# 1

# Appendix 1

## Statement of Admitted Facts

Plaintiff Kyphon Inc. ("Kyphon") and Defendants Disc-O-Tech Medical Technologies Ltd. and Disc Orthopaedic Technologies, Inc. (collectively, "DOT"), stipulate to the following uncontested facts, which may be received as evidence in this action:

1. Kyphon is a Delaware corporation, with its principal place of business located in Sunnyvale, California.

2. Defendant Disc-O-Tech Medical Technologies Ltd. is an Israeli corporation located in Israel. Defendant Disc Orthopaedic Technologies, Inc. is a Delaware corporation located in Monroe Township, New Jersey. Disc-O-Tech Medical Technologies Ltd. and Disc Orthopaedic Technologies, Inc. are collectively referred to as "DOT."

3. U.S. Patent No. 4,969,888, entitled "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device," was issued by the United States Patent and Trademark Office to named inventors Arie Scholten and Mark A. Reiley on November 13, 1990. The patent application was filed on February 9, 1989, and the patent is assigned to Kyphon.

4. U.S. Patent No. 5,108,404, entitled "Surgical Protocol for Fixation of Bone Using Inflatable Device," was issued by the United States Patent and Trademark Office to named inventors Arie Scholten and Mark A. Reiley on April 28, 1992. The patent application was filed on August 15, 1990, and the patent is assigned to Kyphon.

5. U.S. Patent No. 6,235,043, entitled "Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone," was issued by the United States Patent and Trademark Office to named inventors Mark Reiley, Arie Scholten, and Karen Talmadge on May 22, 2001. The patent application was filed on January 23, 1997, and the patent is assigned to Kyphon.

6. Kyphon is the owner of all right, title, and interests to the '888, '404, and '043 patents.

7. Kyphon, through the sales of and instruction regarding KyphX IBTs and related devices, practices one or more asserted claims in U.S. Patent Nos. 4,969,888; 5,108,404; and 6,235,043 B1.

8. DOT first became aware of Kyphon's kyphoplasty products in late 1999 or early 2000.

9. DOT has made, used, sold, and offered for sale medical devices called the SKy Bone Expander, with associated accessories. The SKy Bone Expander System was formerly known as the B-Twin Bone Expander System.

10. DOT instructs physicians on how to use the SKy Bone Expander and accessories in Instructions for Use and other materials. DOT provides Instructions for Use with each SKy Bone Expander System and expects that doctors will follow those Instructions for Use. DOT manufactures the SKy Bone Expander and accessories specifically to be used as instructed, and to DOT's knowledge, there are no substantial uses of the DOT devices that are not described in the Instructions for Use and other materials.

11. DOT has attended surgical procedures and during such procedures has provided guidance to surgeons regarding the use of the SKy Bone Expander System.

12. When a surgeon performs a procedure on a vertebra using the SKy Bone Expander System as directed by DOT's Instructions for Use, a drill is used to form a passage in the cancellous bone.

13. In surgeries using the SKy Bone Expander System on vertebrae that have been witnessed by DOT employees or representatives in the United States, to the best of DOT's knowledge, after using the SKy Bone Expander System, most all of the surgeons have completed the surgery by putting bone cement into the vertebra.

# 2

# A

# Appendix 2A

## Kyphon's June 10, 2005 Statement of Issues of Fact[1]

Plaintiff Kyphon presents below the issues of fact for trial. To the extent that any issues of law set forth in Appendix 3A of the Joint Pretrial Order may be considered issues of fact, Kyphon incorporates those portions of Appendix 3A by reference.

A. Infringement by DOT

1. Whether DOT's SKy Bone Expander System and accessories, and the use thereof, infringes Claims 17, 20, 24, and 26 of U.S. Patent No. 6,235,043.

B. Validity of Kyphon's Patents

1. Whether Claims 1, 3, 7-9, 11, and 14 of U.S. Patent No. 4,969,888; and Claims 1, 3, 8-10, 12, and 15 of U.S. Patent No. 5,108,404 are anticipated by the prior art.

2. [What the level of ordinary skill in the art was at the time of the patents-in-suit invention.

3. The content and scope of the prior art asserted by DOT as rendering the invention of Claims 1, 3, 7-9, 11, and 14 of U.S. Patent No. 4,969,888; Claims 1, 3, 8-10, 12, and 15 of U.S. Patent No. 5,108,404; and Claims 17, 20, 24, and 26 of U.S. Patent No. 6,235,043 obvious.

4. The differences between Claims 1, 3, 7-9, 11, and 14 of U.S. Patent No. 4,969,888; Claims 1, 3, 8-10, 12, and 15 of U.S. Patent No. 5,108,404; and Claims 17,

[1] This statement of issues of fact includes only those facts to be tried in the liability trial starting June 20, 2005, and does not include issues of fact to be tried in the damages/willfulness trial to be scheduled at a later date.

20, 24, and 26 of U.S. Patent No. 6,235,043 and the prior art asserted by DOT as rendering those patents obvious.

5. Whether any of the following objective evidence of nonobviousness tends to show that Claims 1, 3, 7-9, 11, and 14 of U.S. Patent No. 4,969,888; Claims 1, 3, 8-10, 12, and 15 of U.S. Patent No. 5,108,404; and Claims 17, 20, 24, and 26 of U.S. Patent No. 6,235,043 are not obvious, the extent of any proffered objective evidence of nonobviousness, and whether a nexus exists between the evidence and the claimed inventions:

a. Commercial success of products covered by the patent in suit;

b. A long felt, unmet need in the art that was satisfied by the invention;

c. The failure of others to make the invention;

d. Copying of the invention by others in the field;

e. Initial skepticism of the invention by others in the field; and

f. Praise of the invention by the infringer or others in the field.

6. Where DOT is relying on a combination of references to assert invalidity under 35 U.S.C. §103, whether there is a suggestion to combine the references.

7. Whether there is a suggestion or motivation in the prior art to modify the prior art asserted by DOT to arrive at the invention claimed in the patents-in-suit.][2]



[2] As explained in one of its motions *in limine*, Kyphon believes that the issue of obviousness is not properly presented. However, in the event that the Court decides otherwise, the bracketed, greyed text sets forth Kyphon's statement of the issues of fact regarding the issue of obviousness.

# B

**Appendix 2B**

**DOT'S STATEMENT OF CONTESTED ISSUES OF FACT**

I. NON-INFRINGEMENT

A. Non-Infringement of Claims 1, 3, 7, 8, 9, 11 and 14 of the '888 patent and Claims 1, 3, 8, 9, 10, 12 and 15 of the '404 Patent

1. Whether Kyphon can establish that the manufacture, use, sale and/or offer for sale of the accused DOT SKy Bone Expander System ("the SKy Device") infringes Claims 1, 3, 7, 8, 9, 11 and/or 14 of the '888 Patent and Claims 1, 3, 8, 9, 10, 12 and/or 15 of the '404 Patent, under 35 U.S.C. § 271 (a), either literally or under the doctrine of equivalents. Specifically:

a. Given the Court's claim construction, whether Kyphon can establish that the accused SKy Device literally contains each of the elements of Claims 1, 3, 7, 8, 9, 11 and/or 14 of the '888 patent and Claims 1, 3, 8, 9, 10, 12 and/or 15 of the '404 Patent.

b. Given the Court's claim construction, whether Kyphon can establish that the accused SKy Device contains each of the elements of Claims 1, 3, 7, 8, 9, 11 and/or 14 of the '888 patent and Claims 1, 3, 8, 9, 10, 12 and/or 15 of the '404 Patent, under the doctrine of equivalents.

B. Non-Infringement of Claims 17, 20, 24 and/or 26 of the '043 Patent

1. Whether Kyphon can establish that the manufacture, use, sale and/or offer for sale of the accused SKy Device infringes Claims 17, 20, 24 and/or 26 of the '043 Patent, under 35 U.S.C. § 271 (a), either literally or under the doctrine of equivalents. Specifically:

a. Given the Court's claim construction, whether Kyphon can establish that the accused SKy Device literally contains each of the elements of Claims 17, 20, 24 and/or 26 of the '043 Patent.

b. Given the Court's claim construction, whether Kyphon can establish that the accused SKy Device contains each of the elements of Claims 17, 20, 24 and/or 26 of the '043 Patent, under the doctrine of equivalents.

## II. INVALIDITY

### A. Invalidity of Claims 1, 3, 7, 8, 9, 11 and 14 of the '888 Patent and Claims 1, 3, 8, 9, 10, 12 and/or 15 of the '404 Patent

1. The scope and content of the relevant prior art, including without limitation the following references, which include patents, publications and/or other evidence:

a. U.S. Patent No. 4,488,549, issued on December 18, 1984 to Lee et al.;

b. U.S. Patent No. 4,518,430, issued on May 21, 1985 to Brown et al.;

c. U.S. Patent No. 4,627,434, issued on December 9, 1986 to Murray;

d. Aebi, M., "The internal skeletal fixation system. A new treatment of thoracolumbar fractures and other spinal disorders," Clin. Orthop., Vol. 227, pp. 30 - 43, 1988;

e. Angel, M. et al., "Vascularization of Tricalcium Phosphate, an Artificial Bone Substitute," Microsurgery, Vol. 6, pp. 175 - 81, 1985;

f. Benum, P. et al., "Porous Ceramics as a Bone Substitute in the Medial Condyle of the Tibia," Acta Orthop. Scand., Vol. 48, pp. 150 - 57, 1977;

g. 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;

h. Bucholz, R. et al., "Hydroxyapatite and Tricalcium Phosphate Bone Graft Substitutes," Orthop. Clin. North Am., Vol. 18, No. 2, pp. 323 - 34, 1987;

i. Campbell's Operative Orthopaedics, A.H. Crenshaw, Ed., 7th ed., Chapter 44, pp. 1653 – 1663, 1987;

j. Carlson, D., et al., "The Use of Methylmethacrylate in Repair of Neoplastic Lesions in Bone," Radiology, Vol. 112, pp. 43 - 46, 1974;

k. Charvet, A. et al., "Pulmonary embolism of cement during vertebroplasty," Ann. Fr. Anesth. Reanim, Vol. 23, No. 8, pp. 827 - 30, 2004;

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

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

n. Dick, W., "The 'fixature interne' as versatile implant for spine surgery," Spine, Vol. 12 (9), pp. 882 - 900, 1987;

o. 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;

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

q. Frame, J. et al., "Hydroxyapatite as a Bone Substitute in the Jaws," Biomaterials, Vol. 2, pp. 19 - 22, 1981;

r. Higgins, K. et al., "Biomechanical Effects of Unipedicular Vertebroplasty on Intact Vertebrae," Spine, Vol. 28, No. 14, pp. 1540 - 1548, 2003;

s. Hillmeier, J. et al., "The evaluation of balloon kyphoplasty for osteoporotic vertebral fractures," Orthopade, Vol. 33, No. 8, pp. 893 - 904, 2004;

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

u. Komp, M. et al., "Minimal-invasive Therapie der funktionell instabilen osteoporotishcen Wirbelkorperfraktur mittels Kyphoplastie: Prospektive Vergleichsstudie von 19 operierten under 17 konservativ behandelten Patienten," J. Miner Stoffwechs, Vol. 11 (Suppl. 1), pp. 13 - 15, 2004;

v. Kraus, G. et al., "Pelvic and leg venous thrombosis as a complication of percutaneous vertebroplasty," Rofo., Vol. 175, No. 4, pp. 565 - 66, 2003;

w. Lee, B. et al., "Paraplegia as a complication of percutaneous vertebroplasty with polymethylmethacrylate: a case report," Spine, Vol. 27, No. 19, pp. E419 - 22, 2002;

x. Lieberman et al., "Vertebroplasty and Kyphoplasty for Osteolytic Vertebral Collapse," Clin. Orthop. And Related Res., No. 415S, pp. S176 - 186, 2003;

y. Limb Salvage in Musculoskeletal Oncology, Chapter 6, "Effectiveness of Methyl Methacrylate as a Physical adjuvant in Local Tumor Control," Enneking, W., Ed., Churchill Livingstone, pp. 443 - 498, 1987;

z. 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;

aa. Malawer, M. et al., "Effect of Cyrosurgery and Polymethyl Methacrylate on the Tumor Cavity," Limb Salvage in Musculoskeletal Oncology, Enneking, W., Ed., Churchill Livingstone, pp. 486 – 498, 1987;

bb. Mathis, J. et al., "Percutaneous Vertebroplasty: A Developing Standard of Care for Vertebral Compression Fractures," Am. J. Neuroradiology, Vol. 22, pp. 373 - 381, 2001;

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

dd. Padovani, B. et al., "Pulmonary Embolism Caused by Acrylic Cement: A Rare Complication of Percutaneous Vertebroplasty," Am. J. Neuroradiology, Vol. 20, pp. 375 - 77, 1999;

ee. Pentelenyi, T., "First Hungarian Neurosurgical Experiences with 'Fixateur Interne' in the Treatment of Thoraco-lumbar Spine Injuries," Acta Neurochir. (Wien), Vol. 93, pp. 104 - 109, 1988;

ff. Phillips, F. et al., "An in Vivo Comparison of the Potential of Extravertebral Cement Leak After Vertebroplasty and Kyphoplasty," Spine, Vol. 27, No. 19, pp. 2173 - 78, 2002;

gg. Pleser, M. et al., "Pulmonary embolism caused by PMMA in percutaneous vertebroplasty," Unfallchirug, Vol. 107, No. 9, pp. 807 - 11, 2004;

hh. Ratliff, J. et al., "Root and spinal cord compression from methylmethacrylate vertebroplasty," Spine, Vol. 26, No. 13, pp. E300 - 2, 2001;

ii. Rauschmann, M. et al., "Complications of vertebroplasty," Orthopade, Vol. 33, No. 1, pp. 40 - 7, 2004;

jj. Rejda, B. et al., "Tri-calcium Phosphate as a Bone Substitute," J. Bioeng., Vol. 1, pp. 93 - 97, 1977;

kk. Ryu, K. et al., "Dose-dependent epidural leakage of polymethylmethacrylate after percutaneous vertebroplasty in patients with osteoporotic vertebral compression fractures," J. Neurosurg. Spine., Vol. 96, No. 1, pp. 56 - 61, 2002;

ll. Schatzker, J., Operative Orthopaedics, M. Chapman, Ed., 1st ed., Ch. 35, pp. 421 – 434, 1988;

mm. Scoville, W., "The Use of Acrylic Plastic for Vertebral Replacement or Fixation in Metastatic Disease of the Spine," J. Neurosurg., Vol. 27, pp. 274 - 79, 1967;

nn. Smith, L., "Ceramic-Plastic Material as a Bone Substitute," Arch. Surg., Vol. 87, pp. 653 - 61, 1963;

oo. Stricker, K. et al., "Severe Hypercapnia Due to Pulmonary Embolism of Polymethylmethacrylate During Vertebroplasty," Anesth. Analg., Vol. 98, pp. 1184 - 1186, 2004; and

pp. Tsai, T. et al., "Polymethylmethacrylate Cement Dislodgement Following Percutaneous Vertebroplasty: A case report," Spine, Vol. 28, No. 22, pp. E457 - 60, 2003.

