attached document for the reason indicated below. Please check the application for the appropriate authorization to charge a deposit account. If an authorization is present, please charge the appropriate fee*. If an authorization is not present, notify the applicant of the fee deficiency.

***If the fee due is for any of the filing fees, check for authorization to charge the surcharge. If authorization is present, charge the surcharge for late payment of the filing fees as well.**

- ☐ Insufficient payment by check or money order.
- ☐ Insufficient funds in deposit account _____ at ____:_____ (time).
- ☐ Insufficient payment by credit card.
- ☑ Declined credit card 10 : 05 (time).
- ☐ No authorization to charge a deposit account.

Fee code(s) to be applied:	2253	$635
	2401	$310
Amount in holding fee code:	1506	
	1622/2622	
	1999	

Total remaining due from applicant: $945

RAM Operator **Zeriya J**

Rev. 12/27/07

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	19

Application Number	12/060,856
Filing Date	April 01, 2008
First Named Inventor	Janine C. ROBINSON
Art Unit	3775
Examiner Name	Christopher J. BECCIA
Attorney Docket Number	SK20025.00

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☑ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  - -- Credit card submission form
  - -- Return Receipt Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	E. Thomas Wheelock, Patent Attorney		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	January 17, 2012	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	January 17, 2012

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson	145912002500	7469

34313 7590 07/19/2011

ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER	
BECCIA, CHRISTOPHER J	
ART UNIT	**PAPER NUMBER**
3775	

MAIL DATE	DELIVERY MODE
07/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/060,856	ROBINSON, JANINE C.	
	Examiner	Art Unit	
	CHRISTOPHER BECCIA	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. As to Claims 1-9, Applicant argues that "The two devices described, respectively, in McKinley and in Lee are devices intended to provides two very different functions: McKinley shows a device that immobilizes two vertebrae with respect to each other; Lee shows a device that is flexible and is intended to provide a flexible joint between two adjacent vertebrae. The teachings of one reference are not applicable to the devices of the other." Examiner respectfully disagrees.

In response to applicant's argument that the teachings of Lee are not applicable to McKinley, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both McKinley and Lee are directed towards intervertebral disc prostheses for reestablishing normal spacing in degenerative discs.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR*

International Co. v. Teleflex, Inc., 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Examiner stresses the structural similarities between McKinley and Lee regarding two endplates, and a central core member. McKinley is relied upon to teach a rotatable core member capable of increasing the distance between the discs. Lee is relied upon to teach a core member with elastomeric fibers. There is motivation to modify the rotatable spacer member of McKinley with the fibrous core of Lee to mimic the properties of a healthy disc.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2005/0216088 to *McKinley et al.* in view of U.S. Patent No. 4,911,718 to *Lee et al.*

As to **Claim 1,** *McKinley* discloses a prosthetic intervertebral disc (Fig. 8), comprising: a first end plate (50); a second end plate (52); and at least one compressible core member (10) configured so that it may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second end plates [0072, 0080].

As to **Claim 2,** *McKinley* discloses a prosthetic intervertebral disc wherein the at least one compressible core member is substantially cylindrical (Fig. 27).

As to **Claim 3,** *McKinley* discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (surfaces 72 and 74, [0088])

As to **Claim 4,** *McKinley* discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 27).

As to **Claim 5,** *McKinley* discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 25).

As to **Claim 6,** *McKinley* discloses a kit for surgically replacing a discs in a spine with a posterior approach, comprising exactly two of the prosthetic discs of claim 1 (two implants of [0071, 0089]).

As to **Claim 7,** *McKinley* discloses a kit further comprising at least one cannula (40a and 40b) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs of claim 1 [0090, 0091].

As to **Claims 1-9,** *McKinley* discloses the claimed invention except for wherein at least one fiber extending between and engaged with said first and second end plates; and wherein said end plates and said core member are held together by said at least one fiber; wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width; and wherein the

first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1.

Lee discloses an insert for a prosthetic disc implant including first and second endplates (8, 10) wherein at least one fiber (4) extending between and engaged with said first and second end plates (Col. 3, Lines 50-64); and wherein said end plates and said core member are held together by said at least one fiber (Col. 3, Lines 65-69 - Col. 4, Lines 1-11); wherein the first and second end plates of each of the prosthetic discs have a length and a width (Fig. 1), and wherein the length is greater than the width; and wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of *about* 1.5:1 to 5.0:1 (Fig. 1. show approximate 1.5:1 ratio) in order to provide end plates and a spacer with biomechanical properties similar to a normal disc (Col. 3, Lines 10-16).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of *McKinley* with the fiber and end plate modifications of *Lee* in order to provide end plates and a spacer with biomechanical properties similar to a normal disc.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775

Notice of References Cited	Application/Control No. 12/060,856	Applicant(s)/Patent Under Reexamination ROBINSON, JANINE C.	
	Examiner CHRISTOPHER BECCIA	Art Unit 3775	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,911,718 A	03-1990	Lee et al.	623/17.15
*	B	US-5,364,400 A	11-1994	Rego et al.	606/304
*	C	US-5,658,336 A	08-1997	Pisharodi, Madhavan	623/17.16
*	D	US-5,888,224 A	03-1999	Beckers et al.	623/17.16
*	E	US-6,251,140 B1	06-2001	Marino et al.	623/17.16
*	F	US-6,821,298 B1	11-2004	Jackson, Roger P.	623/17.15
*	G	US-2005/0216088 A1	09-2005	McKinley et al.	623/017.16
*	H	US-7,341,600 B2	03-2008	Lange et al.	623/17.11
*	I	US-7,655,046 B2	02-2010	Dryer et al.	623/17.15
*	J	US-7,776,094 B2	08-2010	McKinley et al.	623/17.16
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12060856	ROBINSON, JANINE C.
	Examiner	**Art Unit**
	CHRISTOPHER BECCIA	3775

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/26/2010	07/06/2011							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12060856	ROBINSON, JANINE C.
	Examiner	Art Unit
	CHRISTOPHER BECCIA	3775

SEARCHED

Class	Subclass	Date	Examiner
623	17.11-17.16	10/26/2010	CJB

SEARCH NOTES

Search Notes	Date	Examiner
EAST Search Attached	10/26/2010	CJB
Inventor Search	10/26/2010	CJB
EAST Search Attached	7/6/2011	CJB

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

/CHRISTOPHER BECCIA/ Examiner.Art Unit 3775	

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	"12060856"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:24
S2	38	robinson-janine-c.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:25
S3	4708	623/17.11-17.16.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:25
S5	654	S3 and rotatable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:32
S6	30	S3 and (rotatable with insert)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:33
S7	6	US-5658336-$.DID. OR US-5159244-$.DID. OR US-5962608-$.DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:50
S8	92	("3334624" | "3486505" | "4349921" | "4657550" | "4696290" | "4711232" | "4759769" | "4834757" | "4863476" | "4932975" | "5015247" | "5059193" | "5129899" | "5171278" | "5306309" | "5324292" | "5401269" | "5443514" | "5505732").PN. OR ("5658336").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/10/26 14:50

EAST Search History (Prior Art)

S10	162	("20020058950" | "20030105528" | "3486505" | "3518993" | "3604487" | "3745995" | "3848601" | "4026304" | "4026305" | "4646738" | "4657550" | "4743256" | "4781591" | "4834757" | "4877020" | "4878915" | "4932975" | "4961740" | "4962766" | "5026373" | "5055104" | "5062845" | "5092572" | "5133717" | "5133755" | "5171278" | "5192327" | "5217497" | "5269785" | "5284153" | "5290494" | "5300076" | "5304210" | "5306307" | "5306309" | "5322505" | "5334205" | "5336223" | "5364400" | "5395372" | "5397363" | "5405391" | "5413602" | "5425772" | "5431658" | "5443514" | "5443515" | "5445639" | "5454811" | "5458638" | "5484403" | "5489308" | "5505732" | "5522879" | "5522899" | "5524624" | "5527312" | "5534029" | "5534030" | "5540688" | "5545222" | "5562736" | "5565005" | "5571190" | "5571192" | "5593409" | "5609636" | "5611800" | "5611810" | "5632747" | "5645598" | "5653761" | "5653762" | "5658336" | "5658337" | "5662710" | "5665122" | "5669909" | "5676703" | "5683394" | "5683400" | "5683464" | "5690629" | "5700264" | "5700291" | "5700292" | "5702449" | "5702451" | "5702453" | "5702454" | "5702455" | "5703451" | "5707373" | "5711957" | "5716415" | "5720748" | "5720751" | "5723013" | "5741261" | "5755797" | "5766252" | "5772661" | "5775331" | "5779642" | "5782830" | "5782919" | "5785710" | "5797909" | "5800549" | "5800550" | "5814084" | "5851208" | "5865845" | "5865847" | "5865848" | "5885299" | "5888219" | "5888224" | "5893890" | "5904719" | "5910315" | "5954769" | "5961554" | "5968098").PN. OR ("5993474" | "6004326" | "6015436" | "6033405" | "6039761" | "6042582" | "6045580" | "6048342" | "6059790" | "6063088" | "6083225" | "6096080" | "6102948" | "6120506" | "6132472" | "6159211" | "6159215" | "6193756" | "6200347" | "6224607" | "6224631" | "6241769" | "6241771" | "6251140" | "6258125" | "6277149" | "6319257" | "6371989" | "6440142" | "6442814" | "6454806" | "6527773" | "6595998" | "6635086" | "6648895" | "6887248").PN. OR ("7776094").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/10/26 16:06

EAST Search History (Prior Art)

S11	53	S3 and ((mesh or fiber) with insert)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 16:34
S12	3	"20050216088"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 17:06
S13	7	("4911718" | "5192327" | "5211664" | "5429863" | "5906616" | "5968098" | "6224631").PN. OR ("7341600").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/10/26 17:29

EAST Search History (Interference)

		<This search history is empty>				

SK20025.00 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Janine C. ROBINSON

Application No.: 12/060,856

Filing Date: 01 April 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

Confirmation No.: 7469

Examiner: BECCIA, Christopher J.
Art Unit: 3775

RESPONSE TO NON-FINAL OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the non-final Office Action mailed November 9, 2010 in which claims 1-9 were rejcted under 35 USC 103.

Applicant has not amended, cancelled, nor added claims. Consequently, claims 1-9 are under consideration. Allowance is requested.

A **REMARKS** section begins on the following page.

A **SUMMARY** section is on page 4.

