ANTICIPATION OF THE '888 PATENT BY SCHATZKER

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

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

Indeed, Kyphon acknowledged in its 510(k) Premarket Notification Submission to the FDA that its balloon device (the sole embodiment of the '888 Patent) has the "same intended use" as the conventional bone tamp disclosed in Schatzker to reduce fractures and/or create voids. (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842)[4]

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

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

Claim of the '888 Patent	Schatzker
forming a passage in the bone marrow;	Schatzker discloses the introduction of a bone punch or periosteal elevator below the depressed tibial fragments, thereby forming a passage in the cancellous bone. (Fig. 35-9 and text, p. 428) Schatzker also discloses creation of a window by fenestration and insertion of a bone punch through the window; fenestration involves drilling to form a passage in cancellous bone. (Text and Fig. 35-11, pp. 429-430)
compacting the bone marrow to increase the volume of said passage; and	Schatzker teaches the collective elevation of fragments "from their impacted position in the cancellous bone of the metaphysis . . . . To initiate the elevation, insert a periosteal elevator deeply into the compacted cancellous bone of the metaphysis below the fragments. Then, with upward pressure, dislodge the whole segment and complete the reduction with a punch . . ." (p. 428) "[E]n masse elevation of fragments consists of insertion of a bone punch deep to the depressed fragments. Upward blows on the punch effect the reduction." (Fig. 35-9, p. 428) Schatzker further discloses that this procedure creates a hole (i.e. cavity) in the metaphysis below the fragments. (p. 428) Indeed, Kyphon acknowledged in its 510(k) Premarket Notification Submission to the FDA that its balloon device (the sole embodiment of the '888 Patent) has the "same intended use" as the conventional bone tamp disclosed in Schatzker to reduce fractures and/or create voids. (Kyphon's 510(k) at 7-3 and 7-4, KY004841-4842) The pressure of the instruments compacts the cancellous bone on its way to, and in the process of, elevating the fracture, thereby increasing the volume of the passage.

Claim of the '888 Patent	Schatzker
filling the passage with a flowable material capable of setting to a hardened condition.	Schatzker discloses that the procedure produces a hole (i.e. cavity) that can be filled with a "massive bone graft" or bone cement, thereby filling the passage with flowable material capable of setting to a hardened condition. (p. 428)
3. A method as set forth in claim 1, wherein said compacting step includes forcing the osteoporotic bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. In Schatzker, the pressure of the instruments forces the cancellous bone outwardly of the central portion of the bone in order to create a large cavity. (p. 428)
7. A method as set forth in claim 1, wherein said forming step includes drilling said osteoporotic bone marrow to form said passage.	*See* above at claim 1. Schatzker discloses creation of a window by fenestration and insertion of a bone punch through the window; fenestration involves drilling to form a passage in cancellous bone. (Text and Fig. 35-11, pp. 429-430)
8. A method as set forth in claim 7, wherein said drilling step includes guiding a drill through into the proximate corticol bone marrow.	
9. A method as set forth in claim 7, wherein said forming step includes drilling the osteoporotic bone marrow to a predetermined depth.	
11. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	

Claim of the '888 Patent	Schatzker
14. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	*See* above at claim 1. Schatzker discloses that the procedure produces a hole (i.e. cavity) that can be filled with bone cement, thereby filling the passage with a flowable material capable of setting to a hardened condition. (p. 428)

OBVIOUSNESS OF '888 PATENT IN VIEW OF ONE OR MORE OF EDELAND, OLERUD, KENNEDY, DANIAUX 1986, BLAUTH, SCHATZKER, CAMPBELL, MA, DANIAUX 1982, DICK 1986, AND/OR CARLSON REFERENCES

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how one or more of the asserted claims of the '888 Patent is rendered obvious by one or more of the following prior art references:

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

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

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

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

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

To one of ordinary skill in the art, there would have been a suggestion and motivation to combine any of the references above because all of the references pertain to the treatment of a fractured or diseased bone. Each of these references was publicly available to one of ordinary skill in the art prior to the effective filing date of the '888 patent. Moreover, prior to the effective date of the '888 patent, it was well known to those of ordinary skill in the art that treatments for compressed tibial plateau fractures were similar to treatments for compressed vertebral body fractures. The table below sets forth the elements that each of the references teaches. I reserve the right to supplement, modify or amend my opinions.

