B

1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON INC., Plaintiff, v. DISC-O-TECH MEDICAL TECHNOLOGIES LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC., Defendants.	C.A. No. 04-204-JJF

DOT' OPPOSITION TO KYPHON'S MOTION *IN LIMINE* 1 OF 5 TO PRECLUDE DR. MITCHELL'S EXPERT TESTIMONY REGARDING OBVIOUSNESS

Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. ("DOT") submit this memorandum in opposition to Kyphon, Inc.'s ("Kyphon") Motion in Limine to preclude Dr. Mitchell's expert testimony regarding obviousness.

PRELIMINARY STATEMENT

Kyphon's motion to preclude Dr. Mitchell's expert testimony on obviousness is nothing more than a summary judgment motion as to validity of the '404, '888 and '043 patents, in disguise. During the briefing of dispositive motions, Kyphon did not feel strongly enough about the positions it now raises to move for summary judgment on validity. Nor has Kyphon

ever objected to Dr. Mitchell's qualifications to offer expert testimony on the validity of the patents-in-suit. Yet, on the eve of trial, Kyphon seeks to foreclose the entirety of Dr. Mitchell's expert testimony as to obviousness based on the bald assertion that Dr. Mitchell has failed to "properly analyze obviousness." As outlined below, Kyphon bases its motion on incorrect characterizations of Dr. Mitchell's expert report and the opinions contained therein. Kyphon's unsubstantiated contentions to the contrary, Dr. Mitchell's report contains an exhaustive specific analysis with respect to obviousness. Moreover, Kyphon cannot rely on a motion in limine as a procedural tool to bar DOT from presenting its obviousness case at trial. Because Kyphon's motion in limine comprises a belated and unsubstantiated "back door" summary judgment motion as to validity, it must be denied.

ARGUMENT

In support of its motion, Kyphon makes three arguments, each of which is based on incorrect characterizations of Dr. Mitchell's expert report and the opinions contained therein.

First, Kyphon asserts that Dr. Mitchell's report "contains only conclusory statements" and "blanket statements" in support of his ultimate conclusion that the '888, '404 and '043 patents are invalid for obviousness. Kyphon's assertion is meritless.

Kyphon completely ignores Dr. Mitchell's opinion that six references individually anticipate and/or individually render obvious the asserted claims of the '404 and '888 patents. (See Exhibit 1 attached hereto, Dr. Mitchell Report and Tab A thereto, dated March 7, 2005, at ¶ 28) In support of his opinion, Dr. Mitchell submitted twelve separate charts detailing how these six references teach every single limitation of asserted claims of the '404 and '888 patents. (See Exh. 1, at pages 1-22, 30-51 of Tab A). In these charts, Dr. Mitchell separated by row each limitation of every asserted claim of the patents. Dr. Mitchell then specifically addressed each

limitation, citing precisely where that limitation could be found in a specific anticipatory reference. Kyphon has not disputed the legal "sufficiency" of Dr. Mitchell's anticipation analysis. For instance, Kyphon did not file a summary judgment motion as to invalidity based on anticipation, and Kyphon has not filed a motion in limine precluding Dr. Mitchell's testimony as to anticipation.

Because Dr. Mitchell opined that these six references not only anticipate, but also individually render obvious, the asserted claims of the patents, Dr. Mitchell incorporated by reference his detailed analysis of the six reference's disclosures into his obviousness charts. (See Exh. 1 at pp. 23-29, and 52-56 of Tab A). For example, when Dr. Mitchell discussed obviousness of the '404 patent with respect to the first limitation of Claim 1 of the '404 patent, he stated: "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." (See Exh. 1 at p. 24 of Tab A (emphasis added)).

Thus, in his obviousness analysis, Dr. Mitchell does not make "mere conclusory statements" that a specific "element is anticipated and rendered obvious" as Kyphon suggests. Instead, Dr. Mitchell incorporates by reference a chart detailing precisely how a specific reference discloses each and every element of the asserted claims. Because Kyphon has never debated the legal "sufficiency" of Dr. Mitchell's anticipation analysis with respect to the six references that Dr. Mitchell opines render obvious the asserted claims of the patents, Kyphon's motion in limine should be denied on this ground alone.

Second, Kyphon argues that Dr. Mitchell's report fails to specifically identify combinations of prior art references – thereby making the combinations "difficult, if not impossible, to ascertain." Again, Kyphon's assertion is meritless.

