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KYPHON'S MOTION *IN LIMINE* 1 OF 5

Motion *In Limine* to Preclude Admission of, or Reference to, Portions of Dr. Mitchell's Expert Testimony Relating to But Failing to Properly Analyze Obviousness

One of DOT's defenses is that each of the '888, '404 and '043 patents is invalid for obviousness. In support, DOT filed an expert report by Dr. David Mitchell ("Dr. Mitchell's expert report" (attached)), which contends that various, largely unidentified combinations of prior art references render obvious each of the '888, '404 and '043 patents.[1] However, Dr. Mitchell's obviousness opinion is legally improper and incomplete because: (1) it purports to find each claim **element** in the prior art and concludes that each **element** "is anticipated or obvious"; (2) it does not begin to adequately address the requisite motivation to combine; and (3) it purports to rely on many unidentified prior art combinations. Accordingly, Kyphon moves for an order *in limine* excluding any testimony by Dr. Mitchell that relates to obviousness of the '404, '888 or '043 patents.

I. DR. MITCHELL'S OBVIOUSNESS OPINION IS IMPROPER

An expert report must disclose a "complete statement" of all opinions to be expressed and the basis and reasons therefore, as set forth in Fed. R. Civ. P. 26(a)(2)(B). See *In re Pioneer Hi-bred Int'l, Inc.*, 238 F.3d 1370, 1375 (Fed. Cir. 2001). In particular, an expert report must indicate "how" and "why" the expert reached a particular conclusion. *Salgado v. General Motors Corp.*, 150 F.3d 735, 741 n.6 (7th Cir. 1998). "Nothing causes greater prejudice" than to guess "how" and "why" an expert reached a vague conclusion. *Reed v. Binder*, 165 F.R.D. 424, 430 (D.N.J. 1996).

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[1] DOT also filed a motion for summary judgment of invalidity of the '404 and '888 patents. D.I. 137.

Indeed, this Court, in Moore North America, Inc. v. Poser Business Forms, Inc., 2001 WL 253117, at *7 (D.Del. 2001), ruled that a litigant would "not be permitted to go forward" with an enablement defense at trial, because "if the issue of enablement were to go to trial, the testimony of [the litigant's] expert witnesses would be limited to the information contained in their expert reports" and the litigant's expert reports failed to provide legally sufficient information regarding this defense. It is not enough for an expert report to include mere conclusory statements. *Salgado*, 150 F.3d at 741 n.6. Yet, when it comes to obviousness, this is all Dr. Mitchell has done. His report contains only conclusory statements in support of his ultimate conclusion that the '888, '404 and '043 patents are invalid for obviousness.

In particular, Dr. Mitchell's expert report fails to explain how and why Dr. Mitchell reached his ultimate conclusion. Instead, as explained further below, Dr. Mitchell purports to identify where each asserted claim **element** is allegedly disclosed in the prior art. He then concludes, for each element, "this element is anticipated and rendered obvious". This is a meaningless and legally insufficient statement. His further blanket statements to the effect that "one or more of the asserted claims of the [ ] Patent is rendered obvious by one or more of the following prior art references", *see, e.g.,* Mitchell Report at 23, do not solve the problem. As the Court is well aware, "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine,* 837 F.2d 1071, 1075 (Fed. Cir. 1988). The Federal Circuit has consistently and repeatedly explained that "[d]etermination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." *ATD Corp. v.*

Lydall, Inc., 159 F.3d 534, 546 (Fed. Cir. 1998). It is thus not sufficient to show that each element of a claim exists somewhere in scattered prior art references to support an obviousness analysis. *Advanced Med. Optics, Inc. v. Alcon Inc.*, 2005 WL 724630 (D. Del. Mar. 29, 2005). "Instead, there must be a 'reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references, and that would also suggest a reasonable likelihood of success.'" *Id.* at *9 (citations omitted).

Kyphon understands that a motivation to combine does not require one reference to include an explicit reference to another. The motivation or suggestion to combine may be shown from the nature of the problem to be solved, the teachings of the prior art, or the knowledge of the persons of ordinary skill in the art. *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998); *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1348 (Fed. Cir. 2000); *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Nevertheless, a party seeking to invalidate a patent based on obviousness must show by clear and convincing evidence that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the asserted prior art references and combine them in the manner claimed. *In re Rouffet*, 149 F.3d at 1357. Again, as shown below, Dr. Mitchell has not done this for any combination, let alone for each of the combinations to which he potentially refers when he says "one or more of the asserted claims" "is rendered obvious by one or more of the following prior art references".

Moreover, the factual inquiry as to whether there is a motivation or suggestion to combine references must be thorough and searching. *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). It must be based on objective evidence of record. *Id.* Indeed, the

Federal Circuit "case law makes clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references." *Ecolochem, Inc. v. Southern Cal. Edison Co.,* 227 F.3d 1361, 1371-72 (Fed. Cir. 2000); *Winner Int'l,* 202 F.3d at 1349 (noting that that the absence of a suggestion to combine is dispositive in an obvious determination) (citations omitted).

The need for specificity in the analysis of a "motivation to combine" pervades the Federal Circuit case law. *See id.* The Federal Circuit has stated that an examiner's conclusory statements that "'the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software'" and that "'another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial'" do not adequately address the issue of motivation to combine. *In re Lee,* 277 at 1343. The Court has made it clear that particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Even when the level of skill in the art is high, the Court has required the Board to identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. *In re Rouffet*, 149 F.3d at 1359. "In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious." The Federal Circuit has hence made it clear that one can satisfy the burden of showing obviousness of the combination "only by showing some objective teaching in

the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992).

DOT's expert report violates these principles because it does not adequately and specifically show a "motivation to combine" the asserted prior art references only. Rather, as specifically addressed below, it offers only conclusory statements. The law requires DOT to explain why one of ordinary skill in the art would have been motivated to select the specified references and to combine them in such a way as to render obvious the claimed invention(s) of the '404, '888 and/or '043 patents. In the absence of an adequate showing of a motivation to combine, that portion of Dr. Mitchell's report and testimony addressing obviousness should be excluded.

A. Dr. Mitchell's Expert Report Fails To Provide the Requisite Analysis of "Motivation to Combine"

Dr. Mitchell's expert report provides a summary list of various prior art references that he contends somehow render the '404, '888, and '043 patents obvious. Dr. Mitchell's Expert Report at pp. 12-13, 18-20. But the report does not provide the requisite clear and particular showing of a "motivation to combine" with regard to *any* particular combination of prior art. Even assuming that the prior art references disclose each limitation of each asserted claim, an issue Kyphon disputes, the report fails to explain *why* one of ordinary skill in the art would have been taught or motivated at the time of the invention to combine any particular combination of the summarily listed references to produce the invention. Dr. Mitchell only includes a conclusory statement with respect to the '404 and '888 patents that "there would have been a suggestion and motivation to combine any of the references above because all of the references pertain to the treatment of a fractured or diseased bone." Dr. Mitchell's Expert Report at p. 14 and

19, Ex. A at pp. 24 and 53[2]. Being in the same field might make the references relevant to patentability, but hardly acts as a substitute for the rigorous "motivation to combine" requirement. Likewise, with respect to the '043 patent Dr. Mitchell merely states that "there would have been a suggestion and motivation to combine the '404 Patent with any of the references identified above because all of the references pertain to constrained expansion of inflatable medical devices." *Id.* at p. 20 and Ex. A at p. 57. These inadequate, conclusory statements by Dr. Mitchell are exactly the types of purported "analyses" of "motivation to combine" that this Court has held improper because of the danger of hindsight combinations that become clear only in light of the invention itself.

