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May 2, 2005

**VIA HAND DELIVERY**
The Honorable Vincent J. Poppiti
Blank Rome LLP
1201 Market Street, Suite 800
Wilmington, DE 19801-2535

Re: *Kyphon Inc. v. Disc-O-Tech Medical Technologies, et al.*
USDC-D.Del. - C.A. No. 04-204-JJF

Dear Judge Poppiti:

This letter is Kyphon's brief response to a new argument raised by DOT's letter of April 27, 2005, weeks after completion of briefing regarding claim construction.[1] For the Court's convenience, all portions of the '043 prosecution history discussed herein are attached as exhibits.

Kyphon noted in its April 14, 2005 responsive claim construction brief that: (a) DOT's arguments regarding the prosecution history of the '043 were misplaced because they rely upon statements made early in the prosecution, when the pending claims specifically required a "balloon" or an inflatable device; and (b) thereafter, on January 24, 1997, the claims were expressly broadened so that they would not be limited to just inflatable devices. *See* D.I. 139 at 21-23. Kyphon via letter then provided the Court with the portion of the prosecution history quoted in Kyphon's brief, but inadvertently not submitted as an exhibit.

DOT now raises a new argument: that a statement in the Patent Examiner's notes containing the term "balloon" (the preferred embodiment set forth in the '043 specification) apparently provides the type of "clear disavowal" of claim scope that would be required to change the plain and ordinary meaning of the asserted claims. The evidence is to the contrary:

> [i] As noted above, the applicant sought to broaden the claims beyond just balloons and inflatable devices via the January 24, 1997 amendment. Attachment A;
>
> [ii] The applicant met with the Examiner. Although the Examiner's brief summary does mention the word "balloon," the proposed amendments that are attached to the interview summary reflect that ***none***

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DELAWARE
NEW YORK
SAN DIEGO
SILICON VALLEY
TWIN CITIES
WASHINGTON, DC

[1] While Kyphon disagrees with other assertions and characterizations in DOT's letters of April 27 & 28, 2005, there is nothing new therein that warrants further response. Kyphon, however, does note that DOT's letter of April 27, 2005, appears to assert that its obviousness arguments with regard to the Kennedy and Brown & Chow references are properly before the Court, because these references were mentioned in the anticipation section of DOT's brief. DOT's brief, of course, discussed lots of things - but the basis for the invalidity rulings DOT sought was ***expressly*** limited to the Olerud and Edeland references alone or in combination.

of the proposed amendments discussed with the Examiner mentions "balloons" or "inflatable devices." Attachment B;

[iii] On November 1, 1999, when the applicant cancelled all the pending claims and submitted a new set of claims, once again, there is ***no mention*** of balloons or inflatable devices in either the claims or the accompanying remarks. Instead, the claims are directed to devices adapted to "undergo expansion," and the accompanying remarks talk about "constrain[ing] expansion of an expandable body." Attachment C;

[iv] On March 3, 2000, the Patent Office indicated that certain dependent method claims would be allowable if the claims were rewritten in an independent format. Attachment D (Examiner noting that, among the reasons for indicating that subject matter was allowable in the pending claims was "the present invention discloses a method for compacting cancellous bone with constrained expansion of a device body") Attachment D, at p. 4;

[v] After various amendments were made, on November 2, 2000, the Patent Office simply stated:

"The following is an examiner's statement for reasons of allowance: The prior art of record discloses devices that can be used to compact cancellous bone. However, unlike the prior art of record, the present invention discloses methods for compacting cancellous bone with constrained expansion of a device body. Thus, the present invention is distinguishable over the prior art of record, and the claims are allowed." Attachment E, at p. 3.

Thus, as Kyphon has consistently explained, while the preferred device used to practice Kyphon's method is indeed a balloon, the ***claims*** are not so limited. Nothing in the prosecution history provides a clear disavowal of the plain meaning of the claims - indeed, the evidence amply supports a claim scope that is not limited to just a balloon or an inflatable device.