Kyphon fails to mention what is evident from Dr. Mitchell's opinion: in the event the six references do not anticipate or individually render obvious the asserted claims of the '404 and '888 patents, two or more of eleven references (that include the said six references) can be combined to render the asserted claims obvious. (See Exh. 1 at pp. 23-29, and 52-56 of Tab A). In his obviousness analysis, in addition to incorporating by reference the detailed anticipation charts with respect to six references, Dr. Mitchell specifically addressed how five additional references disclosed limitations of the asserted claims. Thus, Dr. Mitchell's analysis, as detailed in his exhaustive obviousness charts, removed the guesswork. The various combinations of references that render the asserted claims obvious are evident, notwithstanding Kyphon's refusal to glean the information from the charts.2 The fact that there are so many invalidating references, and therefore numerous combinations, is a matter of fact, not a function of DOT's expert's disclosure.

Third, Kyphon argues that Dr. Mitchell's opinion does not "adequately address" the requisite motivation to combine references to render the asserted claims obvious because Dr. Mitchell provides merely a "conclusory assertion" that the references are in the same field as the inventions. Kyphon's argument is baseless. In rendering his obviousness opinion on the '404, '888 and '043 patents, Dr. Mitchell does not merely rest on such broad, generalized assertions. For example, Dr. Mitchell opines that six of the references solve the very specific problem of

---

2 Dr. Mitchell's obviousness chart with respect to the '043 patent is similarly specific, detailed and exhaustive. Thus, Kyphon's contentions in its motion with respect to the '043 are baseless for the same reasons set forth with respect to the '404 and '888 patents.

treating fractured bone in such similar ways that each of these references anticipates and/or renders obvious the asserted claims of the '404 and '888 patents. It is hard to imagine how there could not be a motivation to combine any of these six references – these references solve the same problem of treating fractured bone the same specific way as claimed in the patents. Kyphon's position is that Dr. Mitchell has not opined on the requisite motivation to combine references simply because Kyphon wishes it to be so.

Finally, the Court should reject Kyphon's belated and back-door effort to make a summary judgment on validity. "Unlike a summary judgment motion, which is designed to eliminate a trial in cases where there are no genuine issues of fact, a motion in limine is designed to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions." Bradley v. Pittsburgh Bd. Of Educ., 913 F.2d 1064, 1069 (3rd Cir. 1990) Motions in limine typically seek to prevent the injection of prejudicial, confusing, or misleading material into trial. See Fed.R.Evid. 403. As discussed above, Kyphon's motion in limine is based on incorrect characterizations of Dr. Mitchell's opinions and represents nothing more than a summary judgment motion as to validity masquerading as a motion in limine. Given that Kyphon has not sought summary judgment as to invalidity based on obviousness, it is now the fact finder's job to determine whether or not the asserted patents are rendered obvious by the prior art. Dr. Mitchell should be able to testify and elaborate on his proffered opinions on obviousness at trial – including his opinion as one of ordinary skill in the art that there was the requisite suggestion and motivation to combine references in the prior art to render obvious the claimed inventions of the '404, '888 and '043 patents.

CONCLUSION

For the reasons set forth above, DOT respectfully requests that Kyphon's Motion in Limine to preclude Dr. Mitchell's expert testimony regarding obviousness be denied in all respects.

MORRIS, NICHOLS, ARSHT & TUNNELL

Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, Delaware 19899-1347
(302) 658-9200

Attorneys for Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies Inc.

OF COUNSEL:

Eric J. Lobenfeld
Jonathan M. Sobel
Arlene L. Chow
Robert J. DeMento
HOGAN & HARTSON L.L.P.
875 Third Avenue
New York, New York 10022
(212) 918-3000

May 12, 2005

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON, INC. Plaintiff, v. DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. and DISC ORTHOPAEDIC TECHNOLOGIES, INC., Defendants.	Civil Action No. 04-204-JJF

