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 '304 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 Repair 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.

Claims 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, Mc Daniaux 1982, Orck 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	Daniaux 1986, Edeland, Olerud, Kennedy, Daniaux 1982, Blauth, Schatzker, Campbell, Ma 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, 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, Mc 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, Mt. 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 '868 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)
8. 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)[8] 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)

[8] 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 '883 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 '885 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 '883 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)

'588 Claim of the '588 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 '885 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 '838 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.	

ANTICIPATION OF THE '888 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 '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 Schatzker to reduce fractures and/or create voids. (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842)[4]

Claim of the '888 Patent	Schatzker
1. A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic 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*) Schatzker discloses that the most common pattern of a fracture of the tibia is a type 3 fracture that occurs when patients have more severe osteoporosis than patients with type 1 and 2 fractures. (p. 423)

[4] 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 '888 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 '888 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 '588 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 osteoporotic 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)
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. 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)
8. A method as set forth in claim 7, wherein said drilling step includes guiding a drill through into the proximate corticol bone marrow.	
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.	

Claim of the '868 Patent	Schatzker
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. 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 '888 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 '888 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 Repair 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 '888 patent. Moreover, prior to the effective date of the '888 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 '888 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 an osteoporotic bone having osteoporotic 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 '888 patent.
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 '888 patent. In addition to these references, Campbell discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.
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 '888 patent. In addition to these references, each of Campbell, Ma, and Daniaux 1982 discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.
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 '888 patent. In addition to these references, each of Dick 1986 and Carlson discloses this element, as set forth in the obviousness chart with respect to the '404 patent.

Claim of the '888 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Mar, Daniaux 1982, Dick 1986, and/or Carlson References
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. 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 '888 patent. In addition to these references, each of Campbell and Daniaux 1982 discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.
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. 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 '888 patent. In addition to these references, Campbell discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.
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. 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 '888 patent.
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. 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 '888 patent.

Claim of the '888 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References
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. 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 '888 patent. In addition, each of Olerud and Daniaux 1986 discloses the similarities between the treatment of tibial fractures and vertebral fractures, as set forth in the obviousness chart with respect to the '404 patent.
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. 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 '888 patent. In addition to these references, Carlson discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.

OBVIOUSNESS OF '043 PATENT IN VIEW OF COMBINATION OF '404 PATENT WITH ONE OR MORE OF THE '132, '495, '252 AND '949 PATENTS

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 '043 Patent is rendered obvious by the combination of the '404 Patent with one or more of the following prior art references: U.S. Patent No. 5,049,132, U.S. Patent No. 4,878,495, U.S. Patent No. 4,909,252, and U.S. Patent No. 3,626,949. 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 constrained expansion of inflatable medical devices. Each of these references was publicly available to one of ordinary skill in the art prior to the effective filing date of the '043 patent. 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 '043 Patent	Combination of '404 Patent with '132, '495, '252 and/or '949 Patents
2. A method for treating bone comprising the steps of inserting inside bone a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, including the body includes [sic] material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone,	The sole embodiment of the '404 Patent is an inflatable balloon (i.e. a body comprising an expandable wall). 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 '404 Patent discloses inserting inside the bone a balloon adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, with material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone. (Col. 2, ll. 33-38; Col. 2, ll. 15-19; Fig. 28)

Claim of the '043 Patent	Combination of '404 Patent with '132, '495, '252 and/or '949 Patents
and further includes an internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone, causing constrained expansion of the body in cancellous bone, and compacting cancellous bone by the constrained expansion.	One of ordinary skill in the art would have combined the disclosure of the '404 Patent with one or more of the prior art references below describing inflatable medical devices with internal restraints to constrain expansion. *See* '043 Patent at Col. 4, ll. 10-34. The '495 Patent discloses a valvuloplasty device having a plurality of balloons for valvuloplasty with internal restraints coupled to an interior of the body to constrain expansion. The valvuloplasty device can be produced in many configurations. A plurality of ribs or separators in the balloons shape the balloons. (Col. 2, l. 65 – Col. 3, l. 4; Col. 6, l. 5 – Col. 7, l. 62; Figs. 6, 8-13) The '495 Patent further discloses: "the satellite balloons include a plurality of ribs or partitions 662 and 672 respectively which partitions serve primarily for purposes of shaping the satellite balloons so that the balloons can have an oblong shape with relatively narrow edges 674 and 664 respectively." (Col. 6, l. 29-34) The '132 Patent discloses a balloon catheter for delivering therapeutic agents with internal restraints coupled to an interior of the body to constrain expansion. The '132 discloses a second balloon to be "spot-sealed" to the first balloon in a plurality of spaced areas." (Claims 1 and 7; Col. 3, ll. 28-31; Col. 6, ll. 42 – 65; Figs. 2 and 4 (part 50)) The '252 Patent discloses a perfusion balloon catheter utilizing a balloon with internal restraints coupled to an interior of the body to constrain expansion. To ensure that spacing between the inner and outer walls of the balloon remains consistent, the '252 Patent discloses "ribbed members" (part 39) between the inner and outer walls of the balloon. (Figs. 4a and 4b, Col. 5, ll. 38-46)