As this Court has acknowledged, it is well established that the fact that the prior art references are in the same field as the invention does not provide a suggestion or motivation to combine the references. "Obviousness requires more than showing that prior art was in the same field of invention." *Atofina v. Great Lakes Chem. Corp.,* No. Civ. 02-1250-SLR, 2005 WL 984361 at *18 n.20 (D. Del. Mar. 16, 2005) (citing *In re Bigio,* 381 F.3d 1320, 1325 (Fed. Cir. 2004)); *see Oxford Gene Tech. Ltd. v. Mergen Ltd.,* 345 F. Supp. 2d 444, 455 (D. Del. 2004); *Winner Int'l,* 202 F.3d at 1349. As the Federal Circuit explained in *In re Dance,* 160 F.3d 1339, 1343 (Fed. Cir. 1998):

> When the references are in the same field as that of the applicant's invention, knowledge thereof is presumed. However, the test of whether it would have been obvious to select specific teachings and combine them as did the applicant must still be met by identification of some suggestion, teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the filed of the invention.

In *Atofina,* the defendant argued at a bench trial that an asserted claim was invalid for obviousness in view of a reference that presented all the limitations of the claim but for one, which was disclosed in one of three other references. 2005 WL 984361 at * 18.

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[2] DOT's motion for summary judgment of invalidity of the '404 and '888 patents offers no further analysis of the requisite "motivation to combine" evidentiary element. It merely states with respect to the validity of the '404 patent that both allegedly invalidating references "teach the treatment of a fractured bone." D.I. 137 at p. 24.

This Court rejected defendant's obviousness argument because defendant failed to present any evidence of a motivation to combine the first reference with one of the three subsequent references even though the three references were in the same field as the invention. *Id.*

Dr. Mitchell's expert opinion as to the obviousness of the '404, '888 and '043 patents is improper for the same deficiency as the analysis in *Atofina.* The report provides no more than a conclusory assertion that one skilled in the art would have been motivated to combine the asserted prior art references because they are in the same field as the inventions. Thus, the expert report is an incomplete statement as to how and why Dr. Mitchell reached the ultimate conclusion that the patents are invalid for being obvious.

B. Dr. Mitchell's Expert Report Fails To Specifically Identify Combinations

Dr. Mitchell's obviousness opinion is lacking for another critical reason. He fails to identify the purported combinations of prior art references that allegedly render the '404, '888 and '043 patent obvious. He merely lists prior art references and states that "one or more of the asserted claims of the '404 patent is rendered obvious by one or more of the following prior art references." Dr. Mitchell's Expert Report at p. 12 and Ex. A at p. 23[3]. Although he provides one purportedly exemplary combination with respect to one claim in each patent, this is an inadequate analysis. Dr. Mitchell's Expert Report at pp. 14, 19 and 20. The listed references result in innumerable combinations that are difficult, if not impossible, to ascertain and it is not Kyphon's burden to do so. Further, as discussed above, any particular combination resulting from this omnibus assertion of

[3] Dr. Mitchell makes similar statements with regard to the '888 and '043 patents. Dr. Mitchell's Expert Report at p. 17 and Ex. A at p. 52, p. 19 and Ex. A at p. 57.

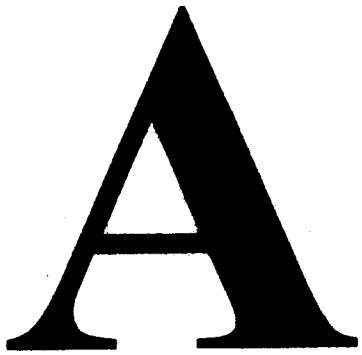
invalidity based on obviousness would clearly lack the requisite clear and particular showing of an essential component, *i.e.*, motivation to combine the references.

II. CONCLUSION

At trial, DOT has the burden of proving by clear and convincing evidence that there is a suggestion in the prior art to combine the cited references. Dr. Mitchell's indisputable failure to even attempt to analyze the requisite evidentiary element of motivation to combine will not allow DOT to carry this burden. Rather, the report's conclusory statements will only serve to confuse the jury – if the general observation that the references are in the same field is enough evidence of motivation for the "expert" Dr. Mitchell, and the Court allows it in, the jury undoubtedly will believe, mistakenly, that such general observations are sufficient evidence of a motivation to combine. Dr. Mitchell should, therefore, be prohibited from presenting evidence at trial in support of his conclusory obviousness assertions with respect to the '404, '888 or '043 patents. Moreover, the report's failure to specifically identify all the allegedly invalidating combinations is another reason to exclude his obviousness analysis as to unidentified combinations.

RULE 7.1.1 CERTIFICATION

Pursuant to Local Rule 7.1.1, counsel for Kyphon certifies that it has in good faith undertaken reasonable efforts, via email and phone, in an attempt to confer with counsel for defendants to discuss the issues raised in Kyphon's Motion *In Limine* to Preclude Admission of, or Reference to, Portions of Dr. Mitchell's Expert Testimony Relating to But Failing to Properly Analyze Obviousness, but the efforts of Kyphon's counsel have not, to date, been successful.



ANTICIPATION OF THE '404 PATENT BY EDELAND

Edeland, H.G., "Open Reduction of Central Compression Fractures of the Tibial Plateau," Acta Orthop. Scand., Vol. 47, pp. 686-689, 1976 ("Edeland")

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Edeland teaches every single limitation of one or more of the asserted claims of the '404 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '404 Patent	Edeland
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	Edeland discloses a method of reduction and fixation of a fracture of the tibia, a bone that contains bone marrow and cancellous bone. (Abstract, p. 686) Edeland refers to the "principle of the fracture reduction and compaction procedure with a curved probe." (Fig. 3, p. 688)
forming a passage in the bone marrow;	Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening), thereby forming a passage in cancellous bone. (p. 687) Edeland further discloses: "[t]he concave 'reduction end' of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control." (p. 687)

Claim of the '404 Patent	Edeland
compacting the bone marrow to increase the volume of said passage; and	Edeland discloses reduction of the compressed fracture site by repeated careful pushes of the probe. (p. 687 and Fig. 3, p. 688) "On its way, the probe transfers and compacts considerable amounts of cancellous bone from the region beneath the depression." (p. 687) The careful pushes of the probe compact the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage.
filling the passage with a flowable material capable of setting to a hardened condition.	Edeland discloses that ceramic material such as tri-calcium phosphate can be introduced into the void, thereby filling the passage with a flowable material capable of setting to a hardened condition. (p. 689)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Edeland, when the pushing of the probe "transfers and compacts considerable amounts of cancellous bone from the region beneath the depression," it forces the cancellous bone outwardly of the central portion of the bone. (p. 687)
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	*See* above at claim 1. Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening); fenestration involves drilling to form a passage in cancellous bone. (p. 687)

Claim of the '404 Patent	Edeland
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	*See* above at claim 8. Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening); fenestration involves drilling to forming a passage in cancellous bone. (p. 687) Edeland further discloses the use of TV-monitored x-ray projectioning and specific positioning of the probe: "[t]he concave 'reduction end' of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control." (Abstract, p. 686; p. 687). In this way, Edeland discloses guiding a drill through and into cancellous bone.
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	*See* above at claim 8. Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening); fenestration involves drilling to form a passage in cancellous bone. (p. 687) Edeland further discloses the use of TV-monitored x-ray projectioning and specific positioning of the probe: "[t]he concave 'reduction end' of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control." (Abstract, p. 686; p. 687). In this way, Edeland discloses drilling into the cancellous bone to a predetermined depth.
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	*See* above at claim 1. Edeland discloses that ceramic material such as tri-calcium phosphate can be introduced into the void, thereby filling the passage with a flowable material capable of setting to a hardened condition. (p. 689)

ANTICIPATION OF '404 PATENT BY OLERUD

Olerud, S., "Transpedicular Fixation of Thoracolumbar Vertebral Fractures," Clin. Orthop., Vol. 227, pp. 44-51, 1988 ("Olerud")

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Olerud teaches every single limitation of one or more of the asserted claims of the '404 Patent. I reserve the right to supplement, modify or amend my opinions.