REMARKS

Claims 1-9 stand rejected under 35 U.S.C. 103 as over U.S. Pub. No. 2005/0216088 (to McKinley et al) in view of U.S. Pat. No. 4,911,718 (to Lee et al). In support of the rejection, the Examiner argues:

> "As to Claim 1, McKinley discloses a prosthetic intervertebral disc (Fig. 8), comprising:
>
> a first end plate (50);
>
> a second end plate (52); and
>
> at least one compressible core member (10) configured so that it may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second end plates [0072, 0080].
>
> "As to Claim 2, McKinley discloses a prosthetic intervertebral disc wherein the at least one compressible core member is substantially cylindrical (Fig. 27).
>
> "As to Claim 3, McKinley discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (surfaces 72 and 74, [0088]) As to Claim 4, McKinley discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 27).
>
> "As to Claim 5, McKinley discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 25).
>
> "As to Claim 6, McKinley discloses a kit for surgically replacing a discs in a spine with a posterior approach, comprising exactly two of the prosthetic discs of claim 1 (two implants of [0071, 0089]).
>
> "As to Claim 7, McKinley discloses a kit further comprising at least one cannula (40a and 40b) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs of claim 1 [0090, 0091].
>
> "As to Claims 1-9, McKinley discloses the claimed invention except for wherein at least one fiber extending between and engaged with said first and second end plates; and wherein said end plates and said core member are held together by said at least one fiber; wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width; and wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1.
>
> "Lee discloses an insert for a prosthetic disc implant including first and second endplates (8, 10) wherein at least one fiber (4) extending between and engaged with said first and second end plates (Col. 3, Lines 50-64); and wherein said end plates and said core member are held together by said at least one fiber (Col. 3, Lines 65-69 - Col. 4, Lines 1-11); wherein the first and second end plates of

each of the prosthetic discs have a length and a width (Fig. 1), and wherein the length is greater than the width; and wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1 (Fig. 1. show approximate 1.5:1 ratio) in order to provide end plates and a spacer with biomechanical properties similar to a normal disc (Col. 3, Lines 10-16).

"It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of McKinley with the fiber and end plate modifications of Lee in order to provide end plates and a spacer with biomechanical properties similar to a normal disc."

Applicant respectfully disagrees. Contrary to the statement in the Office Action, McKinley does not teach nor suggest a compressible core member. The specified element "10" of McKinley is said to be a bone block comprised of "any suitable bone material including autologous, allographic, xenographic, or other osteoinductive and osteoproliferative elements." see paragraph [0022]. Bone, particularly bone used to separate, stabilize, or fuse vertebral elements is not considered to be "compressible."

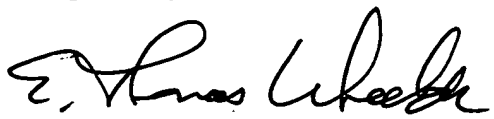
The two devices described, respectively, in McKinley and in Lee are devices intended to provides two very different functions: Mckinley shows a device that immobilizes two vertebrae with respect to each other; Lee shows a device that is flexible and is intended to provide a flexible joint between two adjacent vertebrae. The teachings of one reference are not applicable to the devices of the other.

There are a variety of other differences betweeen the cited references and the claims, but the noted difference is adequate to overcome any prima facie case of obviousness recited in the Office Action. Withdrawal of the rejection is requested.

SUMMARY

Applicants have responded to each matter of substance in the Office Action and request allowance of the claims. Should the Examiner wish to have a telephonic interview to hasten conclusion of this examination, he is invited to contact Applicant's associate attorney, Thomas Wheelock, at 650-302-6286.

Respectfully submitted,



E. Thomas Wheelock

(Reg. No. 28,825)

filed under 37 CFR 1.34

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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TRANSMITTAL FORM

(To be used for all correspondence after initial filing)

Application Number	12/060,856
Filing Date	01 April 2008
First Named Inventor	Janine C. ROBINSON
Art Unit	3775
Examiner Name	Christopher J. BECCIA
Attorney Docket Number	SK20025.00

Total Number of Pages in This Submission: 7

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  - -- Credit Card Payment Form
  - -- Return Receipt Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	E. THOMAS WHEELOCK		
Signature	E. Thomas LeRoy		
Printed name	E. THOMAS WHEELOCK		
Date	09 MAY 2011 ETW	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas LeRoy		
Typed or printed name	E. THOMAS WHEELOCK	Date	09 MAY 2011 ETW

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IFW

PTO/SB/22 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2009** *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)*	Docket Number (Optional) SK20025.00
Application Number 12/060,856	Filed 01 April 2008
For PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLI	
Art Unit 3775	Examiner BECCIA, Christopher J.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$130	$65	$
☐ Two months (37 CFR 1.17(a)(2))	$490	$245	$
☑ Three months (37 CFR 1.17(a)(3))	$1110	$555	$ 555
☐ Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐ Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number _____.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☐ attorney or agent of record. Registration Number _____

☑ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 28,825

E. Thomas Wheelock — Signature

08 May 2011 — Date

E. Thomas Wheelock — Typed or printed name

650-302-6286 — Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of 1 forms are submitted.

05/13/2011 HVUONG1 00000018 12060856

01 FC:2253 555.00 OP

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/060,856	04/01/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 05/13/2011

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 9	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/MYRTLE LEIGH/

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/060,856	04/01/2008	Janine C. Robinson	145912002500	7469

34313 7590 11/09/2010

ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER	
BECCIA, CHRISTOPHER J	
ART UNIT	**PAPER NUMBER**
3775	

MAIL DATE	DELIVERY MODE
11/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/060,856	ROBINSON, JANINE C.	
	Examiner	Art Unit	
	CHRISTOPHER BECCIA	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 1-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2005/0216088 to *McKinley et al.* in view of U.S. Patent No. 4,911,718 to *Lee et al.*

As to **Claim 1,** *McKinley* discloses a prosthetic intervertebral disc (Fig. 8), comprising:

a first end plate (50);

a second end plate (52); and

at least one compressible core member (10) configured so that it may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second end plates [0072, 0080].

As to **Claim 2,** *McKinley* discloses a prosthetic intervertebral disc wherein the at least one compressible core member is substantially cylindrical (Fig. 27).

As to **Claim 3,** *McKinley* discloses a prosthetic intervertebral disc wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered (surfaces 72 and 74, [0088])

As to **Claim 4,** *McKinley* discloses a prosthetic intervertebral disc wherein the disc is bullet-shaped (Fig. 27).

As to **Claim 5,** *McKinley* discloses a prosthetic intervertebral disc wherein the disc is lozenge-shaped (Fig. 25).

As to **Claim 6,** *McKinley* discloses a kit for surgically replacing a discs in a spine with a posterior approach, comprising exactly two of the prosthetic discs of claim 1 (two implants of [0071, 0089]).

As to **Claim 7,** *McKinley* discloses a kit further comprising at least one cannula (40a and 40b) suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs of claim 1 [0090, 0091].

As to **Claims 1-9,** *McKinley* discloses the claimed invention except for wherein at least one fiber extending between and engaged with said first and second end plates; and wherein said end plates and said core member are held together by said at least one fiber; wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width; and wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1.

Lee discloses an insert for a prosthetic disc implant including first and second endplates (8, 10) wherein at least one fiber (4) extending between and engaged with said first and second end plates (Col. 3, Lines 50-64); and wherein said end plates and said core member are held together by said at least one fiber (Col. 3, Lines 65-69 - Col.

4, Lines 1-11); wherein the first and second end plates of each of the prosthetic discs have a length and a width (Fig. 1), and wherein the length is greater than the width; and wherein the first and second end plates of the prosthetic discs have a length to width aspect ratio of the first and second end plates is in the range of *about* 1.5:1 to 5.0:1 (Fig. 1. show approximate 1.5:1 ratio) in order to provide end plates and a spacer with biomechanical properties similar to a normal disc (Col. 3, Lines 10-16).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spinal implant of *McKinley* with the fiber and end plate modifications of *Lee* in order to provide end plates and a spacer with biomechanical properties similar to a normal disc.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on M-F 7:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775

Notice of References Cited	Application/Control No. 12/060,856	Applicant(s)/Patent Under Reexamination ROBINSON, JANINE C.	
	Examiner CHRISTOPHER BECCIA	Art Unit 3775	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,911,718 A	03-1990	Lee et al.	623/17.15
*	B	US-5,364,400 A	11-1994	Rego et al.	606/304
*	C	US-5,658,336 A	08-1997	Pisharodi, Madhavan	623/17.16
*	D	US-5,888,224 A	03-1999	Beckers et al.	623/17.16
*	E	US-6,251,140 B1	06-2001	Marino et al.	623/17.16
*	F	US-6,821,298 B1	11-2004	Jackson, Roger P.	623/17.15
*	G	US-2005/0216088 A1	09-2005	McKinley et al.	623/017.16
*	H	US-7,341,600 B2	03-2008	Lange et al.	623/17.11
*	I	US-7,655,046 B2	02-2010	Dryer et al.	623/17.15
*	J	US-7,776,094 B2	08-2010	McKinley et al.	623/17.16
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12060856	ROBINSON, JANINE C.
	Examiner	Art Unit
	CHRISTOPHER BECCIA	3775

SEARCHED

Class	Subclass	Date	Examiner
623	17.11-17.16	10/26/2010	CJB

SEARCH NOTES

Search Notes	Date	Examiner
EAST Search Attached	10/26/2010	CJB
Inventor Search	10/26/2010	CJB

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12060856	ROBINSON, JANINE C.
	Examiner	**Art Unit**
	CHRISTOPHER BECCIA	3775

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/26/2010								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								

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Alexandria, Virginia 22313-1450
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BIB DATA SHEET

CONFIRMATION NO. 7469

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/060,856	04/01/2008 RULE	623	3775	145912002500

APPLICANTS
Janine C. Robinson, Half Moon Bay, CA;

**** CONTINUING DATA ***************************
This appln claims benefit of 60/909,474 04/01/2007

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
04/21/2008

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☑ No	/CHRISTOPHER J BECCIA/ Examiner's Signature	☐ Initials	CA	3	9	1

ADDRESS

ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558
UNITED STATES

TITLE

Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
527	No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"12060856"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:24
L2	38	robinson-janine-c.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:25
L3	4708	623/17.11-17.16.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:25
L5	654	l3 and rotatable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:32
L6	30	l3 and (rotatable with insert)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:33
L7	6	US-5658336-$.DID. OR US-5159244-$.DID. OR US-5962608-$.DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 14:50
L8	92	("3334624" | "3486505" | "4349921" | "4657550" | "4696290" | "4711232" | "4759769" | "4834757" | "4863476" | "4932975" | "5015247" | "5059193" | "5129899" | "5171278" | "5306309" | "5324292" | "5401269" | "5443514" | "5505732").PN. OR ("5658336").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/10/26 14:50

EAST Search History (Prior Art)

L10	162	("20020058950" | "20030105528" | "3486505" | "3518993" | "3604487" | "3745995" | "3848601" | "4026304" | "4026305" | "4646738" | "4657550" | "4743256" | "4781591" | "4834757" | "4877020" | "4878915" | "4932975" | "4961740" | "4962766" | "5026373" | "5055104" | "5062845" | "5092572" | "5133717" | "5133755" | "5171278" | "5192327" | "5217497" | "5269785" | "5284153" | "5290494" | "5300076" | "5304210" | "5306307" | "5306309" | "5322505" | "5334205" | "5336223" | "5364400" | "5395372" | "5397363" | "5405391" | "5413602" | "5425772" | "5431658" | "5443514" | "5443515" | "5445639" | "5454811" | "5458638" | "5484403" | "5489308" | "5505732" | "5522879" | "5522899" | "5524624" | "5527312" | "5534029" | "5534030" | "5540688" | "5545222" | "5562736" | "5565005" | "5571190" | "5571192" | "5593409" | "5609636" | "5611800" | "5611810" | "5632747" | "5645598" | "5653761" | "5653762" | "5658336" | "5658337" | "5662710" | "5665122" | "5669909" | "5676703" | "5683394" | "5683400" | "5683464" | "5690629" | "5700264" | "5700291" | "5700292" | "5702449" | "5702451" | "5702453" | "5702454" | "5702455" | "5703451" | "5707373" | "5711957" | "5716415" | "5720748" | "5720751" | "5723013" | "5741261" | "5755797" | "5766252" | "5772661" | "5775331" | "5779642" | "5782830" | "5782919" | "5785710" | "5797909" | "5800549" | "5800550" | "5814084" | "5851208" | "5865845" | "5865847" | "5865848" | "5885299" | "5888219" | "5888224" | "5893890" | "5904719" | "5910315" | "5954769" | "5961554" | "5968098").PN. OR ("5993474" | "6004326" | "6015436" | "6033405" | "6039761" | "6042582" | "6045580" | "6048342" | "6059790" | "6063088" | "6083225" | "6096080" | "6102948" | "6120506" | "6132472" | "6159211" | "6159215" | "6193756" | "6200347" | "6224607" | "6224631" | "6241769" | "6241771" | "6251140" | "6258125" | "6277149" | "6319257" | "6371989" | "6440142" | "6442814" | "6454806" | "6527773" | "6595998" | "6635086" | "6648895" | "6887248").PN. OR ("7776094").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/10/26 16:06

