IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON, INC., Plaintiff, vs. DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. and DISC ORTHOPAEDIC TECHNOLOGIES, INC., Defendants.	Civil Action No. 04-0204-JJF **REDACTED – PUBLIC VERSION**

OPENING BRIEF IN SUPPORT OF DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S AND DISC ORTHOPAEDIC TECHNOLOGIES, INC'S MOTION FOR SUMMARY JUDGMENT THAT KYPHON, INC'S U.S. PATENT NOS. 5,108,404 AND 4,969,888 ARE INVALID BASED ON ANTICIPATION AND/OR OBVIOUSNESS

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TABLE OF CONTENTS

Page

NATURE AND STAGE OF THE PROCEEDINGS 1

SUMMARY OF ARGUMENT 1

STATEMENT OF THE FACTS 3

A. The Claimed Inventions are Limited to a Balloon or Inflatable Device, Which Fact Kyphon Has Ignored to Support its Infringement Position 3

B. The Edeland and Olerud References Not Considered by the PTO Render the Asserted Claims Invalid Under Kyphon's Infringement Position 5

C. The Court's Preliminary Injunction Decision Correctly Found that Edeland Undermines the Validity of the '404 Patent 6

ARGUMENT 7

A. DOT is Entitled to Summary Judgment that the '404 Patent is Invalid Based on Anticipation by the Olerud Reference 8

1. Olerud Teaches Every Limitation of Claim 1 of the '404 Patent 8

2. **REDACTED** 10

3. **REDACTED** 12

4. There is No Genuine Issue of Disputed Fact That Olerud Discloses the Second Element of Claim 1, as well as Claim 3, of the '404 Patent 14

5. There is No Genuine Issue of Disputed Fact That Olerud Discloses the Third Element of Claim 1 of the '404 by Filling the Void with Bone Paste 15

6. There is No Genuine Issue of Disputed Fact that Olerud Discloses the "Drilling" Limitations Of Claim 8-10 of the '404 Patent 16

7. Olerud Teaches Every Limitation of Claims 1, 3, 8, 9, 10 and 12 of the '404 Patent 16

B. DOT is Entitled to Summary Judgment that the '404 Patent is Invalid Based on Anticipation by the Edeland Reference 17

1. Edeland Teaches Every Limitation of Independent Claim 1 of the '404 Patent 17

2. There is No Genuine Issue of Disputed Fact That Edeland Discloses the Second Element of Claim 1, as well as Claim 3, of the '404 Patent 19

3. There is No Genuine Issue of Disputed Fact That Edeland Discloses the Third Element of Claim 1 of the '404 By Filling the Void with Ceramic Bone Substitute 20

4. There is No Genuine Issue of Disputed Fact that Edeland Discloses the "Drilling" Limitations Of Claims 8-10 of the '404 Patent 21

5. Edeland Teaches Every Limitation of Claims 1, 3, 8, 9, 10 and 15 of the '404 Patent... 22

C. DOT is Entitled to Summary Judgment that the '404 Patent is Invalid Based on Obviousness in View of the Edeland and Olerud References, Alone or in Combination 23

1. There is No Genuine Issue of Disputed Fact that One of Ordinary Skill in the Art Would Have Had the Suggestion and Motivation to Combine the Teachings of the Edeland and Olerud References 24

D. DOT is Entitled to Summary Judgment that the '888 Patent is Invalid Based on (1) Anticipation by the Edeland Reference; (2) Anticipation by the Olerud Reference and (3) Obviousness in View of the Edeland and Olerud References, Alone or In Combination 25

CONCLUSION 27

TABLE OF AUTHORITIES

Cases

Amazon.com, Inc. v. Barnesandnoble.com,
239 F.3d 1343, 57 U.S.P.Q.2d 1747 (Fed. Cir. 2001) 8

Anderson v. Liberty Lobby, Inc.,
477 U.S. 242 (1986) 7

Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.,
246 F.3d 1368, 58 U.S.P.Q.2d 1508 (Fed. Cir. 2001) 8

Eli Lilly and Co. v. Barr Labs, Inc.,
251 F.3d 955 (Fed. Cir. 2001) 8

General Elec. Co. v. Nintendo Co., Ltd.,
179 F.3d 1350, 50 U.S.P.Q.2d 1910 (Fed. Cir. 1999) 7

Graham v. John Deere Co. of Kansas City,
383 U.S. 1, 148 U.S.P.Q. 459 (1966) 23

In re Cruciferous Sprout Litigation,
301 F.3d 1343, 64 U.S.P.Q.2d 1202 (Fed. Cir. 2002) 7

Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.,
475 U.S. 574 (1986) 7

Ryko Mfg. Co. v. Nu-Star, Inc.,
950 F.2d 714, 21 U.S.P.Q.2d 1053 (Fed. Cir. 1991) 23

Schering Corp. v. Geneva Pharms., Inc.,
339 F.3d 1373 (Fed. Cir. 2003) 8, 26

Telemac Cellular Corp. v. Topp Telecom, Inc.,
247 F.3d 1316, 58 U.S.P.Q.2d 1545 (Fed. Cir. 2001) 7

Statutes and Regulations

35 U.S.C. § 102(a) 2, 7

35 U.S.C. § 103 ..... 3, 23

Fed. R. Civ. P. 56(c) 7

Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. submit this Brief in Support of their Motion for Summary Judgment that U.S. Patent Nos. 5,108,404 and 4,969,888 are Invalid Based on Anticipation and/or Obviousness.