2. The nature and level of knowledge of a person of ordinary skill in the art, with respect to the pertinent art of the '888 and '404 Patents.

3. The differences, if any, between the relevant prior art and the alleged invention(s) claimed in Claims 1, 3, 7, 8, 9, 11 and/or 14 of the '888 Patent and Claims 1, 3, 8, 9, 10, 12 and/or 15 of the '404 Patent.

4. Whether the alleged invention(s) of Claims 1, 3, 7, 8, 9, 11 and/or 14 of the '888 Patent and Claims 1, 3, 8, 9, 10, 12 and/or 15 of the '404 Patent is anticipated, under §§ 102 (a) or (b) by any of the prior art references listed in Section II.A.1.

5. Whether the alleged invention(s) of Claims 1, 3, 7, 8, 9, 11 and/or 14 of the '888 Patent and Claims 1, 3, 8, 9, 10, 12 and/or 15 of the '404 Patent would have been obvious to one of ordinary skill in the art under § 103(a), in view of the relevant prior art.

6. Whether Kyphon can establish the existence of any secondary considerations, such as commercial success of the alleged invention(s) claimed in Claims 1, 3, 7, 8, 9, 11 and/or 14 of the '888 Patent and Claims 1, 3, 8, 9, 10, 12 and/or 15 of the '404 Patent.

7. Whether Kyphon can establish a causal connection between any alleged commercial success and the specifically claimed, alleged invention(s) of Claims 1, 3, 7, 8, 9, 11 and/or 14 of the '888 Patent and Claims 1, 3, 8, 9, 10, 12 and/or 15 of the '404 Patent.

B. Invalidity of Claims 17, 20, 24 and/or 26 of the '043 Patent

1. The scope and content of the relevant prior art, including without limitation the following patent references:

a. U.S. Patent No. 3,626,949, issued on December 14, 1971 to Shute;

b. U.S. Patent No. 4,878,495, issued on November 7, 1989 to Grayzel;

c. U.S. Patent No. 4,909,252, issued on March 20, 1990 to Goldberger;

d. U.S. Patent No. 5,049,132, issued on September 17, 1991 to Shaffer et al.; and

e. U.S. Patent No. 5,108,404, issued on April 28, 1992 to Scholten et al.

2. The nature and level of knowledge of a person of ordinary skill in the art, with respect to the pertinent art of the '043 Patent.

3. The differences, if any, between the relevant prior art and the alleged invention(s) claimed in Claims 17, 20, 24 and/or 26 of the '043 Patent.

4. Whether the alleged invention(s) of Claims 17, 20, 24 and/or 26 of the '043 Patent is anticipated, under §§ 102 (a) or (b) by any of the prior art references listed in Section II.B.1.

5. Whether the alleged invention(s) of Claims 17, 20, 24 and/or 26 of the '043 Patent would have been obvious to one of ordinary skill in the art under § 103(a), in view of the relevant prior art.

6. Whether Kyphon can establish the existence of any secondary considerations, such as commercial success of the alleged invention(s) claimed in Claims 17, 20, 24 and/or 26 of the '043 Patent.

7. Whether Kyphon can establish a causal connection between any alleged commercial success and the specifically claimed, alleged invention(s) of Claims 17, 20, 24 and/or 26 of the '043 Patent.

## III. REMEDIES

### A. Lost Profits

1. If infringement is proved, whether Kyphon can establish it is entitled to lost profits related to DOT's sale of the SKy Device, i.e., profits Kyphon would have made but for DOT's alleged infringement. Specifically:

a. Whether Kyphon can establish demand for the purported invention(s) of the asserted claims of the '888, '404 and '043 Patents;

b. Whether Kyphon can establish the absence of any acceptable non-infringing substitutes during the relevant period of infringement;

c. Whether Kyphon can establish, at all relevant times, that Kyphon had the manufacturing and marketing capability to make the infringing sales; and

d. Whether Kyphon can establish the amount of profit that it would have made but for the alleged infringement.

B. Reasonable Royalty

1. If infringement of the '888, '404 and '043 Patents is proved:

a. Whether Kyphon's damages for DOT's sales of the SKy Device must be based solely on a reasonable royalty.

b. Whether Kyphon is entitled to a reasonable royalty rate of, at most, 5%, based upon a hypothetical negotiation between the parties.

C. Prejudgment Interest

1. If infringement is proved, the amount of prejudgment interest, if any, to which Kyphon is entitled.

IV. WILLFULNESS

1. If patent infringement is proved, whether, in light of the totality of the circumstances, DOT willfully infringed.

* * *

DOT reserves the right to litigate factual issues raised by Kyphon even if not specifically set forth herein.

# 3

# A

# Appendix 3A

## Kyphon's June 10, 2005 Statement of Issues of Law[1]

Plaintiff Kyphon presents below the issues of law for trial. To the extent that any issues of fact set forth in Appendix 2A of the Joint Pretrial Order may be considered issues of fact, Kyphon incorporates those portions of Appendix 2A by reference. In addition to these issues of law for trial, the claim construction issues currently pending before the Court are issues of law.

A. Infringement of the Patents-in-suit

To the extent that DOT is asserting a reverse doctrine of equivalents defense, Kyphon objects because that defense has never been pled, noted in contention interrogatory responses, or expert reports. Moreover, to the extent that this issue were properly before the Court, it is an issue for the Court, not for the jury.

B. Validity of the Patents-in-suit

1. [Whether Claims 1, 3, 7-9, 11, and 14 of U.S. Patent No. 4,969,888; Claims 1, 3, 8-10, 12, and 15 of U.S. Patent No. 5,108,404; and Claims 17, 20, 24, and 26 of U.S. Patent No. 6,235,043 are invalid under 35 U.S.C. §103 as obvious in light of the prior art.

2. Authority

- *Carella v. Starlight Archery*, 804 F.2d 135 (Fed. Cir. 1986)
- *In re Dance*, 160 F.3d 1339 (Fed. Cir. 1998)
- *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999)
- *Echolochem v. Southern California Edison*, 227 F.3d 1361 (Fed. Cir. 2000)
- *Graham v. John Deere Co.*, 383 U.S. 1 (1966)
- *Hodosh v. Block Drug Co.*, 786 F.2d 1136 (Fed. Cir. 1986)

[1] This statement of issues of law includes only those issues of law to be tried in the liability trial starting June 20, 2005, and does not include issues of law to be tried in the damages/willfulness trial to be scheduled at a later date.

- *Monarch Knitting Machine Corp. v. Sulzur Morat GmbH.*, 139 F.3d 877 (Fed. Cir. 1998)
- *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995)
- *Orthopedic Equip. Co. Inc. v. United States*, 702 F.2d 1005 (Fed. Cir. 1983)
- *Panduit Corp. v. Dennison Manufacturing Co.*, 810 F.2d 1561 (Fed. Cir. 1987)
- *Pro-Mold and Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568 (Fed. Cir. 1996)
- *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998)
- *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358 (Fed. Cir. 1998)
- *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 950 F.2d 714 (Fed. Cir. 1991)
- *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573 (Fed. Cir. 1984)
- *Stratoflex Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983)
- *Tec Air, Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353 (Fed. Cir. 1999)
- *W.L. Gore & Associate, Inc. v. Garlock, Inc.*, 842 F.2d 1275 (Fed. Cir. 1983)
- 35 U.S.C. § 102
- 35 U.S.C. § 103
- 35 U.S.C. § 282][2]

B. Non-Jury Issues for Court

1. The scope of the permanent injunction to which Kyphon is entitled

enjoining DOT from further infringement of the asserted claims in the patents-in-suit.

Authority:

- 35 U.S.C. § 283.
- *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1247 (Fed. Cir. 1989).
- *Windsurfing Intern, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986).
- *Genentech, Inc. v. Wellcome Foundation Ltd.*, 826 F. Supp. 828 (D. Del. 1993).



[2] As explained in a motion *in limine*, Kyphon believes that the issue of obviousness is not properly presented. However, in the event that the Court decides otherwise, the bracketed, greyed text sets forth Kyphon's statement of the issues of fact regarding the issue of obviousness.

# B

# APPENDIX 3B

## DOT'S STATEMENT OF CONTESTED ISSUES OF LAW[1]

DOT reserves the right to review and revise these statements of contested issues of law, based on the Court's claim construction.

I. NON-INFRINGEMENT OF THE ASSERTED CLAIMS OF THE '888, '404, AND '043 PATENTS

A. Burden

1. Whether Kyphon bears the burden of proving infringement by a preponderance of the evidence. 35 U.S.C. § 271; Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677, 685 (Fed. Cir. 1990), cert. denied, 498 U.S. 992 (1990).

B. No Literal Infringement

1. Whether a claim for literal infringement requires the patentee to prove that every limitation in the claim(s) at issue, properly construed, is literally met by the accused products. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1466-67 (Fed. Cir. 1998); Mannesman Demag Corp. v. Engineered Metal Prods., Co., 793 F.2d 1279, 1282 (Fed. Cir. 1986).

C. No Infringement Under the Doctrine of Equivalents

1. Where an accused device does not literally contain an element of an asserted claim, whether that claim can nevertheless be met under the doctrine of equivalents, only if the device has some element that is "insubstantially different" from the claimed element, e.g., performs substantially the same function in substantially the same way to obtain the same

[1] DOT has identified what it currently believes to be the most relevant issues of law that may be disputed by Kyphon at trial. DOT reserves the right to litigate legal issues raised by Kyphon even if not specifically set forth herein. Additionally, to the extent that any issues of law are deemed to be issues of fact (and vice versa), they should be so considered.

result as the claimed subject matter. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997); Graver Tank & Mfg. Co. v. Linde Air Prods., Co., 339 U.S. 605, 607 (1950); Leggett & Platt, Inc. v. Hickory Springs Mfg. Co., 285 F.3d 1353, 1358-59 (Fed. Cir. 2002); Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1315 (Fed. Cir. 1998); Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed. Cir. 1997).

2. Whether infringement under the doctrine of equivalents requires that the accused device literally contain each limitation of the claim or an equivalent. Leggett & Platt, Inc. v. Hickory Springs Mfg. Co., 285 F.3d 1353, 1358-59 (Fed. Cir. 2002).

3. Whether the doctrine of equivalents must be applied to the individual elements of the claim asserted, not to the invention as a whole. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997).

4. Whether it is improper to apply the doctrine of equivalents in such a way as to effectively read a limitation out of a claim. Fin Control Sys. Pty, Ltd. v. OAM, Inc., 265 F.3d 1311, 1320 (Fed. Cir. 2001); Wolverine World Wide, Inc. v. Nike, Inc., 38 F.3d 1192, 1199 (Fed. Cir. 1994); Conopco, Inc. v. May Dept. Stores Co., 46 F.3d 1556, 1562 (Fed. Cir. 1994); Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1424 (Fed. Cir. 1997); Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1280 (Fed. Cir. 2001).

5. Whether a patentee is not entitled to a range of equivalents that would encompass the prior art. Day Int'l, Inc. v. Reeves Bros., Inc., 260 F.3d 1343, 1350 (Fed. Cir. 2001); Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 981 (Fed. Cir. 1999).

6. Whether the doctrine of equivalents is not designed to permit wholesale redrafting of a claim to cover non-equivalent devices, i.e., to permit a claim expansion that

would encompass more than an insubstantial change. Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532-33 (Fed. Cir. 1987).

7. Whether "interchangeability" is relevant to the doctrine of equivalents, and if so, whether the analysis with respect to interchangeability must be performed by determining whether a particular element of the accused device or process is interchangeable with respect to the corresponding element of the claimed device or process, and not by comparing the accused device to the patentee's competing device. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29-30 (1997); Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1386 (Fed. Cir. 1999).

8. If literal infringement were found, whether an accused device does not infringe under the doctrine of equivalents because it is so far changed in principle, that although it performs the same or a similar function to produce substantially the same result as that defined by a patent claim, it does so in a substantially different way. Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 569 (1898); Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607-610 (1950).

## II. INVALIDITY OF THE ASSERTED CLAIMS OF THE PATENTS-IN-SUIT

### A. Burden

1. Whether, in order to invalidate a claim based on anticipatory prior art, DOT must prove by clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim. In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002).

B. Invalidity of the Asserted Claims of the Patents-In-Suit under 35 U.S.C. §§ 102(a), (b) and/or (e) – Anticipation

1. If the subject matter of the Claims of the '888, '404, and '043 Patents is anticipated by the relevant prior art (because each limitation of that claim is found expressly or inherently in a single prior art reference), whether those claims are invalid, under 35 U.S.C. §§ 102(a), (b) and/or (e). Celeritas Techs., Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir. 1998).

2. Whether a particular reference may anticipate the patented invention without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003); Eli Lilly and Co. v. Barr Labs., Inc., 251 F.3d 955, 970 (Fed. Cir. 2001).

3. Whether the claims of the patents-in-suit must be interpreted and given the same meaning for purposes of both validity and infringement analyses. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001); Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001).