Respectfully,

Thomas L. Halkowski

TLH:sb

cc Clerk of Court (via hand delivery)
Maryellen Noreika (via hand delivery)
Jonathan M. Sobel (via facsimile)

# A

Patent

4-13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

File Wrapper Continuation Application of:

Parent Case

Application of : Reiley et al. Examiner: M. Leonardo

Serial No. : 08/188,224 Group Art Unit: 3309

Filed : January 26, 1994

For : Improved Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone

08788786.012497

**PRELIMINARY AMENDMENT**

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Dear Sir:

Please amend this file wrapper continuation application prior to the first office action as follows:

IN THE CLAIMS:

Please amend claim 31 as follows:

~~31 (Twice Amended)~~. A balloon for use in treating a bone [predisposed to fracture or to collapse, or that is fractured or collapsed,] comprising:

a [hollow balloon] body having a [flexible, non-elastic, imperforate] wall structure formed of a pair of stackable inflatable parts bonded together [, said balloon body being] which are deflatable to permit removable insertion of the body into said bone and [being] inflatable to cause said wall structure to compress cancellous bone and form a cavity in cancellous bone, said body [providing a configuration with] having a predetermined doughnut geometry [shape and size for the body] when said [body] wall structure is inflated, [said wall structure being capable of exerting equal pressure in all directions when said body is inserted in the bone and when said body is inflated, the outer surface of said wall structure being operable to engage and compress at least a portion of the

File Wrapper Continuation of
Serial No. 08/188,224

cancellous bone as the wall structure provides said shape and size,] said wall structure [having restraint means] including material to limit said [configuration] inflation of said [body] wall structure to [said predetermined shape and size so that the balloon body is preventing from applying] prevent the application of harmful pressure to the bone, and said [balloon] body having a passage to allow an inflating fluid to pass into and out of the body[;

wherein the balloon is formed of a pair of hollow, stackable inflatable parts, each part having a pair of opposed faces, and means for bonding the adjacent faces of the parts together; and

wherein the balloon parts are doughnut shaped].

Please amend claim 76 as follows:

76 (Third Amendment). A method for treating a bone [predisposed to fracture or to collapse, or fractured or collapsed,] comprising the steps of:

providing [a hollow, collapsible, inflatable,] a generally inelastic, [imperforate] expandable cavity former restrained to a predetermined geometry, when expanded, appropriate for the bone to be treated;

inserting the cavity former [while collapsed] into said bone [with said cavity former having a predetermined shape and size, when substantially inflated]; and

[inflating] expanding the cavity former [to a sufficient fluid pressure] to compress [a substantial portion of the inner] cancellous bone [at the site being treated] to form a cavity, which generally corresponds to the predetermined geometry of the cavity former, without [:

forming a cavity in the cancellous bone as a function of the inflating step wherein said cavity will have the predetermined shape and size appropriate for the bone to be treated; and

restraining expansion of the cavity former to create said predetermined shape and size, preventing the cavity former from] applying [excessive] harmful pressure to the inner surface of the cortical bone [if said bone is unfractured or uncollapsed].

In claims 79, 80, 81, 82, and 83, please change "inflating" to -- expanding --.

In claim 85, line 4, please delete "hollow elongate".

In claim 86, line 3, please delete "hollow elongate".

In claim 91, line 3, please change "an elongate" to -- a --.

Please consider the following new claims 99 to 113:

99 (New). A device for insertion into bone having cortical bone surrounding an interior volume occupied, at least in part, by cancellous bone, the device comprising a wall adapted

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to selectively assume a collapsed geometry for insertion into the interior volume and an expanded geometry for compacting cancellous bone to form a cavity in the interior volume, the wall including material that limits the expanded geometry prior to wall failure.

100 (New). A device according to claim 99

wherein the material includes an essentially non-elastic material.

101 (New). A device according to claim 99

wherein the material includes an essentially semi-elastic material.

102 (New). A device according to claim 99

wherein the material includes an essentially elastic material.