NATURE AND STAGE OF THE PROCEEDINGS

This is an action by Kyphon Inc. ("Kyphon") against Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively "DOT") for infringement of U.S. Patent Nos. 4,969,888 (the "'888 patent"), 5,108,404 (the "'404 patent"), 6,235,043 B1 ("the '043 patent"), 6,248,110 B1 ("the '110 patent"), 6,241,734 B1 ("the '734 patent") and 6,613,054 B1 ("the '054 patent"). DOT has counterclaimed against Kyphon for declaratory judgments of non-infringement and invalidity of the patents-in-suit. As reflected in its letter to the Special Master herein, Kyphon no longer asserts any claims of the '110 patent against DOT. (Exhibit O.)[1] Likewise, DOT no longer asserts its related counterclaims.

Fact discovery has closed. Expert reports have been exchanged, and expert discovery is scheduled to close on April 27, 2005. A claim construction and summary judgment hearing is scheduled for April 19, 2005. Trial is scheduled to begin on June 1, 2005.

SUMMARY OF ARGUMENT

1. As set forth in DOT's Claim Construction Memorandum Regarding Kyphon's U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1, DOT's Opening Brief in Support of Motion for Summary Judgment of Non-Infringement of Kyphon's U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1, and the Mitchell Balloon Bone Tamp Non-Infringement Report

[1] Exhibits cited herein are contained in DOT's Appendix of Exhibits to Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. Claim Construction Memoranda and Motions for Summary Judgment of Non-Infringement and Invalidity ("DOT's Appendix of Exhibits"), submitted herewith.

(see Exhibit C), DOT submits that the claims of the '404 and '888 Patents, properly construed, are limited to an inflatable device, and therefore are not broad enough to cover DOT's SKy Device. The sole embodiment of the '404 and '888 Patents is an inflatable device such as a balloon to create a void in a fractured bone. In order to cover the accused SKy Device, Kyphon has expanded the scope of the asserted claims to cover any means of creating a void in a fractured bone (i.e. any means of increasing the volume of the passage).

2. To the extent the asserted claims of the '404 and '888 Patents cover the accused SKy device (i.e. are not limited to an inflatable device), there is clear and convincing evidence and no genuine issue of material fact that such claims are invalid under 35 U.S.C. § 102(a) based on anticipation by the Olerud reference. The Olerud reference teaches every limitation of Claims 1, 3, 8, 9, 10, and 12 of the '404 and Claims 1, 3, 7, 8, 9, and 11 of the '888 Patent. The Olerud reference is highlighted at Tab A hereto, showing how Olerud anticipates each of Claims 1, 3, 8, 9, 10, and 12 of the '404 Patent.

3. To the extent the asserted claims of the '404 and '888 Patents cover the accused SKy device (i.e. are not limited to an inflatable device), there is clear and convincing evidence and no genuine issue of material fact that such claims are invalid under 35 U.S.C. § 102(a) based on anticipation by the Edeland reference. The Edeland reference teaches every limitation of Claims 1, 3, 8, 9, 10, and 15 of the '404 and Claims 1, 3, 7, 8, 9, and 14 of the '888 Patent. The Edeland reference is highlighted at Tab B hereto, showing how Edeland anticipates each of Claims 1, 3, 8, 9, 10, and 15 of the '404 Patent.

3. To the extent the asserted claims of the '404 and '888 Patents cover the accused SKy device (i.e. are not limited to an inflatable device), there is clear and convincing evidence and no genuine issue of material fact that all the asserted claims of the '404 and '888 Patents are

invalid under 35 U.S.C. § 103 based on obviousness in view of the Olerud and Edeland references, alone or in combination. One of ordinary skill in the art would have had the suggestion and motivation to combine the teachings of the Olerud and Edeland references, because both references teach the treatment of a fractured bone.

STATEMENT OF THE FACTS

A. The Claimed Inventions are Limited to a Balloon or Inflatable Device, Which Fact Kyphon Has Ignored to Support its Infringement Position

The '404 and '888 patents generally relate to the treatment of fractured bone.[2] (See Exhibits A-2 and A-3.) The '404 and '888 patents generally describe the process of treating fractured bone by drilling a passage into a bone containing bone marrow, inflating a balloon within the bone marrow such that the bone marrow is compacted in order to increase the volume of the passage, and filling the passage created with a flowable material capable of hardening, such as bone cement. The application which became the '888 patent was filed on February 9, 1989; the '888 patent issued on November 13, 1990. The application which became the '404 patent was filed on August 15, 1990; the '404 patent is a continuation-in-part of the '888 patent and issued on April 28, 1992. The '404 and '888 patents share a substantially identical specification; the two patents share substantially identical claims, except that the '404 patent is broader, in that it does not have an "osteoporotic" limitation.

Kyphon alleges that DOT's Sky Bone Expander Device (the "SKy Device")[3] infringes independent claim 1 and dependent claims 3, 8, 9, 10, 12, and 15 of the '404 Patent, and

[2] A description of the relevant bone anatomy is set forth in DOT's Claim Construction Memorandum Regarding Kyphon's U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1 ("DOT's Inflatable Bone Tamp Claim Construction Brief"), at pp. 6-7.

[3] A description of DOT's SKy Bone Expander Device is set forth in DOT's Inflatable Bone Tamp Claim Construction Brief, at pp. 3-6.

independent claim 1 and dependent claims 3, 7, 8, 9, 11, and 14 of the '888 Patent. Claim 1 of the '404 Patent is set forth below:

> 1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:
> forming a passage in the bone marrow;
> compacting the bone marrow to increase the volume of said passage; and
> filling the passage with a flowable material capable of setting to a hardened condition.

As discussed at length in DOT's Claim Construction Memorandum Regarding Kyphon's U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1, DOT's Opening Brief in Support of Motion for Summary Judgment of Non-Infringement of Kyphon's U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1, and the Mitchell Balloon Bone Tamp Non-Infringement Report (see Exhibit C), the '404 and '888 patents are entirely directed to inflatable devices such as balloons to create a void in a fractured bone. Thus, the claim step of "compacting the bone marrow to increase the volume of said passage" (see independent Claim 1 of the '404 Patent) is limited to performing that step using a inflatable device to form a void in the interior of the bone.