EXPERT REPORT OF DR. DAVID MITCHELL REGARDING THE INVALIDITY OF U.S. PATENT NOS. 5,108,404, 4,969,888 AND 6,235,043 B1

TABLE OF CONTENTS

Page

I. INTRODUCTION 1
II. SUBJECT MATTER OF POSSIBLE EXPERT TESTIMONY AT TRIAL 2
III. PROFESSIONAL BACKGROUND AND BASES FOR OPINIONS 3
A. The Person of Ordinary Skill in the Art 5
B. Background of Bone Anatomy 5
C. The '404, '888, and '043 Patents-in-Suit 5
D. Kyphon's Contentions 6
IV. SUMMARY OF OPINIONS RELATING TO INVALIDITY 7
V. INVALIDITY OF THE PATENTS-IN-SUIT 8
A. General Principles of Invalidity 8
B. Anticipation of the '404 Patent by Edeland 9
C. Anticipation of the '404 Patent by Olerud 10
D. Anticipation of the '404 Patent by Kennedy 10
E. Anticipation of the '404 Patent by Daniaux 1986 11
F. Anticipation of the '404 Patent by Blauth 11
G. Anticipation of the '404 Patent by Schatzker 12
H. Obviousness of the '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 12
I. Anticipation of the '888 Patent by Edeland 14
J. Anticipation of the '888 Patent by Olerud 15
K. Anticipation of the '888 Patent by Kennedy 15
L. Anticipation of the '888 Patent by Daniaux 1986 16
M. Anticipation of the '888 Patent by Blauth 16
N. Anticipation of the '888 Patent by Schatzker 17
O. Obviousness of the '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 17
P. Obviousness of the '043 Patent in View of Combination of '404 Patent and One or More of '132, '495, '252 and '949 Patents 19
Q. Invalidity of the '404 and '888 Patents Due to Prior Printed Publication and/or Offer for Sale 20

I, Dr. David Mitchell, submit the following expert report in this action on behalf of Defendants Disc-O-Tech Medical Technologies, Ltd., and Disc Orthopaedic Technologies, Inc. ("DOT").

I. INTRODUCTION

1. I understand that Kyphon, Inc. ("Kyphon") alleges that DOT's Sky Bone Expander Device (the "SKy Device") infringes Claims 1, 3, 8, 9, 10, 12, and 15 of U.S. Patent No. 5,108,404 entitled "Surgical Protocol for Fixation of Bone Using Inflatable Device" (" '404 Patent"); Claims 1, 3, 7, 8, 9, 11, and 14 of U.S. Patent No. 4,969,888 entitled "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device" (" '888 Patent"); Claims 2, 17, 20, 23, 24, 25, 26, and 28 of U.S. Patent No. 6,235,043 (B1) entitled "Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone" (" '043 Patent"); Claims 1, 3, 4, 5, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 19, 20, and 21 of U.S. Patent No. 6,241,734 B1 entitled "Systems and Methods for Placing Materials into Bone" (" '734 Patent"); and Claims 26, 27, 28, 29, 36, 37, 38, 39, 41, 42, 43, 44, 46, 47, 48, and 49 of U.S. Patent No. 6,613,054 B2 entitled "Systems and Methods for Placing Materials into Bone" (" '054 Patent") (collectively, the "patents-in-suit"). Copies of the '888, '404 and '043 Patents are attached as Exhibits 2, 3 and 4 hereto.

2. Because I understand the parties have agreed that my opinion as to the invalidity of the '734 and '054 Patents will be submitted on March 10, 2005, this report does not include my opinions with respect to those patents. I intend to submit separate reports with respect to the '734 and '054 Patents.

3. I also understand that Kyphon brought this suit against DOT alleging that the SKy Device infringes Claim 27 of the '043 Patent and certain claims of U.S. Patent No. 6,248,110 (B1) (" '110 Patent"). Because it is my understanding that Kyphon is no longer asserting any claims of the '110 Patent, or Claim 27 of the '043 Patent, I have not examined these claims and do not submit an expert report with respect thereto. I reserve all of my rights to submit an expert report with respect to the '110 Patent, or Claim 27 of the '043 Patent, should the need arise.

4. I have been retained by counsel for DOT as an expert in the field of orthopedic surgery, and to opine on issues of non-infringement and invalidity of the patents-in-suit. I am being compensated at the rate of $300 per hour. My compensation does not depend upon the outcome of this litigation, the opinions I express, or my testimony. This report sets forth my opinions relating to invalidity of the '404, '888 and '043 Patents.

II. SUBJECT MATTER OF POSSIBLE EXPERT TESTIMONY AT TRIAL

5. I may testify as to orthopedic surgery technology, the state of the art, the knowledge of one of ordinary skill in the art as of the effective filing dates of the patents-in-suit, the disclosures of the patents-in-suit, the prosecution file histories of the patents-in-suit, and the prior art to the patents-in-suit.