EAST Search History (Prior Art)

L11	53	l3 and ((mesh or fiber) with insert)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 16:34
L12	3	"20050216088"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/10/26 17:06
L13	7	("4911718" | "5192327" | "5211664" | "5429863" | "5906616" | "5968098" | "6224631").PN. OR ("7341600").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/10/26 17:29

EAST Search History (Interference)

		<This search history is empty>				

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

CONFIRMATION NO. 7469

POWER OF ATTORNEY NOTICE

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

OC000000036488136

Date Mailed: 06/23/2009

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/11/2009.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/fstephanos/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

CONFIRMATION NO. 7469

POA ACCEPTANCE LETTER

34313
ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

OC000000036488145

Date Mailed: 06/23/2009

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/11/2009.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/fstephanos/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/SB/80 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

☑ Practitioners associated with the Customer Number: 34313

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

☑ The address associated with Customer Number: 34313

OR

☐ Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

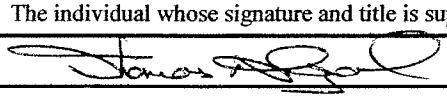
Assignee Name and Address:

Spinal Kinetics Inc.
595 N. Pastoria Avenue
Sunnyvale, Ca 94085

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	2/8/09
Name	Thomas A. Afzal	Telephone	408-636-2505
Title	President and CEO		

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

25.00

PTO/SB/96 (01-09)
Approved for use through 02/28/2009. OMB 0651-0031
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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: SPINAL KINETICS INC.

Application No./Patent No.: 12/060856 Filed/Issue Date: April 1, 2008

Titled: Prosthetic Intervertebral Discs Implantable By Minimally Invasive, Posterior Approach, Surgical Techniques (XI)

SPINAL KINETICS INC. , a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.

states that it is:

1. [X] the assignee of the entire right, title, and interest in;

2. [ ] an assignee of less than the entire right, title, and interest in (The extent (by percentage) of its ownership interest is _____ %); or

3. [ ] the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

A. [X] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 022125, Frame 0768, or for which a copy therefore is attached.

OR

B. [ ] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet(s).

[X] As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Signature 2/8/09 Date

Thomas A. Afzal Printed or Typed Name

President and CEO Title

Electronic Acknowledgement Receipt

EFS ID:	5502611
Application Number:	12060856
International Application Number:	
Confirmation Number:	7469
Title of Invention:	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques
First Named Inventor/Applicant Name:	Janine C. Robinson
Customer Number:	60154
Filer:	Donald Erik Daybell/Angela Wendel
Filer Authorized By:	Donald Erik Daybell
Attorney Docket Number:	145912002500
Receipt Date:	11-JUN-2009
Filing Date:	01-APR-2008
Time Stamp:	19:23:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	12060856.pdf	163513 ca4b30372e6b23459884c2ec7b47c6561bd32e63	no	2

Warnings:

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Information:

Total Files Size (in bytes):	163513

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

CONFIRMATION NO. 7469

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

PUBLICATION NOTICE

OC00000035858642

Title: Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques

Publication No.US-2009-0118835-A1
Publication Date:05/07/2009

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/060,856	04/01/2008	3733	527	145912002500	9	1

CONFIRMATION NO. 7469

UPDATED FILING RECEIPT

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

OC000000034210100

Date Mailed: 01/27/2009

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Janine C. Robinson, Half Moon Bay, CA;

Assignment For Published Patent Application

Spinal Kinetics, Inc., Sunnyvale, CA

Power of Attorney: The patent practitioners associated with Customer Number 60154

Domestic Priority data as claimed by applicant

This appln claims benefit of 60/909,474 04/01/2007

Foreign Applications

If Required, Foreign Filing License Granted: 04/21/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/060,856**

Projected Publication Date: 05/07/2009

Non-Publication Request: No

Early Publication Request: No
** **SMALL ENTITY** **

Title

Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques

Preliminary Class

623

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

CONFIRMATION NO. 7469

FORMALITIES LETTER

OC000000033535176

Date Mailed: 12/12/2008

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$27** for a small entity

- The application examination fee has not been paid. Applicant must submit **$110** to complete the examination fee for a small entity in compliance with 37 CFR 1.27.

(A previous payment of **$83** will be applied to the additional fees indicated above.)

01/13/2009 WASFAW1 00000052 12060856
01 FC:2311 110.00 OP

Adjustment date: 01/13/2009 WASFAW1
12/01/2008 RFEKADU1 00000002 12060856
05 FC:2622 -83.00 OP

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

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PTO/SB/21 (12-08)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	

Application Number	12/060,856
Filing Date	01 April 2008
First Named Inventor	ROBINSON, Janine C
Art Unit	3733
Examiner Name	N/A
Attorney Docket Number	145912002500

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☒ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please Identify below):
  - This Transmittal Form (1pg)
  - Reply to Notice (1pg)
  - $27 Check
  - Copy of Notice (2pp)
  - Return Receipt postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Wheelock Chan LLP		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	07 January 2009	Reg. No.	28,825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	07 January 2009

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Deposit: 07 January 2009

Typed Name: E. Thomas Wheelock

Signature: E. Thomas Wheelock

Docket No. 145912002500
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Janine C. ROBINSON

Confirmation No.: 7469

Application No.: 12/060,856

Art Unit: 3733

Filing Date: 01 April 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

REPLY TO NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice to File Missing Parts of Nonprovisional Application, dated December 12, 2008, the applicants hereby submit:

--Transmittal Form (1 sheet)
--This Reply to Notice to File Missing... (1 sheet)
--Check in the amount of $27 to cover the remainder of the Examination Fee
--Copy of Notice to File Missing Parts of Nonprovisional Application (2 sheets)
--Return receipt postcard

Respectfully submitted,

E. Thomas Wheelock

E. Thomas Wheelock, Reg. No. 28,825
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, California 94306
(650) 302-6286

Dated: January 07, 2009

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

CONFIRMATION NO. 7469

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

FORMALITIES LETTER

OC000000033535176

Date Mailed: 12/12/2008

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is $**27** for a small entity

- The application examination fee has not been paid. Applicant must submit $**110** to complete the examination fee for a small entity in compliance with 37 CFR 1.27.

(A previous payment of $**83** will be applied to the additional fees indicated above.)

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/eulanday/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

CONFIRMATION NO. 7469

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

WITHDRAWAL NOTICE

OC00000033535174

Date Mailed: 12/12/2008

Letter Regarding a New Notice and/or the Status of the Application

If a new notice or Filing Receipt is enclosed, applicant may disregard the previous notice mailed on 04/22/2008. The time period for reply runs from the mail date of the new notice. Within the time period for reply, applicant is required to file a reply in compliance with the requirements set forth in the new notice to avoid abandonment of the application.

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If the reply is not filed electronically via EFS-Web, the reply must be accompanied by a copy of the new notice.

If the Office previously granted a petition to withdraw the holding of abandonment or a petition to revive under 37 CFR 1.137, the status of the application has been returned to pending status.

/eulanday/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/060,856	04/01/2008	3733	500	145912002500	9	1

CONFIRMATION NO. 7469

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

FILING RECEIPT

OC000000033535175

Date Mailed: 12/12/2008

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Janine C. Robinson, Half Moon Bay, CA;

Assignment For Published Patent Application

Spinal Kinetics, Inc., Sunnyvale, CA

Power of Attorney: The patent practitioners associated with Customer Number 60154

Domestic Priority data as claimed by applicant

This appln claims benefit of 60/909,474 04/01/2007

Foreign Applications

If Required, Foreign Filing License Granted: 04/21/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/060,856**

Projected Publication Date: Supplemental Fees Missing

Non-Publication Request: No

Early Publication Request: No
** **SMALL ENTITY** **

Title

Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques

Preliminary Class

623

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where

the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PTO/SB/21 (10-08)
Approved for use through 11/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 211

Application Number	12/060856
Filing Date	01 April 2008
First Named Inventor	Janine C. ROBINSON
Art Unit	3733
Examiner Name	
Attorney Docket Number	145912002500

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☑ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☑ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Declaration (3 sheets); Copy of Notice to File Missing Parts (2 sheets); Checks in the amount of $435, $65, and $1175; Return Receipt Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Wheelock Chan LLP		
Signature	E. Thomas Wheelock		
Printed name	E. Thomas Wheelock		
Date	24 November 2008	Reg. No.	28825

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	E. Thomas Wheelock		
Typed or printed name	E. Thomas Wheelock	Date	24 November 2008

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

CONFIRMATION NO. 7469

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

FORMALITIES LETTER

OC000000029508792

12/01/2008 RFEKABU1 00000002 12060856

01 FC:2051 1105.00 OP

12/01/2008 RFEKABU1 00000002 12060856

01 FC:2051 65.00 OP
02 FC:2051 82.00 OP
03 FC:4011 270.00 OP
04 FC:2111 83.00 OP

Date Mailed: 04/22/2008

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  Applicant must submit $75 to complete the basic filing fee for a small entity.
- The oath or declaration is missing.
  A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 1-2, 3a.
  - The drawings have a line quality that is too light to be reproduced (weight of all lines and letters must be heavy enough to permit adequate reproduction) or text that is illegible (reference characters, sheet numbers, and view numbers must be plain and legible) see 37 CFR 1.84(l) and (p)(1)); See Figure(s) 3a-c, 4.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of **$65** for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this notice.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$500** for a small entity

- **$75** Statutory basic filing fee.
- **$65** Surcharge.
- The application search fee has not been paid. Applicant must submit **$255** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **$105** to complete the examination fee for a small entity in compliance with 37 CFR 1.27.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/tnguyen/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

I hereby certify that this correspondence is being deposited with the United Sates Postal Service as first class mail in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Deposit: 24 November 2008

Typed Name: E. Thomas Wheelock

Signature: E. Thomas Wheelock

Docket No. 145912002500
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Janine C. ROBINSON

Confirmation No.: 7469

Application No.: 12/060,856

Art Unit: 3733

Filing Date: 01 April 2008

For: PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

REPLY TO NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice to File Missing Parts of Nonprovisional Application, dated April 22, 2008, the applicants hereby submit:

--Transmittal Form (1 sheet)
--This Reply to Notice to File Missing... (1 sheet)
--Declaration (3 sheets)
--Replacement Drawings (3 sheets)
--Check in the amount of $435 to cover the Filing, Search and Examination Fee
--Copy of Notice to File Missing Parts of Nonprovisional Application (2 sheets)
--Petition for Extension of Time (1 sheet) with check in the amount of $1175.00
--Check in the amount of $65.00 for surcharge fee
--Return receipt postcard

Respectfully submitted,

E. Thomas Wheelock

E. Thomas Wheelock, Reg. No. 28,825
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, California 94306
(650) 302-6286

Dated: November 24, 2008

Document Code: IMIS

Notice of Fee Due

Date: 12-01-08

Application Number: 12/060 856

A fee is due for the attached document for the reason indicated below. Please check the application for the appropriate authorization to charge a deposit account. If an authorization is present, please charge the appropriate fee*. If an authorization is not present, notify the application of the fee deficiency.