Indeed, Kyphon acknowledged in its 510(k) Premarket Notification Submission to the FDA that its balloon device (the sole embodiment of the '404 Patent) has the "same intended use" as the conventional bone tamp disclosed in Olerud. In its 510(k), Kyphon disclosed that (1) the conventional bone tamps used in Olerud are substantially equivalent devices to Kyphon's Inflatable Bone Tamp and (2) the conventional bone tamps in Olerud have the "same intended uses" as Kyphon's Inflatable Bone Tamp to reduce fractures and/or create voids. (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842)[1] Kyphon acknowledged that Fig. 3 of Olerud shows "a conventional bone tamp being rotated in various directions to compact the cancellous bone and push the end plates apart, to achieve the desired reduction." (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842)

[1] In its 510(k), Kyphon reprinted a figure from an article in which Olerud is an author, Karlström, G., Olerud, S., and Sjoström, L., "Transpedicular Fixation of Thoracolumbar Fractures," Contemporary Orthopaedics, Vol. 20 (3), March 1990 ("Karlström"). Karlström contains precisely the same disclosure as Olerud. *Compare* Fig. 4D of Karlström *to* Fig. 3 of Olerud; *compare* text of p. 292 of Karlström *to* p. 47 of Olerud.

Claim of the '404 Patent	Olerud
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	Olerud discloses a procedure called "Transpedicular Fixation of Thoracolumbar Vertebral Fractures." The vertebral body contains both bone marrow and cancellous bone.
forming a passage in the bone marrow;	Olerud discloses that a slightly curved punch is brought through the pedicle into the vertebral body under fluoroscopic control, thereby forming a passage in the cancellous bone. (Fig. 3 and text, p. 47) Olerud also discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body," thereby forming a passage in the cancellous bone. (p. 47)

Claim of the '404 Patent	Olerud
compacting the bone marrow to increase the volume of said passage; and	Olerud discloses that a slightly curved punch is brought through the pedicle into the vertebral body in order to reduce fragments of the vertebral body, and further reduce the end plates and anterior wall of the vertebra. (Fig. 3 and text, p. 47) Olerud discloses that reduction of compressed vertebral bodies creates defects (i.e. cavities) in the cancellous bone like the defects created in compression fractures in tibial condyles. *Id.* Olerud further discloses that, similarly, defects can be created by use of transpedicularly introduced punch. *Id.* Olerud further cites to the procedure disclosed in Daniaux 1982. *Id.* The movement of the punch compacts the cancellous bone on its way to, and in the process of, elevating the fracture, thereby increasing the volume of the passage. Indeed, Kyphon has acknowledged that Fig. 3 of Olerud shows "a conventional bone tamp being rotated in various directions to compact the cancellous bone and push the end plates apart, to achieve the desired reduction." Kyphon has admitted that its Inflatable Bone Tamp (i.e. an inflatable balloon, the sole embodiment of the '404 patent) has the same intended uses as the punch (i.e. conventional bone tamp) used in Olerud in "reducing fractures and/or creating voids." (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842) See also Reiley Deposition Day 2, at 52:5-17, 53:21-54:6, 70:5-72:13, 94:23-95:15
filling the passage with a flowable material capable of setting to a hardened condition.	Olerud discloses that cancellous bone graft, described as "bone paste," is pressed into the defect (i.e. cavity) of the vertebra, thereby filling the passage with flowable material capable of setting to a hardened condition. (Fig. 3 and text, p. 47)

Claim of the '404 Patent	Olerud
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Olerud, when the transpedicularly introduced punch reduces the vertebral fracture, it compacts the cancellous bone and creates cavities (i.e. increased passage volume) in the vertebral fracture, thereby forcing the cancellous bone outwardly of the central portion of the bone. (Fig. 3 and text, p. 47)
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	*See* above at claim 1. Olerud discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body," thereby drilling the cancellous bone to form a passage. (p. 47)
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	*See* above at claim 8. Olerud discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body." (p. 47) Olerud further discloses that a slightly curved punch is brought through the pedicle into the vertebral body under fluoroscopic control. (p. 47) In this way, Olerud teaches guiding the 5-mm drill through and into the cancellous bone proximate to the cortical bone.
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	*See* above at claim 8. Olerud discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body." (p. 47) Olerud further discloses that a slightly curved punch is brought through the pedicle into the vertebral body under fluoroscopic control. (p. 47) In this way, Olerud teaches drilling the cancellous bone to a predetermined depth.

Claim of the '404 Patent	Olerud
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	*See* above at claim 1. Olerud discloses a procedure called "Transpedicular Fixation of Thoracolumbar Vertebral Fractures."
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	

ANTICIPATION OF THE '404 PATENT BY KENNEDY

Kennedy, W., "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," Clin. Orthop., Vol. 134, pp. 153-157, 1978 ("Kennedy")

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Kennedy teaches every single limitation of one or more of the asserted claims of the '404 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '404 Patent	Kennedy
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	Kennedy discloses a method of reduction and fixation of a fracture of the tibia, a bone that contains bone marrow and cancellous bone. (*passim*)
forming a passage in the bone marrow;	Kennedy discloses fashioning a "window" in the bone and introducing a "blunt instrument" through the "window," thereby forming a passage in the cancellous bone. (p. 154)
compacting the bone marrow to increase the volume of said passage; and	Kennedy teaches: "Through the window in the tibia, a blunt instrument could be inserted and used to push up the depressed bone fragments [so that] reduction was carried out." (p. 154) "[O]nce the articular fragments had been put into their proper place an obvious cavity was present in the subarticular bone. The crushed cancellous bone beneath the articular surface usually left a space. . ." (*Id.*) The pressure of the instrument compacts the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage.