6. I may testify as to the invalidity of the asserted claims of the patents-in-suit.

7. I may testify as to how one of ordinary skill in the art would understand the limitations of the asserted claims of the patents-in-suit.

8. I may testify as to the non-infringement of the asserted claims of the patents-in-suit. My non-infringement opinions will be set forth in a separate expert report.

III. PROFESSIONAL BACKGROUND AND BASES FOR OPINIONS

9. My full curriculum vitae is attached as Exhibit 1 to this report.

10. I received a B.S. in Chemistry from the University of North Carolina at Greensboro in 1979. I received a M.S. in Chemistry from the University of South Carolina at Columbia in 1982. I received a M.D. from the Medical University of South Carolina in 1986. From 1986 to 1987, I did my General Surgery Internship at the Spartanburg Regional Medical Center. From 1987 to 1991, I did my Residency training in Orthopaedic Surgery at the Medical University of South Carolina.

11. I am licensed to practice medicine in North Carolina and South Carolina.

12. I presently practice medicine at a private practice, Orthopedic Associates, located in Spartanburg, South Carolina.

13. I presently hold the following positions: Associate Councilor Southern Medical Association, South Carolina Orthopaedic Association Secretary-Treasurer, South Carolina Spine Society President, Orthopaedic Division Chief of

the Spartanburg Regional Medical Center, and South Carolina Orthopaedic Associate Delegate to the South Carolina Medical Association.

14. In addition to the foregoing, I am a member of the following professional organizations: the American Medical Association, the South Carolina Orthopaedic Association, the American Board of Orthopaedic Surgeons, the American Academy of Orthopaedic Surgeons, the South Carolina Spine Society, the Southern Medical Association, the Southern Orthopaedic Association, the North American Spine Society, and the Spinal Arthroplasty Society.

15. I have more than 18 years experience in performing spinal surgery, including minimally invasive vertebral surgery such as that involved in this case.

16. I have performed approximately 500 kyphoplasties. In approximately 80% of those cases, I used Kyphon's KyphX Inflatable Bone Tamp. In approximately 20% of those cases, I used DOT's SKy Bone Expander Device.

17. I have not been previously engaged as an expert involving litigation. I have not authored publications within the last 10 years.

18. In forming my opinions, I have reviewed and considered the exhibits to this report. I also reviewed and considered the deposition testimony cited in the charts attached to this report as Exhibit A.

19. It is my understanding that Kyphon is to serve its initial expert report(s) relating to the alleged infringement of the patents-in-suit simultaneously with this report. I intend to respond to such report(s) in a rebuttal expert report.

A. The Person of Ordinary Skill in the Art

20. In my opinion, one of ordinary skill in the art would be an orthopedic surgeon, neurosurgeon, interventional radiologist or interventional neuroradiologist who regularly treats patients with vertebral fractures.

B. Background of Bone Anatomy

21. The vertebral bones, like other bones in the human body, are made up of several distinct structures. The outer, hard portion of the bone that we all recognize is called the cortical bone. Cancellous bone, which is solid, porous mineral, fills the interior volume of the bone formed by the cortical bone walls. The cancellous bone contains a latticework of delicate bone that forms small cavities. These cavities are filled with bone marrow, a viscous liquid material which primarily acts to generate new blood cells.

C. The '404, '888, and '043 Patents-in-Suit

22. The '888 patent is entitled "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device." The application which became the '888 patent was filed on February 9, 1989; the '888 patent issued on November 13, 1990. It generally describes the process of drilling a passage into a bone containing bone marrow, inflating a balloon within the bone marrow such that the bone marrow is compacted in order to increase the volume of the passage, and filling the passage created with a flowable material capable of hardening, such as bone cement.

23. The '404 patent is entitled "Surgical Protocol for Fixation of Bone Using Inflatable Device." The application which became the '404 patent was

filed on August 15, 1990. The '404 patent is a continuation-in-part ("CIP") of the '888 patent which was filed on February 9, 1989. The '404 patent issued on April 28, 1992.

24. From my review of the patents, the only substantive difference between the '888 and '404 patents is that where the '888 patent includes claims directed only to osteoporotic bones, the '404 patent claims are directed to bones generally.