C. Invalidity of the Asserted Claims of the Patents-In-Suit under 35 U.S.C. §§ 102(a), (b) and/or (e) and 103(a) – Obviousness

1. If the subject matter of the Claims of the '888, '404, and '043 Patents would have been obvious to one of ordinary skill in the art in view of combinations of the relevant prior art, whether those claims are invalid, under 35 U.S.C. §§ 102(a), (b) and/or (e) and 103(a).

D. Prior Art Not Before the Examiner

1. Whether a party's burden to prove invalidity of a patent by clear and convincing evidence is more easily met where the prior art relied upon was not before the Examiner during the prosecution of the patent. EWP Corp. v. Reliance Universal Inc., 755 F.2d 898, 905 (Fed. Cir. 1985).

2. Whether a patentee may read limitations into a claim to avoid invalidity, particularly to avoid reading on prior art that was not previously before the examiner. Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1384 (Fed. Cir. 2001).

E. Secondary Considerations

1. Whether secondary considerations, such as commercial success, are only relevant as objective evidence of nonobviousness to the extent the patentee establishes a causal connection between the secondary considerations and the specifically claimed invention. U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1565 (Fed. Cir. 1997).

III. REMEDIES

A. Lost Profits for Patent Infringement

1. If infringement is proved, whether Kyphon is entitled to lost profits, only if it (1) establishes a reasonable probability that it would have made the sales but for the infringement, i.e., causation existed, and (2) introduces proper evidence for the computation of lost profits. BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc., 1 F.3d 1214, 1218 (Fed. Cir. 1993); Slimfold Mfg. Co. v. Kinkead Indus., Inc., 932 F.2d 1453, 1458 (Fed. Cir. 1991); SmithKline Diagnostics, Inc. v. Helena Labs., Inc., 926 F.2d 1161, 1166 (Fed. Cir. 1991);

Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978). Specifically:

a. Whether Kyphon is not entitled to any lost profits if it cannot establish demand for the patented product;

b. Whether Kyphon is not entitled to any lost profits if it cannot establish the absence of acceptable non-infringing substitutes. Grain Processing Corp. v. American Maize-Prods. Co., 185 F.3d 1341, 1349 (Fed. Cir. 1999);

c. Whether Kyphon is not entitled to any lost profits if it cannot establish the marketing and manufacturing capability to make the allegedly infringing sales; and

d. Whether Kyphon is not entitled to any lost profits if it cannot establish the amount of lost profits to which it claims it is entitled.

B. Reasonable Royalty for Patent Infringement

1. If infringement of the '888, '404 and '043 Patents is proved, whether Kyphon's damages must be limited to a reasonable royalty of, at most 5%, on sales of the SKy Device, based upon a hypothetical arms length negotiation between Kyphon and DOT, at the time infringement began. 35 U.S.C. § 284; Unisplay, S.A. v. American Elec. Sign Co., 69 F.3d 512, 517-19 (Fed. Cir. 1995); Georgia Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), modified, 446 F.2d 295 (2d Cir. 1971), cert. denied, 404 U.S. 870 (1971).

C. Prejudgment Interest

1. If any infringement is proved, whether Kyphon can establish entitlement to any prejudgment interest.

D. Willful Infringement

1. If infringement is proved, whether Kyphon can establish by clear and convincing evidence, in view of the totality of the circumstances, that such infringement was willful, i.e., that DOT knew of the '888, '404, and/or '043 Patents, and had no honest belief that it was not infringing the patents and/or that the patents were invalid. Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 944-945 (Fed. Cir. 1992); Rolls-Royce Ltd. v. GTE Valeron Corp., 800 F.2d 1101, 1110 (Fed. Cir. 1986).

2. If willfulness is proved, whether a finding of willful infringement merely authorizes, but does not mandate, an award of increased damages under 35 U.S.C. § 284. Modine Mfg. Co. v. Allen Group, Inc., 917 F.2d 538, 543 (Fed. Cir. 1990), cert. denied, 500 U.S. 918 (1991).

3. If willfulness is proved, whether and to what extent Kyphon is entitled to any enhanced damages.

E. Attorneys' Fees under 35 U.S.C. § 285

1. Whether awarding attorneys' fees under § 285 is a two-step process, and specifically, whether a court must first determine whether the case is "exceptional," and then, whether, in the court's discretion, attorneys' fees are appropriate. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1460 (Fed. Cir. 1998).

2. Whether a finding of willfulness does not necessarily mean that a case is "exceptional" for purposes of § 285, i.e., even where damages are increased under § 284, a court may decline to award attorneys' fees under § 285. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1461 (Fed. Cir. 1998).

3. If DOT prevails, whether DOT is entitled to an award of attorneys' fees (i) if Kyphon knew or reasonably should have known that DOT did not infringe the patents-in-suit and/or that the patents-in-suit are invalid, or (ii) based on Kyphon's conduct during the course of this litigation. Eltech Sys. Corp. v. PPG Indus., Inc., 903 F.2d 805, 810-811 (Fed. Cir. 1990).

4. If Kyphon prevails, whether Kyphon is entitled to attorneys' fees.

# 4

# A

Kyphon v. DOT
USDC-DE CA 04-204-JJF

Kyphon's June 10th 2005 Pre-Trial Order Exhibit List

**Kyphon reserves the right to supplement or otherwise amend this exhibit list in with respect to evidence that is the subject of pending motions *in limine,* and to the extent that other decisions by the Court necessitate. This list contains the exhibits Kyphon may use at the liability trial scheduled to begin June 20, 2005, as well as a preliminary list of those documents Kyphon presently intends to use in the damages/willfulness trial to be scheduled at a later date. Kyphon reserves the right to use any document listed on DOT's exhibit list served June 6, 2005.**

| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0001 | News articles re Kyphon/Kyphoplasty | | Various | DOTINC 002730-002731; DOTINC 002392; DOTINC 002738-002741; KY 045686; KY 022533-022534; KY 022549; KY 261446-261448; KY 285293-285303; KY 285305-285358; KY 285361-285362; KY 285368-285369; KY 285372-285373; KY 377458; KY 386741- 386742 | Compilation exhibit; Hearsay; Authentication (as to the articles that are undated and lack a source or author); Kyphon's expert lacks personal knowledge regarding vertebroplasty; Prejudicial and misleading; KY26146, KY 285294-95, KY 285306, KY 285311 and KY 285312 lack an author |
| PTX 0002 | Presentation: The SKy Bone Expander System for Void Creation and Vertebral Height Restoration | Mitchell Ex. 3 | 12/1/2004 | DM 001001-001058 | |
| PTX 0003 | Kazaz email to Magal | Kazaz Ex. 4 (7/7/04) | 5/14/2004 | DOTINC 007447 | Irrelevant |
| PTX 0004 | Product Delivered Goods forms from Mary Black Memorial Hospital | Saunders Ex. 314 (1/28/05) | N/A | DOTINC 000317-000330 | Irrelevant |
| PTX 0005 | Letter from Kazaz to Saunders | Saunders Ex. 306 (1/28/05) | 4/29/2004 | DOTINC 000595 | Irrelevant |
| PTX 0006 | Exhibit Not Used | | | | |
| PTX 0007 | SKy Bone Expander System IFU--various copies | Kazaz Ex. 15 (7/7/04) Globerman Ex. 85 (7/29/04) | Various | DOTINC 000686-000689; DOTLTD 014120-014122; DOTLTD 000413-000416 | |



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| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0008 | SKy Surgical Technique brochures | Kazaz Exs. 48, 49, 207, 208; Reilly Ex. 263 | Various | DOTINC 000988-001001; DOTLTD 006341-006353; TR 000197-TR00208; DOTLTD 015359-015373; DOTLTD 014707-014713; DOTINC 001399-001409; DOTLTD 15835-15849 | Compilation exhibit (5 documents); DOTINC 000988 - 1001 - irrelevant (draft) |
| PTX 0009 | Letter from Shaw to Saunders | Saunders Ex. 308 (1/28/05) | 5/21/2004 | DOTINC 001024-001025 | Irrelevant |
| PTX 0010 | SKy case studies | Expert Witness Report of Michael Marks, M.D., MBA | N/A | DOTINC 002511-002531 | |
| PTX 0011 | Exhibit Not Used | | | | |
| PTX 0012 | Memo from Tamir Kazaz to Motti Beyar | | 6/3/2004 | DOTINC 003954 | Irrelevant |
| PTX 0013 | Competitive Comparison Document | Kazaz Ex. 235 (1/28/05) | 4/28/2004 | DOTINC 004795-004798 | |
| PTX 0014 | DOT SKy Bone Expander System - FAQ | Kazaz Ex. 14 (7/7/04) | 1/00/2004 | DOTINC 004891-004893 | |
| PTX 0015 | Exhibit Not Used | | | | |
| PTX 0016 | SKy Bone Expander System V2.0 basic information | Kazaz Ex. 218 (1/28/05) | 12/15/2003 | DOTINC 005270-005271 | |
| PTX 0017 | Email regarding Corvus Medical | | N/A | DOTINC 005503-005507 | Irrelevant |
| PTX 0018 | Email to Kazaz from Barak | Expert report of Brian W. Napper | N/A | DOTINC 006357 | Irrelevant |
| PTX 0019 | Email from Elkayam to Kazaz and Barak cc'ing Magal | Magal Ex. 179 (1/26/05) | 1/26/2004 | DOTINC 006633 | |
| PTX 0020 | Email to Jeff Lubin from Ronny Barak | Barak Ex. 295 (2/14/05) | 4/23/2004 | DOTINC 006685-006773 | |
| PTX 0021 | Morales email to Kazaz | Kazaz Ex. 12 (7/7/04) | N/A | DOTINC 006917-006918 | |



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| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0022 | Email from Weinstein to Kazaz | Magal Ex. 180 (1/26/05) | 5/23/2004 | DOTINC 007172-007173 | Irrelevant |
| PTX 0023 | Email between Kazaz and Barak | Expert report of Brian W. Napper | N/A | DOTINC 007255 | Irrelevant |
| PTX 0024 | Barak email to Kazaz | Kazaz Ex. 17 (7/7/04) | 6/1/2004 | DOTINC 007304-007323 | |
| PTX 0025 | Exhibit Not Used | | | | |
| PTX 0026 | Email between Kazaz and Barak | | 2/00/2004 | DOTINC 008033-008034 | Irrelevant |
| PTX 0027 | Email between Kazaz and Barak | Expert report of Brian W. Napper | 4/27/2004 | DOTINC 008435 | Irrelevant |
| PTX 0028 | Email between Barak and Whitaker | Expert report of Brian W. Napper | 4/29/2004 | DOTINC 008470 | Irrelevant |
| PTX 0029 | Exhibit Not Used | | | | |
| PTX 0030 | Letter from Kazaz to Mitchell and attachment | Mitchell Ex. 2 | 6/30/2004 | DOTINC 008834, DOTINC 008837-008846 | |
| PTX 0031 | Exhibit Not Used | | | | |
| PTX 0032 | Portion of SKy Bone Expander System Training Manual | Kazaz Ex. 236 (1/28/05) | 11/00/2004 | DOTINC 009430-009449 | |
| PTX 0033 | Report for 12 month period ending December 31st, 2004 for the SKy bone expander system in the US | Kazaz Ex. 204 (1/28/05) | 1/6/2005 | DOTINC 009593-009639 | |
| PTX 0034 | Exhibit Not Used | | | | |
| PTX 0035 | Physical-SKy Bone Expander System (4mm)-physical | | N/A | DOTINC 050009/050010 | |
| PTX 0036 | CD | | | DOTINC 050012 | Compilation exhibit (more than 10 documents) |
| PTX 0037 | Exhibit Not Used | | | | |
| PTX 0038 | Surgeon and procedure list | | N/A | DOTINC 050452-050477 | |
| PTX 0039 | Exhibit Not Used | | | | |
| PTX 0040 | Exhibit Not Used | | | | |



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| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0041 | Email exchange between Barak and David Smith | Expert report of Brian W. Napper | 5/00/2004 | DOTINC 7621-7622 | Irrelevant |
| PTX 0042 | Saunders fax to DOT | Saunders Ex. 307 (1/28/05 ) | 5/12/2004 | DOTINC 000613-000614 | Irrelevant; Hearsay |
| PTX 0043 | WRHAMBRECHT+CO report re Kyphon stock | Rebuttal Expert Witness Report of Michael Marks, M.D. | N/A | DOTINC 002473-002479 | Hearsay |
| PTX 0044 | SKy Bone Expander System, Training Manual - First Draft | Kazaz Ex. 43 (7/15/04) | 6/002004 | DOTINC 004023-004306 | Compilation exhibit |
| PTX 0045 | Email to Martin from Morales | Kazaz Ex. 65 (7/15/04) | 4/28/2004 | DOTINC 004792-004794 | |
| PTX 0046 | Exhibit Not Used | | | | |
| PTX 0047 | The SKy Bone Expander System for Void Creation and Vertebral Height Restoration | Kazaz Ex. 37 (7/15/04) | 5/23/2004 | DOTINC 008753- 008805 | |
| PTX 0048 | Exhibit Not Used | | | | |
| PTX 0049 | Email from Mott to Beyar | Beyar Ex. 174 (1/25/05) | 4/7/2004 | DOTLTD 000040 | Hearsay; Irrelevant |
| PTX 0050 | Exhibit Not Used | | | | |
| PTX 0051 | SKy System, Manufacturing Flow Chart | Globerman Ex. 80 (7/29/04) | N/A | DOTLTD 000702-000723 | |
| PTX 0052 | Exhibit Not Used | | | | |
| PTX 0053 | 510(k) Premarket Notification re B-Twin Bone Expander System | Beyar Ex. 168 (1/25/05 ) | 7/30/2003 | DOTLTD 001982-002052 | Irrelevant |
| PTX 0054 | Correspondence from Kahan to FDA | Beyar Ex. 169 (1/25/05) | 10/00/2003 | DOTLTD 002055-002063 | Irrelevant |
| PTX 0055 | Communication from Shavit to FDA | Beyar Ex. 170 (1/25/05) | 11/00/2003 | DOTLTD 002069-002074 | Irrelevant |
| PTX 0056 | Communication with FDA submitting Special 510(k) | Beyar Ex. 171 (1/25/05) | 12/29/2003 | DOTLTD 002081-002137 | Irrelevant |
| PTX 0057 | Specification sheets | | N/A | DOTLTD 002324; DOTLTD 000048 | |