***If the fee due is for any of the filing fees, check for authorization to charge the surcharge. If authorization is present, charge the surcharge for late payment of the filing fees as well.**

- [x] Insufficient payment by check or money order.
- [ ] Insufficient funds in deposit account _____ at ____:____ (time).
- [ ] Insufficient payment by credit card.
- [ ] Declined credit card.
- [x] No authorization to charge a deposit account.

Fee code(s) to be applied:

2311	110.00

Amount in holding fee code:

1506	
1622/2622	83.00
1999	

Total remaining due from applicant: 27.00

RAM Operator Ruth

Rev. [illegible] 07

PTO/SB/22 (10-08)
Approved for use through 11/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2009** *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)*	Docket Number (Optional) 145912002500
Application Number 12/060,856	Filed 01 April 2008
For Janine C. ROBINSON	
Art Unit 3733	Examiner

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	
☐	One month (37 CFR 1.17(a)(1))	$130	$65	$
☐	Two months (37 CFR 1.17(a)(2))	$490	$245	$
☐	Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐	Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☑	Five months (37 CFR 1.17(a)(5))	$2350	$1175	$ 1175.00

☑ Applicant claims small entity status. See 37 CFR 1.27.

☑ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number _____.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 28,825

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

E. Thomas Wheelock — Signature

24 November 2008 — Date

E. Thomas Wheelock — Typed or printed name

650-302-6286 — Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of 1 forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:
My residence, post office address and citizenship are as stated below next to my name.
I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

the specification of which was filed on April 1, 2008 as Application No. 12/060,856.
I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by an amendment, if any, specifically referred to herein.

I acknowledge the duty to disclose all information known to me that is material to patentability in accordance with Title 37, Code of Federal Regulations, § 1.56.

FOREIGN PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

[x] no foreign applications have been filed

[ ] foreign application(s) have been filed as follows:

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

Application Number	Country	Date of Filing	*Priority Claimed* Under 35 USC 119
			___ Yes No ___
			___ Yes No ___
			___ Yes No ___

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

Application Number	Country	Date of Filing

CLAIM FOR BENEFIT OF EARLIER U.S. PROVISIONAL APPLICATIONS

I hereby claim priority benefits under Title 35, United States Code §119(e), of any United States provisional patent application(s) listed below:

[ ] no U.S. provisional applications have been filed.

[X] U.S. provisional application(s) have been filed as follows:

Application Number	Date of Filing	Priority Claimed Under 35 USC 119
60/909,474	April 1, 2007	X Yes No ___
		___ Yes No ___
		___ Yes No ___

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, §120 of the United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information that is material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56 which became available to me between the filing date of the prior application and the national or PCT international filing date of this application:

[X] no U.S./PCT applications have been filed.

[ ] U.S./PCT application(s) have been filed as follows:

Application Number	Date of Filing	Status (Patented/Pending/Abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint:
All practitioners at Customer Number **60154**

all of name address of firm, jointly, and each of them severally, my attorneys at law/patent agent(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the U. S. Patent and Trademark Office connected therewith.

Please mail all correspondence to **E. Thomas Wheelock** , whose address is:
E. Thomas Wheelock
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, California 94306

Please direct telephone calls to: (650) 302-6286
Please direct facsimiles to: (650) 302-6286
Please direct e-mail to: twheelock@wchiplaw.com or
tom@etwheelocklaw.com

Full name of sole or first inventor, Janine C. ROBINSON	
First Inventor's signature	Date 15SEP08
Residence Half Moon Bay, California	
Citizenship US	
Mailing Address 101 Alameda Ave., Half Moon Bay, California 94019 US	

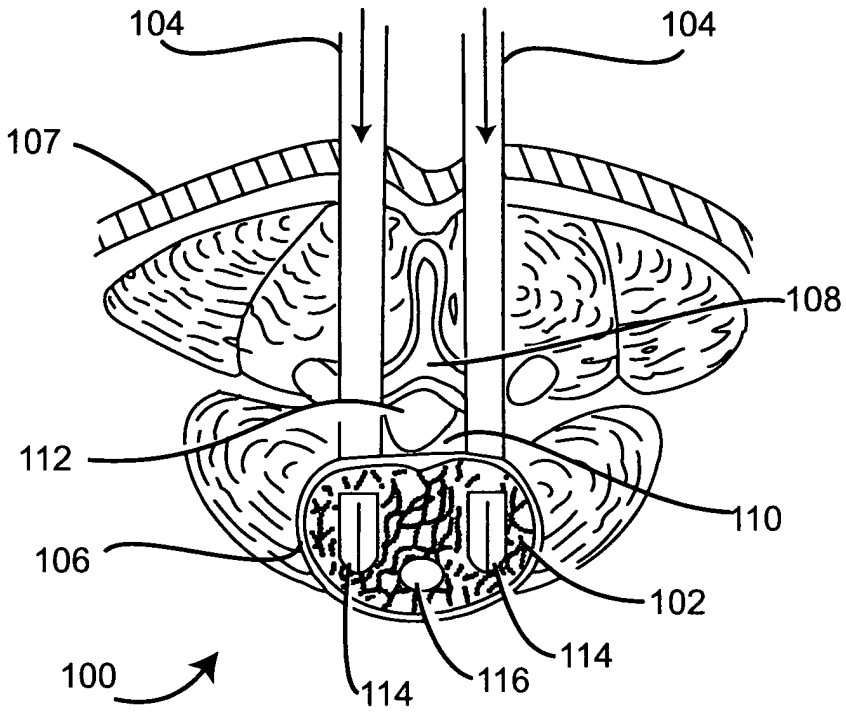


Figure 1

Replacement Page

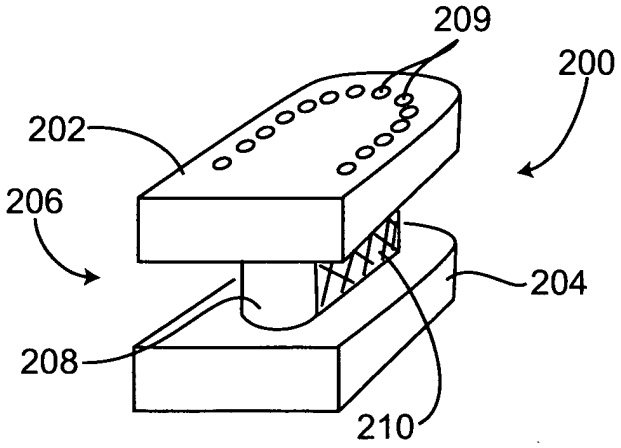


Figure 2

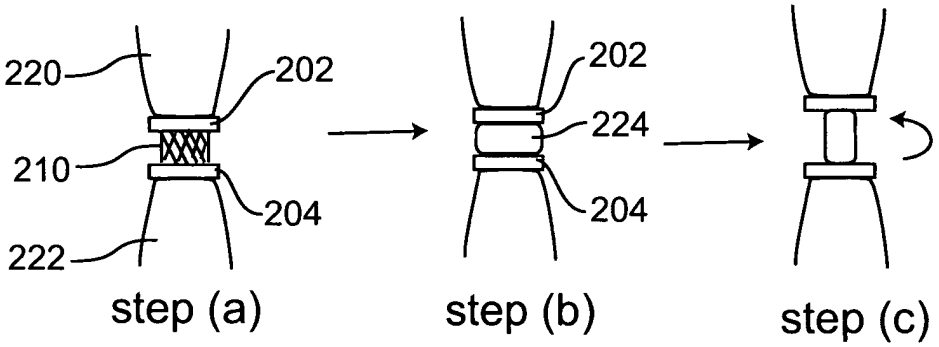
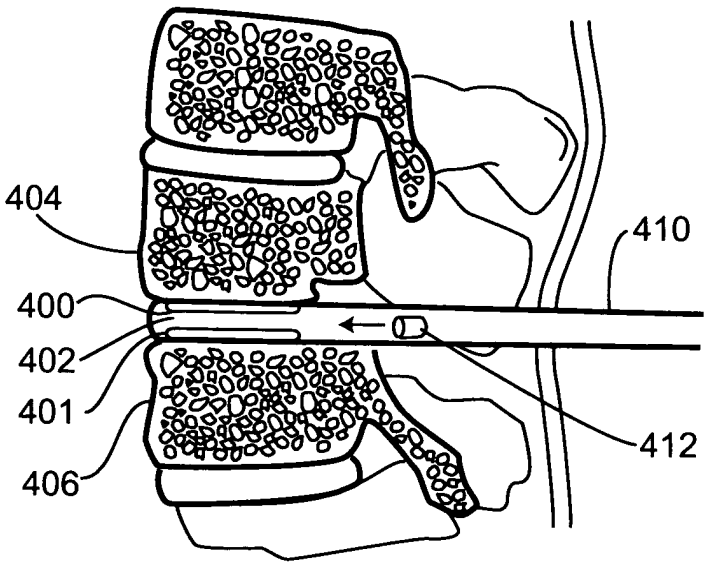


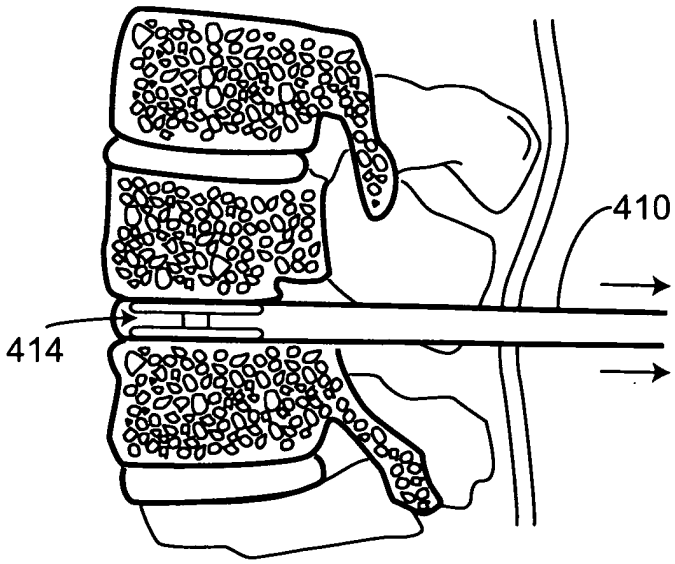
Figure 3

Replacement Page

Figure 4



Step (a)



Step (b)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/060,856	04/01/2008	Janine C. Robinson	145912002500