However, in support of its infringement position, Kyphon seeks to expand the scope of the asserted claims to cover any means of creating a void in a fractured bone (i.e. any means of increasing the volume of the passage). Thus, Kyphon has construed the second element of independent Claim 1, "compacting the bone marrow to increase the volume of said passage," to mean "compacting the bone marrow *with a device* that increases the volume of the passage created by the surgeon such that the resulting cavity can then be safely filled with a flowable material." (See Exhibit S, ¶ 47 (emphasis added).) In this way, Kyphon has expanded the scope of the asserted claims to cover the accused SKy device. However, as shown below, to the extent

the asserted claims cover the accused SKy device (i.e. are not limited to an inflatable device), prior art renders those claims invalid.[4]

B. The Edeland and Olerud References Not Considered by the PTO Render the Asserted Claims Invalid Under Kyphon's Infringement Position

Kyphon was admittedly not the first to invent the use of a device to create a void in a fractured bone. (See, e.g., Exhibit A-27, Section 7.) Thus, Kyphon's expansion of the asserted claims in order to capture any means of creating a void in a fractured bone, including the structure of the accused SKy device, renders the claims of the '404 and '888 Patents invalid in light of prior art. Several prior art references teach the use of conventional bone tamps to create a void in a fractured bone, including (1) Olerud, S., "Transpedicular Fixation of Thoracolumbar Vertebral Fractures," Clin. Orthop., Vol. 227, pp. 44-51, 1988 ("Olerud") and (2) Edeland, H.G., "Open Reduction of Central Compression Fractures of the Tibial Plateau," Acta Orthop. Scand., Vol. 47, pp. 686-689, 1976 ("Edeland"). (See Tabs A and B hereto.) Both references were published prior to the effective filing dates of the '404 and '888 Patents, and neither reference was before the PTO during prosecution of the '404 and '888 Patents.

Edeland and Olerud contain the same disclosures; an instrument is introduced into the bone (i.e. forms a passage); the pressure of the instrument compacts cancellous bone on its way to, and in the process of, reducing the fracture (i.e. compacts to increase the volume of the passage); and bone filler such as a ceramic calcium phosphate or bone paste is introduced into the void (i.e. fills the passage with flowable material capable of setting to a hardened condition).

[4] As detailed in Exhibit A-A, DOT submits there are six anticipatory references in the prior art; for this motion, DOT is focusing on only two of the six anticipatory references.

C. The Court's Preliminary Injunction Decision Correctly Found that Edeland Undermines the Validity of the '404 Patent

At the preliminary injunction stage of this litigation, this Court found[5] that the Edeland reference could be read to anticipate Claim 1 of the '404 patent:

> "The [Edeland] reference discloses a method of fixation of a fracture of the tibia by surgically inserting a concave prove via fenestration into the fracture site, pushing the probe into the bone to reduce the fracture by compacting cancellous bone, and injection a material into the void. Because the probe is inserted via fenestration, the Edeland method appears to form a passage in the bone. With regard to the element 'compacting bone marrow to increase the volume of said passage,' the probe is pushed in order to transfer and compact cancellous bone in front of the probe. The Court finds that pushing the probe to compact cancellous bone could be read to 'increase the volume' of the passage. Furthermore, the Court finds that the [Edeland] reference could be read to disclose 'filling the passage with a flowable material capable of setting to a hardened condition.' "

(See Exhibit A-30, p. 7.) In this way, this Court found that the Edeland reference[6] could be read to teach every limitation of Claim 1 of the '404 Patent. The reasoning underlying the Court's Preliminary Injunction decision should be applied at the summary judgment stage; because Edeland and Olerud contain the same disclosures and disclose every limitation of Claim 1 of the '404 Patent, the asserted claims of the '404 Patent are invalid based on anticipation by either and both of these references.

To the extent the asserted claims cover the accused SKy device (i.e. are not limited to an inflatable device), DOT submits that there is clear and convincing evidence and no genuine issue of material fact that such claims are invalid based on anticipation and/or obviousness in view of the Edeland and Olerud references.

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[5] The Court's conclusions of fact and law in its preliminary injunction decision are not binding for purposes of continued proceedings and trial.

[6] The Olerud reference was not before the Court at the preliminary injunction stage. DOT independently searched for invalidating prior art and discovered the Olerud prior art reference; in addition, Kyphon's 510(K) submission (featuring a figure taken from Olerud) was produced during discovery.

ARGUMENT

Under Rule 56(c) of the Federal Rules of Civil Procedure, summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(c). If the moving party has demonstrated an absence of material fact, the nonmoving party "must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986) (emphasis removed). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury to reasonably to find for the nonmoving party on that issue. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

Section 102(a) of the United State Code Title 35 provides, in relevant part: "A person shall be entitled to a patent unless . . . the invention was. . . patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." "Although anticipation is a question of fact, it still may be decided on summary judgment if the record reveals no genuine dispute of material fact." Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1327, 58 U.S.P.Q.2d 1545, 1552 (Fed. Cir. 2001) (citing General Elec. Co. v. Nintendo Co., Ltd., 179 F.3d 1350, 1353, 50 U.S.P.Q.2d 1910, 1912 (Fed. Cir. 1999)). To invalidate a claim based on anticipatory prior art, a party must prove by clear and convincing evidence that a single prior art discloses, either expressly or inherently, each limitation of the claim. In re Cruciferous Sprout Litigation, 301 F.3d 1343, 1349, 64 U.S.P.Q.2d 1202, 1208 (Fed. Cir. 2002). A particular reference may anticipate the patented invention "without disclosing a feature of the claimed invention if that missing characteristic is necessarily present,

or inherent, in the single anticipating reference." Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003); Eli Lilly and Co. v. Barr Labs, Inc., 251 F.3d 955, 970 (Fed. Cir. 2001) (finding that an element is inherent in a prior art reference where the "characteristic is the 'natural result' flowing from the reference's explicitly explicated limitations.")

"Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses." Amazon.com, Inc. v. Barnesandnoble.com, 239 F.3d 1343, 1351, 57 U.S.P.Q.2d 1747, 1752 (Fed. Cir. 2001). Thus, a patent may not be twisted, like "a nose of wax," to find infringement on the one hand, but to avoid invalidity on the other. Id.; see also Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376, 58 U.S.P.Q.2d 1508, 1513 (Fed. Cir. 2001) ("[Patentee] would have us construe the claims as limited to those instances of practicing the claimed method that achieve the stated result for purposes of validity, but as encompassing all instances of carrying out the physical steps for purposes of infringement . . . [the Patentee] cannot have it both ways.")

A. DOT is Entitled to Summary Judgment that the '404 Patent is Invalid Based on Anticipation by the Olerud Reference

1. Olerud Teaches Every Limitation of Claim 1 of the '404 Patent

Olerud discloses every element of independent Claim 1 of the '404 Patent. (See Tabs A and D hereto.) First, Olerud discloses the preamble to Claim 1 of the '404 Patent, a method of fixation and reduction of fractures of the vertebra.

Second, Olerud discloses the "forming the passage" step of Claim 1 of the '404 patent[7]:

> Similarly, with the insertion of transpedicular screws, a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebra into the vertebral body. A slightly curved punch is brought through the pedicle into

[7] Kyphon concedes that Olerud discloses the first element of Claim 1 of the '404 Patent. (See Exhibit V, p. 11.)

> the vertebral body (Fig. 3); under fluoroscopic control with the image intensifier, the end plates and anterior wall of the vertebra are reduced, if possible. (Tab A hereto, p. 47, emphasis added.)

Third, to the extent the asserted claims of the '404 are not limited to an inflatable device, Olerud further discloses the "compacting" step of Claim 1 of the '404 patent:

> With a transpedicularly introduced punch, further reduction of fragments in the vertebral body can be reduced. The defect in the vertebra is then filled with a graft in the form of bone paste.[8, 13] (Tab A hereto, text accompanying Fig. 3, p. 47, emphasis added.)

> On reduction of a compressed vertebral body, defects will occur in the cancellous bone (as in compression fractures in tibial condyles). Similarly, with the insertion of transpedicular screws, a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebra into the vertebral body. A slightly curved punch is brought through the pedicle into the vertebral body (Fig. 3); under fluoroscopic control with the image intensifier, the end plates and anterior wall of the vertebra are reduced, if possible. An aural speculum is inserted into the pedicular hole and a cancellous bone graft – bone paste obtained from the posterior aspect of the iliac crest with an acetabular reamer[14] – is pressed into the vertebra.[8] (Tab A hereto, p. 47, emphasis added.)

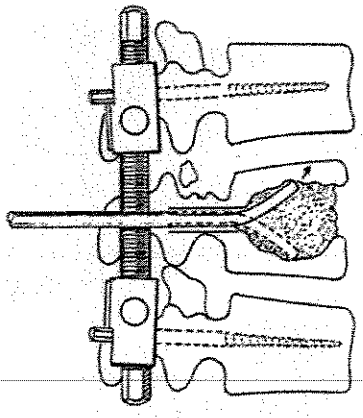


FIG. 3. With a transpedicularly introduced punch, further reduction of fragments in the vertebral body can be reduced. The defect in the vertebra is then filled with a graft in the form of bone paste.[8,13]

Finally, Olerud discloses the "filling the passage" step of Claim 1 of the '404 patent:

> An aural speculum is inserted into the pedicular hole and a cancellous bone graft – bone paste obtained from the posterior aspect of the iliac crest with an acetabular reamer[14] – is pressed into the vertebra.[8] (Tab A hereto, p. 47, emphasis added.)

As the name suggests, bone paste is ground bone graft mixed with blood. Bone paste constitutes a "flowable material" capable of filling the void created by the punch because it can be inserted into bone via a tube-and-plunger type instrument or bone filler device; bone paste further hardens over time and becomes bone. (See Exhibit E, Mitchell Decl., ¶18.) Thus, to the extent the asserted claims are not limited to an inflatable device, Olerud discloses all the limitations of Claim 1 of the '404 patent.

2.

REDACTED

Almost a year before the effective filing date of the '404 and '888 patents, Kyphon filed a 510(k) Premarket Notification Submission to the FDA for its balloon device, the Kyphx® Inflatable Bone Tamp (and sole embodiment of the '404 Patent). In its 510(k), Kyphon made the following admissions:

REDACTED

REDACTED

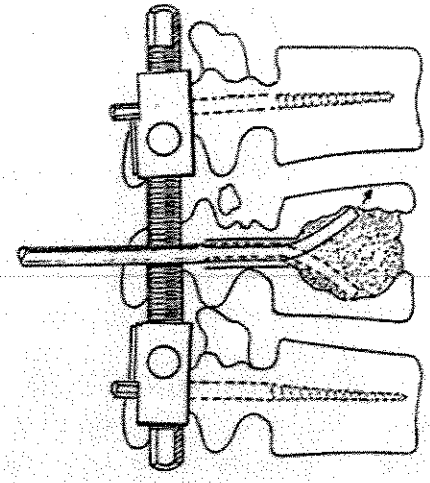
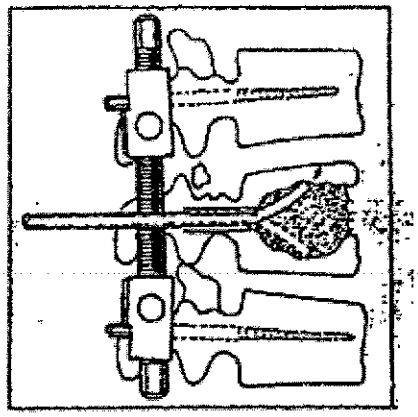


FIG. 3. With a transpedicularly introduced punch, further reduction of fragments in the vertebral body can be reduced. The defect in the vertebra is then filled with a graft in the form of bone paste.[8,13]



REDACTED

REDACTED

8

REDACTED

REDACTED

3. REDACTED

With respect to the final element of Claim 1 of the '404 Patent (i.e. "filling the passage with a flowable material capable of setting to a hardened condition"), Kyphon's statements to the FDA demonstrate that the bone graft paste disclosed in Olerud meets this claim element.