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| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0058 | SKy System-Design Review, in Hebrew, with translation | | | DOTLTD 003357-003371, 003377, 003387 | |
| PTX 0059 | 510(k) Pre Market Notification re Sky Bone Expander | Beyar Ex. 172 (1/25/05) | 3/4/2004 | DOTLTD 003692-003732 | Irrelevant |
| PTX 0060 | Document listing revenues re BE/Twin Sky and trauma | Kazaz Ex. 203 (1/28/05) | 6/30/2004 | DOTLTD 005533-005548 | |
| PTX 0061 | List of SKy Bone Expander US Surgeons | | 05/00/2004 | DOTLTD 005584 | Incomplete; Irrelevant |
| PTX 0062 | SKy Surgical Notes | Kazaz Ex. 210 (/28/05) | 5/20/2004 | DOTLTD 006176-006178 | |
| PTX 0063 | Email from Magal to Beyar and Globerman | Magal Ex. 178 (1/26/05) | 11/6/2003 | DOTLTD 006427-006428 | Irrelevant |
| PTX 0064 | Email from Kazaz to Globerman | Globerman Ex. 198 (1/27/05) | N/A | DOTLTD 010883 | |
| PTX 0065 | Exhibit Not Used | | | | |
| PTX 0066 | DOT written material attached to opinion letters | Eisenhart Ex. 352 (3/17/05) | N/A | DOTLTD 014239-014250 | |
| PTX 0067 | Exhibit Not Used | | | | |
| PTX 0068 | Exhibit Not Used | | | | |
| PTX 0069 | "Potential 2004 Conferences/Events to Launch SKy…" | | N/A | DOTLTD 014740-014743 | Irrelevant |
| PTX 0070 | SKy Surgical Notes | Magal Ex. 183 (1/26/05) | 5/20/2004 | DOTLTD 015459-015462 | Irrelevant |
| PTX 0071 | Exhibit Not Used | | | | |
| PTX 0072 | CD | | N/A | DOTLTD 050017 | Irrelevant (Portugal presentation); Compilation exhibit |
| PTX 0073 | Exhibit Not Used | | | | |
| PTX 0074 | SKy Systems, Design and Development Plan | Globerman Ex. 95 (7/29/04) | Undated | DOTLTD 000431-000437 | |
| PTX 0075 | B-Twin BE System, Risk Analysis | Globerman Ex. 76 (7/29/04) | Undated | DOTLTD 000438-000467 | |



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| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0076 | Product (tube) spec, updated to 12/03 | Expert Witness Report of Michael Marks, M.D., MBA | N/A | DOTLTD 000560-000572 | |
| PTX 0077 | Tecoflex Tube-Product Specifications | Expert Witness Report of Michael Marks, M.D., MBA | N/A | DOTLTD 000755-000767 | |
| PTX 0078 | Delivery System - Product Technical Specifications | Expert Witness Report of Michael Marks, M.D., MBA | N/A | DOTLTD 000866-000877 | |
| PTX 0079 | Document in Hebrew, with translation | Globerman Ex. 98 (7/29/04) | 5/25/2003 | DOTLTD 001227 | Irrelevant; Authentication (inaccurate translation); Misleading, confusing and prejudicial |
| PTX 0080 | Surgical Technique, The SKy Bone Expander System, Kyphoplasty | Globerman Ex. 87 (7/29/04) | Undated | DOTLTD 001560-001576 | Irrelevant; Compilation exhibit |
| PTX 0081 | B-Twin BE – Design Review (DR), in Hebrew, with translation | Globerman Ex. 100 (7/29/04) | 8/17/2003 | DOTLTD 001630-001635 | Authentication (inaccurate translation); Misleading, confusing and prejudicial |
| PTX 0082 | SKy System, Clinical Evaluation – Spinal Indication | Globerman Ex. 94 (7/29/04) | Undated | DOTLTD 001843-001860 | Irrelevant; Misleading, confusing and prejudicial |
| PTX 0083 | Handwritten document in Hebrew, with translation | Globerman Ex. 99 (7/29/04) | 6/23/2003 | DOTLTD 003387 | Authentication (inaccurate translation); Irrelevant; Misleading, confusing and prejudicial; |
| PTX 0084 | Disc-o-Tech Medical Technologies Ltd. Annual Reports | | 2003 | DOTLTD 010048-010155 | |
| PTX 0085 | Ads and Brochures | Expert Witness Report of Michael Marks, M.D., MBA | N/A | DOTLTD 014714-014715; DOTLTD 015126-015127 | Irrelevant |
| PTX 0086 | Exhibit Not Used | | | | |
| PTX 0087 | Exhibit Not Used | | | | |



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|---|---|---|---|---|---|
| PTX 0088 | SKy Bone Expander Instrumentation Sets | | N/A | Including: DOTINC 50008; 50009; 51001 | Irrelevant with respect to bone filler |
| PTX 0089 | Balloon drawings | | N/A | KY 004260-004265 | |
| PTX 0090 | CVof Mark Reiley | | N/A | KY 018204-018207 | |
| PTX 0091 | CVof Karen Talmadge | | N/A | KY 018209-018211 | |
| PTX 0092 | Reiley Orthopedics Business Plan | | 1993 | KY 018311-018401 | Irrelevant;<br>Authentication (no date);<br>Incomplete (only includes first four pages of document);<br>Compilation exhibit;<br>Hearsay |
| PTX 0093 | Letter from Dr. Riggs to Karen Talmadge | | 8/1/1994 | KY 021608 | Hearsay;<br>Irrelevant |
| PTX 0094 | Letter from Dr. Riggs to Mark Reiley | | 6/17/1994 | KY 021609 | Hearsay;<br>Irrelevant |
| PTX 0095 | Kushwaha and Laliberte, Abstract: Vertebral height restoration after kyphoplasty | | N/A | KY 024020-024022 | Hearsay;<br>Irrelevant |
| PTX 0096 | Ledlie & Renfro, "Balloon kyphoplasty: one-year outcomes in vertebral body height restoration, chronic pain, and activity levels" | Rebuttal Expert Witness Report of Michael Marks, M.D. | 1/00/2003 | KY 024038-024044 | Irrelevant;<br>Hearsay |
| PTX 0097 | Gehlbach et al., "Hospital care of osteoporosis-related vertebral fractures" | Rebuttal Expert Witness Report of Michael Marks, M.D. | 2003 | KY 024092-024099 | Irrelevant;<br>Hearsay |
| PTX 0098 | 2003 Financial and Operations Summary | Expert report of Brian W. Napper | N/A | KY 038903-038908 | |
| PTX 0099 | Theodorou, et al. "Percutaneous balloon kyphoplasty for the correction of spinal deformity in painful vertebral body compression fractures" | | N/A | KY 045782-045786 | Irrelevant;<br>Hearsay |
| PTX 0100 | New Heights in Compression Fracture Management | | N/A | KY 074834-074879 | Irrelevant;<br>Hearsay |



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|---|---|---|---|---|---|
| PTX 0101 | Brochure for Kyphx Xpander IBT | | N/A | KY 114345-114346 | Irrelevant;<br>Misleading, confusing and prejudicial |
| PTX 0102 | Brochure - Elevate IBT | | N/A | KY 114976-114978 | Irrelevant |
| PTX 0103 | Exhibit Not Used | | | | |
| PTX 0104 | Reiley-Scholten Agreement | | 7/2/1986 | KY 116754-116755 | Hearsay;<br>Irrelevant;<br>Misleading, confusing and prejudicial |
| PTX 0105 | Letter from Melton to Reiley re kyphoplasty | | 7/26/2004 | KY 123799 | Irrelevant;<br>Hearsay |
| PTX 0106 | Exhibit Not Used | | | | |
| PTX 0107 | Handwritten Notes | | N/A | KY 124271-124280 | Hearsay;<br>Irrelevant;<br>Authentication;<br>Misleading, confusing and prejudicial |
| PTX 0108 | Strategic Marketing Kyphon # 974, San Francisco, CA (CD) | Rebuttal Expert Witness Report of Michael Marks, M.D. | 6/6/1994 | KY 152400 | Hearsay;<br>Irrelevant; |
| PTX 0109 | Balloon kyphoplasty video (CD) | Rebuttal Expert Witness Report of Michael Marks, M.D. | N/A | KY 152401 | Irrelevant;<br>Hearsay;<br>Misleading, confusing and prejudicial |
| PTX 0110 | Exhibit Not Used | | | | |
| PTX 0111 | Exhibit Not Used | | | | |
| PTX 0112 | Kyphoplasty review 2002 (CD) and hard copy of CD | Rebuttal Expert Witness Report of Michael Marks, M.D. | N/A | KY 152406 | Hearsay;<br>Irrelevant;<br>Authentication |
| PTX 0113 | Presentation re VCF and kyphoplasty results | | N/A | KY 154159-154183 | Hearsay;<br>Irrelevant;<br>Misleading, confusing and prejudicial |
| PTX 0114 | ThinkEquity report, "KYPH: Expect NASS meeting to be a positive effect for Kyphon" | Rebuttal Expert Witness Report of Michael Marks, M.D. | 10/15/2003 | KY 155597-155611 | Hearsay;<br>Irrelevant |
| PTX 0115 | Presentation: Kyphon Health Care Conference | | N/A | KY 158089 - 158129 | Hearsay;<br>Irrelevant |



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| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0116 | VMS news monitoring report (local and national TV network) re Kyphon | Rebuttal Expert Witness Report of Michael Marks, M.D. | 4/11/2002 - 4/18/2002 | KY 159761-159782 | Hearsay; Irrelevant; |
| PTX 0117 | Gold et al., "Unexpected consequences of osteoporosis" | Rebuttal Expert Witness Report of Michael Marks, M.D. | 1996 | KY 163634-163640 | Hearsay; Irrelevant; |
| PTX 0118 | Kyphon Mission presentation | | 2002 | KY 165570-165590 | Hearsay; Irrelevant; |
| PTX 0119 | ThinkEquity report, "KYPH: Reiterate overweight following two important milestones" | Rebuttal Expert Witness Report of Michael Marks, M.D. | 4/5/2004 | KY 177602-177611 | Hearsay; Irrelevant |
| PTX 0120 | Minimally Invasive Therapy for Functionally Unstable Osteoporotic Vertebral Fracture by Means of Kyphoplasty: Prospective Comparative Study of 19 Surgically and 17 Conservatively Treated Patients (Komp, et al.) | Expert report of Brian W. Napper | N/A | KY 178124-178127 | Hearsay; Irrelevant; |
| PTX 0121 | Exhibit Not Used | | | | |
| PTX 0122 | Letter from Scribner to Scribner | Rebuttal Expert Witness Report of Michael Marks, M.D. | N/A | KY 229840-229841 | Hearsay; Authentication; Irrelevant |
| PTX 0123 | Presentation by Dr. Garfin et al. at NASS | Rebuttal Expert Witness Report of Michael Marks, M.D. | 10/31/1998 | KY 230118-230122 | Hearsay; Irrelevant |
| PTX 0124 | Handwritten notes | | N/A | KY 285086 - 285090 | Hearsay; Irrelevant; Authentication; Compilation exhibit |
| PTX 0125 | Handwritten notes | | N/A | KY 285123 - 285124 | Hearsay; Irrelevant; Authentication |



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Kyphon's June 10th 2005 Pre-Trial Order Exhibit List

| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0126 | Channel 12 Connecticut evening news re Dr. Marks' kyphoplasty surgery (CD) | Rebuttal Expert Witness Report of Michael Marks, M.D. | 07/00/2001 | KY 375745 | Hearsay;<br>Irrelevant;<br>Misleading, confusing and prejudicial |
| PTX 0127 | Exhibit Not Used | | | | |
| PTX 0128 | Channel 3 CBS Kyphoplasty Segment (CD) | | 2/4/2005 | KY 386743 | Hearsay;<br>Irrelevant;<br>Misleading, confusing and prejudicial |
| PTX 0129 | Slides: The Downward Spiral : Impact of Vertebral Body Comression Fractures; Slides: Vertebral Body Compression Fracture Treatment Options | Mitchell Exs. 5 and 8 | N/A | KY 387436-387475; KY 387517-387555 | Hearsay;<br>Compilation exhibit |
| PTX 0130 | Taylor review article | | N/A | KY 387578-387711 | Produced weeks before trial;<br>Hearsay; |
| PTX 0131 | Presentation: Innovation in Spinal Surgery: Kyphoplasty | | N/A | MARKS 000220-000275 | Hearsay;<br>Irrelevant; |
| PTX 0132 | Exhibit Not Used | | | | |
| PTX 0133 | Exhibit Not Used | | | | |
| PTX 0134 | Presentation: Ending the Downward Spiral | | N/A | MARKS 000624-000679 | Hearsay;<br>Irrelevant |
| PTX 0135 | Exhibit Not Used | | | | |
| PTX 0136 | Exhibit Not Used | | | | |
| PTX 0137 | Spine. 2002 Oct 1: 27(19):E419-22. Parapalegia as a complication of percutaneous vertebroplasty with polymethylmethacrylate: a case report. Lee BJ, Lee SR, Yoo TY | Rebuttal Expert Witness Report of Michael Marks, M.D. | N/A | N/A | Misleading, confusing and prejudicial;<br>Hearsay;<br>Irrelevant |
| PTX 0138 | Anesth. Analg. 2004 Apr; 98(4):1184-6. Severe hypercapnia due to pulmonary embolism of polymethylmethacrylate during vertebroplasty. Stricker K, Orler R, Yen K, Takala J, Luginbuhl M. | Rebuttal Expert Witness Report of Michael Marks, M.D. | N/A | N/A | Misleading, confusing and prejudicial;<br>Hearsay;<br>Irrelevant |