Claim of the '888 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References
1. A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic bone marrow therein comprising:	This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '888 patent.
forming a passage in the bone marrow;	This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '888 patent. In addition to these references, Campbell discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.
compacting the bone marrow to increase the volume of said passage; and	This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '888 patent. In addition to these references, each of Campbell, Ma, and Daniaux 1982 discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.
filling the passage with a flowable material capable of setting to a hardened condition.	This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '888 patent. In addition to these references, each of Dick 1986 and Carlson discloses this element, as set forth in the obviousness chart with respect to the '404 patent.

Claim of the '888 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References
3. A method as set forth in claim 1, wherein said compacting step includes forcing the osteoporotic bone marrow outwardly of the central portion of the bone.	*See* above at claim 1. This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '888 patent. In addition to these references, each of Campbell and Daniaux 1982 discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.
7. A method as set forth in claim 1, wherein said forming step includes drilling said osteoporotic bone marrow to form said passage.	*See* above at claim 1. This element is anticipated and rendered obvious by each of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, and Schatzker, as set forth in the anticipation charts with respect to the '888 patent. In addition to these references, Campbell discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.
8. A method as set forth in claim 7, wherein said drilling step includes guiding a drill through into the proximate corticol bone marrow.	*See* above at claim 7. This element is anticipated and rendered obvious by each of Edeland, Olerud, Daniaux 1986, and Blauth, as set forth in the anticipation charts with respect to the '888 patent.
9. A method as set forth in claim 7, wherein said forming step includes drilling the osteoporotic bone marrow to a predetermined depth.	*See* above at claim 7. This element is anticipated and rendered obvious by each of Edeland, Olerud, Daniaux 1986, and Blauth, as set forth in the anticipation charts with respect to the '888 patent.

Claim of the '888 Patent	One or More of Edeland, Olerud, Kennedy, Daniaux 1986, Blauth, Schatzker, Campbell, Ma, Daniaux 1982, Dick 1986, and/or Carlson References
11. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	*See* above at claim 1. This element is anticipated and rendered obvious by each of Olerud, Blauth, and Daniaux 1986, as set forth in the anticipation charts with respect to the '888 patent. In addition, each of Olerud and Daniaux 1986 discloses the similarities between the treatment of tibial fractures and vertebral fractures, as set forth in the obviousness chart with respect to the '404 patent.
14. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	*See* above at claim 1. This element is anticipated and rendered obvious by each of Edeland, Kennedy, and Schatzker, as set forth in the anticipation charts with respect to the '888 patent. In addition to these references, Carlson discloses and renders obvious this element, as set forth in the obviousness chart with respect to the '404 patent.

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

In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the chart set forth below illustrates how one or more of the asserted claims of the '043 Patent is rendered obvious by the combination of the '404 Patent with one or more of the following prior art references: U.S. Patent No. 5,049,132, U.S. Patent No. 4,878,495, U.S. Patent No. 4,909,252, and U.S. Patent No. 3,626,949. To one of ordinary skill in the art, there would have been a suggestion and motivation to combine any of the references above because all of the references pertain to constrained expansion of inflatable medical devices. Each of these references was publicly available to one of ordinary skill in the art prior to the effective filing date of the '043 patent. The table below sets forth the elements that each of the references teaches. I reserve the right to supplement, modify or amend my opinions.

Claim of the '043 Patent	Combination of '404 Patent with '132, '495, '252 and/or '949 Patents
2. A method for treating bone comprising the steps of inserting inside bone a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, including the body includes [sic] material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone,	The sole embodiment of the '404 Patent is an inflatable balloon (i.e. a body comprising an expandable wall). In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the '404 Patent discloses inserting inside the bone a balloon adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, with material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone. (Col. 2, ll. 33-38; Col. 2, ll. 15-19; Fig. 28)

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

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

Claim of the '043 Patent	Combination of '404 Patent with '132, '495, '252 and/or '949 Patents
20. A method according to claim 1 or 2 or 8 or 17 wherein the constrained expansion lifts vertebral end plates.	*See* above at claim 2 or 17. The '404 Patent discloses the fixation of vertebral body compression.
23. A method according to claim 1 or 2 or 8 or 17 wherein the constrained expansion lifts cortical bone.	*See* above at claim 2 or 17. The inflatable balloon disclosed in the '404 Patent undergoes expansion in the cancellous bone to compact cancellous bone (Col. 2., ll. 15-19) and applies force capable of moving fractured cortical bone. (Fig. 28)
24. A method according to claim 1 or 2 or 8 or 17 wherein the step of compacting forms a cavity.	*See* above at claim 2 or 17. In light of Kyphon's contention that the term "bone marrow" should be construed to include cancellous bone, and Kyphon's contention as to how "compacting" should be construed in the context of the patent, the '404 Patent discloses that the inflated balloon compacts cancellous bone and leaves a void in the interior of the vertebral body. (Col. 7, ll. 26-34)
25. A method according to claim 24 further including the step of filling the cavity with a material.	*See* above at claim 24. Claim 1 of the '404 Patent includes "filling the passage with a flowable material capable of setting to a hardened condition."
26. A method according to claim 25 wherein the material comprises bone cement.	*See* above at claim 25. Claim 15 of the '404 Patent is dependant on Claim 1 and sets forth the limitation: "wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement."
27. A method according to claim 25 wherein the material comprises synthetic bone substitute.	*See* above at claim 25. Claim 15 of the '404 Patent is dependant on Claim 1 and sets forth the limitation: "wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement."