CONFIRMATION NO. 7469

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

FORMALITIES LETTER

OC00000002950879 2

Date Mailed: 04/22/2008

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  *Applicant must submit $**75** to complete the basic filing fee for a small entity.*
- The oath or declaration is missing.
  A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 1-2, 3a.
  - The drawings have a line quality that is too light to be reproduced (weight of all lines and letters must be heavy enough to permit adequate reproduction) or text that is illegible (reference characters, sheet numbers, and view numbers must be plain and legible) see 37 CFR 1.84(l) and (p)(1)); See Figure(s) 3a-c, 4.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $**65** for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this notice.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is $**500** for a small entity

- $**75** Statutory basic filing fee.
- $**65** Surcharge.
- The application search fee has not been paid. Applicant must submit $**255** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit $**105** to complete the examination fee for a small entity in compliance with 37 CFR 1.27.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/tnguyen/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/060,856	04/01/2008	3733	0.00	145912002500	9	1

CONFIRMATION NO. 7469

60154
Wheelock Chan LLP
P.O. Box 61168
Palo Alto, CA 94306

FILING RECEIPT

OC00000029508791

Date Mailed: 04/22/2008

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Janine C. Robinson, Half Moon Bay, CA;

Assignment For Published Patent Application

Spinal Kinetics, Inc., Sunnyvale, CA

Power of Attorney: None

Domestic Priority data as claimed by applicant

This appln claims benefit of 60/909,474 04/01/2007

Foreign Applications

If Required, Foreign Filing License Granted: 04/21/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/060,856**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****

Title

Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques

Preliminary Class

623

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where

the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PTO/SB/05 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	145912002500
First Inventor	Janine C. Robinson
Title	Prosthetic Intervertebral Discs Hav
Express Mail Label No.	Via EFS Web on 2008-04-01

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (e.g., PTO/SB/17)
   (Submit an original and a duplicate for fee processing)
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification** [*Total Pages* 23]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. ☑ **Drawing(s)** (*35 U.S.C. 113*) [*Total Sheets* 3]
5. **Oath or Declaration** [*Total Sheets* _____]
   a. ☐ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 18 completed)
   i. ☐ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☑ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
   (if applicable, items a. – c. are required)
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

ADDRESS TO:
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee _____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☐ **Return Receipt Postcard** (MPEP 503)
    (Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
    (if foreign priority is claimed)
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☐ Other: _____

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information: *Examiner* _____ *Art Unit:* _____

19. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 60154 ***OR*** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	E. Thomas Wheelock	Date	2008-04-01
Name (Print/Type)	E. Thomas Wheelock	Registration No. (Attorney/Agent)	28825

PTO/SB/14 (02-07)
Approved for use through 02/28/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145912002500
	Application Number	
Title of Invention	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Janine	C.	Robinson	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Half Moon Bay	State/Province	CA	Country of Residence	US

Citizenship under 37 CFR 1.41(b) US

Mailing Address of Applicant:

Address 1	101 Alameda Ave.
Address 2	

City	Half Moon Bay	State/Province	CA
Postal Code	94019	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	60154		
Email Address	tom@etwheelocklaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques		
Attorney Docket Number	145912002500	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	3	Suggested Figure for Publication (if any)	

PTO/SB/14 (02-07)
Approved for use through 02/28/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145912002500
	Application Number	
Title of Invention	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not been and will not be the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ US Representative (37 CFR 11.9)
Customer Number	60154		

Domestic Priority Information:

This section allows for the applicant to claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c). Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	60/909474	2007-04-01

Additional Domestic Priority Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country[1]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			◉ Yes ○ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1

If the Assignee is an Organization check here. ☒

PTO/SB/14 (02-07)
Approved for use through 02/28/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145912002500
	Application Number	
Title of Invention	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques	

Organization Name	Spinal Kinetics, Inc.		
Mailing Address Information:			
Address 1	595 N. Pastoria Avenue		
Address 2			
City	Sunnyvale	**State/Province**	CA
Country	US	Postal Code	94085
Phone Number	408-636-2900	Fax Number	408-636-2599
Email Address			
Additional Assignee Data may be generated within this form by selecting the **Add** button.			

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/E. Thomas Wheelock/			Date (YYYY-MM-DD)	2008-04-01
First Name	E. Thomas	Last Name	Wheelock	Registration Number	28825

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PROSTHETIC INTERVERTEBRAL DISCS HAVING ROTATABLE, EXPANDABLE CORES THAT ARE IMPLANTABLE USING MINIMALLY INVASIVE SURGICAL TECHNIQUES

Related Applications

[001] This application derives benefit from U.S. Provisional Application No. 60/909,474, filed April 1, 2007.

Field

[002] The described devices are spinal implants that may be surgically implanted into the spine to replace damaged or diseased discs using a posterior approach. The discs are prosthetic devices that approach or mimic the physiological motion and reaction of the natural disc.

Background

[003] The intervertebral disc is an anatomically and functionally complex joint. The intervertebral disc is composed of three component structures: (1) the nucleus pulposus; (2) the annulus fibrosus; and (3) the vertebral end plates. The biomedical composition and anatomical arrangements within these component structures are related to the biomechanical function of the disc.

[004] The spinal disc may be displaced or damaged due to trauma or a disease process. If displacement or damage occurs, the nucleus pulposus may herniate and protrude into the vertebral canal or intervertebral foramen. Such deformation is known as herniated or slipped

disc. A herniated or slipped disc may press upon the spinal nerve that exits the vertebral canal through the partially obstructed foramen, causing pain or paralysis in the area of its distribution.

[005] To alleviate this condition, it may be necessary to remove the involved disc surgically and fuse the two adjacent vertebrae. In this procedure, a spacer is inserted in the place originally occupied by the disc and the spacer is secured between the neighboring vertebrae by the screws and plates or rods attached to the vertebrae. Despite the excellent short-term results of such a "spinal fusion" for traumatic and degenerative spinal disorders, long-term studies have shown that alteration of the biomechanical environment leads to degenerative changes particularly at adjacent mobile segments. The adjacent discs have increased motion and stress due to the increased stiffness of the fused segment. In the long term, this change in the mechanics of the motion of the spine causes these adjacent discs to degenerate.

[006] Artificial intervertebral replacement discs may be used as an alternative to spinal fusion.

Summary

[007] Prosthetic intervertebral discs and methods for using such discs are described. The subject prosthetic discs include an upper end plate, a lower end plate, and a compressible core member disposed between the two end plates. The described prosthetic discs have shapes, sizes, and other features that are particularly suited for implantation using minimally invasive surgical procedures, particularly from a posterior approach.

[008] In one variation, the described prosthetic discs include top and bottom end plates separated by one or more compressible core members. The two plates may be held together by at least one fiber wound around at least one region of the top end plate and at least one region of

the bottom end plate. The described discs may include integrated vertebral body fixation elements. When considering a lumbar disc replacement from the posterior access, the two plates are preferably elongated, having a length that is substantially greater than its width. Typically, the dimensions of the prosthetic discs range in height from 8mm to 15mm; the width ranges from 6mm to 13mm. The height of the prosthetic discs ranges from 9mm to 11mm. The widths of the disc may be 10mm to 12mm. The length of the prosthetic discs may range from 18mm to 30mm, perhaps 24mm to 28mm. Typical shapes include oblong, bullet-shaped, lozenge-shaped, rectangular, or the like

[009] The described disc structures may be held together by at least one fiber wound around at least one region of the upper end plate and at least one region of the lower end plate. The fibers are generally high tenacity fibers with a high modulus of elasticity. The elastic properties of the fibers, as well as factors such as the number of fibers used, the thickness of the fibers, the number of layers of fiber windings in the disc, the tension applied to each layer, and the crossing pattern of the fiber windings enable the prosthetic disc structure to mimic the functional characteristics and biomechanics of a normal-functioning, natural disc.

[010] A number of conventional surgical approaches may be used to place a pair of prosthetic discs. Those approaches include a modified posterior lumbar interbody fusion (PLIF) and a modified transforaminal lumbar interbody fusion (TLIF) procedures. We also describe apparatus and methods for implanting prosthetic intervertebral discs using minimally invasive surgical procedures. In one variation, the apparatus includes a pair of cannulae that are inserted posteriorly, side-by-side, to gain access to the spinal column at the disc space. A pair of prosthetic discs may then be implanted by way of the cannulae to be located between two vertebral bodies in the spinal column.

[011] The prosthetic discs may be configured by selection of sizes and structures suitable for implantation by minimally invasive procedures.

[012] Other and additional devices, apparatus, structures, and methods are described by reference to the drawings and detailed descriptions below.

Brief Description of the Drawings

[013] The Figures contained herein are not necessarily drawn to scale. Some components and features may be exaggerated for clarity.

[014] Figure 1 shows a method for placement of prosthetic intervertebral discs using a posterior approach.

[015] Figure 2 is a perspective view of a variation of my prosthetic disc.

[016] Figure 3 is a stylized version of a method for introducing the compressible into the space between the end plates.

[017] Figure 4 schematically illustrates a method for implanting the described prosthetic discs.

Detailed Description

[018] Described below are prosthetic intervertebral discs, methods of using such discs, apparatus for implanting such discs, and methods for implanting such discs. It is to be understood that the prosthetic intervertebral discs, implantation apparatus, and methods are not limited to the particular embodiments described, as these may, of course, vary. It is also to be understood that the terminology used here is only for the purpose of describing particular embodiments, and is not intended to be limiting in any way.

[019] Insertion of the prosthetic discs may be approached using modified conventional procedures, such as a posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF). In the modified PLIF procedure, the spine is approached via midline incision in the back. The erector spinae muscles are stripped bilaterally from the vertebral lamina at the required levels. A laminectomy is then performed to further allow visualization of the nerve roots. A partial facetectomy may also be performed to facilitate exposure. The nerve roots are retracted to one side and a discectomy is performed. Optionally, a chisel may then used to cut one or more grooves in the vertebral end plates to accept the fixation components on the prostheses. Appropriately-sized prostheses may then be inserted into the intervertebral space on either side of the vertebral canal.

[020] In a modified TLIF procedure, the approach is also posterior, but differs from the PLIF procedure in that an entire facet joint is removed and the access is only on one side of the vertebral body. After the facetectomy, the discectomy is performed. Again, a chisel may be used to create on or more grooves in the vertebral end plates to cooperatively accept the fixation components located on each prosthesis. The prosthetic discs may then be inserted into the intervertebral space. One prosthesis may be moved to the contralateral side of the access and then a second prosthesis then inserted on the access side.

[021] It should be apparent that we refer to these procedures as "modified" in that neither procedure is used to "fuse" the two adjacent vertebrae.

[022] Figure 1 shows a top, cross section view of a spine (100), sectioned across an intervertebral disc (102). This Figure depicts a minimally invasive surgical procedure for implanting a pair of intervertebral discs in an intervertebral region formed by the removal of a natural disc. This minimally invasive surgical implantation method is performed using a

posterior approach, rather than the conventional anterior lumbar disc replacement surgery or the modified PLIF and TLIF procedures described above.