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Kyphon's June 10th 2005 Pre-Trial Order Exhibit List

| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0139 | Clin Ortho. and Rel. Rsrch., No. 415S, Oct. 2003 S1760-S186. Lieberman and Reinhardt, Vertebroplasty and Kyphoplasty for Osteolytic Vertebral Collapse | Rebuttal Expert Witness Report of Michael Marks, M.D. | N/A | N/A | Hearsay;<br>Irrelevant; |
| PTX 0140 | Spine. 2002 Oct 1: 27(19) 2173-2179. Phillips, et al., "An *In Vivo* Comparison of the Potential for Extravertebral Cement Leak After Vertebroplasty and Kyphoplasty" | Rebuttal Expert Witness Report of Michael Marks, M.D. | N/A | N/A | Misleading, confusing and prejudicial;<br>Hearsay;<br>Irrelevant |
| PTX 0141 | J. of Women's Imaging 2000 Aug: 2(3) 117-124. Wong et al., "Vertebroplasty/Kyphoplasty" | ITC Complaint Public Exhibit 30 | N/A | N/A | Hearsay;<br>Irrelevant; |
| PTX 0142 | Garfin et al. "Vertebroplasty and Kyphoplasty (Chapter 32-The Practice of Minimally Invasive Spinal Techniquem Savitz, et al., 2000) | ITC Complaint Public Exhibit 30 | | N/A | Hearsay;<br>Irrelevant |
| PTX 0143 | Copy of The SKy Bone Expander System, Percutaneous Bone Void Creation, rev 01, | Kazaz Ex. 13 (7/7/04) | 3/4/2005 | N/A | |
| PTX 0144 | Document with Power Point Slides and Case Studies | Barak Ex. 351 (2/14/05) | N/A | N/A | Compilation exhibit; |
| PTX 0145 | Exhibit Not Used | | | | |
| PTX 0146 | SKy Bone Expander Demonstration System (including DOTINC 50743 and 50010) | | N/A | N/A | |
| PTX 0147 | Kyphon's IBT devices-physical | | N/A | N/A | |
| PTX 0148 | Marks CV | Marks Ex. 3 (portion) | N/A | N/A | |
| PTX 0149 | Medical Device Alliance, Inc. Form 10-KSB/A | Expert report of Brian W. Napper, Ex. 11 | N/A | N/A | Hearsay;<br>Irrelevant;<br>Not produced in the litigation |
| PTX 0150 | Exhibit Not Used | | | | |
| PTX 0151 | Exhibit Not Used | | | | |
| PTX 0152 | Exhibit Not Used | | | | |



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Kyphon's June 10th 2005 Pre-Trial Order Exhibit List

| KY TRIAL EXHIBIT NO. | DESCRIPTION | DESIGNATED AT DEPO OF /USED IN | DOC DATE | BATES RANGE | DOT'S OBJECTIONS |
|---|---|---|---|---|---|
| PTX 0153 | Exhibit Not Used | | | | |
| PTX 0154 | SKy Bone Expander 2005 Plan of Attack | Reilly, Tom Ex. 246 (2/4/05) | N/A | TR 000004-TR 000016 | Hearsay; Irrelevant |
| PTX 0155 | Exhibit Not Used | | | | |
| PTX 0156 | Letter from Reilly to Rudy, Pete and Mark | Reilly, Tom Ex. 250 (2/4/05) | N/A | TR 000094 | Hearsay; Irrelevant; |
| PTX 0157 | SKy sales pitch | Reilly, Tom Ex. 252 (2/4/05) | N/A | TR 000138-TR 000139 | Hearsay; Irrelevant |
| PTX 0158 | ID Words - cheat sheet for using SKy | Reilly, Tom Ex. 272 (2/4/05) | N/A | TR 000143 | Hearsay; Irrelevant |
| PTX 0159 | Exhibit Not Used | | | | |
| PTX 0160 | Disc-O-Tech Medical Technologies Ltd. SKy Bone Expander Surgical Technique Tutorial | Reilly, Tom Ex. 268 (2/4/05) | N/A | TR 000245-TR 000277 | |
| PTX 0161 | Letter from Martin | Martin Ex. 155 (1/20/05) | N/A | WM 000001 - 000005 | Hearsay; Irrelevant; Compilation exhibit (5 documents) |
| PTX 0162 | Kyphon Request for Purchase Orders, KyphoPak Tray brochure | Martin Ex. 153 (1/20/05) | Various | WM 000202-000213 | Hearsay; Irrelevant; |
| PTX 0163 | SKy Bone Expander System Brochure | Kazaz Ex. 22 (7/15/04) | 2/2/2004 | DOTINC006166-6177 | Irrelevant; |
| PTX 0164 | Exhibit Not Used | | | | |
| PTX 0165 | Summary of DOT sales and costs to be prepared prior to damages trial on a schedule to be addressed by the parties | | | | |
| PTX 0166 | Summary of Kyphon sales and costs to be prepared prior to damages trial on a schedule to be addressed by the parties | | | | |
| PTX 0167 | U.S. Patent No. 4,969,888 | | | KY 181053-181069 | |
| PTX 0168 | U.S. Patent No. 5,108,404 | | | KY 181104-181120 | |
| PTX 0169 | U.S. Patent No. 6,235,043 | | | KY 181227-181246 | |
| PTX 0170 | Kyphon's Designations of Discovery For Use at Trial | | | | |



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# B

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UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

KYPHON INC.,
v.
DISC-O-TECH MEDICAL TECHNOLOGIES LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC.

C.A. No. 04-204-JJF

# *DOT's Trial Exhibit List*[1]

| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1001 | | KY 228787 – 228907 | N/A | File History for U.S. Patent No. 4,969,888 (which includes issued patent) | |
| 1002 | | KY 228908 – 229043 | N/A | File History for U.S. Patent No. 5,108,404 (which includes issued patent) | |

[1] This Trial Exhibit List contains exhibits for all three phases of trial. DOT reserves the right to supplement, modify or amend its Trial Exhibit List, and to rely on any exhibit on Kyphon's Trial Exhibit List. DOT further reserves the right to supplement, modify or amend this list in the event the Special Master's findings are reversed or modified.

[2] DOT Appendix = Appendix of Exhibits submitted by DOT in support of Claim Construction and Summary Judgment Briefs, D.I. Nos. 140-144.

| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1003 | | KY 229044 – 229364 | N/A | File History for U.S. Patent No. 6,235,043 B1 (which includes issued patent) | |
| 1004 | DOT Appendix Ex. A-23 | | 9/1967 | Scoville, W., "The Use of Acrylic Plastic for Vertebral Replacement or Fixation in Metastatic Disease of the Spine," J. Neurosurg., Vol. 27: 274-279, Sept. 1967 | |
| 1005 | | | 12/14/1971 | U.S. Patent No. 3,626,949 ("Shute") | |
| 1006 | DOT Appendix Ex. A-12 | | 7/1974 | Carlson, "The Use of Methylmethacrylate in Repair of Neoplastic Lesions in Bone," Radiology, Vol. 112, pp. 43-46, July 1974 | |
| 1007 | DOT Appendix Ex. A-17 | | 1976 | Edeland, H.G., "Open Reduction of Central Compression Fractures of the Tibial Plateau," Acta Orthop. Scand., Vol. 47, pp. 686-689, 1976 | |
| 1008 | DOT Appendix Ex. A-18 | | 1978 | Kennedy, W., "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," Clin. Orthop., Vol. 134, pp. 153-157, 1978 | |

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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1009 | DOT Appendix Ex. A-13 | | 1982 | Daniaux, H., "Technik und Ergebnisse der transpedikulären Spongiosaplastik bei Kompressionsbrüchen im Lendenwirbelsäulenbereich," Acta Chir. Austr. (Suppl.), Vol. 43, pp. 79-80, 1982 | |
| 1010 | DOT Appendix Ex. A-19 | | 1984 | 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 | |
| 1011 | | | 12/18/1984 | U.S. Patent No. 4,488,549 ("Lee") | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports. |
| 1012 | | | 5/21/1985 | U.S. Patent No. 4,518,430 ("Brown & Chow") | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports. |
| 1013 | DOT Appendix Ex. A-14 | | 1986 | Daniaux, H., "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," Unfallchirurg, Vol. 89, pp. 197-213, 1986 | |

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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1014 | DOT Appendix Ex. A-15 | | 1986 | 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 | |
| 1015 | | | 12/9/1986 | U.S. Patent No. 4,627,434 ("Murray") | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports. |
| 1016 | DOT Appendix Ex. A-10 | | 1987 | 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 | |
| 1017 | DOT Appendix Ex. A-11 | | 1987 | Campbell's Operative Orthopaedics, A.H. Crenshaw, Ed., 7th ed., Chapter 44, pp. 1653–1663, 1987 | |
| 1018 | DOT Appendix Ex. A-16 | | 1987 | Dick, W., "The 'Fixatuer Interne' as versatile implant for spine surgery," Spine, Vol. 12 (9), pp. 882-900, 1987 | |
| 1019 | | DOTINC 050479 – DOTINC 050537 | 1987 | Limb Salvage in Musculoskeletal Oncology, Chapter 6, "Effectiveness of Methyl Methacrylate as a Physical adjuvant in Local Tumor Control,", Enneking, W., Ed., Churchill Livingstone, pp. 443 - 498, 1987 | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports. |

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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1020 | DOT Appendix Ex. A-9 | | 1988 | Aebi, M., "The internal skeletal fixation system. A new treatment of thoracolumbar fractures and other spinal disorders," Clin. Orthop., Vol. 227, pp. 30-43, 1988 | |
| 1021 | DOT Appendix Ex. A-20 | | 1988 | Olerud, S., "Transpedicular Fixation of Thoracolumbar Vertebral Fractures," Clin. Orthop., Vol. 227, pp. 44-51, 1988 | |
| 1022 | DOT Appendix Ex. A-21 | | 1988 | Pentelenyi, T., "First Hungarian Neurosurgical Experiences with 'Fixateur Interne' in the Treatment of Thoraco-lumbar Spine Injuries," Acta Neurochir. (Wien), Vol. 93, pp. 104-109, 1988 | |
| 1023 | DOT Appendix Ex. A-22 | | 1988 | Schatzker, J., Operative Orthopaedics, M. Chapman, Ed., 1st ed., Ch. 35, pp. 421 – 434, 1988 | |
| 1024 | Reiley Ex. 3 | KY116725-116739 | 9/26/1988 | Record of Invention for Balloon Assisted Fixation of Osteoporotic Fractures (Arie Scholten and Mark Reiley) | |
| 1025 | | | 11/7/1989 | U.S. Patent No. 4,878,495 ("Grayzel") | |
| 1026 | | | 3/20/1990 | U.S. Patent No. 4,909,252 ("Goldberger") | |

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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1027 | Reiley Ex. 11 | | 12/17/1990 | The Effect of Internal Augmentation on Vertebral Body Mechanical Properties: A Preliminary Study, by A.U. Daniels, Ph.D. and Karl Wenger | Kyphon objects to the use of this exhibit because it violates the stipulation regarding Dr. Constantz. Further, Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports. In addition, Kyphon makes the following objections: 402, 403, foundation, and hearsay. |
| 1028 | | | 9/17/1991 | U.S. Patent No. 5,049,132 ("Shaffer") | |
| 1029 | | CM 0347 – 0356 | 6/1992 | McGavock, Daniel M., David A. Haas, and Michael P. Patin, "Factors Affecting Royalty Rates," *les Nouvelles*, Vol. 27, No. 2, June 1992 | |
| 1030 | | KY 004433 – 004865 | 4/3/1998 | 510(k) Premarket Notification Submission, KyphX ™ Inflatable Bone Tamp – K981251 | Subject of motion *in limine*. Also, Kyphon objects under FRE 402 and 403. |
| 1031 | | KY 116135-116137 | 8/9/2000 | Letter from Mark Reiley to Invention Disclosure File Re: Balloon Reduction and Fixation of Distal Radius Fracture | FRE 402/403 |



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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1032 | | KY 004932 – 004959 | 2001 | Presentation regarding Kyphon Meeting with FDA on January 16, 2001 | Subject of motion *in limine*. Kyphon also objects under FRE 402 and 403. |
| 1033 | | CM 0338 – 0346 | 2/2001 | Mathis, John M., et al., "Percutaneous Vertebroplasty: A Developing Standard of Care for Vertebral Compression Fractures," AJNR Am J. Neuroradiology 22:373-381, February 2001 | |
| 1034 | Scholten Ex. 523 | KY 386667- 386685 | 8/27/2002 | U.S. Patent No. 6,440,138 ("Reiley et al.") | FRE 402/403 |
| 1035 | Globerman Ex. 193 | DOTLTD 001835-1840 | 11/2002 | Delphion patent search results on Kyphon | |
| 1036 | | | 2003 | Lieberman et al., "Vertebroplasty and Kyphoplasty for Osteolytic Vertebral Collapse," Clin. Orthop. And Related Res., No. 415S, pp. S176-186, 2003 | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports. FRE 402/403. |
| 1037 | | CM 00256 - 00260 | 2/2003 | Hiwatashi, A., et al., "Increase in Vertebral Body Height after Vertebroplasty", *AJNR Am J Neuroradiology* 23:185-189, February 2003 | |
| 1038 | | KY 230242 – 230410 | 3/28/2003 | Kyphon's 2002 10-K SEC Filing | |
| 1039 | | DOTLTD 002058 – 002063 | 10/2/2003 | Letter to FDA from Ronen Shavit re: K032358 – B-Twin Bone Expander System | |