103 (New). A device according to claim 99

wherein the material includes restraints coupled to the wall to limit the expanded geometry prior to wall failure.

104 (New). A method for treating bone comprising the steps of

selecting a device comprising an expandable wall including material that limits expansion prior to wall failure,

inserting the device into a bone having cortical bone surrounding an interior volume occupied, at least in part, by cancellous bone, and

causing the device to assume an expanded geometry while in the interior volume to compact cancellous bone and form a cavity in the interior volume.

105(New). A method according to claim 104

wherein the selecting step includes selecting a device in which the wall includes an essentially non-elastic material.

106 (New). A method according to claim 104

wherein the selecting step includes selecting a device in which the wall includes an essentially semi-elastic material.

107 (New). A method according to claim 104

wherein the selecting step includes selecting a device in which the wall includes an essentially non-elastic material.

108 (New). A method according to claim 104

wherein the selecting step includes selecting a device in which the wall includes restraints coupled to the wall to limit expansion prior to wall failure.

File Wrapper Continuation of
Serial No. 08/188,224

109 (New). A system of expandable wall structures for treating bones, which are characterized by cortical bone surrounding an interior volume occupied, at least in part, by cancellous bone, including a first bone structure having a first interior volume and a second bone structure having a second interior volume different than the first interior volume, the system comprising a first expandable wall structure adapted to assume a first expanded geometry to compact cancellous bone to form a cavity in the first interior volume, and including material to limit expansion, prior to failure of the first expandable wall structure, based upon the first interior volume, and a second expandable wall structure adapted to assume a second expanded geometry, different than the first expanded geometry, to compact cancellous bone to form a cavity in the second interior volume, and including material to limit expansion, prior to failure of the second expandable wall structure, based upon the second interior volume.

110 (New). A system according to claim 109

wherein the material of at least one of the first and second wall structures includes an essentially non-elastic material.

111 (New). A system according to claim 109

wherein the material of at least one of the first and second wall structures includes an essentially semi-elastic material.

112 (New). A system according to claim 109

wherein the material of at least one of the first and second wall structures includes an essentially elastic material.

113 (New). A system according to claim 109

wherein the material of at least one of the first and second wall structures includes restraints coupled to the respective wall to limit expansion, based upon the respective first or second interior volumes, prior to wall failure.

08/188,224 - 05/04/98

**REMARKS**

At the close of prosecution of the parent application, claims 4 to 22; 24; 25; 28 to 40; 45; 46; and 76 to 98 stood allowed. Applicants have filed this file wrapper continuation to amend certain of the allowed claims and to submit additional claims for consideration.

Allowed claims 31; 76; 79 to 83; 85; 86; and 91 have been amended. New claims 99 to 113 have been added. Claims 4 to 22; 24; 25; 28 to 40; 45; 46; and 76 to 113 remain in the

application.

The amendments to the allowed claims remove what applicants believe are unnecessary limitations. The amendments also modify terminology to define the nature of applicants' invention with improved clarity.

The new claims define subject matter broader than the previously allowed claims in a manner that is commensurate with the scope of protection applicants believe their inventions warrant in view of the prior art. The new claims define an expandable wall structure for use in treating bone. The wall structure is capable of assuming an expanded geometry within the bone. The wall structure includes material to limit the expanded geometry prior to wall failure. The expansion-limited wall structure can comprise elastic, non-elastic, or semi-elastic material (see Specification, page 10, lines 6 to 12). The expansion-limited wall structure compacts cancellous bone to form a cavity in the interior volume of the bone, and, in this respect, can achieve a variety of physiological results. Applicants do not believe the prior art teaches or suggests the structure or use of expansion-limited walls to form cavities within bones, as defined in the claims.

Applicants thereby believe that the claims are in condition for allowance.