25. The '043 patent is entitled "Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone." The application which became the '043 patent was filed on January 23, 1997; the '043 patent issued on May 22, 2001. It generally describes an improved inflatable balloon for use in carrying out the methods claimed in the '404 and '888 patent. More specifically, the '043 patent describes balloons with additional design elements that are intended to change the shape of the balloon and constrain the expansion of the balloon when inflated.

D. Kyphon's Contentions

26. Based on my review of the '404 and '888 Patents and the Court's decision dated December 10, 2004 denying Kyphon's Preliminary Injunction Motion (Exhibit 30 hereto, at 3), it is my understanding that Kyphon is contending that the term "bone marrow" should be construed to include cancellous bone. I further understand that Kyphon interprets the term "compacting" to encompass any means of creating a void within the bone (i.e., any means of increasing the volume of the passage). See, e.g., Claim 1 of the '888 patent and Claim 1 of the '404 patent in

Appendix A of Kyphon's Supplemental Responses to Disc Orthopaedic Technologies, Inc.'s First Set of Interrogatories dated July 9, 2004, attached hereto as Exhibit 25.

IV. SUMMARY OF OPINIONS RELATING TO INVALIDITY

27. My opinions relating to invalidity of the '404, '888, and '043 patents-in-suit are not necessarily limited to the opinions set forth below. I reserve the right to supplement, modify or amend my opinions.

28. It is my opinion that the '404 patent is anticipated by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth and Schatzker, as those references are defined in the Index to the exhibits hereto.

29. It is my opinion that the '404 patent is rendered obvious by one or more of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson, as those references are defined in the Index to the exhibits hereto.

30. It is my opinion that the '888 patent is anticipated by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth and Schatzker, as those references are defined in the Index to the exhibits hereto.

31. It is my opinion that the '888 patent is rendered obvious by one or more of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson, as those references are defined in the Index to the exhibits hereto.

32. It is my opinion that the '043 patent is rendered obvious by the combination of the '404 patent with one or more of the '132, '495, '252 and '949 patents, as those references are defined in the Index to the exhibits hereto.

33. It is my opinion that a business plan dated in 1987 (attached hereto as Exhibit 29) and disseminated by an entity known as Norian sets forth one or more claims of the '404 and '888 patents, and it is my understanding that DOT contends that this document reflects a printed publication and/or offer for sale of the invention, more than one year prior to the effective filing dates of the '404 and '888 patents.

V. INVALIDITY OF THE PATENTS-IN-SUIT

A. General Principles of Invalidity

34. I understand that a patent claim can be found invalid as being anticipated if each element of the claim is found in a single prior art reference. I understand that prior art under 35 U.S.C. § 102(a) includes patents or printed publications or uses in this country which predate the invention by applicants and that until proven otherwise by Kyphon, the date of invention is the effective filing date of the patent.

35. I understand that prior art under 35 U.S.C. § 102(b) includes patents or printed publications, public use, or offers for sale that were available or occurred more than one year before the effective filing date of the patent-in-suit. I also understand that a United States patent issued after the filing date of the

patent at issue can be considered prior art under 35 U.S.C. § 102(e) if the patent was filed before the invention by the applicant of the claimed subject matter.

36. I understand that even if a patent claim is not invalidated due to anticipation, the claim can be invalid under 35 U.S.C. § 103(a) for obviousness if the differences between the claimed subject matter and the prior art would have been obvious at the time of the invention to a person of ordinary skill in the art. I understand that when considering obviousness, the teachings in two or more prior art references can be combined if there is a teaching, suggestion, or motivation to do so or if it would be apparent to one of ordinary skill in the art.

B. Anticipation of the '404 Patent by Edeland

37. 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, it is my opinion that one or more of the asserted claims of the '404 patent is anticipated by Edeland, H.G., "Open Reduction of Central Compression Fractures of the Tibial Plateau," Acta Orthop. Scand., Vol. 47, pp. 686-689, 1976 ("Edeland"), as set forth in Exhibit A hereto. Thus, it is my opinion that Edeland teaches every single limitation of one or more of the asserted claims of the '404 Patent. The bases for my opinions are set forth in Exhibit A at pp. 1-3. I reserve the right to supplement, modify or amend my opinions.