Claim of the '404 Patent	Kennedy
filling the passage with a flowable material capable of setting to a hardened condition.	Kennedy discloses that the procedure leaves a "space which we elected to fill with methylmethacrylate rather than a bone graft," thereby filling the passage with flowable material capable of setting to a hardened condition. (p. 154)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Kennedy, the pressure of the instrument forces the cancellous bone outwardly of the central portion of the bone in order to create a large cavity. (p. 154)
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	*See* above at claim 1. Kennedy discloses fashioning a "window" in the bone, which includes drilling to forming a passage in cancellous bone. (p. 154)
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	

Claim of the '404 Patent	Kennedy
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	See above at claim 1. Kennedy discloses introducing methylmethacrylate into the space, thereby filling the passage with a flowable material capable of setting to a hardened condition. (p. 154)

ANTICIPATION OF '404 PATENT BY DANIAUX 1986

Daniaux, H., "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," Unfallchirurg, Vol. 89, pp. 197-213, 1986 ("Daniaux 1986")

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Daniaux 1986 teaches every single limitation of one or more of the asserted claims of the '404 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '404 Patent	Daniaux 1986
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	Daniaux 1986 discloses a procedure called "Transpedicular Reduction and Cancellous Bone Grafting Procedures in Fractures of Vertebral Bodies of the Lower Thoracic and Lumbar Spine." The vertebral body contains both bone marrow and cancellous bone.
forming a passage in the bone marrow;	Daniaux 1986 discloses the introduction of rams into the cancellous bone in the vertebrae, thereby forming a passage in the cancellous bone. (Translation, p. 7)

Claim of the '404 Patent	Daniaux 1986
compacting the bone marrow to increase the volume of said passage; and	Daniaux 1986 discloses using rams with different curvatures to slightly press the existing cancellous bone in the vertebrae against the covering plate and the upper front edge. (Translation p. 7, Fig. 2 upper line and Fig. 3) By means of rams with different curvature, the vertebra is repositioned from the inside. (Translation, p. 8) Daniaux 1986 discloses that a cavity can be formed by the fracture or by instrumental reposition (i.e. pressure from the rams). (Translation, p. 18) The slight pressure of the ram compacts the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage.
filling the passage with a flowable material capable of setting to a hardened condition.	Daniaux 1986 discloses (1) processing harvested cancellous bone to chips with a maximum diameter of 5 mm and (2) filling up the cavity in the vertebra with the processed cancellous bone by using cancellous bone funnels with impactor, thereby filling the passage with a flowable material capable of setting to a hardened condition. (Translation, pp. 1, 3, 7, and 10; Fig. 4)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. Daniaux 1986 discloses using rams with different curvature to slightly press the existing cancellous bone in the vertebrae against the covering plate and the upper front edge, thereby forcing the cancellous bone outwardly of the central portion of the bone. (Translation p. 7; Fig. 2 upper line, and Fig. 3)

Claim of the '404 Patent	Daniaux 1986
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	*See* above at claim 1. In Daniaux 1986, access into the vertebra is a drill hole following the central axis of the article. (p. 197) Short, 2 mm thick drilling wires are driven in the vertebra, followed by sensitive manual boring of Steinmann nails into the root of the arch's center of the fractured vertebra. (Translation, p. 7) In this way, cancellous bone is drilled to form a passage.
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	*See* above at claim 8. In Daniaux 1986, access into the vertebra is a drill hole following the central axis of the article. (p. 197) Short, 2 mm thick drilling wires are driven in the vertebra. The correctness of the position of the drilling wires is controlled by means of the image converter, and corrected, if necessary, followed by sensitive manual boring of Steinmann nails into the root of the arch's center of the fractured vertebra. (Translation, p. 7) In this way, the drill is guided through and into the cancellous bone proximate to the cortical bone.
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	*See* above at claim 8. In Daniaux 1986, access into the vertebra is a drill hole following the central axis of the article. (p. 197) Short, 2 mm thick drilling wires are driven in the vertebra. The correctness of the position of the drilling wires is controlled by means of the image converter, and corrected, if necessary, followed by sensitive manual boring of Steinmann nails. "The roots of the arch are manually bored into the vertebra until ca. 40 mm deep with an ascending series of Steinmann nails from 3 to 6 mm." "In this context, Steinmann nails in the sensitive manual boring always find the central way in the root of the arch." (Translation, p. 7) In this way, the cancellous bone is drilled to a predetermined depth.

Claim of the '404 Patent	Daniaux 1986
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	*See* above at claim 1. Daniaux 1986 discloses a procedure called "Transpedicular Reduction and Cancellous Bone Grafting Procedures in Fractures of Vertebral Bodies of the Lower Thoracic and Lumbar Spine."
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	

ANTICIPATION OF '404 PATENT BY BLAUTH

Blauth, M., "Therapeutic Concept and Results of Operative Treatment in Acute Trauma of the Thoracic and Lumbar Spine: The Hannover Experience," J. of Orthop. Trauma, Vol. 1, No. 3, pp. 240 – 252, 1987 ("Blauth")

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Blauth teaches every single limitation of one or more of the asserted claims of the '404 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '404 Patent	Blauth
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	Blauth discloses a method of reduction and fixation of a fractured vertebra, a bone that contains bone marrow and cancellous bone. (Summary, p. 240)
forming a passage in the bone marrow;	Blauth discloses the introduction of a punch into the vertebral body, thereby forming a passage in the cancellous bone. (Fig. 7 and text, p. 244)
compacting the bone marrow to increase the volume of said passage; and	Blauth discloses using a punch to transpedicularly lift (i.e. reduce) a fractured vertebral body. "[T]he upper endplate of the vertebra can be lifted back transpedicularly." (p. 244) Blauth cites to the procedure disclosed in Daniaux 1986 and discloses that a defect (i.e. cavity) in the vertebra evolves from this procedure. (Fig. 7 and text, p. 244) The pressure of the punch compacts the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage.

Claim of the '404 Patent	Blauth
filling the passage with a flowable material capable of setting to a hardened condition.	Blauth discloses filling up the defect (i.e. cavity) in the vertebra with cancellous bone graft, using a funnel, thereby filling the passage with a flowable material capable of setting to a hardened condition. (Fig. 7 and text, p. 244)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Blauth, the pressure of the punch forces the cancellous bone outwardly of the central portion of the bone. (Fig. 7 and text, p. 244)
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	*See* above at claim 1. Blauth cites to the procedure disclosed in Daniaux 1986, which includes drilling cancellous bone to form a passage. (Fig. 7, p. 244)
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	*See* above at claim 8. Blauth cites to the procedure disclosed in Daniaux 1986, which includes guiding a drill through and into the cancellous bone. (Fig. 7, p. 244)
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	*See* above at claim 8. Blauth cites to the procedure disclosed in Daniaux 1986, which includes drilling cancellous bone to a predetermined depth. (Fig. 7, p. 244)
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	*See* above at claim 1. Blauth discloses a method of reduction and fixation of a fractured vertebra. (Summary, p. 240)

Claim of the '404 Patent	Blauth
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	

ANTICIPATION OF THE '404 PATENT BY SCHATZKER

Schatzker, J., Operative Orthopaedics, M. Chapman, Ed., 1st ed., Ch. 35, pp. 421 – 434, 1988 ("Schatzker")

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Schatzker teaches every single limitation of one or more of the asserted claims of the '404 Patent. I reserve the right to supplement, modify or amend my opinions.