REDACTED

[9] Kyphon's disclosure to the FDA is also consistent with its disclosure in its 2004 10-K: "Conventional bone tamps are rigid stainless steel instruments that move fractured hard bone and compact soft bone [i.e. cancellous bone] using indirect mechanical force." (See Exhibit Z, p. 10.)
[10] See also Exhibit E, Mitchell Decl. at ¶ 9.

REDACTED

Because its Inflatable Bone Tamp device is the sole embodiment of the '404, Kyphon acknowledged that any bone filler material – which would include bone graft, methylmethacrylate or tri-calcium phosphate ceramics – constitutes the "flowable material capable of setting to a hardened condition" used in the "filling the passage" element of Claim 1 of the '404 patent.

REDACTED

REDACTED

4. There is No Genuine Issue of Disputed Fact That Olerud Discloses the Second Element of Claim 1, as well as Claim 3, of the '404 Patent

In order to circumvent Olerud's disclosure of the second element of Claim 1 of the '404 patent (i.e. compacting to increase the volume of the passage), Kyphon contends that the punch in Olerud is incapable of increasing the volume of the passage in the bone. (See Exhibit V, pp. 10-12.) Yet, Kyphon's expert concedes that the movement of the punch in Olerud (1) compacts cancellous bone and (2) further reduces the vertebral fracture. (See Exhibit V, p. 11.) In this way, Kyphon concedes that Olerud meets element two of Claim 1 of the '404 patent. Indeed, as confirmed by DOT's expert, the movement of the punch in Olerud compacts the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage. (See Exhibit E, Mitchell Decl., ¶ 20.) Moreover, as discussed above, to the extent the "compacting" step is not limited to an inflatable device,

REDACTED

There is similarly no genuine issue of disputed fact that Olerud discloses Claim 3 of the '404 patent (i.e. "compacting step includes forcing the bone marrow outwardly of the central portion of the bone.") Kyphon contends that the procedure in Olerud is limited to the periphery of the bone (see Exhibit V, p. 12). Kyphon's contention is without merit. Figure 3 of Olerud provides a snapshot of one single push of the probe that is repeated in different areas of the bone, from the center to the outer portion of the bone, both upwards and downwards. (See Exhibit E, Mitchell Decl., ¶ 21)

5. There is No Genuine Issue of Disputed Fact That Olerud Discloses the Third Element of Claim 1 of the '404 by Filling the Void with Bone Paste

In order to circumvent Olerud's disclosure of the third element of Claim 1 of the '404 patent (i.e. "filling the passage with a flowable material capable of setting to a hardened condition"), Kyphon argues that only methyl methacrylate bone cement in its liquid state meets this third element. (See, e.g. Exhibit V, p. 13, distinguishing bone cement that is not in its liquid state as "non-flowable.") Based on this premise, Kyphon argues that bone cement in its liquid state is not "substitutable" for the bone paste disclosed in Olerud and could not "safely" fill the void created by the conventional bone tamp in Olerud - the bone cement would "leak" out of the void created by the conventional bone tamp, whereas the bone cement would not leak out of the void created by Kyphon's inflatable device. (See Exhibit V, pp. 10, 12.) For the reasons below, Kyphon does not raise a genuine issue of disputed fact with respect to Olerud's disclosure of the third element.

First, methyl methacrylate bone cement is regularly used by surgeons in a putty or toothpaste-like state to fill voids created by a conventional bone tamp or by Kyphon's inflatable device (the sole embodiment of the '404 Patent); when in this state, the bone cement is still "flowable" because it can be injected or tamped with a bone filler device into a void. (See

Exhibit E, Mitchell Decl., ¶ 13.) Kyphon's contentions about "leakage" and "safety" are without merit. Indeed, Kyphon's expert, Dr. Marks authored a publication disclosing the use of bone cement to fill large cavities in the bone created by curettage. (See Exhibit E-4.) Second, the bone paste disclosed in Olerud to fill the void meets the third element of Claim 1 of the '404 Patent.

REDACTED

Moreover, bone paste constitutes a "flowable material" because it can be inserted into bone via a tube-and-plunger instrument or a bone filler device; this substance would then harden over time. (See Exhibit E, Mitchell Decl., ¶ 18.) On these grounds, Kyphon does not raise a genuine issue of disputed fact that Olerud discloses the third element of Claim 1 of the '404 Patent.

6. There is No Genuine Issue of Disputed Fact that Olerud Discloses the "Drilling" Limitations Of Claim 8-10 of the '404 Patent

Kyphon concedes that Olerud expressly discloses the limitations of Claim 8-10 of the '404 Patent. Kyphon's expert, Dr. Marks, does not dispute the fact that Olerud discloses the limitations of Claim 8 ("drilling said bone marrow to form said passage"); Claim 9 ("guiding a drill through and into the proximate cortical bone marrow"); and Claim 10. (See Exhibit V, pp. 10-12; see also Exhibit E, Mitchell Decl., ¶ 22.)