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

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KYPHON'S MOTION *IN LIMINE* 4 OF 5

Motion *In Limine* to Preclude Admission of, or Reference to, Any DOT Patents or Patent Applications that Cover the Accused Device

DOT purportedly has patents or patent applications[1] that cover various portions of the accused SKy Bone Expander System. Because any such patents are not relevant to any issue being decided by the jury, Kyphon moves *in limine* to exclude reference to any of DOT's patents that purportedly cover the accused the device, as well as any testimony or argument related to them under FRE 401 and 402. Even if DOT were to articulate some way in which any such patents could conceivably be viewed as having relevance to these proceedings, the danger of the jury being confused or misled is high and the evidence addressing, explaining and distinguishing DOT's patents would not be an efficient use of the Court's or the jury's time. Therefore, Kyphon moves, in the alternative, to exclude any DOT patents that cover the accused devices, and any reference or argument regarding any such patents, under FRE 403.

The Court has previously addressed this precise issue and precluded admission of patents on the defendant's accused device. In *CIENA v. Corvis*, C.A. No. 00-662-JJF, the patentee moved to exclude "any mention of Corvis' separate patents during the course of the instant trial." *CIENA* Order, D.I. 517 at 2. After noting the Federal Circuit's position that "it is well established that separate patentability does not avoid equivalency as a matter of law," this Court ruled that the accused infringer's separate patents were irrelevant to the issue of infringement. *Id.* (quoting *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1324 (Fed.Cir. 2000)). Also, in the alternative, this Court ruled that to the extent the accused infringer's patents had any relevance, "their probative value is

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[1] Kyphon will use the generic term "patent" hereafter to refer to both patents and patent applications.

substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury and thus will be excluded under Rule 403 of the Federal Rules of Evidence." *Id.* at 3. The Court quoted *Union Carbide Corp. v. Tarancon Corp.*, 742 F.Supp. 1565, 1577 (N.D. Ga. 1990), as follows:

> [M]ost lay people believe that once they receive a patent, their invention has been held unique and non-infringing. Lay persons are often surprised by the idea that they can still be responsible for infringing another dominating patent.

CIENA Order, D.I. 517 at 3. This Court's Order in *CIENA* went on to explain:

> In the Court's experience, the likelihood of jury confusion in a complex patent trial is high and, in the Court's view, introducing the issue of separate patentability in this case makes the likelihood of jury confusion even higher. In contrast the probative value of the separate patentability of the accused product is marginal. Separate patentability represents the Patent and Trademark Office's ("PTO") conclusion regarding the patentability of some aspect of the accused product. However, because separate patentability is merely a conclusion, it is not helpful to the jury. The danger here is that the jury will forgo reaching its own conclusion and adopt the one presented to it.

Id. Here, the lack of relevance of DOT's patents on the accused device, as well as the risk of confusion to the jury, similarly requires exclusion of any such patents.

Moreover, decisions from both the Federal Circuit and the U.S. Supreme Court are consistent with the approach adopted by this Court in *CIENA*. In *Blanchard v. Putnam*, 75 U.S. 420 (1869), the accused infringer introduced evidence that it had a license under a different patent and that the accused device was built in accord with that separate patent. The Court ruled that this evidence was irrelevant to the issue of infringement and should not have been admitted:

> What the jury have to determine is, does the machine of the defendant infringe the machine of the plaintiff; and if it does not, then the defendant is entitled to a verdict; but if it does infringe the plaintiff's machine, then the plaintiff is entitled to his remedy, and **it is no answer to the cause of action to plead or prove that the defendant is the licensee of the owner**

> **of another patent, and that his machine is constructed in accordance with that patent**.