[023] In Figure 1, two cannulae (104) are inserted posteriorly, through the skin (107), to provide access to the spinal column. More particularly, a small incision is made and a pair of access windows created through the lamina (106) of one of the vertebrae (108) on each side of the vertebral canal (110) to access the natural vertebral disc. The spinal cord (112) and nerve roots are avoided or moved to provide access. Once access is obtained, the two cannulae (104) are inserted. The cannulae (104) may be used as access passageways in removing the natural disc with conventional surgical tools. Alternatively, the natural disc may be removed prior to insertion of the cannulae. The cannulae are also used to introduce the prosthetic intervertebral discs (114) to the intervertebral region.

[024] The described prosthetic discs are of a design and capability that they may be employed at more than one level, i.e., disc location, in the spine. Specifically, several natural discs may be replaced with my discs. As will be described in greater detail below, each such level will be implanted with at least two of my discs. Kits, containing two of my discs for a single disc replacement or four of my discs for replacement of discs at two levels in the spine, perhaps with sterile packaging are contemplated. Such kits may also contain one or more cannulae having a central opening allowing passage and implantation of my discs.

[025] Once the natural disc has been removed and the cannulae (104) located in place, two prosthetic discs (114) are implanted between adjacent vertebral bodies. The prosthetic discs have a shape and size suitable making them suitable for use with (or adapted for) various minimally invasive procedures. The discs may have a shape such as the elongated one-piece prosthetic discs described below.

[026] Two prosthetic discs (114) are guided through the cannulae such that each of the prosthetic discs (114) is implanted between the adjacent vertebral bodies. The two prosthetic discs (114) may be located side-by-side and spaced slightly apart, as viewed from above. Optionally, prior to implantation, grooves may be formed on the internal surfaces of one or both of the vertebral bodies in order to engage anchoring components or features located on or integral with the prosthetic discs (114). The grooves may be formed using a chisel tool adapted for use with the minimally invasive procedure, i.e., adapted to extend through a relatively small access space (such as the tunnel-like opening found in through the cannulae) and to chisel the noted grooves within the intervertebral space present after removal of the natural disc.

[027] These discs may be used as shown in Figure 1 or, optionally, they may be implanted with an additional prosthetic disc or discs, perhaps in the position shown for auxiliary disc (116).

[028] Additional prosthetic discs may also be implanted in order to obtain desired performance characteristics, and the implanted discs may be implanted in a variety of different relative orientations within the intervertebral space. In addition, the multiple prosthetic discs may each have different performance characteristics. For example, a prosthetic disc to be implanted in the central portion of the intervertebral space may be configured to be more resistant to compression than one or more prosthetic discs that are implanted nearer the outer edge of the intervertebral space. For instance, the stiffness of the outer discs (e.g., 114) may each be configured such that those outer discs exhibit approximately 5% to 80% of the stiffness of the central disc (116), perhaps in the range of about 30% to 60% of the central disc (116) stiffness. Other performance characteristics may be varied as well.

[029] This description may describe a number of variations of prosthetic intervertebral discs. By “prosthetic intervertebral disc” is meant an artificial or manmade device that is so configured

or shaped that it may be employed as a total or partial replacement of an intervertebral disc in the spine of a vertebrate organism, e.g., a mammal, such as a human. The described prosthetic intervertebral discs have dimensions that permit them, either alone or in combination with one or more other prosthetic discs, to substantially occupy the space between two adjacent vertebral bodies that is present when the naturally occurring disc between the two adjacent bodies is removed, i.e., a void disc space. By "substantially occupy" is meant that, in the aggregate, the discs occupy at least about 30% by surface area, perhaps at least about 80% by surface area or more. The subject discs may have a roughly bullet or lozenge shaped structure adapted to facilitate implantation by minimally invasive surgical procedures.

[030] The discs may include both an upper (or top) and lower (or bottom) end plate, where the upper and lower end plates are separated from each other by a compressible element such as one or more core members, where the combination structure of the end plates and compressible element provides a prosthetic disc that functionally approaches or closely mimics a natural disc. The top and bottom end plates may be held together by at least one fiber attached to or wound around at least one portion of each of the top and bottom end plates. As such, the two end plates (or planar substrates) are held to each other by one or more fibers that are attached to or wrapped around at least one domain, portion, or area of the upper end plate and lower end plate such that the plates are joined to each other.

[031] Figure 2 shows a variation of my prosthetic intervertebral disc (200). This variation comprises an upper end plate (202) and a lower end plate (204) separated by a compressible core (206) comprising two core members (208). As discussed below in more detail, the compressible core (206) may comprise one or more core members (208) and be bounded by one or more fibers (210) extending between the upper end plate (202) and the lower end plate (204). The upper and

lower end plates (202, 204) may include apertures (212), through which the fibers (210) may pass. Other components (woven or nonwoven fabrics, wires, etc.) may be used in functional substitution for the fibers (210).

[032] Figure 3 provides a summary method for placement of my prosthetic disc. In step (a), a pair of end plates (202, 204) optionally having a portion of the fiber windings (210) included, are placed in the implantation site between an upper vertebra (220) and a lower vertebra (222). In step (b), a core member (224) is inserted between the two end plates (202, 204). The core member (224) may be substantially cylindrical and have a diameter less than its height. In step (b), the core member (224) may be inserted on its side. In step (c), the core member (224) is rotated such that the axis of the core member (224) aligns with the spine axis, or is upright.

[033] The geometry of the core member (224) may be modified to ease the step of rotating the core member (224). For instance, imposing a radius or chamfer on the edge of the cylinder will help with the rotation.

[034] Additionally, more than one such core member (224) may be placed between the end plates. The disc (200 in Figure 2) is one such variation. Exactly one core member (224) may also be introduced into the prosthetic disc.

[035] The end plates may be planar substrates having a length of from about 12mm to about 45mm, such as from about 13mm to about 44mm, a width of from about 11mm to about 28mm, such as from about 12mm to about 25mm, and a thickness of from about 0.5mm to about 5mm, such as from about 1mm to about 3mm. The top and bottom end plates are fabricated or formed from a physiologically acceptable material that provides for the requisite mechanical properties, primarily structural rigidity and durability. Representative materials from which the end plates may be fabricated are known to those of skill in the art and include: metals such as titanium,

titanium alloys, stainless steel, cobalt/chromium, etc.; plastics such as polyethylene with ultra high molar mass (molecular weight) (UHMW-PE), polyether ether ketone (PEEK), etc.; ceramics; graphite; etc.

[036] The discs may also include fibers (210) wound between and connecting the upper end plate (202) to the lower end plate (204). These fibers (210) may extend through a plurality of openings or apertures (209) formed on portions of each of the upper and lower end plates (202, 204). Thus, a fiber (210) extends between the pair of end plates (202, 204), and extends up through a first aperture (209) in the upper end plate (202) and back down through an adjacent aperture (209) in the upper end plate (202). The fibers (210) may not be tightly wound, thereby allowing a degree of axial rotation, bending, flexion, and extension by and between the end plates. The amount of axial rotation generally is in the range from about 0° to about 15°, perhaps from about 2° to 10°. The amount of bending generally has a range from about 0° to about 18°, perhaps from about 2° to 15°. The amount of flexion and extension generally has a range from about 0° to about 25°, perhaps from about 3° to 15°. Of course, the fibers (210) may be more or less tightly wound to vary the resultant values of these rotational values. The core members (not shown) forming compressible core (206) may be provided in an uncompressed or in a compressed state.

[037] My described prosthetic discs may include a compressible core (206) comprising a larger single elongated core member, a generally circular core member, or two or more generally cylindrical core members. The dual core structure may better simulate the performance characteristics of a natural disc. In addition, the fibers (210) found in the dual core structure are believed to endure less stress relative to the fibers (210) found in the single core structure.

[038] The lateral, or horizontal, surface area of each of the end plates (202, 204) – i.e., the area of the disc surfaces that engage the vertebral bodies – is substantially larger than the cross-sectional surface area of the core member or members. The cross-sectional surface area of the core member or members may be from about 5% to about 80% of the cross-sectional area of a given end plate (202, 204), perhaps from about 10% to about 60%, or from about 15% to about 50%. In this way, for a given compressible core (206) having sufficient compression, flexion, extension, rotation, and other performance characteristics but having a relatively small cross-sectional size, the core member may be used to support end plates having a relatively larger cross-sectional size in order to help prevent subsidence into the vertebral body surfaces. In the variations described here, the compressible core (206) and end plates (202, 204) also have a size that is appropriate for or adapted for implantation by way of posterior access or minimally invasive surgical procedures, such as those described above.

[039] Figure 4, step (a), shows placement of upper and lower end plates (400, 401) into the intervertebral space (402) between an upper vertebra (404) and the adjacent lower vertebra (406). The upper and lower end plates (400, 401) have been passed through the cannula (410) to the implantation site. Any fibrous members have been omitted from the drawing for ease of explanation. The core member (412) is shown approaching the site of the upper and lower end plates (400, 401).

[040] Figure 4, step (b), shows the high profile disc (414) after expansion, i.e., placement of the core member and rotation of the core member into the final position. The cannula (410) is then removed.

[041] Each of the described prosthetic discs depicted in the Figures has a greater length than width. The aspect ratio (length:width) of the discs may be about 1.5:1 to 5.0:1, perhaps about

2.0:1 to 4.0:1, or about 2.5:1 to 3.5:1. Exemplary shapes to provide these relative dimensions include rectangular, oval, bullet-shaped, lozenge-shaped, and others. These shapes facilitate implantation of the discs by the minimally invasive procedures described above.

[042] The surfaces of the upper and lower end plates, those surfaces in contact with and eventually adherent to the respective opposed bony surfaces of the upper and lower vertebral bodies, may have one or more anchoring or fixation components or mechanism for securing those end plates to the vertebral bodies. For example, the anchoring feature may be one or more "keels," a fin-like extension often having a substantially triangular cross-section and having a sequence of exterior barbs or serrations. This anchoring component is intended to cooperatively engage a mating groove that is formed on the surface of the vertebral body and to thereby secure the end plate to its respective vertebral body. The serrations enhance the ability of the anchoring feature to engage the vertebral body.

[043] Further, this variation of the anchoring component may include one or more holes, slots, ridges, grooves, indentations, or raised surfaces to further assist in anchoring the disc to the associated vertebra. These physical features will so assist by allowing for bony ingrowth. Each end plate may have a different number of anchoring components, and those anchoring features may have a different orientation on each end plate. The number of anchoring features generally ranges in number from about 0 to about 500, perhaps from about 1 to 10. Alternatively, another fixation or anchoring mechanism may be used, such as ridges, knurled surfaces, serrations, or the like. In some variations, the discs will have no external fixation mechanism. In such variations, the discs are held in place laterally by the friction forces between the disc and the vertebral bodies.

[044] Further, each of the described variations may additionally include a porous covering or layer (e.g., sprayed Ti metal) allowing boney ingrowth and may include some osteogenic materials.

[045] As noted above, in the variations shown herein, the upper end plate and lower end plate may each contain a plurality of apertures through which the fibers may be passed through or wound, as shown. The actual number of apertures contained on an end plate is variable. Increasing the number of apertures allows an increase in the circumferential density of the fibers holding the end plates together. The number of apertures may range from about 3 to 100, perhaps in the range of 10 to 30. In addition, the shape of the apertures may be selected so as to provide a variable width along the length of the aperture. For example, the width of the apertures may taper from a wider inner end to a narrow outer end, or visa versa. Additionally, the fibers may be wound multiple times within the same aperture, thereby increasing the radial density of the fibers. In each case, this improves the wear resistance and increases the torsional and flexural stiffness of the prosthetic disc, thereby further approximating natural disc stiffness. In addition, the fibers may be passed through or wound on each aperture, or only on selected apertures, as needed. The fibers may be wound in a uni-directional manner, where the fibers are wound in the same direction, e.g., clockwise, which closely mimics natural annular fibers found in a natural disc, or the fibers may be wound bi-directionally. Other winding patterns, both single and multi-directional, may also be used.