C. Anticipation of the '404 Patent by Olerud

38. 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, it is my opinion that one or more of the asserted claims of the '404 patent is anticipated by Olerud, S., "Transpedicular Fixation of Thoracolumbar Vertebral Fractures," Clin. Orthop., Vol. 227, pp. 44-51, 1988 ("Olerud"), as set forth in Exhibit A hereto. Thus, it is my opinion that Olerud teaches every single limitation of one or more of the asserted claims of the '404 Patent. The bases for my opinions are set forth in Exhibit A at pp. 4-8. I reserve the right to supplement, modify or amend my opinions.

D. Anticipation of the '404 Patent by Kennedy

39. 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, it is my opinion that one or more of the asserted claims of the '404 patent is anticipated by Kennedy, W., "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," Clin. Orthop., Vol. 134, pp. 153-157, 1978 ("Kennedy"), as set forth in Exhibit A hereto. Thus, it is my opinion that Kennedy teaches every single limitation of one or more of the asserted claims of the '404 Patent. The bases for my opinions are set forth in Exhibit A at pp. 9-11. I reserve the right to supplement, modify or amend my opinions.

E. Anticipation of the '404 Patent by Daniaux 1986

40. 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, it is my opinion that one or more of the asserted claims of the '404 patent is anticipated by Daniaux, H., "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," Unfallchirurg, Vol. 89, pp.197-213, 1986 ("Daniaux 1986"), as set forth in Exhibit A hereto. Thus, it is my opinion that Daniaux 1986 teaches every single limitation of one or more of the asserted claims of the '404 Patent. The bases for my opinions are set forth in Exhibit A at pp. 12-15. I reserve the right to supplement, modify or amend my opinions.

F. Anticipation of the '404 Patent by Blauth

41. 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, it is my opinion that one or more of the asserted claims of the '404 patent is anticipated by 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"), as set forth in Exhibit A hereto. Thus, it is my opinion that Blauth teaches every single limitation of one or more of the asserted claims of the '404 Patent. The bases for my opinions are set forth in

Exhibit A at pp. 16-18. I reserve the right to supplement, modify or amend my opinions.

G. Anticipation of the '404 Patent by Schatzker

42. 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, it is my opinion that one or more of the asserted claims of the '404 patent is anticipated by Schatzker, J., Operative Orthopaedics, M. Chapman, Ed., 1st ed., Ch. 35, pp. 421 – 434, 1988 ("Schatzker"), as set forth in Exhibit A hereto. Thus, it is my opinion that Schatzker teaches every single limitation of one or more of the asserted claims of the '404 Patent. The bases for my opinions are set forth in Exhibit A at pp. 19-22. I reserve the right to supplement, modify or amend my opinions.

H. Obviousness of the '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

43. 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, it is my opinion 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, as set forth in Exhibit A hereto:

> 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").

44. Thus, by way of example only, the combination of Edeland and Daniaux 1986 renders obvious claim 12 of the '404 patent. By further way of example only, the combination of Campbell and Carlson renders obvious claim 15 of the '404 patent.

45. 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 filing date of the '404 patent, it was well known to those of ordinary skill in the art that treatments for compressed tibial plateau fractures were similar to treatments for compressed vertebral body fractures. The bases for my opinions are set forth in Exhibit A at pp. 23-29. I reserve the right to supplement, modify or amend my opinions.

I. Anticipation of the '888 Patent by Edeland

46. 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, it is my opinion that one or more of the asserted claims of the '888 patent is anticipated by Edeland, H.G., "Open Reduction of Central Compression Fractures of the Tibial Plateau," Acta

Orthop. Scand., Vol. 47, pp. 686-689, 1976 ("Edeland"), as set forth in Exhibit _ hereto. Thus, it is my opinion that Edeland teaches every single limitation of one or more of the asserted claims of the '888 Patent. The bases for my opinions are set forth in Exhibit A at pp. 30-32. I reserve the right to supplement, modify or amend my opinions.

J. Anticipation of the '888 Patent by Olerud

47. 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, it is my opinion that one or more of the asserted claims of the '888 patent is anticipated by Olerud, S., "Transpedicular Fixation of Thoracolumbar Vertebral Fractures," Clin. Orthop., Vol. 227, pp. 44-51, 1988 ("Olerud"), as set forth in Exhibit A hereto. Thus, it is my opinion that Olerud teaches every single limitation of one or more of the asserted claims of the '888 Patent. The bases for my opinions are set forth in Exhibit A at pp. 33-37. I reserve the right to supplement, modify or amend my opinions.