7. Olerud Teaches Every Limitation of Claims 1, 3, 8, 9, 10 and 12 of the '404 Patent

In summary, the chart attached as Tab D hereto sets forth how the Olerud reference teaches every limitation of Claims 1, 3, 8, 9, 10, and 12 of the '404 Patent. DOT's expert, Dr. David Mitchell has confirmed that Olerud anticipates 1, 3, 8, 9, 10, and 12 of the '404 Patent. (See Exhibit A-A, pp. 4-8.) Because there is no issue of material fact that Olerud teaches every

limitation of Claims 1, 3, 8, 9, 10, and 12 of the '404 Patent, DOT is entitled to summary judgment declaring that 1, 3, 8, 9, 10, and 12 of the '404 Patent are invalid based on anticipation by Olerud.

B. DOT is Entitled to Summary Judgment that the '404 Patent is Invalid Based on Anticipation by the Edeland Reference

As previously discussed, the court's preliminary injunction decision correctly found that Edeland undermines the validity of the '404 patent by disclosing each and every limitation of Claim 1 of the '404 Patent. For the reasons stated below, Edeland anticipates Claims 1, 3, 8, 9, 10, and 15 of the '404 Patent.

1. Edeland Teaches Every Limitation of Independent Claim 1 of the '404 Patent

Edeland discloses every element of Claim 1 of the '404 Patent. (See Tabs B and E hereto) First, Edeland discloses the preamble to Claim 1 of the '404 Patent, a method of reduction and fixation of a fractured bone; in Edeland, the bone is the tibial condyle. (See Tab B hereto, Abstract.)

Second, Edeland discloses the "forming the passage" step of Claim 1 of the '404 patent[11]:

> A new method of reduction and fixation of a uniformly depressed fracture of the tibial condyle is described. A curved steel probe, introduced through a cortical window . . . is used to reduce the fracture fragments as well as to compact the fracture region (TV-monitored x-ray projectioning is desired). (Tab B hereto, Abstract, p. 686; emphasis added.)

> The probe is introduced into the bone via fenestration . . . The concave "reduction end" of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control. (Tab B hereto, p.687, emphasis added.)

Third, to the extent the asserted claims of the '404 are not limited to an inflatable device, Edeland further discloses the "compacting" step of Claim 1 of the '404 patent:

[11] Kyphon concedes that Edeland discloses the first element of Claim 1 of the '404 Patent. (See Exhibit V, p. 9)

> A new method of reduction and fixation of a uniformly depressed fracture of the tibial condyle is described. A curved steel probe, introduced through a cortical window . . . is used to reduce the fracture fragments as well as to compact the fracture region (TV-monitored x-ray projectioning is desired). (Tab B hereto, Abstract, p. 686; emphasis added.)

> The probe is introduced into the bone via fenestration . . . The concave "reduction end" of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control. The compressed fracture region is reduced by repeated careful pushes of the probe (Figure 3). On its way, the probe transfers and compacts considerable amounts of cancellous bone from the region beneath the depression. The curvature of the probe permits some "swing" and thus makes some minor adjustments of the reduction possible and also compacts and forms transverse bone bridges immediately beneath the fracture parts. This stabilizes the reduced fracture parts. (Tab B hereto, p.687, emphasis added.)

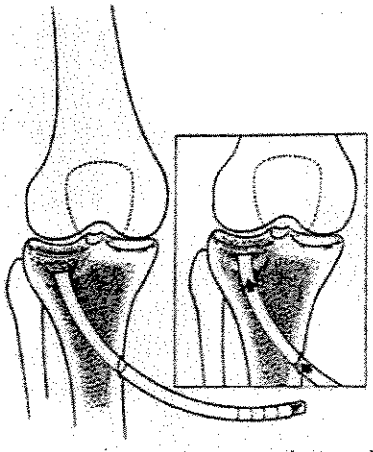


Figure 3. Principle of the fracture reduction and compaction procedure with a curved probe.

Finally, Edeland discloses the "filling the passage" step of Claim 1 of the '404 patent:

> Instead of bone grafts to compensate for the bone defects, porous ceramic material could be used as suggested by [Benum and Cameron]. The ceramic material (e.g. tri-calcium phosphate) could be introduced into the bone defect region [i.e. void] by the use of a cylinder-and-piston type of instrument arrangement, as shown in Figure 6. (Tab B hereto, p. 689.)

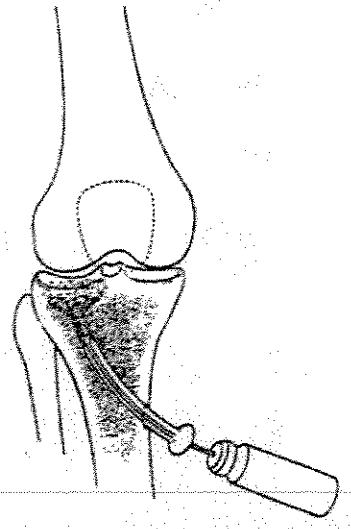


Figure 6. Principle of the use of the bone graft and/or ceramic "loaded" tube-and-plunger instrument set-up.

Figure 6 discloses a "tube-and-plunger" instrument for delivering bone graft and/or ceramic (e.g. tri-calcium phosphate) filler to the void created by the probe.[12] Figure 6 aptly sums up the fact that both bone graft and ceramic fillers are "flowable material" that can fill the void created by the probe; moreover, both bone graft and ceramic fillers can be made into pastes or slurries that harden over time and become bone. (See Exhibit E, Mitchell Decl., ¶¶ 12, 18.) Thus, to the extent the asserted claims are not limited to an inflatable device, Edeland discloses all limitations of Claim 1 of the '404 patent.