Respectfully submitted,

By _____
Daniel D. Ryan
Registration No. 29,243

RYAN, MAKI, MANN & HOHENFELDT, S.C.
633 West Wisconsin Avenue
Milwaukee, Wisconsin 53203
(414) 271-6555
January 23, 1997
188224pa.fwc

# B

## Interview Summary

| Application No. | Applicant(s) |
|---|---|
| 08/788,786 | Reilly et al. |
| **Examiner** | **Group Art Unit** |
| Daphna Shai | 3731 |

All participants (applicant, applicant's representative, PTO personnel):

(1) *Daphna Shai* (3) *Karen Talmadge*

(2) *Daniel Ryan* (4) _____

Date of Interview *Jul 1, 1999*

Type: ☐ Telephonic ☒ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☒ Yes ☐ No. If yes, brief description:
approach, and presentation of the problem leading to the apparatus

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: all

Identification of prior art discussed:

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:
Applicant's representative will amend claims now under restriction requirement and add new claims directed to a more specific description of invention. New added claims will include limitations directed to ways of limiting expansion of balloon in certain specific directions.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendents which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a seperate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Daphna Shai

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

U. S. Patent and Trademark Office
PTO-413 (Rev. 10-95) Interview Summary Paper No. 20

KY 229270

Cancel claims 4 to 22; 24 to 25; 28 to 40; 46 to 46; 76 to 98; and 114 to 143.

**Remaining Apparatus Claims**

Please amend claim 99 as follows:

99 (Once Amended). A device for insertion into bone having cortical bone surrounding an interior volume occupied, at least in part, by cancellous bone, the device comprising a wall adapted to selectively assume a collapsed geometry for insertion into the interior volume and an expanded geometry for compacting cancellous bone to form a cavity in the interior volume, characterized in that the wall [including] includes material that [limits the expanded geometry prior to wall failure], when expanded inside bone, applies a force having a magnitude capable of moving fractured cortical bone, and further includes material restraints to constrain the application of the force to a predetermined, preferred direction in the presence of cancellous bone.

Please amend claim 103 as follows:

103 (Once Amended). A device according to claim 99

wherein the material [includes] restraints include internal restraints coupled to the wall material [to limit the expanded geometry prior to wall failure].

Please consider the following new claims 144 to 146:

144 (New). A device according to claim 99

wherein the material restraints include external restraints coupled to the wall material.

145 (New). A device according to claim 99

wherein the material restraints include changes in thickness of the wall material.

146 (New). A device for insertion into bone having cortical bone surrounding an interior volume occupied, at least in part, by cancellous bone, the device comprising a wall adapted to selectively assume a collapsed geometry for insertion into the interior volume and an expanded geometry for compacting cancellous bone to form a cavity in the interior volume, characterized in that the wall includes material that, when expanded inside bone, applies a force having a magnitude capable of moving fractured cortical bone, and further includes material restraints that direct the application of the force in the presence of cancellous bone substantially more in a predetermined, preferred direction than in a different, predetermined direction that is not preferred.

**Remaining Method Claims**

Please amend claim 104 as follows:

104 (Once Amended). A method for treating bone comprising the steps of

selecting a device comprising an expandable wall including material that [limits expansion prior to wall failure] when expanded inside bone, applies a force having a magnitude capable of moving fractured cortical bone, and further includes material restraints to constrain the application of the force to a predetermined, preferred direction in the presence of cancellous bone,

inserting the device into a bone having cortical bone surrounding an interior volume occupied, at least in part, by cancellous bone, and

causing the device to [assume an expanded geometry] expand while in the interior volume to compact cancellous bone and form a cavity in the interior volume while moving fractured cortical bone in the preferred direction.

Please amend claim 108 as follows:

108 (New). A method according to claim 104

wherein the selecting step includes selecting a device in which the [wall includes] material restraints include internal restraints coupled to the wall material [to limit expansion prior to wall failure].

Please consider the following new claims 147 to 149:

147 (New). A method according to claim 104

wherein the selecting step includes selecting a device in which the material restraints include external restraints coupled to the wall material.

148 (New). A method according to claim 104

wherein the selecting step includes selecting a device in which the material restraints include changes in thickness of the wall material.