K. Anticipation of the '888 Patent by Kennedy

48. 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, it is my opinion that one or more of the asserted claims of the '888 patent is anticipated by Kennedy, W., "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," Clin. Orthop., Vol. 134, pp. 153-157, 1978

("Kennedy"), as set forth in Exhibit A hereto. Thus, it is my opinion that Kennedy teaches every single limitation of one or more of the asserted claims of the '888 Patent. The bases for my opinions are set forth in Exhibit A at pp. 38-40. I reserve the right to supplement, modify or amend my opinions.

L. Anticipation of the '888 Patent by Daniaux 1986

49. 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, it is my opinion that one or more of the asserted claims of the '888 patent is anticipated by Daniaux, H., "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," Unfallchirurg, Vol. 89, pp.197-213, 1986 ("Daniaux 1986"), as set forth in Exhibit A hereto. Thus, it is my opinion that Daniaux 1986 teaches every single limitation of one or more of the asserted claims of the '888 Patent. The bases for my opinions are set forth in Exhibit A at pp. 41-44. I reserve the right to supplement, modify or amend my opinions.

M. Anticipation of the '888 Patent by Blauth

50. 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, it is my opinion that one or more of the asserted claims of the '888 patent is anticipated by 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"), as set forth in Exhibit A hereto. Thus, it is my opinion that Blauth teaches every single limitation of one or more of the asserted claims of the '888 Patent. The bases for my opinions are set forth in Exhibit A at pp. 45-47. I reserve the right to supplement, modify or amend my opinions.

N. Anticipation of the '888 Patent by Schatzker

51. 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, it is my opinion that one or more of the asserted claims of the '888 patent is anticipated by Schatzker, J., Operative Orthopaedics, M. Chapman, Ed., 1st ed., Ch. 35, pp. 421 – 434, 1988 ("Schatzker"), as set forth in Exhibit A hereto. Thus, it is my opinion that Schatzker teaches every single limitation of one or more of the asserted claims of the '888 Patent. The bases for my opinions are set forth in Exhibit A at pp. 48-51. I reserve the right to supplement, modify or amend my opinions.

O. Obviousness of the '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

52. 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, it is my opinion that one or more of the asserted claims of the '888 patent is rendered obvious by one or more of the following prior art references, as set forth in Exhibit A hereto:

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").

53. Thus, by way of example only, the combination of Edeland and Daniaux 1986 renders obvious claim 11 of the '888 Patent.

54. 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 filing 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 bases for my opinions are set forth in Exhibit A at pp. 52-56. I reserve the right to supplement, modify or amend my opinions.

P. Obviousness of the '043 Patent in View of Combination of '404 Patent and One or More of '132, '495, '252 and '949 Patents

55. 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, it is my opinion that 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,

as set forth in Exhibit A hereto: 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.

56. Thus, by way of example only, the combination of the '404 patent and the '132 patent renders obvious claim 2 of the '043 Patent.

57. To one of ordinary skill in the art, 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. 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 bases for my opinions are set forth in Exhibit A at pp. 57-62. I reserve the right to supplement, modify or amend my opinions.

Q. Invalidity of the '404 and '888 Patents Due to Prior Printed Publication and/or Offer for Sale

58. It is my understanding that Norian laboratory prepared a business plan in 1987. It is also my understanding that (1) this business plan was both presented and distributed to numerous venture capitalists in an attempt by Norian to secure additional corporate funding and (2) the business plan was distributed with no expectation of confidentiality.

59. The Norian business plan (attached hereto as Exhibit 29) states on page 32 in relevant part (emphasis added):

> Vertebral Fractures Many of the 500,000 fractures of the vertebral spine annually in the U.S. may someday be treated with injections of Norian's SuperBone, thus reducing (if not eliminating altogether) the incidence of "dowager's hump".

> Many of these fractures occur in the lumbar and thoraco lumbar junction and are thus susceptible to simple percutaneous treatment. *This treatment could restore the height of the fracture by first inserting a balloon or expander to reduce the vertebral body, prior to injecting SuperBone.*

60. It is my opinion that the Norian business plan discloses one or more claims of the '404 and '888 patents. It is my understanding that DOT contends that this document reflects a printed publication and/or offer for sale of the invention, more than one year prior to the effective filing dates of the '404 and '888 patents.

Dated: March 7, 2005

Dr. David Mitchell

A

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 Parent	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 '104 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. 8 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 1 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 '104 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 '204 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.

Claims 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 '104 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 6 of the '407 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.	