[046] The apertures provided in the various end plates discussed here, may be of a number of shapes. Such aperture shapes include slots with constant width, slots with varying width, openings that are substantially round, oval, square, rectangular, etc. Elongated apertures may be

radially situated, circumferentially situated, spirally located, or combinations of these shapes. More than one shape may be utilized in a single end plate.

[047] One purpose of the fibers is to hold the upper and lower end plates together and to limit the range-of-motion to mimic or at least to approach the range-of-motion of a natural disc. The fibers may comprise high tenacity fibers having a high modulus of elasticity, for example, at least about 100 MPa, perhaps at least about 500 MPa. By high tenacity fibers is meant fibers able to withstand a longitudinal stress of at least 50 MPa, and perhaps at least 250 MPa, without tearing. The fibers (207) are generally elongate fibers having a diameter that ranges from about 100 μm to about 1000 μm, and preferably about 200 μm to about 400 μm. The fibrous components may be single strands or, more typically, multi-strand assemblages. Optionally, the fibers may be injection molded or otherwise coated with an elastomer to encapsulate the fibers, thereby providing protection from tissue ingrowth and improving torsional and flexural stiffness. The fibers may be coated with one or more other materials to improve fiber stiffness and wear. Additionally, the core may be injected with a wetting agent such as saline to wet the fibers and facilitate the mimicking of the viscoelastic properties of a natural disc. The fibers may comprise a single or multiple component fibers.

[048] The fibers may be fabricated from any suitable material. Examples of suitable materials include polyesters (e.g., Dacron® or the Nylons), polyolefins such as polyethylene, polypropylene, low-density and high density polyethylenes, linear low-density polyethylene, polybutene, and mixtures and alloys of these polymers. HDPE and UHMWPE are especially suitable. Also suitable are various polyaramids, poly-paraphenylene terephthalamide (e.g., Kevlar®), carbon or glass fibers, various stainless steels and superelastic alloys (such as nitinol), polyethylene terephthalate (PET), acrylic polymers, methacrylic polymers, polyurethanes,

polyureas, other polyolefins (such as polypropylene and other blends and olefinic copolymers), halogenated polyolefins, polysaccharides, vinylic polymers, polyphosphazene, polysiloxanes, liquid crystal polymers such as those available under the tradename VECTRA, polyfluorocarbons such as polytetrafluoroethylene and e-PTFE, and the like.

[049] The fibers may be terminated on an end plate in a variety of ways. For instance, the fiber may be terminated by tying a knot in the fiber on the superior or inferior surface of an end plate. Alternatively, the fibers may be terminated on an end plate by slipping the terminal end of the fiber into an aperture on an edge of an end plate, similar to the manner in which thread is retained on a thread spool. The aperture may hold the fiber with a crimp of the aperture structure itself, or by an additional retainer such as a ferrule crimp. As a further alternative, tab-like crimps may be machined into or welded onto the end plate structure to secure the terminal end of the fiber. The fiber may then be closed within the crimp to secure it. As a still further alternative, a polymer may be used to secure the fiber to the end plate by welding, including adhesives or thermal bonding. That terminating polymer may be of the same material as the fiber (e.g., UHMWPE, PE, PET, or the other materials listed above). Still further, the fiber may be retained on the end plates by crimping a cross-member to the fiber creating a T-joint, or by crimping a ball to the fiber to create a ball joint.

[050] The core members provide support to and maintain the relative spacing between the upper and lower end plates. The core members may comprise one or more relatively compliant materials. In particular, the compressible core members in this variation and the others discussed herein, may comprise a thermoplastic elastomer (TPE) such as a polycarbonate-urethane TPE having, e.g., a Shore value of 50D to 60D, e.g. 55D. An example of such a material is the

commercially available TPE, BIONATE. Shore hardness is often used to specify flexibility or flexural modulus for elastomers.

[051] We have had success with core members comprising TPE that are compression molded at a moderate temperature from an extruded plug of the material. For instance, with the polycarbonate-urethane TPE mentioned above, a selected amount of the polymer is introduced into a closed mold upon which a substantial pressure may be applied, while heat is applied. The TPE amount is selected to produce a compression member having a specific height. The pressure is applied for 8-15 hours at a temperature of 70°-90°C, typically about 12 hours at 80°C.

[052] Other examples of suitable representative elastomeric materials include silicone, polyurethanes, or polyester (e.g., Hytrel®).

[053] Compliant polyurethane elastomers are discussed generally in, M. Szycher, J. Biomater. Appl. "Biostability of polyurethane elastomers: a critical review", 3(2):297 402 (1988); A. Coury, et al., "Factors and interactions affecting the performance of polyurethane elastomers in medical devices", J. Biomater. Appl. 3(2):130 179 (1988); and Pavlova M, et al., "Biocompatible and biodegradable polyurethane polymers", Biomaterials 14(13):1024 1029 (1993). Examples of suitable polyurethane elastomers include aliphatic polyurethanes, segmented polyurethanes, hydrophilic polyurethanes, polyether-urethane, polycarbonate-urethane, and silicone-polyether-urethane.

[054] Other suitable elastomers include various polysiloxanes (or silicones), copolymers of silicone and polyurethane, polyolefins, thermoplastic elastomers (TPE's) such as atactic polypropylene, block copolymers of styrene and butadiene (e.g., SBS rubbers), polyisobutylene, and polyisoprene, neoprene, polynitriles, artificial rubbers such as produced from copolymers produced of 1-hexene and 5-methyl-1,4-hexadiene.

[055] One variant of the construction for the core member comprises a nucleus formed of a hydrogel and an elastomer reinforced fiber annulus.

[056] For example, the nucleus, the central portion of the core member, may comprise a hydrogel material. Hydrogels are water-swellable or water-swollen polymeric materials typically having structures defined either by a crosslinked or an interpenetrating network of hydrophilic homopolymers or copolymers. In the case of physical crosslinking, the linkages may take the form of entanglements, crystallites, or hydrogen-bonded structures to provide structure and physical integrity to the polymeric network.

[057] Suitable hydrogels may be formulated from a variety of hydrophilic polymers and copolymers including polyvinyl alcohol, polyethylene glycol, polyvinyl pyrrolidone, polyethylene oxide, polyacrylamide, polyurethane, polyethylene oxide-based polyurethane, and polyhydroxyethyl methacrylate, and copolymers and mixtures of the foregoing.

[058] Silicone-base hydrogels are also suitable. Silicone hydrogels may be prepared by polymerizing a mixture of monomers including at least one silicone-containing monomer and or oligomer and at least one hydrophilic co-monomer such as N-vinyl pyrrolidone (NVP), N-vinylacetamide, N-vinyl-N-methyl acetamide, N-vinyl-N-ethyl acetamide, N-vinylformamide, N-vinyl-N-ethyl formamide, N-vinylformamide, 2-hydroxyethyl-vinyl carbonate, and 2-hydroxyethyl-vinyl carbamate (beta-alanine).

[059] The annulus may comprise an elastomer, such as those discussed just above, reinforced with a fiber.

[060] The fiber may be wrapped around the core member in a variety of different configurations, e.g., wrapping the core member in a random pattern, circumferential wrapping,

radial wrapping, progressive polar (or near-polar) wrapping moving around the core, and combinations of these patterns and with other patterns.

[061] The shape of each of the core members may be cylindrical, although the shape (as well as the materials making up the core member and the core member size) may be varied to obtain desired physical or performance properties. For example, the core member's shape, size, and materials will directly affect the degree of flexion, extension, lateral bending, and axial rotation of the prosthetic disc.

[062] The annular capsule may be made of an appropriate polymer, such as polyurethane or silicone or the materials discussed above, and may be fabricated by injection molding, two-part component mixing, or dipping the end plate-core-fiber assembly into a polymer solution. The annular capsule may be oblong with straight sidewalls or with one or more bellows formed in the sidewalls. A function of the annular capsule is to act as a barrier that keeps the disc materials (e.g., fiber strands) within the body of the disc, and that keeps potential, natural in-growth outside the disc.

[063] Where a range of values is provided, it is understood that each intervening value within the range, to the tenth of the unit of the lower limit (unless the context clearly dictates otherwise), between the upper and lower limit of that range and any other stated or intervening value in that stated range is described. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also described, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also described.

[064] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the medical devices art. Although

methods and materials similar or equivalent to those described here may also be used in the practice or testing of the described devices and methods, the preferred methods and materials are described in this document. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[065] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

[066] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual variations described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of this disclosure. For example, and without limitation, several of the variations described here include descriptions of anchoring features, protective capsules, fiber windings, and protective covers covering exposed fibers for integrated end plates. It is expressly contemplated that these features may be incorporated (or not) into those variations in which they are not shown or described.

[067] All patents, patent applications, and other publications mentioned herein are hereby incorporated herein by reference in their entireties. The patents, applications, and publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that contents of those patents, applications, and publications are "prior" as that term is used in the Patent Law.

[068] The preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles otherwise described here and are

included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the described principles of my devices and methods. Moreover, all statements herein reciting principles, aspects, and variation as well as specific examples thereof, are intended to encompass both structural and functional equivalents. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure.

What is claimed is:

1. A prosthetic intervertebral disc, comprising:

a first end plate;

a second end plate;

at least one compressible core member configured so that it may be introduced in a first lower profile and positioned between said first and second end plates and be rotated to a second higher profile while located between said first and second end plates;

at least one fiber extending between and engaged with said first and second end plates; and

wherein said end plates and said core member are held together by said at least one fiber.

2. The prosthetic intervertebral disc of claim 1 wherein the at least one compressible core member is substantially cylindrical.

3. The prosthetic intervertebral disc of claim 1 wherein the at least one cylindrical compressible core member includes edges that have been radiused or chamfered.

4. The prosthetic intervertebral disc of claim 1 wherein the disc is bullet-shaped.

5. The prosthetic intervertebral disc of claim 1 wherein the disc is lozenge-shaped.

6. A kit for surgically replacing a discs in a spine with a posterior approach, comprising exactly two of the prosthetic discs of claim 1.

7. The kit of claim 6 further comprising at least one cannula suitable for a posterior approach configured to access a disc to be replaced and to bypass the spinal cord and local nerve roots and further sized for passage of at least one of the two prosthetic discs of claim 1.

8. The kit of claim 6 wherein the first and second end plates of each of the prosthetic discs have a length and a width, and wherein the length is greater than the width.

9. The kit of claim 8 wherein the first and second end plates of the prosthetic discs have a length:width aspect ratio of the first and second end plates is in the range of about 1.5:1 to 5.0:1.

ABSTRACT OF THE DISCLOSURE

The described devices are spinal implants that may be surgically implanted into the spine to replace damaged or diseased discs using a posterior approach. The discs are prosthetic devices that approach or mimic the physiological motion and reaction of the natural disc.