149 (New). A method for treating bone comprising the steps of

selecting a device comprising an expandable wall including material that, when expanded inside bone, applies a force having a magnitude capable of moving fractured cortical bone, and further includes material restraints that direct the application of the force in the presence of cancellous bone substantially more in a predetermined, preferred direction than in a different, predetermined direction that is not preferred,

inserting the device into a bone having cortical bone surrounding an interior volume occupied, at least in part, by cancellous bone, and

causing the device to expand while in the interior volume to compact cancellous bone and form a cavity in the interior volume while moving fractured cortical bone in the preferred direction.

# C

*Patent*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | | |
|---|---|---|---|
| Application of : | Reiley et al. | | Examiner: D. Shai |
| Serial No. : | 08/788,786 | | Group Art Unit: 3731 |
| Filed : | January 23, 1997 | | |
| For : | Improved Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone | | |

**RESPONSE TO RESTRICTION REQUIREMENT**
**AMENDMENT A**

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Applicant responds to the restriction requirement mailed April 30, 1999, with a shortened one month period to respond.

Applicant respectfully requests an automatic five month extension of time to respond, up to and including October 30, 1999.

The Examiner's time and attention at an interview conducted July 1, 1999 is appreciated. As discussed with the Examiner during the interview, in lieu of a species election, please amend the application as follows:

**IN THE CLAIMS:**

Please cancel claims 4 to 22, 24, 25, 28 to 40, 45, 46, and 78 to 113, which were presented in the First Preliminary Amendment, filed at the time this continuation application was filed.

Please also cancel claims 114 to 143, which were submitted in the Second Preliminary Amendment, filed by fax on March 20, 1999 (and which were not acknowledged as having been entered in the April 30, 1999 restriction requirement).

Please consider the following new claims 144 to 172:

144 (New). A device for compacting cancellous bone comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, characterized in that the body includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further includes changes in thickness

of the body to constrain the expansion in cancellous bone.

145 (New). A device for compacting cancellous bone comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, characterized in that the body includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further includes an internal restraint coupled to the body to constrain the expansion in cancellous bone.

146 (New). A device according to claim 145 wherein the internal restraint includes mesh material.

147 (New). A device according to claim 145 wherein the internal restraint includes string material.

148 (New). A device according to claim 145 wherein the internal restraint includes a woven material.

149 (New). A device according to claim 145 wherein the internal restraint includes a seam.

150 (New). A device according to claim 145 wherein the internal restraint includes an essentially non-elastic material.

151 (New). A device for compacting cancellous bone comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, characterized in that the body includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further includes an external restraint coupled to the body to constrain the expansion in cancellous bone.

152 (New). A device according to claim 151 wherein the external restraint includes mesh material.

153 (New). A device according to claim 151 wherein the external restraint includes string material.

154 (New). A device according to claim 151 wherein the external restraint includes a woven material.

155 (New). A device according to claim 151 wherein the external restraint includes a seam.

156 (New). A device according to claim 151 wherein the external restraint includes an essentially non-elastic material.

157 (New). A device according to claim 154 or 145 or 151 wherein the material includes an essentially non-elastic material.

158 (New). A device according to claim 144 or 145 or 151 wherein the material includes an essentially semi-elastic material.

159 (New). A device according to claim 144 or 145 or 151 wherein the material includes an essentially elastic material.

160 (New). A device for compacting cancellous bone comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, characterized in that the body includes at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion in cancellous bone.

161 (New). A device according to claim 160 wherein the at least two materials possess essentially similar elastic properties.

162 (New). A device according to claim 160 wherein the at least two materials possess essentially different elastic properties.

163 (New). A method for treating bone comprising the steps of inserting a device as defined in claims 144 or 145 or 151 or 160 inside bone, causing constrained expansion of the body in cancellous bone, and compacting cancellous bone by the constrained expansion.

164 (New). A method according to claim 163 wherein the constrained expansion lifts vertebral end plates.