2. There is No Genuine Issue of Disputed Fact That Edeland Discloses the Second Element of Claim 1, as well as Claim 3, of the '404 Patent

In order to circumvent Edeland's disclosure of the second element of Claim 1 of the '404 patent (i.e. compacting to increase the volume of the passage), Kyphon contends that the probe in Edeland is incapable of increasing the volume of the passage in the bone. (See Exhibit V, pp. 8-9.) Yet, Kyphon's expert concedes that the movement of the probe in Edeland compacts cancellous bone (See Exhibit V, p. 11). Indeed, as confirmed by DOT's expert, the repeated careful pushes of the probe in Edeland compacts the cancellous bone on its way to, and in the

[12] Ceramic bone filler constitutes the "bone substitute" that the '404 discloses as a suitable void filler. (See Exhibit E, Mitchell Decl. at ¶ 11.)

process of, reducing the fracture, thereby increasing the volume of the passage. (See Exhibit E, Mitchell Decl., ¶ 2.) Moreover, as discussed above, to the extent the "compacting" step is not limited to an inflatable device,

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There is similarly no genuine issue of disputed fact that Edeland discloses Claim 3 of the '404 patent (i.e. "compacting step includes forcing the bone marrow outwardly of the central portion of the bone.") As with Olerud, Kyphon contends that the procedure in Edeland is limited to the periphery of the bone (see Exhibit V, p. 10). Kyphon's contention is similarly without merit. Figure 3 of Edeland provides a snapshot of one single push of the probe, from the center to the outer portion of the bone, that is repeated in different areas of the bone. (See Exhibit E, Mitchell Decl., ¶ 8.) DOT's expert has performed the procedure disclosed in Edeland and confirms that it involves pressing outwardly from the center of the bone. Id.

3. There is No Genuine Issue of Disputed Fact That Edeland Discloses the Third Element of Claim 1 of the '404 By Filling the Void with Ceramic Bone Substitute

Kyphon does not raise a genuine issue of disputed fact that Edeland discloses the third element of Claim 1 of the '404 Patent (i.e. "filling the passage with a flowable material capable of setting to a hardened condition"). As with Olerud, on the premise that only bone cement in its liquid state meets this third element, Kyphon raises the same "leakage" and "safety" contentions (See Exhibit V, p. 9); these contentions are without merit because bone cement is regularly used in a putty or toothpaste-like state to fill voids.

In addition, the ceramic calcium phosphate compound disclosed in Edeland to fill the void meets the third element of Claim 1 of the '404 Patent. First, ceramic calcium phosphate compounds are commonly-used bone fillers that are referred to as "synthetic bone," "artificial

bone" and/or "bone substitute." (See Exhibit E, Mitchell Decl., ¶ 11.)

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Second, calcium phosphate ceramics constitute "flowable material" because they can be made into a slurry by suspension in a liquid medium and then inserted into bone via a tube-and-plunger instrument or a bone filler device; this substance would then harden over time into bone. (See Exhibit E, Mitchell Decl., ¶ 12.) Third, the Kennedy article (see Tab C hereto) confirms that bone cement is interchangeable with the ceramic bone substitute and bone graft bone fillers disclosed in Edeland to fill the void created by a conventional bone tamp (see Exhibit E, Mitchell Decl., ¶ 9); as Kyphon's expert concedes, Kennedy discloses the same procedure as Edeland -- except that the void created by the conventional bone tamp is filled with bone cement. (See Exhibit V, p. 12.) And, as DOT's expert attests, there are certain circumstances where methylmethacrylate bone cement is the preferable bone filler for filling voids created by conventional bone tamps in the tibia. (See Exhibit E, Mitchell Decl., ¶ 15.) On these grounds, Kyphon does not raise a genuine issue of disputed fact that Olerud discloses the third element of Claim 1 of the '404 Patent.

4. There is No Genuine Issue of Disputed Fact that Edeland Discloses the "Drilling" Limitations Of Claims 8-10 of the '404 Patent

Kyphon's expert opines that Edeland does not disclose the drilling limitations of Claims 8-10 of the '404 Patent.[13]

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[13] The drilling limitations are as follows: (1) "drilling said bone marrow to form said passage" (Claim 8); (2) "guiding a drill through and into the proximate cortical bone marrow" (Claim 9); and (3) "drilling the bone marrow to a predetermined depth (Claim 10).

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Kyphon repeatedly represented to the FDA what DOT's expert opines is standard protocol: fenestration or the creation of a cortical window involves drilling through the cortical bone to form a passage in cancellous bone. (See Exhibit E, Mitchell Decl., ¶¶ 6, 24.) Because Edeland discloses, in addition to fenestration, the use of TV-monitored x-ray projectioning and specific positioning of the probe, there is no genuine issue of disputed fact with respect to Edeland anticipating claims 8-10 of the '404 patent. (See Exhibit E, Mitchell Decl., ¶7.)

5. Edeland Teaches Every Limitation of Claims 1, 3, 8, 9, 10 and 15 of the '404 Patent

In summary, the chart attached as Tab E hereto sets forth how the Edeland reference teaches every limitation of Claims 1, 3, 8, 9, 10, and 15 of the '404 Patent. DOT's expert, Dr. David Mitchell has confirmed that Edeland anticipates 1, 3, 8, 9, 10, and 15 of the '404 Patent. (See Exhibit A-A, pp. 1-3.) Because there is no issue of material fact that Edeland teaches every limitation of Claims 1, 3, 8, 9, 10, and 15 of the '404 Patent, DOT is entitled to summary judgment declaring that Claims 1, 3, 8, 9, 10, and 15 of the '404 Patent are invalid based on anticipation by Edeland.

C. DOT is Entitled to Summary Judgment that the '404 Patent is Invalid Based on Obviousness in View of the Edeland and Olerud References, Alone or in Combination

A patent is invalid 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 . . ." 35 U.S.C. § 103. The issue of obviousness is a question of law based on underlying facts. Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966). In determining whether the claimed subject matter would have been obvious, the court (1) determines the scope and content of the prior art; (2) ascertains the differences between the prior art and the claims at issue; (3) resolves the level of ordinary skill in the pertinent art[14]; and (4) considers any secondary considerations of non-obviousness that may be relevant. Graham, 383 U.S. at 17-18, 148 U.S.P.Q. at 467; Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 716, 21 U.S.P.Q.2d 1053, 1055 (Fed. Cir. 1991).