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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1040 | | DOTINC 050586 - 050738 | 2004 | Worldwide Orthopaedic Market & Equity Research Document | |
| 1041 | | DOTINC 050096 – 050198 | 2/9/2004 | PowerPoint Presentation: "Osteoporosis and the Spinal Surgeon" | FRE 802; Kyphon also objects to use of this exhibit by Dr. Mitchell, as it is not cited in his report. |
| 1042 | | DOTLTD 000042 | 3/3/2004 | Letter from Richard Mott to Motti Beyar | |
| 1043 | | KY 230411 – 230491 | 3/10/2004 | Kyphon's 2003 10-K SEC Filing | |
| 1044 | Mott Ex. 502 | KY 142117-142123 | 3/31/2004 | Competitive Activities - Q1 2004 | Foundation,<br>FRE 802 |
| 1045 | | CM 0064 - 0084 | 4/12/2004 | Banc of America Securities, Equity Research United States, "Kyphon Inc. Extraordinary Growth, but Valuation keeps Us at bay; Coverage Initiated with a Rating of Neutral, April 12, 2004 | |
| 1046 | | | 5/2004 | Mathis, John M., et al., "Vertebroplasty versus Kyphoplasty: A Comparison and Contrast." Am. J. Neuroradiol 25: 840-45, May 2004 | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports; nor was it ever produced during discovery. |

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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1047 | | CM 0036 - 0063 | 5/6/2004 | Banc of America Securities, Equity Research United States, "Kyphon Inc. Extraordinary Growth, but Valuation Keeps Us at Bay; Coverage Initiated with a Rating of Neutral," May 6, 2004 | |
| 1048 | Globerman Ex. 190 | DOTLTD 014123-203 | 6/18/2004 | Letter from John C. Eisenhart to Oren Globerman regarding non-infringement opinion for U.S. Patent No. 6,235,043 | |
| 1049 | Kazaz Ex. 203 | DOTLTD 005533-548 | 6/30/2004 | Disc-O-Tech Breakdown of revenues, costs of goods sold, operating expenses | Kyphon reserves an objection to use of this document, due to DOT's failure to produce a 30b6 witness with the necessary familiarity with this document. |
| 1050 | Globerman Ex. 188 | DOTLTD 014204-271 | 7/14/2004 | Letter from John C. Eisenhart to Oren Globerman regarding non-infringement opinion for U.S. Patent No. 5,108,404 | |
| 1051 | Globerman Ex. 189 | DOTLTD 014272-338 | 7/14/2004 | Letter from John C. Eisenhart to Oren Globerman regarding non-infringement opinion for U.S. Patent No. 4,969,888 | |
| 1052 | Marks Ex. 14 | MARKS 000524 – 623 | 9/18/2004 | PowerPoint Presentation: "Advanced Concepts in Minimally Invasive Vertebral Compression Fracture Management" | |



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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1053 | | | 10/27/2004 | Kyphon's Responses to Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc.'s First Set of Interrogatories To Plaintiff Kyphon Inc. (Nos. 1-17) | 402/403/802; Kyphon objects to the admission of an entire discovery response, rather than particular enumerated portions. DOT needs to specifically designate portions. |
| 1054 | Barak Ex. 297 | DOTINC 050205-300 (hard copy); DOTINC 050012 (electronic) | 11/2004 | Disc-O-Tech's SKy Bone Expander System Training Manual (in both hard copy and electronic format) | |
| 1055 | | | 11/5/2004 | Kyphon's 3Q 2004 10-Q SEC Filing | |
| 1056 | | DOTLTD 014120-14122 | 12/2004 | SKy Bone Expander System Instructions For Use | |
| 1057 | | DOTINC 050741 - 050742 | 2005 | SKy Bone Expander Surgical Technique | |

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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1058 | | | 2005 | Expert Reports of Michael Marks, M.D. M.B.A. [for rebuttal purposes only]:<br><br>A. Expert Witness Report of Michael Marks, M.D.,<br>M.B.A. dated March 8, 2005;<br>B. Supplemental Expert Witness Report of Michael<br>Marks, M.D., M.B.A. Re Infringement Issues dated<br>March 11, 2005;<br>C. Rebuttal Expert Witness Report of Michael Marks,<br>M.D. dated March 23, 2005;<br>D. Second Rebuttal Expert Witness Report of Michael<br>Marks, M.D., dated April 4, 2005; and<br>E. Declaration of Michael Marks, M.D., M.B.A. In<br>Support of Kyphon's Oppositions to Defendants'<br>Summary Judgment Motions, dated April 14, 2005. | FRE 802 |
| 1059 | Marks Ex. 1 | | 2005 | Invoices for Dr. Marks' time spent on Kyphon v. DOT litigation (to be updated) | |
| 1060 | | | 3/2/2005 | Kyphon's 2004 10-K SEC Filing | |



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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1061 | | DOTINC 050478 | 3/3/2005 | X-Ray of Fractured Tibia, Edeland Procedure performed by Dr. David Mitchell | Subject of motion *in limine*. FRE 402 and 403. |
| 1062 | Marks Ex. 13 | MARKS 000472 - 000523 | 3/3/2005 | PowerPoint Presentation: "Osteoporosis, Back Pain and Treatment Options" | |
| 1063 | Marks Ex. 12 | MARKS 000276 – 000325 | 3/14/2005 | PowerPoint Presentation: "Advanced Concepts in Minimally Invasive Vertebral Compression Fracture Management" | |
| 1064 | | KY 387421 – 387432 | 4/1/2005 | Berger License Agreement | |
| 1065 | | | 4/29/2005 | Kyphon's 1Q 2005 10-Q SEC Filing | |
| 1066 | | | 4/29/2005 | Presentation by Dr. James Merritt IV, regarding study of height restoration, presented April 29, 2005 in Charleston, SC | DOT has not produced this document. Therefore Kyphon cannot make specific objections. Kyphon objects to its use as it is simply too late in the case. |
| 1067 | Marks Ex. 5 | | 5/20/2005 | Hand drawn illustration of awl by Dr. Marks | FRE 802, 402, 403 |



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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1068 | Mitchell Ex. 12 | DOTINC 050749 – 050798 | 5/24/2005 | Response to Medicare Coverage Advisory Committee Questions Concerning the Treatment of Vertebral Compression Fractures | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports. In addition, Kyphon objects that it lacks foundation and under FRE 402/403/802. |
| 1069 | | DOTINC 050801-839 | 5/31/2005 | Procedure Summary Spreadsheets | |
| 1070 | Mitchell Ex. 4 | DM 1059 – DM 1109 | N/A | PowerPoint Presentation: "Traumatic Treatment of Spinal Fractures by Kyphoplasty" | |
| 1071 | DOT Appendix Ex. A-1 | | N/A | Curriculum Vitae of Dr. David Mitchell | |
| 1072 | DOT Appendix Ex. C-A | | N/A | Kyphon "Key Points of Difference Between KyphX IBTs and SKy Device" Document | Foundation |
| 1073 | | KY 072428 – 72446 | N/A | KyphX System Demonstration | |



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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1074 | | KY 268929 – 958 | N/A | Meyers, Mark,"Surgical Interventions for Vertebral Compression Fractures: An Update on Procedures and Outcomes" | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports. Also, lack of foundation and FRE 402/403/802. |
| 1075 | | DOTINC 050000 – 050001 | N/A | DOT Marketing Pamphlet: "Vertebral Compression Fractures and Osteoporosis" | |
| 1076 | | DOTINC 050002 – 050003 | N/A | DOT Marketing Pamphlet: "SKy Bone Expander for Percutaneous Vertebral Fracture Reduction" | |
| 1077 | | DOTINC 050012 | N/A | PowerPoint Presentation contained in SKy Presentations Folder: "Updated SKy Presentation" | |
| 1078 | | DOTINC 050012 | N/A | Animation Contained in SKy Bone Expander System Folder: "SKy Bone Expander System" | |
| 1079 | | DOTINC 050743 | N/A | SKy Bone Expander Demonstration Kit/Device | |
| 1080 | | KY 020218-020223 | N/A | Use of Balloon in Tibial Plateau Fractures | FRE 402/403 and 802 |
| 1081 | | DOTINC 003165 – 003279 | N/A | Kyphon Surgeon List | |



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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1082 | Globerman Ex. 195 | DOTLTD 014722-727 | N/A | Document comparing SKy and Balloon Kyphoplasty | |
| 1083 | Mott Ex. 503 | KY 115003-115020 | N/A | Selected Kyphx Product Quick Reference Guide | |
| 1084 | | DOTLTD 002124-27 | N/A | Tecoflex Tube Engineering Drawings | |
| 1085 | Scholten Ex. 524A -527 | | N/A | Pictures of Curetting Device | |
| 1086 | Eisenhart Ex. 352 | DOTLTD 014239 - 14242 | N/A | Schematic of Disc-O-Tech Sky Device Assembly | |
| 1087 | | | N/A | Kyphon Curette CD | |
| 1088 | | | 3/1965 | Gutman, D, et al., "The Use of the Foley Catheter in the Treatment of Zygotic Bone Fractures," Br. J. Oral Surg. March 1965, 27:153-7 | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports; nor was it ever produced during discovery. FRE 402/403. |

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| DTX | Dep. Exhibit or Exhibit to Court Filing[2] | Production No. | Date | Description | Objections |
|---|---|---|---|---|---|
| 1089 | | | 5/1976 | Laufer, D, et al., "Treatment of Fractures of the zygomatic bone," J. Oral Surg. May 1976, 34(5):445-7. | Kyphon objects to the use of this document in expert testimony, as it is not cited in DOT's expert reports; nor was it ever produced during discovery. FRE 402/403. |
| 1090 | | | N/A | Demonstratives to be used by experts | Kyphon objects that demonstratives are not evidence. |

KEY TO KYPHON'S OBJECTIONS TO DOT'S TRIAL EXHIBITS

| | | |
|---|---|---|
| A | = | Authenticity under FRE 901 et. seq. not established |
| C | = | Competency |
| H | = | Hearsay, FRE 802 |
| I | = | Incomplete, FRE 106 |
| IO | = | Improper Opinion Testimony by non-expert |
| IS | = | Improper summary of voluminous writings under FRE 1006 |



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| | | |
|---|---|---|
| M | = | Not material, under FRE 401 |
| P | = | Prejudicial, confusing or misleading, FRE 403 |
| R | = | Not relevant, FRE 402 |
| ? | = | Not sufficiently identified for DOT/Kyphon to determine whether this item constitutes relevant evidence |

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C

FISH & RICHARDSON P.C.

500 Arguello Street
Suite 500
Redwood City, California
94063-1526

Telephone
650 839-5070

Facsimile
650 839-5071

Web Site
www.fr.com

Frederick P. Fish
1855-1930

W.K. Richardson
1859-1951

**VIA FEDERAL EXPRESS**

June 10, 2005

Jonathan M. Sobel
Hogan & Hartson, L.L.P.
875 Third Avenue
New York, NY 10022

Re: Kyphon Inc. v. Disc-O-Tech Medical Technologies, et al.
USDC-D. Del. - C.A. 04-204-JJF

FR

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

Dear Jonathan,

Enclosed please find copies of Kyphon marked trial exhibits PTX 7, 8, 44, and 167-169.

The enclosed copies of Kyphon trial exhibits PTX 7, 8, and 44 replace the copies with the same PTX numbers served on Tuesday, June 7, 2005. We are re-serving PTX 7, 8, and 44 due to modifications of the exhibit list served on June 7, 2005.

Specifically, PTX 7 now includes three versions of SKy Bone Expander System IFUs. It is a combination of previously served PTX 7 and PTX 73, with the addition of DOTLTD 014120-14122.

PTX 8 now includes eight versions of SKy Surgical Technique brochures. It is a combination of previously served PTX 8 and PTX 71, with the addition of DOTINC 001399-001409.

We noted and corrected a typographic error in the bates range description of PTX 44. A full copy of the exhibit is enclosed.

PTX 167-169 are the three patents-in-suit, which are included in Kyphon's exhibit list to be filed with the PTO today.

Following is a list of the exhibit numbers not used: PTX 6, 11, 15, 25, 29, 31, 34, 37, 39, 40, 46, 48, 50, 52, 65, 67, 68, 71, 73, 86, 87, 103, 106, 110, 111, 121, 127, 132, 133, 135, 136, 145, 150-153, 155, 159, and 164. Placeholders for these exhibit numbers are also enclosed for your use.

Very truly yours,



Limin Zheng

enclosure

50282326 (2).doc

# 5

# A

**Appendix 5A**

**Kyphon's June 10, 2005 Witness List**

## I. FACT WITNESSES

Kyphon may call some or all of the following witnesses in its case-in-chief during the liability trial scheduled to begin June 20, 2005.[1] Kyphon may also call any witnesses listed by DOT.

The addresses and telephone numbers of the individuals affiliated with Kyphon are listed as "Kyphon" and can be reached through litigation counsel. Unless otherwise noted, Kyphon intends to have these individuals testify live at trial.

John C. Eisenhart—by deposition
Fleshner & Kim, LLP
2325 Dulles Corner Blvd, Suite 1100
Herndon, VA 20171

Dr. Andrea Halliday
1200 Hilyard St., Suite S530A
Eugene, OR 97401

Richard Mott
Kyphon

Dr. Mark Reiley
Kyphon

Thomas Rielly—by deposition
5300 North Lamar Blvd., Suite 107
Austin, TX 78751

Arie Scholten
Kyphon

[1] Kyphon reserves the right to call some or all of the following witnesses at the damages/willfulness trial, to be scheduled for a later date: Tamir Kazaz (by deposition), William Martin (by deposition), David Mitchell (by deposition), Tom Reilly (by deposition), John Steck (by deposition), and Chad Saunders (by deposition). The witnesses listed for the liability trial may also be called in the damages/willfulness trial, as may any witnesses listed by DOT.

Dr. Karen Talmadge
Kyphon

## II. EXPERT WITNESSES

Kyphon intends to call for following expert witness during the liability trial scheduled to begin June 20, 2005.[2]

Dr. Michael Marks
Coastal Orthopaedics, PC
40 Cross St.
Norwalk CT 06851
(203) 845-2200
specialty: orthopedic surgery

Kyphon's expert has disclosed his opinions in his expert reports and deposition.

[2] In addition, Kyphon presently anticipates calling Brian Napper as a damages expert witness for the damages/willfulness trial, to be scheduled for a later date.

