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April 22, 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. 04-204-JJF

Dear Judge Poppiti:

FR

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

Pursuant to Kyphon's commitment made during argument on April 19, 2005, attached is the portion of the prosecution history of the '043 patent referenced by counsel. Attachment A (January 24, 1997, Preliminary Amendment) (where applicant first broadens claims beyond balloons and inflatable devices and directly advises, "The amendments to the allowed claims remove what applicants believe are unnecessary limitations."); *see also* Attachment B (November 1, 1999, Amendment) (similarly noting that a new claim format is presented "which is directed to a generic definition of one aspect of the invention").

Secondly, Kyphon has now completed a review of the slides provided by DOT at the hearing, and, respectfully, wishes to note a few items of concern. To minimize the burden upon the record, Kyphon has avoided rehashing the issues already presented to the Court and has not discussed every objectionable aspect of DOT's slides:[1]

PART 1 (Claim Construction and Infringement Slides):

Slides 48-49: Claim 1 does not recite any device for performing the "compacting" step. Claim 16 expressly requires use of an "inflatable device." At argument, DOT asserted that the applicant expressly limited the plain meaning of Claim 1 by stating that Claims 1 and 16 were treated alike in the prosecution history, quoting the following excerpt:

> Claim 16, like Claim 1, recites the step of inflating the device to force the bone marrow outwardly of the recess and against the bone to form a void in the bone. Thus, the bone marrow is not removed from the bone as in the case of Murray, and Murray fails to teach or suggest the combination of steps of Claim 16. Thus, Claim 16 is allowable under 35 U.S.C. 102(b) over Murray.

[1] For example, Kyphon will not detail its objection to DOT's characterization of its development efforts regarding the SKy Bone Expander system as being wholly independent of Kyphon's work. Kyphon believes the evidence at trial will not support DOT's assertions.

DOT, however, failed to advise the Court that the sentence *immediately preceding* the excerpt quoted by DOT made clear the distinction between claims 1 and 16:

> Claim 16 recites the same combination of elements as allowable Claim 1 and **is distinguished over Claim 1 by reciting the step of inserting an inflatable device** in the recess.

See DOT Exh. G at KY 228859 (emphasis added).[2] The applicant, therefore, first distinguished the scope of claims 1 and 16, and then, in the limited portion quoted by DOT, made clear that claim 16, like claim 1, required bone marrow compaction – as opposed to the removal of bone marrow taught by the prior art. Thus, the prosecution history does not support the proposition asserted by DOT.

Slides 84-86: All of these excerpts that DOT relies upon from the prosecution history of the '043 came before January 24, 1997, when the applicant first expressly amended the claims so that they would not be limited to a balloon or an inflatable device. See Attachments A (January 24, 1997, Preliminary Amendment); see also Attachment B (November 1, 1999, Amendment).

PART 2 (Validity Slides):

Slides 3, 23, 24, 39, and 47: DOT's motion re invalidity of the asserted patents did not rely upon Kennedy or any of the other additional references it relies upon in its slides. DOT's motion expressly relied upon only Edeland and Olerud (alone or in combination).

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[2] DOT's slide 50 likewise omits the critical limitation of claim 16 that requires "inserting an inflatable device in said [passage] recess." See DOT Exh. G, at KY 228857.

Kyphon also notes that, prior to oral argument, DOT had cited the prosecution history merely as part of its argument that "safely" should not be included within the definition of the "compacting" step. DOT's Responsive Brief re Claim Construction, at 10. DOT had not asserted in its briefing to the Court that the prosecution history contained the type of statements required under Federal Circuit precedent that expressly limited the plain meaning of the "compacting" step – DOT's Slide 48 was the *first* assertion that the prosecution history contained "Explicit statements that 'compacting' step requires an inflatable device." As noted above, the record, when reviewed in full, does not support DOT's position.

Also, on slide 48, DOT asserts that the original application had 16 apparatus claims, all limited to an inflatable device. While true, this statement neglects to mention that the more general method claims, like those that are asserted in this suit, included no such limitations.

PART 3 (Bone Filler Device Slides):

Slides 4-7: None of DOT's briefs appear to mention the new argument raised in these slides -- that the claims of the bone filler device patents should be limited to tamping via one tube because the prior art would otherwise invalidate the patents. There are multiple reasons why the prior art cited by DOT re the bone filler device patents does not come close to invalidating Kyphon's patents under the proper plain meaning interpretations proposed by Kyphon. If this becomes an issue of concern for the Court, Kyphon is prepared to submit a copy of the report from Dr. Marks, which explains in detail the numerous elements missing from the prior art asserted by DOT against the bone filler device patents.

Respectfully,

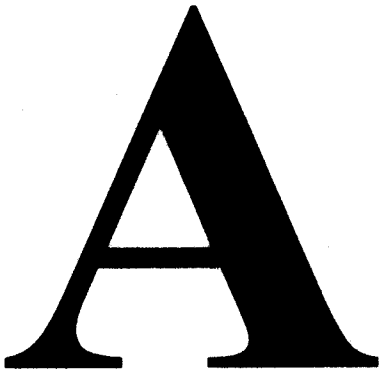
Thomas L. Halkowski

TLH:sb

Enclosures

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

80024149.doc



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

08/188,224 01/26/94

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:

31

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

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.

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

KY 229252

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
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January 23, 1997
188224pa.fwc

B

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 76 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~~ method according to claim 145 wherein the internal restraint includes mesh material.

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

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

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

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

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

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

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

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

157 (New). A ~~device~~ method according to claim 144 or 145 or 151 wherein the material includes an essentially non-elastic material.

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

159 (New). A ~~device~~ method 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.

~~172~~ 35 (New). A method according to claim ~~169~~ 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.

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 _____
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