Claim of the '043 Patent	Combination of '404 Patent with '132, '495, '252 and/or '949 Patents
17. A method for treating bone comprising the steps of inserting inside bone a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion in cancellous bone, causing constrained expansion of the body in cancellous bone, and compacting cancellous bone by the constrained expansion.	The sole embodiment of the '404 Patent is an inflatable balloon (i.e. a body comprising an expandable wall). 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 '404 Patent discloses inserting inside the bone a balloon adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, with material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone. (Col. 2, ll. 33-38; Col. 2, ll. 15-19; Fig. 28) One of ordinary skill in the art would have combined the disclosure of the '404 Patent with one or more of the prior art references below describing inflatable medical devices with at least two materials that constrain expansion. *See* '043 Patent at Col. 4, ll. 10-34. The '949 Patent discloses a cervical dilator with a body including at least 2 materials that undergoes constrained expansion. The '949 patent discloses an inflatable bag with a waist portion that has a continuous thread embedded therein which restricts radial expansion of the waist portion on inflation of the bag. (Col. 2, ll. 35-38 and Fig. 2) The waist portion is adapted with a relatively inextensible fiber providing resistance at the waist to radial expansion in contrast to the remainder of the walls of the bag. (Col. 1, ll. 48-56 and Col. 1, l. 69 - Col. 2, l. 7). The '495 Patent discloses a valvuloplasty device having a plurality of balloons for valvuloplasty that includes at least two materials that constrain expansion. (Col. 2, l. 65 – Col. 3, l. 4; Col. 6, l. 5 – Col. 7, l. 62; Figs. 6, 8-13). The '132 Patent discloses a balloon catheter for delivering therapeutic agents that includes at least two materials that constrain expansion. (Claims 1 and 7; Col. 3, ll. 28-31; Col. 6, ll. 42 – 65; Figs. 2 and 4 (part 50)) The '252 Patent discloses a perfusion balloon catheter utilizing a perfusion balloon that includes at least two materials that constrain expansion. (Figs. 4a and 4b (part 39), Col. 5, ll. 38-46)

Claim of the '049 Patent	Combination of '404 Patent with '182, '495, '252 and/or '949 Patents
20. A method according to claim 1 or 2 or 8 or 17 wherein the constrained expansion lifts vertebral end plates.	*See* above at claim 2 or 17. The '404 Patent discloses the fixation of vertebral body compression.
23. A method according to claim 1 or 2 or 8 or 17 wherein the constrained expansion lifts cortical bone.	*See* above at claim 2 or 17. The inflatable balloon disclosed in the '404 Patent undergoes expansion in the cancellous bone to compact cancellous bone (Col. 2., ll. 15-19) and applies force capable of moving fractured cortical bone. (Fig. 28)
24. A method according to claim 1 or 2 or 8 or 17 wherein the step of compacting forms a cavity.	*See* above at claim 2 or 17. 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 '404 Patent discloses that the inflated balloon compacts cancellous bone and leaves a void in the interior of the vertebral body. (Col. 7, ll. 26-34)
25. A method according to claim 24 further including the step of filling the cavity with a material.	*See* above at claim 24. Claim 1 of the '404 Patent includes "filling the passage with a flowable material capable of setting to a hardened condition."
26. A method according to claim 25 wherein the material comprises bone cement.	*See* above at claim 25. Claim 15 of the '404 Patent is dependant on Claim 1 and sets forth the limitation: "wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement."
27. A method according to claim 25 wherein the material comprises synthetic bone substitute.	*See* above at claim 25. Claim 15 of the '404 Patent is dependant on Claim 1 and sets forth the limitation: "wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement."

Claim of the '043 Patent	Combination of '404 Patent with '132, '495, '252 and/or '949 Patents
28. A method according to claim 25 wherein the material comprises a flowable material that sets to a hardened condition.	*See* above at claim 25. Claim 1 of the '404 Patent includes "filling the passage with a flowable material capable of setting to a hardened condition."

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 12th day of May, 2005 upon the following in the manner indicated:

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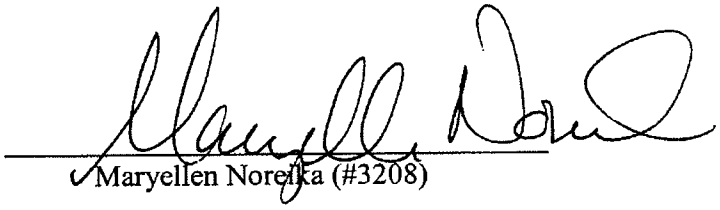

Maryellen Noreika (#3208)