Indeed, Kyphon acknowledged in its 510(k) Premarket Notification Submission to the FDA that its balloon device (the sole embodiment of the '404 Patent) has the "same intended use" as the conventional bone tamp disclosed in Schatzker to reduce fractures and/or create voids. (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842)[2]

Claim of the '404 Patent	Schatzker
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	Schatzker discloses a method of reduction and fixation of a fracture of the tibia, a bone that contains bone marrow and cancellous bone. (*passim*)

[2] In Section 6.0, Appendix E ("Clinical Papers on Open Procedures with Conventional Bone Tamps") of its 510(k), Kyphon submitted an article in which Schatzker is an author, Watson, J. and Schatzker, J., "Tibial Plateau Fractures, " Chapter 54, pp. 2143–2186 ("Watson") (KY 004669–4711). Watson contains the same disclosure as Schatzker. *Compare* Fig. 54-25 of Watson *to* Fig. 35-9 of Schatzker; *compare* text of p. 2168 of Watson *to* text of p. 428 of Schatzker.

Claim of the '404 Patent	Schatzker
forming a passage in the bone marrow;	Schatzker discloses the introduction of a bone punch or periosteal elevator below the depressed tibial fragments, thereby forming a passage in the cancellous bone. (Fig. 35-9 and text, p. 428) Schatzker also discloses creation of a window by fenestration and insertion of a bone punch through the window; fenestration involves drilling to form a passage in cancellous bone. (Text and Fig. 35-11, pp. 429-430)
compacting the bone marrow to increase the volume of said passage; and	Schatzker teaches the collective elevation of fragments "from their impacted position in the cancellous bone of the metaphysis . . . . To initiate the elevation, insert a periosteal elevator deeply into the compacted cancellous bone of the metaphysis below the fragments. Then, with upward pressure, dislodge the whole segment and complete the reduction with a punch . . ." (p. 428) "[E]n masse elevation of fragments consists of insertion of a bone punch deep to the depressed fragments. Upward blows on the punch effect the reduction." (Fig. 35-9, p. 428) Schatzker further discloses that this procedure creates a hole (i.e. cavity) in the metaphysis below the fragments. (p. 428) Indeed, Kyphon acknowledged in its 510(k) Premarket Notification Submission to the FDA that its balloon device (the sole embodiment of the '404 Patent) has the "same intended use" as the conventional bone tamp disclosed in Schatzker to reduce fractures and/or create voids. (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842) The pressure of the instruments compacts the cancellous bone on its way to, and in the process of, elevating the fracture, thereby increasing the volume of the passage.

Claim of the '404 Patent	Schatzker
filling the passage with a flowable material capable of setting to a hardened condition.	Schatzker discloses that the procedure produces a hole (i.e. cavity) that can be filled with a "massive bone graft" or bone cement, thereby filling the passage with flowable material capable of setting to a hardened condition. (p. 428)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Schatzker, the pressure of the instruments forces the cancellous bone outwardly of the central portion of the bone in order to create a large cavity. (p. 428)
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	*See* above at claim 1. Schatzker discloses creation of a window by fenestration and insertion of a bone punch through the window; fenestration involves drilling to form a passage in cancellous bone. (Text and Fig. 35-11, pp. 429-430)
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	

Claim of the '404 Patent	Schatzker
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	*See* above at claim 1. Schatzker discloses that the procedure produces a hole (i.e. cavity) that can be filled with bone cement, thereby filling the passage with a flowable material capable of setting to a hardened condition. (p. 428)

OBVIOUSNESS OF '404 PATENT IN VIEW OF ONE OR MORE OF EDELAND, OLERUD, KENNEDY, DANIAUX 1986, BLAUTH, SCHATZKER, CAMPBELL, MA, DANIAUX 1982, DICK 1986, AND/OR CARLSON REFERENCES

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how one or more of the asserted claims of the '404 Patent is rendered obvious by one or more of the following prior art references:

> Edeland, H.G., "Open Reduction of Central Compression Fractures of the Tibial Plateau," Acta Orthop. Scand., Vol. 47, pp. 686-689, 1976 ("Edeland");
>
> Olerud, S., "Transpedicular Fixation of Thoracolumbar Vertebral Fractures," Clin. Orthop., Vol. 227, pp. 44-51, 1988 ("Olerud");
>
> Kennedy, W., "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," Clin. Orthop., Vol. 134, pp. 153-157, 1978 ("Kennedy");
>
> Daniaux, H., "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," Unfallchirurg, Vol. 89, pp. 197-213, 1986 ("Daniaux 1986");
>
> Blauth, M., "Therapeutic Concept and Results of Operative Treatment in Acute Trauma of the Thoracic and Lumbar Spine: The Hannover Experience," J. of Orthop. Trauma, Vol. 1, No. 3, pp. 240–252, 1987 ("Blauth");
>
> Schatzker, J., Operative Orthopaedics, M. Chapman, Ed., 1st ed., Ch. 35, pp. 421 – 434, 1988 ("Schatzker");
>
> Campbell's Operative Orthopaedics, A.H. Crenshaw, Ed., 7th ed., Chapter 44, pp. 1653–1663, 1987 ("Campbell");
>
> Ma, Yuan-zhang, "Os Calsis Fracture Treated by Percutaneous Poking Reduction and Internal Fixation,"

Chinese Medical Journal, Vol. 97, No. 2, pp. 105-110, 1984 ("Ma");

Daniaux, H., "Technik und Ergebnisse der transpedikulären Spongiosaplastik bei Kompressionsbrüchen im Lendenwirbelsäulenbereich," Acta Chir. Austr. (Suppl.), Vol. 43, pp. 79-80, 1982 ("Daniaux 1982");

Dick, W., "Use of the Acetabular Reamer to Harvest Autogeneic Bone Graft Material: A Simple Method for Producing Bone Paste," Arch. Orthop. Trauma Surg., Vol. 105, pp. 235 – 238, 1986 ("Dick 1986"); and/or

Carlson, "The Use of Methylmethacrylate in Rèpair of Neoplastic Lesions in Bone," Radiology, Vol. 112, pp. 43-46, July 1974 ("Carlson").

To one of ordinary skill in the art, there would have been a suggestion and motivation to combine any of the references above because all of the references pertain to the treatment of a fractured or diseased bone. Each of these references was publicly available to one of ordinary skill in the art prior to the effective filing date of the '404 patent. Moreover, prior to the effective date of the '404 patent, it was well known to those of ordinary skill in the art that treatments for compressed tibial plateau fractures were similar to treatments for compressed vertebral body fractures. The table below sets forth the elements that each of the references teaches. I reserve the right to supplement, modify or amend my opinions.

Claim of the '404 Patent	**One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References**
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '404 patent.

Claim of the '404 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References
forming a passage in the bone marrow;	This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '404 patent. In addition to these references, Campbell discloses and renders obvious this element. Campbell teaches the introduction of a "periosteal elevator or similar instrument" below the depressed tibial fragments, thereby forming a passage in the cancellous bone. (Fig. 44-59, p. 1660) Campbell further discloses the removal of a "window" in the bone and insertion of a small thin osteotome or periosteal elevator through the window into the cancellous bone, thereby forming a passage in the cancellous bone. (p. 1660)

Claim of the '404 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References
compacting the bone marrow to increase the volume of said passage; and	This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '404 patent. In addition to these references, Campbell discloses and renders obvious this element. Campbell teaches: "insert a periosteal elevator well beneath the depressed fragments and by slow and meticulous pressure elevate the bone fragments and compressed cancellous bone in one large mass. (Fig. 44-59) This produces a large cavity in the metaphysis that must be filled with bone." (p. 1660) Campbell further discloses inserting a small thin osteotome or periosteal elevator through the window into the cancellous bone in order to "elevate to normal level the depressed fragments of the articular surface"; this procedure produces a defect (i.e. cavity) to be filled with cancellous bone. (p. 1660) Ma also discloses and renders obvious this element. Ma discloses the insertion of a Steinmann pin to effect percutaneous poking reduction of a fracture. (pp. 106-107) The Steinmann pin percutaneously pokes the posterial articular, medial and lateral fragments, in order to reduce the fracture. Indeed, Kyphon has admitted in its 510(k) Premarket Notification Submission to the FDA that its Inflatable Bone Tamp (i.e. an inflatable balloon, the sole embodiment of the '404 patent) has the same intended uses as the Steinman pin (i.e. conventional bone tamp) used percutaneously in Ma to "reduce fractures and/or create voids." (Kyphon's 510(k) at 7-2, KY004840) Daniaux 1982 also discloses and renders obvious this element. Daniaux 1982 teaches using an instrument to press the cancellous bone against the cover plates, ground plates and front vertebral body wall to create a central cavity in the central vertebra. As disclosed, these instruments compact the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage.