DOT's invalidity motion as to obviousness does not require that the Edeland and Olerud references be combined, since either reference, alone, can form a basis for obviousness. To the extent an asserted claim is not anticipated by Edeland and/or Olerud, the combined teachings of the Edeland and Olerud renders all the asserted claims of the '404 Patent obvious, as DOT's expert confirmed in his expert report. (See Exhibit A, ¶¶ 43-45; Exhibit A-A, pp. 23-25.) By way of example, the combination of Edeland and Olerud renders obvious claim 15 of the '404 patent ("flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement"); to the extent the Olerud reference, alone, does not render claim 15 obvious, the combination of Olerud with Edeland (which, as set forth in the Edeland chart

[14] For the purposes of determining the legal question of obviousness in this brief, DOT will assume Kyphon's definition of one of ordinary skill in the art: one "capable of designing or using the product, or performing the procedure." (See Exhibit V, ¶ 52.)

above, expressly discloses this limitation) renders claim 15 obvious. Similarly, the combination of Edeland and Olerud renders obvious claim 12 of the '404 patent ("the fracture is a fracture of a vertebral body of the human spine"); to the extent the Edeland reference, alone, does not render claim 12 obvious, the combination of Edeland with Olerud (which, as set forth in the Olerud chart above, expressly discloses this limitation) renders claim 12 obvious.

1. There is No Genuine Issue of Disputed Fact that One of Ordinary Skill in the Art Would Have Had the Suggestion and Motivation to Combine the Teachings of the Edeland and Olerud References

One of ordinary skill in the art would have had the suggestion and motivation to combine the teachings of the Edeland and Olerud references, because both references teach the treatment of a fractured bone. Indeed, as detailed above, both references contain similar disclosures.[15] (See Exhibit A, ¶ 45; Exhibit A-A, p. 24.) Moreover, as DOT's expert confirmed in his expert report, prior to the effective filing date of the '404 patent, it was well known to those of ordinary skill in the art that treatments for compressed tibial plateau fractures (as disclosed in Edeland) were similar to treatments for compressed vertebral body fractures (as disclosed in Olerud). (See Exhibit A, ¶ 45; see also Exhibit E, Mitchell Decl., ¶ 23.)

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[15] As discussed in detail above, in Edeland and Olerud, an instrument is introduced into the bone (i.e. forms a passage); the pressure of the instrument compacts cancellous bone on its way to, and in the process of, reducing the fracture (i.e. compacts to increase the volume of the passage); and bone filler material such as ceramic bone substitute or bone graft is introduced into the void (i.e. fills the passage with flowable material capable of setting to a hardened condition).

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Thus, there is no genuine issue of disputed fact that there would have been a suggestion and motivation to combine the Edeland and Olerud references.

Based on the charts attached as Tabs D and E hereto, and as confirmed by Dr. Mitchell in his expert report dated March 7, 2005 (see Exhibit A, ¶¶ 43-45), DOT submits that the Edeland and Olerud references, alone or in combination, render all of the asserted Claims of the '404 Patent obvious. As the foregoing demonstrates, there is no genuine issue of material fact, and DOT is entitled to summary judgment that the '404 Patent is invalid based on obviousness in view of the Edeland and Olerud references, either alone or in combination.

D. DOT is Entitled to Summary Judgment that the '888 Patent is Invalid Based on (1) Anticipation by the Edeland Reference; (2) Anticipation by the Olerud Reference and (3) Obviousness in View of the Edeland and Olerud References, Alone or In Combination

The only substantive difference between the '888 and '404 patents is that the '404 patent is broader, in that it does not have an "osteoporotic" limitation. The '404 and '888 patents share

[16] See also Exhibit E-6, Section 6.2.2 entitled "Vertebral Body Testing" at KY 004597-4602 and Section 6.2.3 entitled "Tibial Plateau Testing" at KY 004603 – 4605; Exhibit E-7, KY004944 – 4949.

a substantially identical specification, and the two patents share substantially identical claims. Edeland expressly discloses the "osteoporotic" limitation: Edeland discloses that a fracture of one of the condyles of the tibia is common in the elderly osteoporotic patient and that such fractures will benefit from the method outlined in the paper. (See Tab B hereto, p. 686.) Olerud inherently discloses this limitation, in that Olerud discloses treatment of fractured bone, which includes both osteoporotic and non-osteoporotic bone.[17] (See A-A, p. 34.)

For the same reasons as set forth above with respect to the '404 Patent and as confirmed by DOT's expert, DOT submits that (1) Edeland teaches every limitation of Claims 1, 3, 7, 8, 9, and 14 of the '888 patent; (2) Olerud teaches every limitation of Claims 1, 3, 7, 8, 9, and 11 of the '888 patent; and that (3) Edeland and Olerud, alone or in combination, renders obvious all the asserted claims of the '888 patent. (See Exhibit A, pp. 44, 47, 52-54 and Exhibit A-A, pp. 30-37, 52-56.) As the foregoing demonstrates, there is no genuine issue of material fact, and DOT is entitled to summary judgment that the '888 Patent is invalid based on obviousness in view of the Edeland and Olerud references, either alone or in combination.

[17] See Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003) (a particular reference may anticipate the patented invention "without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference").

CONCLUSION

For the reasons set forth above, DOT's motion for summary judgment declaring that the '404 and '888 Patents are invalid due to anticipation and/or obviousness should be granted. To the extent the asserted claims are not limited to an inflatable device, DOT submits that there is clear and convincing evidence and no issue of material fact, that the Edeland and Olerud prior art references render these claims invalid based on anticipation and/or obviousness.

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April 6, 2005

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 6h day of April, 2005 upon the following in the manner indicated:

BY HAND DELIVERY

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