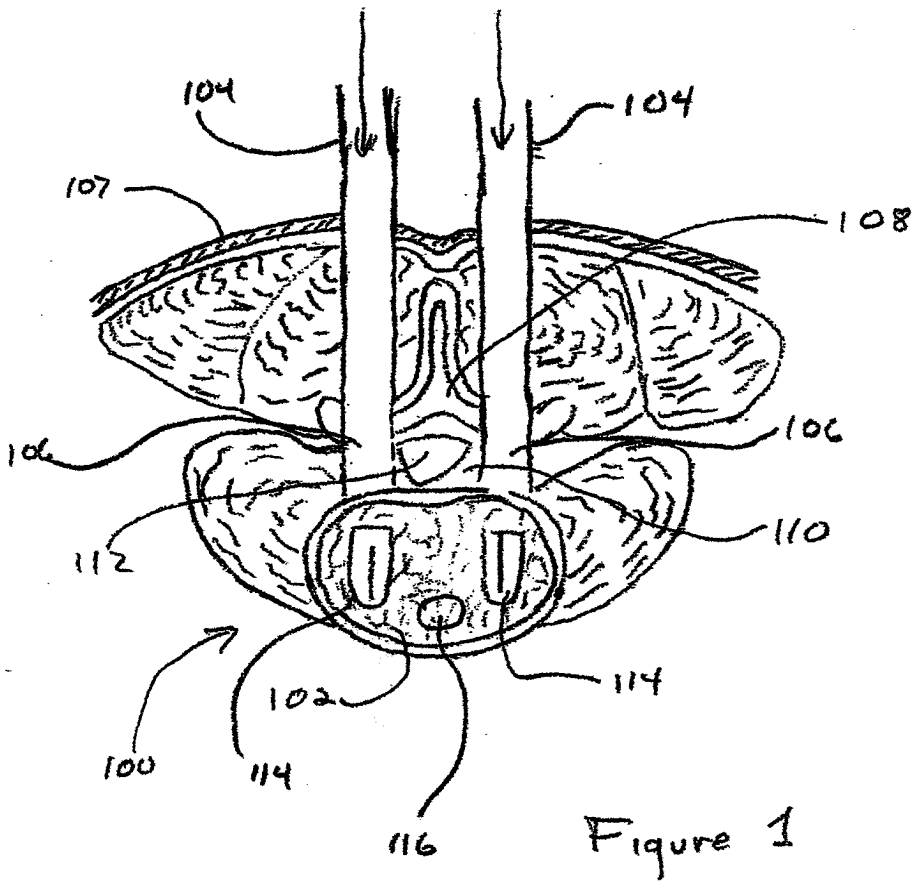


Figure 1

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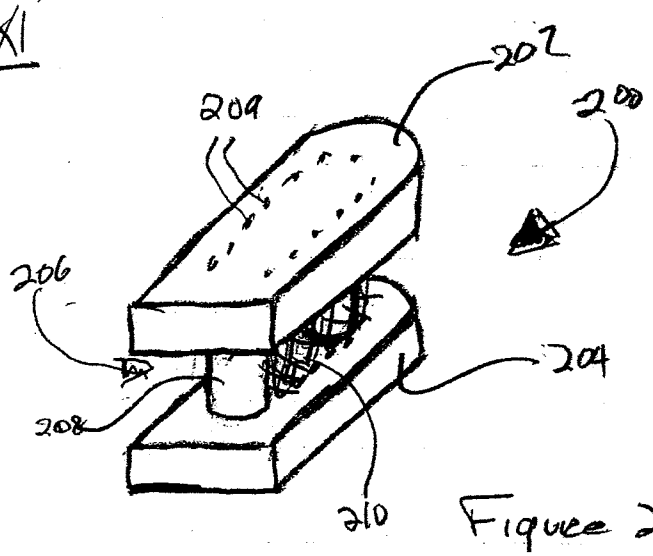


Figure 2

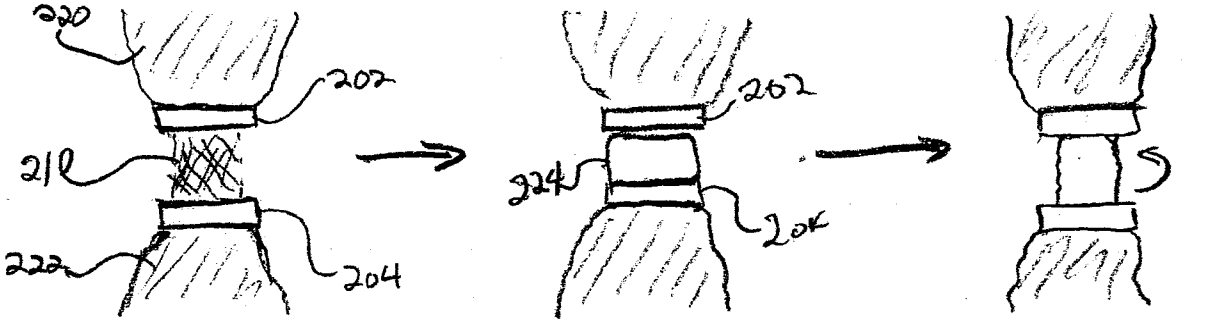
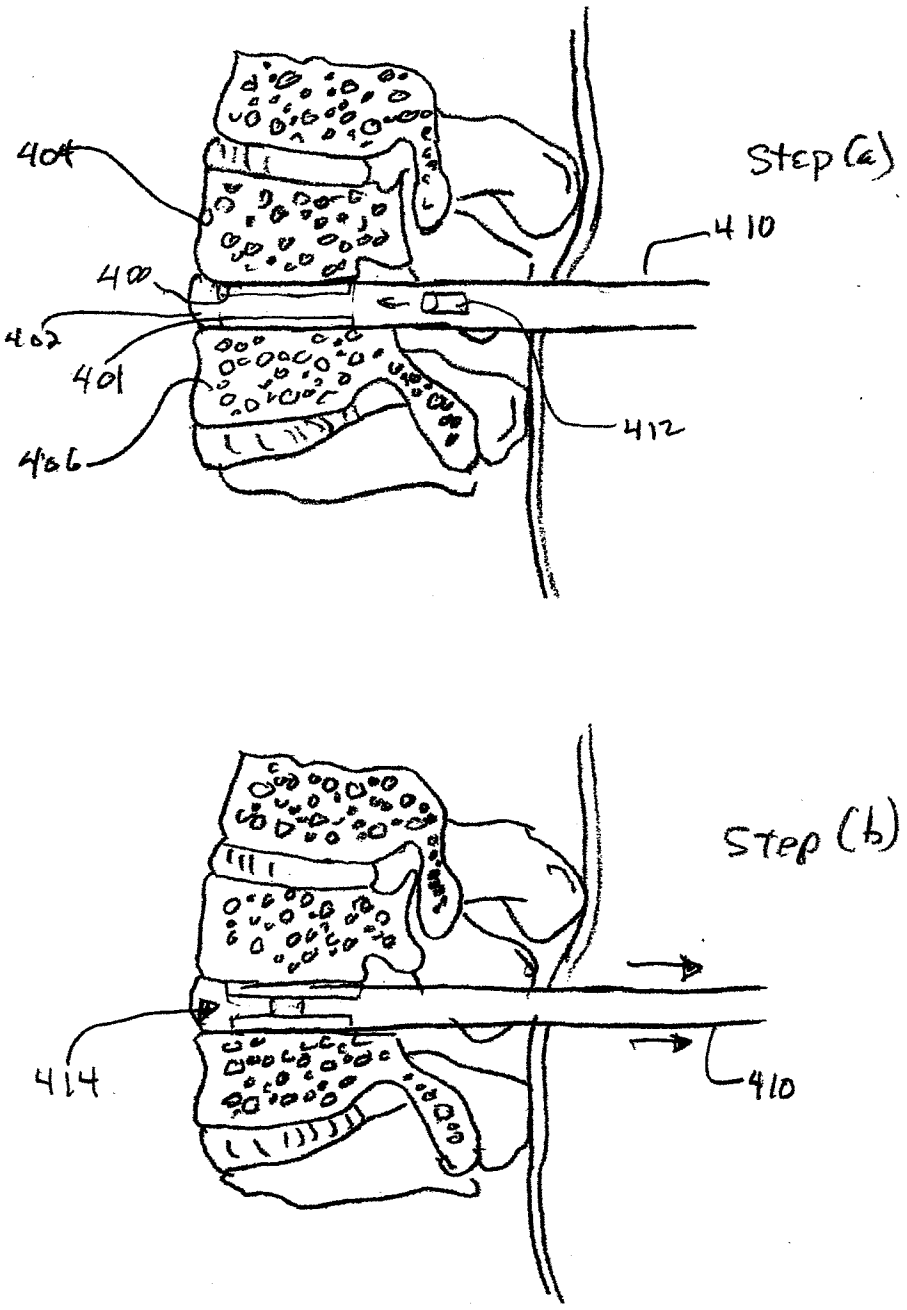


Figure 3

XI

Figure 4



Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques
First Named Inventor/Applicant Name:	Janine C. Robinson
Filer:	E. Thomas Wheelock
Attorney Docket Number:	145912002500

Filed as Small Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	75	75
Utility Search Fee	2111	1	255	255
Utility Examination Fee	2311	1	105	105
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**435**

Electronic Acknowledgement Receipt

EFS ID:	3089210
Application Number:	12060856
International Application Number:	
Confirmation Number:	7469
Title of Invention:	Prosthetic Intervertebral Discs Having Rotatable, Expandable Cores That Are Implantable Using Minimally Invasive Surgical Techniques
First Named Inventor/Applicant Name:	Janine C. Robinson
Customer Number:	60154
Filer:	E. Thomas Wheelock
Filer Authorized By:	
Attorney Docket Number:	145912002500
Receipt Date:	01-APR-2008
Filing Date:	
Time Stamp:	23:29:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		145912002500TransADS.pdf	270339 57df5dca49e2e8a5f4875012eaab34a14f57dafd	yes	4

	Multipart Description/PDF files in .zip description				
	Document Description	**Start**	**End**		
	Transmittal of New Application	1	1		
	Application Data Sheet	2	4		
Warnings:					
Information:					
2		145912002500specification.pdf	169427 50cb4b2203502096a9fba88d28ae215d25a84650	yes	23

	Multipart Description/PDF files in .zip description				
	Document Description	**Start**	**End**		
	Specification	1	20		
	Claims	21	22		
	Abstract	23	23		
Warnings:					
Information:					
3	Drawings-only black and white line drawings	145912002500drawings.pdf	73062 b3c5e9374b89b3da2e85e5812b49017e6dabd88d	no	3
Warnings:					
Information:					
4	Fee Worksheet (PTO-06)	fee-info.pdf	8439 7811e5ce134b806eeab19a7f43652b793e426e01	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	521267		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (12-04)

Filing Date: **04/01/08**

Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/060,856

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)			RATE ($)	
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	**75**		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	**255**		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	**105**		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	**9**		X$ 25		OR	X$50	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	**1**		X$105			X$210	
APPLICATION SIZE FEE (37 CFR 1.16(s))							
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			185			370	
			TOTAL	**435**		TOTAL	**0**

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED – PART II

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDI-TIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDI-TIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
					TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDI-TIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDI-TIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
					TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/060,856	04/01/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/LINDA A. WASHINGTON/