Claim of the '404 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References
filling the passage with a flowable material capable of setting to a hardened condition.	This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '404 patent. In addition to these references, each of Dick 1986 and Carlson discloses this element. Dick 1986 describes the use of "bone paste," a flowable material capable of setting to a hardened condition, to fill the passage. (Dick 1986 (*passim*)) Indeed, Kyphon cited to Dick 1986 in its 510(k) Premarket Notification Submission to the FDA in support of its admission that the Inflatable Bone Tamp (i.e. an inflatable balloon, the sole embodiment of the '404 patent) has the same intended uses as conventional bone tamps to "reduce fractures and/or create voids." (Kyphon's 510(k) at 7-2, KY004809-12 and KY004840) Carlson discloses the use of methylmethacrylate in repair of lesions in bone. (*passim*)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '404 patent. In addition to these references, each of Campbell and Daniaux 1982 discloses and renders obvious this element. In Campbell, the slow and meticulous pressure of the instrument forces the cancellous bone outwardly of the central portion of the bone in order to create a large cavity. (p. 1660) In Daniaux 1982, the pressure of the instrument forces the cancellous bone outwardly of the central portion of the bone in order to create a central cavity in the central vertebra.

Claim of the '404 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	*See* above at claim 1. This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '404 patent. In addition to these references, Campbell discloses and renders obvious this element. Campbell discloses the removal of a "window" in the bone, which includes drilling to forming a passage in cancellous bone. (p. 1660)
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	*See* above at claim 8. This element is anticipated and rendered obvious by each of Edeland, Olerud, Daniaux 1986, and Blauth, as set forth in the anticipation charts with respect to the '404 patent.
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	*See* above at claim 8. This element is anticipated and rendered obvious by each of Edeland, Olerud, Daniaux 1986, and Blauth, as set forth in the anticipation charts with respect to the '404 patent.

Claim of the '404 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	*See* above at claim 1. This element is anticipated and rendered obvious by each of Olerud, Blauth, and Daniaux 1986, as set forth in the anticipation charts with respect to the '404 patent. In addition, each of Olerud and Daniaux 1986 discloses the similarities between the treatment of tibial fractures and vertebral fractures. Olerud discloses that reduction of compressed vertebral bodies creates defects (i.e. cavities) in the cancellous bone like the defects created in compression fractures in tibial condyles. (Fig. 3 and text, p. 47) Daniaux 1986 discloses: "it was obvious not only to reposition and indirectly stabilize vertebra[l] fractures, but by analogy to the treatment of other fractures, in cases of mainly cancellous bones (tibia head etc.) to fill up defects with autologous cancellous bone. . ." (Translation, p. 3)
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	*See* above at claim 1. This element is anticipated and rendered obvious by each of Edeland, Kennedy, and Schatzker, as set forth in the anticipation charts with respect to the '404 patent. In addition to these references, Carlson discloses and renders obvious this element. Carlson discloses the use of methylmethacrylate in repair of lesions in bone. (*passim*)

ANTICIPATION OF '888 PATENT BY EDELAND

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Edeland teaches every single limitation of one or more of the asserted claims of the '888 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '888 Patent	Edeland
1. A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic bone marrow therein comprising:	Edeland discloses a method of reduction and fixation of a fracture of the tibia, a bone that contains bone marrow and cancellous bone. (Abstract, p. 686) Edeland refers to the "principle of the fracture reduction and compaction procedure with a curved probe." (Fig. 3, p. 688) 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. (p. 686)
forming a passage in the bone marrow;	Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening), thereby forming a passage in cancellous bone. (p. 687) Edeland further discloses: "[t]he concave 'reduction end' of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control." (p. 687)

Claim of the '888 Patent	Edeland
compacting the bone marrow to increase the volume of said passage; and	Edeland discloses reduction of the compressed fracture site by repeated careful pushes of the probe. (p. 687 and Fig. 3, p. 688) "On its way, the probe transfers and compacts considerable amounts of cancellous bone from the region beneath the depression." (p. 687) The careful pushes of the probe compact the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage.
filling the passage with a flowable material capable of setting to a hardened condition.	Edeland discloses that ceramic material such as tri-calcium phosphate can be introduced into the void, thereby filling the passage with a flowable material capable of setting to a hardened condition. (p. 689)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the osteoporotic bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Edeland, when the pushing of the probe "transfers and compacts considerable amounts of cancellous bone from the region beneath the depression," it forces the cancellous bone outwardly of the central portion of the bone. (p. 687)
7. A method as set forth in claim 1, wherein said forming step includes drilling said osteoporotic bone marrow to form said passage.	*See* above at claim 1. Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening); fenestration involves drilling to form a passage in cancellous bone. (p. 687)

Claim of the '888 Patent	Edeland
8. A method as set forth in claim 7, wherein said drilling step includes guiding a drill through into the proximate corticol bone marrow.	*See* above at claim 7. Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening); fenestration involves drilling to forming a passage in cancellous bone. (p. 687) Edeland further discloses the use of TV-monitored x-ray projectioning and specific positioning of the probe: "[t]he concave 'reduction end' of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control." (Abstract, p. 686; p. 687). In this way, Edeland discloses guiding a drill through and into cancellous bone.
9. A method as set forth in claim 7, wherein said forming step includes drilling the osteoporotic bone marrow to a predetermined depth.	*See* above at claim 7. Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening); fenestration involves drilling to form a passage in cancellous bone. (p. 687) Edeland further discloses the use of TV-monitored x-ray projectioning and specific positioning of the probe: "[t]he concave 'reduction end' of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control." (Abstract, p. 686; p. 687). In this way, Edeland discloses drilling into the cancellous bone to a predetermined depth.
11. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	
14. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	*See* above at claim 1. Edeland discloses that ceramic material such as tri-calcium phosphate can be introduced into the void, thereby filling the passage with a flowable material capable of setting to a hardened condition. (p. 689)

ANTICIPATION OF '888 PATENT BY OLERUD

Olerud, S., "Transpedicular Fixation of Thoracolumbar Vertebral Fractures," Clin. Orthop., Vol. 227, pp. 44-51, 1988 ("Olerud")

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Olerud teaches every single limitation of one or more of the asserted claims of the '888 Patent. I reserve the right to supplement, modify or amend my opinions.