165 (New). A method according to claim 163 wherein the constrained expansion lifts tibial plateau depressions.

166 (New). A method according to claim 163 wherein the constrained expansion lifts proximal humerus depressions.

167 (New). A method according to claim 163 wherein the constrained expansion lifts cortical bone.

168 (New). A method according to claim 163 wherein the step of compacting forms a cavity.

169 (New). A method according to claim 168 further including the step of filling the cavity with a material.

170 (New). A method according to claim 169 wherein the material comprises bone cement.

171 (New). A method according to claim 169 wherein the material comprises synthetic bone substitute.

33

28 172 (New). A method according to claim 169 35
wherein the material comprises a flowable material that sets to a hardened condition.

REMARKS

As discussed during the interview in July 1, 1999, in an effort to simplify prosecution, applicant has canceled the pending claims and substituted a new claim format, which is directed to a generic definition of one aspect of the invention. Applicant respectfully requests that the election of species requirement be withdrawn in view of the submission of the new claim format.

Claims 144 to 172 remain in the application. Of these, claims 144, 145, 151, and 160 are independent device claims, and claim 163 is a multiple dependent method claim.

New claims 144 to 162 are directed to a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone. As defined in the claims, the body is characterized in that it includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone. The body is further characterized in that its expansion in cancellous bone is constrained.

As was discussed during the interview, there is a need to constrain expansion of an expandable body within cancellous bone, in order to provide proper compaction and/or *en masse* reduction of fractured cortical bone and restore pre-fracture anatomy. The discovery of this need was surprising and unexpected. It was not known or appreciated at the time the invention arose, that variations in density in cancellous bone were sufficient to cause significantly non-uniform and unpredictable volume expansion of an expandable body inside bone, unless expansion of the body is constrained. Unless constrained, an expandable body follows paths of least density resistance through cancellous bone, assuming non-uniform and unpredictable geometries inside bone that are not oriented for proper compaction and/or *en masse* reduction of fractured cortical bone. Without constrained expansion in cancellous bone, the proper compaction of cancellous bone and /or restoration of pre-fracture anatomy using an expandable body becomes problematic.

As discussed during the interview, constrained expansion of the body can be achieved in various ways. As defined in independent claim 144, the body includes changes in thickness to constrain the expansion in cancellous bone. As defined in independent claim 145, an internal restraint is coupled to the body to constrain the expansion in cancellous bone. As defined in independent claim 151, an external restraint is coupled to the body to constrain the expansion in cancellous bone. As defined in independent claim 160, the body includes at least two materials that constrain the expansion in cancellous bone. Support for the subject matter defined in these claims is found, e.g., on Specification page 9, line 14, to page 10, line 18.

34.

New multiple dependent claim 163 defines a method for treating bone by inserting a device as defined in claims 144 or 145 or 151 or 160 inside bone, causing constrained expansion of the body in cancellous bone, and compacting cancellous bone by the constrained expansion.

The Examiner's attention is directed to the prior submission of three Information Disclosure Statements in this application, on June 20, 1997 and July 1, 1997, and March 16, 1998.

Allowance of new claims 144 to 172 is respectfully requested.

Respectfully submitted,

By _____
Daniel D. Ryan
Registration No. 29,243

RYAN KROMHOLZ & MANION, S.C.
633 West Wisconsin Avenue
Milwaukee, Wisconsin 53203
(414) 271-6555
November 1, 1999
788786A.DDR.wpd

# D

UNITED STAT DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

N K

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 08/788,786 | 01/23/97 | REILEY | M 2570-CON |

0M12/0307

DANIEL D RYAN
RYAN MAKI MANN AND HOHENFELDT
SUITE 1900
633 WEST WISCONSIN AVENUE
MILWAUKEE WI 53203

| EXAMINER | |
|---|---|
| WOO, J | |
| ART UNIT | PAPER NUMBER |
| 3731 | 28 |

DATE MAILED: 03/07/00

#28

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

**Commissioner of Patents and Trademarks**

PTO-90C (Rev. 2/95) U.S. G.P.O. 1999 460-093 1- File Copy

## Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 08/788,786 | Reiley et al. |
| **Examiner** | **Group Art Unit** |
| Julian W. Woo | 3731 |

☒ Responsive to communication(s) filed on *11-4-99*.