# B

AS OF 6/10/05

**APPENDIX 5B**

**DOT'S LIST OF WITNESSES**

I. FACT WITNESSES

DOT may call each of the following live witnesses:

1. Barak, Ronnie (Phase 3 only)
Disc Orthopaedic Technologies, Inc.
7 Center Dr., Suite 1
Monroe Twp., NJ 08831

2. Beyar, Motti
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot Street, 2nd Floor
Herzliya 46728
Israel

3. Eisenhart, John (Phase 3 only)
Fleshner & Kim LLP
14500 Avion Parkway, Suite 125
Chantilly, VA 20151

4. Globerman, Oren
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot Street, 2nd Floor
Herzliya 46728
Israel

5. Pell, Lewis (Phase 3 only; if necessary as rebuttal on willfulness issues)

DOT reserves the right to call additional witnesses in rebuttal to those witnesses called by Kyphon.

II. EXPERT WITNESSES

DOT may present expert testimony from the following persons. These experts are expected to testify as to the facts and the opinions stated in their expert reports, which are

incorporated herein by reference. In addition, the specialties of these experts are set forth in their respective expert reports and their curriculum vitae thereto.

1. David Mitchell, M.D.
   Orthopedic Associates
   110 Dillon Drive
   Spartanburg, S.C. 29307

2. Christine Meyer, Ph. D. (Phase 3)
   NERA Economic Consulting
   50 Main Street, 14th Floor
   White Plains, NY 10606

# 6

# A

# Appendix 6A

## Kyphon's June 10, 2005 Statement of Anticipated Proofs[1]

Kyphon will offer the following proof at trial:

1) **Background**

   a) The founding and business of Kyphon.

   b) The invention of the patents-in-suit.

   c) The development and commercialization of the patented technology by Kyphon.

   d) Communications and competition with DOT

2) **Infringement by DOT**

   a) Proof that DOT infringes Claims 2, 20, 24, and 26 of U.S. Patent No. 6,235,043.

3) **Validity of Kyphon' Patents**

   a) Proof that rebuts DOT's assertion that Claims 1, 3, 7-9, 11, and 14 of U.S. Patent No. 4,969,888; and Claims 1, 3, 8-10, 12, and 15 of U.S. Patent No. 5,108,404 are anticipated by the prior art.

   b) Proof that rebuts DOT's assertion that Claims 1, 3, 7-9, 11, and 14 of U.S. Patent No. 4,969,888; Claims 1, 3, 8-10, 12, and 15 of U.S. Patent No. 5,108,404; and Claims 17, 20, 24, and 26 of U.S. Patent No. 6,235,043 would have been

[1] This statement of anticipated proofs includes only those proofs for the liability trial starting June 20, 2005, and does not include proofs for the damages/willfulness trial to be scheduled at a later date.

obvious to one of ordinary skill in the art in light of the prior art, including objective indicia of nonobviousness.][2]



[2] As explained in a motion *in limine*, Kyphon believes that the issue of obviousness is not properly presented. However, in the event that the Court decides otherwise, the bracketed, greyed text sets forth Kyphon's statement of anticipated proofs regarding the issue of obviousness.

# B

**APPENDIX 6B**

**DOT'S STATEMENT OF INTENDED PROOF**

DOT reserves the right to review and revise these statements of intended proof based on the Court's claim construction.

I. ISSUES OF INFRINGEMENT OF KYPHON'S PATENTS

A. INFRINGEMENT OF THE '888 AND '404 PATENTS

1. Although Kyphon has the burden of proof on this issue, DOT will prove that DOT has not directly infringed and/or contributorily infringed Kyphon's '888 and/or '404 Patents, either literally or under the doctrine of equivalents. Kyphon's invention requires a balloon. Even if it does not require a balloon, the SKy Device does not "compact" cancellous bone to increase the size of the void, as meant by that term in the asserted claims of the '888 and '404 Patents. The SKy Device does not perform substantially the same function, in substantially the same way, to achieve substantially the same result, with respect to each element of the asserted claims of the '404 and '888 Patents.

B. INFRINGEMENT OF THE '043 PATENT

1. Although Kyphon has the burden of proof on this issue, DOT will prove that DOT has not directly infringed and/or contributorily infringed Kyphon's '043 Patent, either literally or under the doctrine of equivalents. As with the '888 and '404 Patents, the '043 Patent requires an inflatable device. In addition, the '043 Patent requires an internal restraint on the inflatable device, where the restraint and the inflatable device are comprised of two different materials. The SKy Device does not infringe the '043 Patent for at least the following reasons:

a. The SKy Device does not use an inflatable device or an equivalent thereof, as required by all asserted claims of the '043 Patent.

b. The SKy Device does not have internal restraints as required by Claim 2 of the '043 Patent.

c. The SKy Device does not have first and second materials to constrain expansion of the device, as required by Claims 17, 20, 23, 24, 25, 26 and/or 28.

d. The SKy Device does not compact cancellous bone as required by all asserted claims of the '043 Patent.

e. The SKy Device does not perform substantially the same function, in substantially the same way, to achieve substantially the same result, with respect to each element of the asserted claims of the '043 Patent.

C. WILLFULNESS

1. Although Kyphon has the burden of proof on this issue, if Kyphon proves infringement by DOT of the asserted Claims of the '888, '404 and/or '043 Patents, DOT will prove that its infringement was not willful because it did not know of the '888, '404 and/or '043, Patents, and/or had no reason to believe that it was infringing another's valid intellectual property rights.

II. ISSUES OF INVALIDITY OF KYPHON'S PATENTS

A. INVALIDITY OF THE '888 AND '404 PATENTS

1. DOT will prove that the asserted claims of the '888 and/or '404 Patents are invalid by proving at least each of the following, either one of which invalidates the asserted claims:

a. The asserted claims of the '888 and/or '404 Patents are invalid as anticipated by the prior art; and

b. The asserted claims of the '888 and/or '404 Patents are invalid as obvious over the prior art.

B. INVALIDITY OF THE '043 PATENT

1. DOT will prove that the asserted claims of the '043 Patent is invalid by proving at least each of the following, either one of which invalidates the asserted claims:

a. The asserted claims of the '043 Patent are invalid as anticipated by the prior art; and

b. The asserted claims of the '043 Patent are invalid as obvious over the prior art.

III. DAMAGES

DAMAGES RELATED TO THE '888, '404 AND '043 PATENTS

1. Although Kyphon has the burden of proof on this issue, if Kyphon proves infringement by DOT of the asserted claims of the '888, '404 and/or '043 Patents, DOT will prove that Kyphon is not entitled to lost profits, but is entitled to a royalty of at most, 5%, on sales of the SKy Device.

2. Although Kyphon has the burden of proof on this issue, if Kyphon proves infringement by DOT, DOT will prove whether, and in what amount, prejudgment interest should be added to a damages award for infringement.

# 7

# A

**Appendix 7A**

**Kyphon's June 10, 2004 Discovery Designations**

Kyphon designates the following discovery responses for use in the liability trial scheduled to begin June 20, 2005:

1. DOT's responses to Interrogatories 2, 3, 4, 12, 16, 17, 20, and 22 served in the Delaware action.
2. DOT's responses to Requests for Admission 1, 8-10, 24, and 25.
3. DOT, Inc.'s response to Interrogatories 23, 33, 35, 36, 38 served in the ITC action.

# B

**Appendix 7B**
**DOT's Objections to Kyphon's June 10, 2005 Discovery Designations**

| DOT Discovery Response Designated by Kyphon | DOT's Objections |
|---|---|
| DOT Resp. to Interr. No. 2 in Delaware action | |
| DOT Resp. to Interr. No. 3 in Delaware action | |
| DOT Resp. to Interr. No. 4 in Delaware action | DOT objects to the extent this response is used in first trial on liability issues of infringement/validity. |
| DOT Resp. to Interr. No. 12 in Delaware action | DOT objects to the extent this response is used in first trial on liability issues of infringement/validity. |
| DOT Resp. to Interr. No. 16 in Delaware action | DOT objects to the extent this response is used in first trial on liability issues of infringement/validity. |
| DOT Resp. to Interr. No. 17 in Delaware action | DOT objects to the extent this response is used in first trial on liability issues of infringement/validity. |
| DOT Resp. to Interr. No. 20 in Delaware action | DOT objects to the extent this response is used in first trial on liability issues of infringement/validity. |
| DOT Resp. to Interr. No. 22 in Delaware action | DOT objects to the extent this response is used in first trial on liability issues of infringement/validity. |
| DOT Resp. to Request for Admission No. 1 | |
| DOT Resp. to Request for Admission No. 8 | |
| DOT Resp. to Request for Admission No. 9 | |
| DOT Resp. to Request for Admission No. 10 | |
| DOT Resp. to Request for Admission No. 24 | |
| DOT Resp. to Request for Admission No. 25 | |
| DOT Resp. to Interr. No. 23 in ITC | DOT objects to this designation as irrelevant, confusing and prejudicial to the extent it refers to DOT's cessation of (1) importation of accused products and (2) U.S. sales and demonstrations of previously imported accused products.<br><br>DOT further notes that the response to this interrogatory is within the scope of Kyphon's motion *in limine* to preclude DOT's patent applications. |
| DOT Resp. to Interr. No. 33 in ITC | DOT objects to this designation as irrelevant, confusing and prejudicial to the extent it refers to DOT's cessation of (1) importation of accused products and (2) |

| | |
|---|---|
| | U.S. sales and demonstrations of previously imported accused products. |
| DOT Resp. to Interr. No. 35 in ITC | DOT objects to this designation as irrelevant, confusing and prejudicial to the extent it refers to DOT's cessation of (1) importation of accused products and (2) U.S. sales and demonstrations of previously imported accused products. |
| DOT Resp. to Interr. No. 36 in ITC | DOT objects to this designation as irrelevant, confusing and prejudicial to the extent it refers to DOT's cessation of (1) importation of accused products and (2) U.S. sales and demonstrations of previously imported accused products. |
| DOT Resp. to Interr. No. 38 in ITC | DOT objects to this designation as irrelevant, confusing and prejudicial to the extent it refers to DOT's cessation of (1) importation of accused products and (2) U.S. sales and demonstrations of previously imported accused products. |

C

**Appendix 7C**

**DOT's June 10, 2004 Discovery Designations**

DOT designates the following discovery responses for use in the liability trial scheduled to begin June 20, 2005:

Kyphon's responses to Interrogatories 1 and 2, dated October 27, 2004 (PTX 1053).

# D

**Appendix 7D**

**Kyphon's Objections to DOT's Discovery Designations**

Kyphon objects to the designation of its responses to interrogatories 1 and 2 as irrelevant.

# 8

6/10/05

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

**DISC-O-TECH MEDICAL TECHNOLOGIES LTD., AND DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S, PROPOSED FORM OF VERDICT AND SPECIAL INTERROGATORIES**[1]

We, the jury, unanimously find as follows:

**A. Infringement**

**Infringement of U.S. Patent Nos. 4,969,888 (the "'888 Patent") and 5,108,404 (the "'404 Patent)**

1. Has Kyphon proven by a preponderance of the evidence that Disc-O-Tech literally infringed Claim 1 of the '888 and '404 Patents?

**Yes_____ (for Kyphon)** **No_____ (for Disc-O-Tech)**

2. Has Kyphon proven by a preponderance of the evidence that Disc-O-Tech infringed Claim 1 of the '888 and '404 Patents under the doctrine of equivalents?

**Yes_____ (for Kyphon)** **No_____ (for Disc-O-Tech)**

[1] This form lists just one claim per patent group, to be supplemented as required before submission to the jury.

**Infringement of U.S. Patent No. 6,235,043 (the '043 Patent")**

3. Has Kyphon proven by a preponderance of the evidence that Disc-O-Tech literally infringed Claim 17 of the '043 Patent?

**Yes_____ (for Kyphon)** **No_____ (for Disc-O-Tech)**

4. Has Kyphon proven by a preponderance of the evidence that Disc-O-Tech infringed Claim 17 of the '043 Patent under the doctrine of equivalents?

**Yes_____ (for Kyphon)** **No_____ (for Disc-O-Tech)**

## B. Invalidity

**Invalidity of the '404 Patent – Anticipation**

5. Has Disc-O-Tech proven by clear and convincing evidence that the following claims of the '404 Patent are anticipated, and therefore invalid?

| | | |
|---|---|---|
| Claim 1 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 3 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 8 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 9 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 10 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 12 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 15 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |

If you answered yes to Question 5 as to one or more claims, indicate the anticipated claims of the '404 patent by each of the following prior art references:

| **Prior Art References** | **Anticipated Claim(s)** |
|---|---|
| Article entitled "Transpedicular Fixation of Thoracolumbar Vertebral Fractures" by Olerud et al., February 1988 ("Olerud"). | _____ |

Article entitled "Open Reduction of Central Compression Fractures of the Tibial Plateau" by Edeland, 1976 ("Edeland"). _____

Article entitled "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," by Kennedy, 1978 ("Kennedy"). _____

Article entitled "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," by Daniaux, 1986 ("Daniaux 1986"). _____

Article entitled "Therapeutic Concept and Results of Operative Treatment in Acute Trauma of the Thoracic and Lumbar Spine: The Hannover Experience," by Blauth, 1987 ("Blauth"). _____

Chapter 35 in Operative Orthopaedics, by Schatzker, 1988 ("Schatzker"). _____

**Invalidity of the '888 Patent – Anticipation**

6. Has Disc-O-Tech proven by clear and convincing evidence that the following claims of the '888 Patent are anticipated, and therefore invalid?

| | | |
|---|---|---|
| Claim 1 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 3 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 7 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 8 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 9 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 11 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 14 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |

If you answered yes to Question 6 as to one or more claims, indicate the anticipated claims of the '888 patent by each of the following prior art references:

| **Prior Art References** | **Anticipated Claim(s)** |
|---|---|
| Article entitled "Transpedicular Fixation of Thoracolumbar Vertebral Fractures" by Olerud et al., February 1988 ("Olerud"). | _____ |
| Article entitled "Open Reduction of Central Compression Fractures of the Tibial Plateau" by Edeland, 1976 ("Edeland"). | _____ |
| Article entitled "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," by Kennedy, 1978 ("Kennedy"). | _____ |
| Article entitled "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," by Daniaux, 1986 ("Daniaux 1986"). | _____ |
| Article entitled "Therapeutic Concept and Results of Operative Treatment in Acute Trauma of the Thoracic and Lumbar Spine: The Hannover Experience," by Blauth, 1987 ("Blauth"). | _____ |
| Chapter 35 in Operative Orthopaedics, by Schatzker, 1988 ("Schatzker"). | _____ |

**Invalidity of the '404 Patent – Obviousness**

7. Has Disc-O-Tech proven by clear and convincing evidence that the following claims of '404 Patent are invalid for obviousness?

| | | |
|---|---|---|
| Claim 1 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 3 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |

| | | |
|---|---|---|
| Claim 8 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 9 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 10 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 12 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 15 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |

If you answered yes to Question 7 as to one or more claims, indicate the claims of the '404 patent rendered obvious by any of the following references alone, or in combination with one of more of the other references listed here:

| **Prior Art References** | **Claim(s) Rendered Obvious** |
|---|---|
| Article entitled "Transpedicular Fixation of Thoracolumbar Vertebral Fractures" by Olerud et al., February 1988 ("Olerud"). | _____ |
| Article entitled "Open Reduction of Central Compression Fractures of the Tibial Plateau" by Edeland, 1976 ("Edeland"). | _____ |
| Article entitled "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," by Kennedy, 1978 ("Kennedy"). | _____ |
| Article entitled "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," by Daniaux, 1986 ("Daniaux 1986"). | _____ |
| Article entitled "Therapeutic Concept and Results of Operative Treatment in Acute Trauma of the Thoracic and Lumbar Spine: The Hannover Experience," by Blauth, 1987 ("Blauth"). | _____ |

Chapter 35 in Operative Orthopaedics, by Schatzker, 1988 ("Schatzker").