Indeed, Kyphon acknowledged in its 510(k) Premarket Notification Submission to the FDA that its balloon device (the sole embodiment of the '888 Patent) has the "same intended use" as the conventional bone tamp disclosed in Olerud. In its 510(k), Kyphon disclosed that (1) the conventional bone tamps used in Olerud are substantially equivalent devices to Kyphon's Inflatable Bone Tamp and (2) the conventional bone tamps in Olerud have the "same intended uses" as Kyphon's Inflatable Bone Tamp to reduce fractures and/or create voids. (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842)[3] Kyphon acknowledged that Fig. 3 of Olerud shows "a conventional bone tamp being rotated in various directions to compact the cancellous bone and push the end plates apart, to achieve the desired reduction." (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842)

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[3] In its 510(k), Kyphon reprinted a figure from an article in which Olerud is an author, Karlström, G., Olerud, S., and Sjoström, L., "Transpedicular Fixation of Thoracolumbar Fractures," Contemporary Orthopaedics, Vol. 20 (3), March 1990 ("Karlström"). Karlström contains precisely the same disclosure as Olerud. *Compare* Fig. 4D of Karlström *to* Fig. 3 of Olerud; *compare* text of p. 292 of Karlström *to* p. 47 of Olerud.

Claim of the '888 Patent	Olerud
1. A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic bone marrow therein comprising:	Olerud discloses a procedure called "Transpedicular Fixation of Thoracolumbar Vertebral Fractures." The vertebral body contains both bone marrow and cancellous bone. Olerud discloses treatment of fractured bone, which would include both osteoporotic and non-osteoporotic bone.
forming a passage in the bone marrow;	Olerud discloses that a slightly curved punch is brought through the pedicle into the vertebral body under fluoroscopic control, thereby forming a passage in the cancellous bone. (Fig. 3 and text, p. 47) Olerud also discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body," thereby forming a passage in the cancellous bone. (p. 47)

Claim of the '888 Patent	Olerud
compacting the bone marrow to increase the volume of said passage; and	Olerud discloses that a slightly curved punch is brought through the pedicle into the vertebral body in order to reduce fragments of the vertebral body, and further reduce the end plates and anterior wall of the vertebra. (Fig. 3 and text, p. 47) Olerud discloses that reduction of compressed vertebral bodies creates defects (i.e. cavities) in the cancellous bone like the defects created in compression fractures in tibial condyles. *Id.* Olerud further discloses that, similarly, defects can be created by use of transpedicularly introduced punch. *Id.* Olerud further cites to the procedure disclosed in Daniaux 1982. *Id.* The movement of the punch compacts the cancellous bone on its way to, and in the process of, elevating the fracture, thereby increasing the volume of the passage. Indeed, Kyphon has acknowledged that Fig. 3 of Olerud shows "a conventional bone tamp being rotated in various directions to compact the cancellous bone and push the end plates apart, to achieve the desired reduction." Kyphon has admitted that its Inflatable Bone Tamp (i.e. an inflatable balloon, the sole embodiment of the '888 patent) has the same intended uses as the punch (i.e. conventional bone tamp) used in Olerud in "reducing fractures and/or creating voids." (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842) See also Reiley Deposition Day 2, at 52:5-17, 53:21-54:6, 70:5-72:13, 94:23-95:15
filling the passage with a flowable material capable of setting to a hardened condition.	Olerud discloses that cancellous bone graft, described as "bone paste," is pressed into the defect (i.e. cavity) of the vertebra, thereby filling the passage with flowable material capable of setting to a hardened condition. (Fig. 3 and text, p. 47)

Claim of the '888 Patent	Olerud
3. A method as set forth in claim 1, wherein said compacting step includes forcing the osteoporotic bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Olerud, when the transpedicularly introduced punch reduces the vertebral fracture, it compacts the cancellous bone and creates cavities (i.e. increased passage volume) in the vertebral fracture, thereby forcing the cancellous bone outwardly of the central portion of the bone. (Fig. 3 and text, p. 47)
7. A method as set forth in claim 1, wherein said forming step includes drilling said osteoporotic bone marrow to form said passage.	*See* above at claim 1. Olerud discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body," thereby drilling the cancellous bone to form a passage. (p. 47)
8. A method as set forth in claim 7, wherein said drilling step includes guiding a drill through into the proximate corticol bone marrow.	*See* above at claim 7. Olerud discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body." (p. 47) Olerud further discloses that a slightly curved punch is brought through the pedicle into the vertebral body under fluoroscopic control. (p. 47) In this way, Olerud teaches guiding the 5-mm drill through and into the cancellous bone proximate to the cortical bone.
9. A method as set forth in claim 7, wherein said forming step includes drilling the osteoporotic bone marrow to a predetermined depth.	*See* above at claim 7. Olerud discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body." (p. 47) Olerud further discloses that a slightly curved punch is brought through the pedicle into the vertebral body under fluoroscopic control. (p. 47) In this way, Olerud teaches drilling the cancellous bone to a predetermined depth.

Claim of the '888 Patent	Olerud
11. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	*See* above at claim 1. Olerud discloses a procedure called "Transpedicular Fixation of Thoracolumbar Vertebral Fractures."
14. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	

ANTICIPATION OF '888 PATENT BY KENNEDY

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Kennedy teaches every single limitation of one or more of the asserted claims of the '888 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '888 Patent	Kennedy
1. A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic bone marrow therein comprising:	Kennedy discloses a method of reduction and fixation of a fracture of the tibia, a bone that contains bone marrow and cancellous bone. (*passim*) Kennedy discloses that a depressed tibial condylar fracture in the osteoporotic elderly patient provides a difficult problem that the methods discussed in the paper attempt to treat. (p. 153)
forming a passage in the bone marrow;	Kennedy discloses fashioning a "window" in the bone and introducing a "blunt instrument" through the "window," thereby forming a passage in the cancellous bone. (p. 154)

Claim of the '888 Patent	Kennedy
compacting the bone marrow to increase the volume of said passage; and	Kennedy teaches: "Through the window in the tibia, a blunt instrument could be inserted and used to push up the depressed bone fragments [so that] reduction was carried out." (p. 154) "[O]nce the articular fragments had been put into their proper place an obvious cavity was present in the subarticular bone. The crushed cancellous bone beneath the articular surface usually left a space. . ." (*Id.*) The pressure of the instrument compacts the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage.
filling the passage with a flowable material capable of setting to a hardened condition.	Kennedy discloses that the procedure leaves a "space which we elected to fill with methylmethacrylate rather than a bone graft," thereby filling the passage with flowable material capable of setting to a hardened condition. (p. 154)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the osteoporotic bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Kennedy, the pressure of the instrument forces the cancellous bone outwardly of the central portion of the bone in order to create a large cavity. (p. 154)
7. A method as set forth in claim 1, wherein said forming step includes drilling said osteoporotic bone marrow to form said passage.	*See* above at claim 1. Kennedy discloses fashioning a "window" in the bone, which includes drilling to forming a passage in cancellous bone. (p. 154)
8. A method as set forth in claim 7, wherein said drilling step includes guiding a drill through into the proximate corticol bone marrow.	