☐ This action is **FINAL.**

☐ 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.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *144-172* is/are pending in the application.

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

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *144-162* is/are rejected.

☒ Claim(s) *163-172* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

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

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *14,17*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 144-156 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claims 144-150, it is not certain where the "internal restraint" is located. Is the restraint internal to the bone or to the body of the device? With respect to claims 151-156, it is not certain where the "external restraint" is located. Is the restraint external to the bone or to the body of the device?

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 144-151 and 155-162 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonutti (5,295,994). With respect to claims 144-150, Bonutti in col. 4, line 64 - col. 6, line 37, discloses devices that can be used to compact cancellous bone. Each of the devices have a body that can change in thickness to constrain expansion in bone tissue. Bonutti also discloses devices each with an internal restraint coupled to a device body. The internal restraints include a mesh or woven material (see col., 5, lines 31-47), an essentially non-elastic string material (see col. 6, lines 19-25), and a seam (see col. 5, lines 20-30, where broken segments of a body can meet). With respect to claims 151 and 155-159, Bonutti discloses a device where the body is made of materials of varying elasticity (see col. 4, lines 3-35) and includes a non-elastic external constraint (see col. 6, lines 26-34, a plate, or see col. 6, lines 35-37, a bellows with seams). With respect to claims 160-162, he discloses in col. 4, lines 36-45, a device with a body made of two materials of differing elastic properties.

***Allowable Subject Matter***

5. Claims 163-172 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claims 152-154 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record discloses devices that can be used to compact cancellous bone. However, unlike the prior art of record, the present invention discloses devices with differing external restraints (mesh, string, or woven material) for expandable bodies. Additionally, the present invention discloses a method for compacting cancellous bone with constrained expansion of a device body. Thus, allowable subject matter is indicated in the claims cited above.

8. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Conclusion***

9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:30 PM Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Buiz, can be reached at (703) 308-0871.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)305-3579.

Julian W. Woo

Patent Examiner

March 3, 2000

# E

| Notice of Allowability | Application No. 08/788,786 | Applicant(s) Reiley et al. |
|---|---|---|
| | Examiner Julian W. Woo | Group Art Unit 3731 |

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to *the amendment of 9-11-00*.

☒ The allowed claim(s) is/are *144-162 and 164-172*.

☐ The drawings filed on _____ are acceptable.

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

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS FROM THE "DATE MAILED"** of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. *31*.

☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal lettter addressed to the Official Draftsperson.**

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in telephone interviews with Daniel Ryan on October 20 and 27, 2000.

2. The application has been amended as follows:

In claim 144, line 4, delete "characterized in that," and replace "includes" with --including--.

In claim 145, line 4, delete "characterized in that," and replace "includes" with --including--.

In claim 151, line 4, delete "characterized in that," and replace "includes" with --including--.

In claim 160, line 4, delete "characterized in that," and replace "includes" with --including--.

Claims 173-178 are hereby cancelled.

3. The following is an examiner's statement of reasons for allowance: The prior art of record discloses devices that can be used to compact cancellous bone. However, unlike the prior art of record, the present invention discloses methods for compacting cancellous bone with constrained expansion of a device body. Thus, the present invention is distinguishable over the prior art of record, and the claims are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Trotta et al. (5,290,306) teach an inflatable balloon externally contrained by an elastomeric sleeve, while Leoni (5,772,681) teaches an inflatable balloon constrained externally by a mesh.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:30 PM Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Buiz, can be reached at (703) 308-0871.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)305-3590.

Julian W. Woo

Patent Examiner

November 2, 2000

MICHAEL H. THALER
PRIMARY EXAMINER
GROUP 3300