Chapter 44 in Campbell's Operative Orthopaedics, 1987 ("Campbell").

Article entitled "Treated by Percutaneous Poking Reduction and Internal Fixation," by Ma, 1984 ("Ma").

Article entitled "Technik und Ergebnisse der transpedikulären Spongiosaplastik bei Kompressionsbrüchen im Lendenwirbelsäulenbereich," Daniaux, 1982 ("Daniaux 1982").

Article entitled "Use of the Acetabular Reamer to Harvest Autogeneic Bone Graft Material: A Simple Method for Producing Bone Paste," by Dick, 1986 ("Dick 1986").

Article entitled "The Use of Methylmethacrylate in Repair of Neoplastic Lesions in Bone," by Carlson, 1974 ("Carlson").

U.S. Patent No. 4,518,430, issued on May 21, 1985 to Brown et al. ("Brown and Chow patent").

Article entitled "Effect of Cyrosurgery and Polymethyl Methacrylate on the Tumor Cavity," by Malawer and Marks, 1987 ("Malawer and Marks article").

Chapter entitled "Effectiveness of Methyl Methacrylate as a Physical adjuvant in Local Tumor Control," 1987 ("Limb Salvage chapter").

**Invalidity of the '888 Patent – Obviousness**

8. Has Disc-O-Tech proven by clear and convincing evidence that the following claims of 888 Patent are invalid for obviousness?

| | | |
|---|---|---|
| Claim 1 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 3 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 7 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 8 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 9 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 11 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 14 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |

If you answered yes to Question 8 as to one or more claims, indicate the claims of the '888 patent rendered obvious by any of the following references alone, or in combination with one of more of the other references listed here:

| **Prior Art References** | **Claim(s) Rendered Obvious** |
|---|---|
| Article entitled "Transpedicular Fixation of Thoracolumbar Vertebral Fractures" by Olerud et al., February 1988 ("Olerud"). | _____ |
| Article entitled "Open Reduction of Central Compression Fractures of the Tibial Plateau" by Edeland, 1976 ("Edeland"). | _____ |
| Article entitled "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," by Kennedy, 1978 ("Kennedy"). | _____ |
| Article entitled "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," by Daniaux, 1986 ("Daniaux 1986"). | _____ |

Article entitled “Therapeutic Concept and Results of Operative Treatment in Acute Trauma of the Thoracic and Lumbar Spine: The Hannover Experience,” by Blauth, 1987 (“Blauth”). _____

Chapter 35 in Operative Orthopaedics, by Schatzker, 1988 (“Schatzker”). _____

Chapter 44 in Campbell's Operative Orthopaedics, 1987 (“Campbell”). _____

Article entitled “Treated by Percutaneous Poking Reduction and Internal Fixation,” by Ma, 1984 (“Ma”). _____

Article entitled “Technik und Ergebnisse der transpedikulären Spongiosaplastik bei Kompressionsbrüchen im Lendenwirbelsäulenbereich,” Daniaux, 1982 (“Daniaux 1982”). _____

Article entitled “Use of the Acetabular Reamer to Harvest Autogeneic Bone Graft Material: A Simple Method for Producing Bone Paste,” by Dick, 1986 (“Dick 1986”). _____

Article entitled “The Use of Methylmethacrylate in Repair of Neoplastic Lesions in Bone,” by Carlson, 1974 (“Carlson”). _____

U.S. Patent No. 4,518,430, issued on May 21, 1985 to Brown et al. (“Brown and Chow patent”). _____

Article entitled “Effect of Cyrosurgery and Polymethyl Methacrylate on the Tumor Cavity,” by Malawer and Marks, 1987 (“Malawer and Marks article”). _____

Chapter entitled "Effectiveness of Methyl Methacrylate as a Physical adjuvant in Local Tumor Control," 1987 ("Limb Salvage chapter"). _____

**Invalidity of the '043 Patent – Obviousness**

9. Has Disc-O-Tech proven by clear and convincing evidence that the following claims of '043 Patent are invalid for obviousness?

| | | |
|---|---|---|
| Claim 17 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 20 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 24 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |
| Claim 26 | **Yes_____ (for Disc-O-Tech)** | **No_____ (for Kyphon)** |

If you answered yes to Question 9 as to one or more claims, indicate the claims of the '043 patent rendered obvious by any of the following references alone, or in combination with one of more of the other references listed here:

| **Prior Art References** | **Claim(s) Rendered Obvious** |
|---|---|
| U.S. Patent No. 3,626,949, issued on December 14, 1971 to Shute (" '949 Patent"). | _____ |
| U.S. Patent No. 4,878,495, issued on November 7, 1989 to Grayzel (" '495 Patent"). | _____ |
| U.S. Patent No. 4,909,252, issued on March 20, 1990 to Goldberger (" '252 Patent"). | _____ |

U.S. Patent No. 5,049,132, issued on September 17, 1991 to Shaffer et al. (" '132 Patent").

U.S. Patent No. 5,108,404, issued on April 28, 1992 to Scholten et al. (" '404 Patent").

You must each sign this verdict form

Dated: _____

(Foreperson)

_____

_____

_____

_____

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_____

# 9

## Appendix 9

## DOT's [Proposed] Preliminary Jury Instructions

Members of the jury:

Now that you have been sworn, I have the following preliminary instructions for guidance on your role as jurors in this case.

### The Parties

This case is an action for patent infringement arising under the patent laws of the United States. The parties are Kyphon, the plaintiff, and Disc-O-Tech Medical Technologies, Ltd and Disc Orthopaedic Technologies, Inc., the defendants. Disc-O-Tech Medical Technologies, Ltd and Disc Orthopaedic Technologies, Inc. are collectively referred to as "DOT."

Plaintiff is the owner of United States Patent Nos. 4,969,888; 5,108,404; 6,235,043; 6,241,734; and 6,613,054. The lawyers and witnesses in this case may refer to these patents collectively as "the patents-in-suit," or individually by the last three numbers of the patents. Plaintiff contends that defendants make, sell, and offer for sale certain surgical devices that infringe or are used to infringe the patents-in-suit. Noninfringement and invalidity are defenses to a charge of infringement. In this action, DOT denies that it infringes the patent. It also contends that the patents are invalid.

### Patent Law — General

The video you will now see will introduce to you the basics of the patent process.

[Federal Judicial Court Video]

You will hear many of the terms used in the video during the trial. They are summarized in the "Glossary of Patent Terms," which will be given to you along with these instructions. Feel free to refer to this glossary throughout the trial.

## Summary of the Patent Issues

In this case, you must decide several things according to the instructions that I shall give you at the end of the trial. Those instructions will repeat this summary and will provide more detail. In essence, you must decide:

1. Whether Kyphon has proven by a preponderance of the evidence that DOT has infringed any of the asserted claims of the patents-in-suit.

2. If you find any of the asserted claims of the patents-in-suit are infringed, whether Kyphon has proven by clear and convincing evidence that DOT's infringement was willful.

3. Whether DOT has proven by clear and convincing evidence that any of the asserted claims of the patents-in-suit are invalid.

4. If you find any of the asserted claims of the patents-in-suit are valid and infringed, what amount of damages, if any, Kyphon has proven by a preponderance of the evidence is due to it.

## Duty of Jury

It will be your duty to find what the facts are from the evidence as presented at the trial. You, and you alone, are the judges of the facts. You will have to apply those facts to the law as I will instruct you at the close of the evidence. You must follow that law whether you agree with it or not.

You are the judges of the facts. I will decide which rules of law apply to this case.

Nothing I say or do during the course of the trial is intended to indicate what your verdict should be.

**Evidence**

The evidence from which you will find the facts will consist of the testimony of witnesses, and documents and other things admitted into evidence. In addition, the evidence may include certain facts as agreed to by the parties or as I instruct you.

Certain things are not evidence.

1. Statements, arguments, and questions by lawyers are not evidence.

2. Objections to questions are not evidence. Lawyers have an obligation to their clients to make an objection when they believe testimony or exhibits being offered into evidence are not admissible under the rules of evidence. You should not be influenced by a lawyer's objection or by my ruling on the objection. If I sustain or uphold the objection, and find the matter is not admissible, you should ignore the question or document. If I overrule an objection and allow the matter in evidence, you should treat the testimony or document like any evidence. If I instruct you during the trial that some item of evidence is admitted for a limited purpose, you must follow that instruction and consider that evidence for that purpose only. If this does occur during the trial I will try to clarify this for you at that time.

3. Anything you see or hear outside the Courtroom is not evidence and must be disregarded. You are to decide this case solely on the evidence presented here in the Courtroom.

In judging the facts, it will be up to you to decide which witnesses to believe, which witnesses not to believe, and how much of any witness's testimony to accept or reject.

**Burden of Proof**

This is a civil case. Kyphon has the burden of proving infringement and damages by what is called a preponderance of the evidence. That means Kyphon has to produce evidence which, when considered in the light of all the facts, leads you to believe that what Kyphon claims is more likely true than not. To put it differently, if you were to put Kyphon's and DOT's evidence on the opposite sides of a scale, the evidence supporting Kyphon's claims would have to make the scales tip somewhat on its side.

In this case, DOT is urging that Kyphon's patents are invalid. A patent, however, is presumed to be valid. Accordingly, DOT has the burden of proving that the patents-in-suit are invalid by clear and convincing evidence. Clear and convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable. Proof by clear and convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable. Proof by clear and convincing evidence is thus a higher burden then proof by a preponderance of the evidence.

Some of you may have heard the phrase "proof beyond a reasonable doubt." That burden of proof applies only in criminal cases and has nothing to do with a civil case like this one. You should therefore not consider it in this case.

**Conduct of the Jury**

Now, a few words about your conduct as jurors.

First, during the trial and until you have heard all of the evidence and retired to the jury room to deliberate, you are not to discuss the case with anyone, not even among yourselves. If anyone should try to talk to you about the case, bring it to my attention promptly.

Second, do not read or listen to anything touching on this case that is not admitted into evidence. By that I mean, if there may be a newspaper article or radio or television

report relating to this case, do not read the article or watch or listen to the report. In addition, do not try to do any independent research or investigation on your own on matters relating to the case.

Finally, do not reach any conclusion as to the claims until all of the evidence is in. Keep an open mind until you start your deliberations at the end of the case.

If you wish, you may take notes. My Courtroom deputy will arrange for pens, pencils and paper. If you do take notes, leave them in the jury room when you leave at night. And remember that they are for your own personal use-they are not to be given or read to anyone else.

**Course of the Trial**

The trial will now begin. First, each side may make an opening statement. An opening statement is neither evidence nor argument. It is an outline of what that party intends to prove, and is presented to help you follow the evidence as it is offered.

After the opening statements, the plaintiff will present its witnesses, and the defendants may cross-examine them. Then the defendants will present their witnesses, and the plaintiff may cross-examine them.

After all of the evidence is presented, the attorneys will make their closing arguments to summarize and interpret the evidence for you, and I will give you instructions on the law and describe for you the matters you must resolve.

You will then retire to the jury room to deliberate on your verdict.

At the end of this trial and before you begin your deliberations, I will read and give you a copy of written instructions on the law.

## GLOSSARY OF PATENT TERMS

| | |
|---|---|
| Assignment | Transfer of ownership rights in a patent or patent application from one person or company to another. |
| Claims | That part of a patent which defines the metes and bounds of the invention. These are found at the end of the patent specification in the form of numbered paragraphs. |
| Disclosure of description | That part of the patent specification which explains how the invention works and usually includes a drawing. |
| File wrapper | The written record of proceedings in the United States Patent and Trademark Office (Patent Office or PTO) including the original patent application and subsequent communications between the Patent Office and applicant. |
| Patent Application | The initial papers filed in the Patent Office by an applicant. These typically include a specification, drawings and the oath (Declaration) of applicant. |
| Patent Examiners | Personnel employed by the Patent Office having expertise in various technical areas who review (examine) patent applications to determine whether the claims of a patent application are patentable and the disclosure adequately describes the invention. |
| Prior art | Any information which is used to describe public, technical knowledge prior to the invention by applicant or more than a year prior to his/her application. |
| References | Any item of prior art (publication or patent) used to determine patentability. |
| Specification | That part of the patent application or patent that describes the invention and concludes with one or more claims. |