Claim of the '888 Patent	Kennedy
9. A method as set forth in claim 7, wherein said forming step includes drilling the osteoporotic bone marrow to a predetermined depth.	
11. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	
14. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	*See* above at claim 1. Kennedy discloses introducing methylmethacrylate into the space, thereby filling the passage with a flowable material capable of setting to a hardened condition. (p. 154)

ANTICIPATION OF '888 PATENT BY DANIAUX 1986

Daniaux, H., "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," Unfallchirurg, Vol. 89, pp. 197-213, 1986 ("Daniaux 1986")

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Daniaux 1986 teaches every single limitation of one or more of the asserted claims of the '888 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '888 Patent	Daniaux 1986
1. A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic bone marrow therein comprising:	Daniaux 1986 discloses a procedure called "Transpedicular Reduction and Cancellous Bone Grafting Procedures in Fractures of Vertebral Bodies of the Lower Thoracic and Lumbar Spine." The vertebral body contains both bone marrow and cancellous bone. Daniaux 1986 discloses treatment of fractured bone, which would include both osteoporotic and non-osteoporotic bone.
forming a passage in the bone marrow;	Daniaux 1986 discloses the introduction of rams into the cancellous bone in the vertebrae, thereby forming a passage in the cancellous bone. (Translation, p. 7)

Claim of the '888 Patent	Daniaux 1986
compacting the bone marrow to increase the volume of said passage; and	Daniaux 1986 discloses using rams with different curvatures to slightly press the existing cancellous bone in the vertebrae against the covering plate and the upper front edge. (Translation p. 7, Fig. 2 upper line and Fig. 3) By means of rams with different curvature, the vertebra is repositioned from the inside. (Translation, p. 8) Daniaux 1986 discloses that a cavity can be formed by the fracture or by instrumental reposition (i.e. pressure from the rams). (Translation, p. 18) The slight pressure of the ram compacts the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage.
filling the passage with a flowable material capable of setting to a hardened condition.	Daniaux 1986 discloses (1) processing harvested cancellous bone to chips with a maximum diameter of 5 mm and (2) filling up the cavity in the vertebra with the processed cancellous bone by using cancellous bone funnels with impactor, thereby filling the passage with a flowable material capable of setting to a hardened condition. (Translation, pp. 1, 3, 7, and 10; Fig. 4)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the osteoporotic bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. Daniaux 1986 discloses using rams with different curvature to slightly press the existing cancellous bone in the vertebrae against the covering plate and the upper front edge, thereby forcing the cancellous bone outwardly of the central portion of the bone. (Translation p. 7; Fig. 2 upper line, and Fig. 3)

Claim of the '888 Patent	Daniaux 1986
7. A method as set forth in claim 1, wherein said forming step includes drilling said osteoporotic bone marrow to form said passage.	*See* above at claim 1. In Daniaux 1986, access into the vertebra is a drill hole following the central axis of the article. (p. 197) Short, 2 mm thick drilling wires are driven in the vertebra, followed by sensitive manual boring of Steinmann nails into the root of the arch's center of the fractured vertebra. (Translation, p. 7) In this way, cancellous bone is drilled to form a passage.
8. A method as set forth in claim 7, wherein said drilling step includes guiding a drill through into the proximate corticol bone marrow.	*See* above at claim 7. In Daniaux 1986, access into the vertebra is a drill hole following the central axis of the article. (p. 197) Short, 2 mm thick drilling wires are driven in the vertebra. The correctness of the position of the drilling wires is controlled by means of the image converter, and corrected, if necessary, followed by sensitive manual boring of Steinmann nails into the root of the arch's center of the fractured vertebra. (Translation, p. 7) In this way, the drill is guided through and into the cancellous bone proximate to the cortical bone.
9. A method as set forth in claim 7, wherein said forming step includes drilling the osteoporotic bone marrow to a predetermined depth.	*See* above at claim 7. In Daniaux 1986, access into the vertebra is a drill hole following the central axis of the article. (p. 197) Short, 2 mm thick drilling wires are driven in the vertebra. The correctness of the position of the drilling wires is controlled by means of the image converter, and corrected, if necessary, followed by sensitive manual boring of Steinmann nails. "The roots of the arch are manually bored into the vertebra until ca. 40 mm deep with an ascending series of Steinmann nails from 3 to 6 mm." "In this context, Steinmann nails in the sensitive manual boring always find the central way in the root of the arch." (Translation, p. 7) In this way, the cancellous bone is drilled to a predetermined depth.

Claim of the '888 Patent	Daniaux 1986
11. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	*See* above at claim 1. Daniaux 1986 discloses a procedure called "Transpedicular Reduction and Cancellous Bone Grafting Procedures in Fractures of Vertebral Bodies of the Lower Thoracic and Lumbar Spine."
14. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	

ANTICIPATION OF '888 PATENT BY BLAUTH

Blauth, M., "Therapeutic Concept and Results of Operative Treatment in Acute Trauma of the Thoracic and Lumbar Spine: The Hannover Experience," J. of Orthop. Trauma, Vol. 1, No. 3, pp. 240 – 252, 1987 ("Blauth")

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how Blauth teaches every single limitation of one or more of the asserted claims of the '888 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '888 Patent	Blauth
1. A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic bone marrow therein comprising:	Blauth discloses a method of reduction and fixation of a fractured vertebra, a bone that contains bone marrow and cancellous bone. (Summary, p. 240) Blauth discloses treatment of fractured bone, which would include both osteoporotic and non-osteoporotic bone.
forming a passage in the bone marrow;	Blauth discloses the introduction of a punch into the vertebral body, thereby forming a passage in the cancellous bone. (Fig. 7 and text, p. 244)
compacting the bone marrow to increase the volume of said passage; and	Blauth discloses using a punch to transpedicularly lift (i.e. reduce) a fractured vertebral body. "[T]he upper endplate of the vertebra can be lifted back transpedicularly." (p. 244) Blauth cites to the procedure disclosed in Daniaux 1986 and discloses that a defect (i.e. cavity) in the vertebra evolves from this procedure. (Fig. 7 and text, p. 244) The pressure of the punch compacts the cancellous bone on its way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage.

Claim of the '888 Patent	Blauth
filling the passage with a flowable material capable of setting to a hardened condition.	Blauth discloses filling up the defect (i.e. cavity) in the vertebra with cancellous bone graft, using a funnel, thereby filling the passage with a flowable material capable of setting to a hardened condition. (Fig. 7 and text, p. 244)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the osteoporotic bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Blauth, the pressure of the punch forces the cancellous bone outwardly of the central portion of the bone. (Fig. 7 and text, p. 244)
7. A method as set forth in claim 1, wherein said forming step includes drilling said osteoporotic bone marrow to form said passage.	*See* above at claim 1. Blauth cites to the procedure disclosed in Daniaux 1986, which includes drilling cancellous bone to form a passage. (Fig. 7, p. 244)
8. A method as set forth in claim 7, wherein said drilling step includes guiding a drill through into the proximate corticol bone marrow.	*See* above at claim 7. Blauth cites to the procedure disclosed in Daniaux 1986, which includes guiding a drill through and into the cancellous bone. (Fig. 7, p. 244)
9. A method as set forth in claim 7, wherein said forming step includes drilling the osteoporotic bone marrow to a predetermined depth.	*See* above at claim 7. Blauth cites to the procedure disclosed in Daniaux 1986, which includes drilling cancellous bone to a predetermined depth. (Fig. 7, p. 244)
11. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	*See* above at claim 1. Blauth discloses a method of reduction and fixation of a fractured vertebra. (Summary, p. 240)

Claim of the '888 Patent	Blauth
14. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	