Id. at 426 (emphasis added). *See also id.* at 425 (noting that evidence of the patent covering the accused device was "well calculated to mislead the jury by withdrawing their attention from the real subject-matter in controversy"); *Id.* at 426 ("[a]ttempts are often made in the trial of patent cases to introduce such collateral issues on the question of infringement, but they are irregular and cannot be sanctioned").

Similarly, in *Fiskars*, when the trial court properly refused to allow the introduction of a patent covering the accused device, the Federal Circuit stated:

> Hunt complains that the district court did not permit Hunt to present evidence to the jury of the separate patentability of its device. Since it is well established that separate patentability does not avoid equivalency as a matter of law, *see Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1580, 224 USPQ 409, 417 (Fed.Cir.1984) ("where defendant has appropriated the material features of the patent in suit, infringement will be found 'even when those features have been supplemented and modified to such an extent that the defendant may be entitled to a patent for the improvement.' "), we do not intrude upon the trial court's evidentiary ruling [citations omitted]. **The admission or exclusion of evidence *not* material to the issue of infringement is consigned to the discretion of the trial judge**.

Fiskars, 221 F.3d at 1324 (emphasis added); *see also Glaros v. H.H. Robertson Co.*, 797 F.2d 1564 (Fed.Cir. 1986) (affirming refusal of district court to admit evidence of other patent applications, other patents, a patent application declaration, an interference between the parties, and "**a patent on the accused product**," noting such evidence "would have **injected frolics and detours** and would have required introduction of counter-evidence, all likely to create side issues that would have unduly distracted the jury from the main issues.") (emphasis added).

Thus, because evidence regarding any DOT patents covering the accused devices is basically irrelevant and would only serve to confuse members of the jury, Kyphon respectfully requests that the Court exclude evidence regarding any such patents, and preclude DOT from referencing them during trial, pursuant to FRE 401, 402 and/or 403.

RULE 7.1.1 CERTIFICATION

Pursuant to Local Rule 7.1.1, counsel for Kyphon certifies that it has in good faith undertaken reasonable efforts, via email and phone, in an attempt to confer with counsel for defendants to discuss the issues raised in Kyphon's Motion *In Limine* to Preclude Admission of, or Reference to, Any DOT Patents or Patent Applications that Cover the Accused Device, but the efforts of Kyphon's counsel have not, to date, been successful.

CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIENA CORPORATION and CIENA PROPERTIES, INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 00-662-JJF
CORVIS CORPORATION,	:	
Defendant.	:	

MEMORANDUM ORDER

In a February 11, 2003, letter Motion, Ciena Corporation and Ciena Properties, Inc. ("Ciena") objected to Corvis Corporation's ("Corvis") opening statement reference to Corvis' separate patents that are not in suit and requested that Corvis be prohibited from making further reference to such patents during the remainder of the trial. During trial on February 14, 2003, the Court sustained Ciena's objection and stated it would subsequently provide its reasoning in writing. See Trial Transcript, Vol. 5, p. 1029:7-22. This Memorandum Order sets forth the Court's reasoning for its February 14, 2003, ruling.

Ciena contends that Corvis' separate patents are irrelevant to the infringement issue before the jury. Moreover, Ciena, relying on Union Carbide Corp. v. Tarancon Corp., 742 F. Supp. 1565 (N.D. Ga. 1990), further contends that the introduction of Corvis' separate patents in this case would be confusing to the

jury. Thus, Ciena moves for the exclusion of any mention of Corvis' separate patents during the course of the instant trial.

In response, Corvis contends evidence regarding its separate patents is probative on the issue of infringement under the doctrine of equivalents. Corvis intends to demonstrate that there are substantial differences between its products and the patents-in-suit, and it contends that the separate patentability of components of its system is relevant to showing that difference. Additionally, Corvis contends that evidence of separate patentability demonstrates the nonobviousness of the accused devices.

"[I]t is well established that separate patentability does not avoid equivalency as a matter of law." Fiskars, Inc. v. Hunt Mfg. Co., 221 F.3d 1318, 1324 (Fed. Cir. 2000). "The grant of a separate patent on the accused device does not automatically avoid infringement, either literal or by equivalency.... Whether a modified device is within the scope of the prior patent, literally or by equivalency, depends on the particular facts." National Presto Industries, Inc. v. West Bend Co., 76 F.3d 1185, 1191-92 (Fed. Cir. 1996).

Based on the facts of the instant case, the Court concluded that Corvis' separate patents are irrelevant to the issue of infringement. See Fed. R. Evid. 401, 402. Moreover, the Court

concludes that even if the separate patents were relevant, their probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury and thus will also be excluded under Rule 403 of the Federal Rules of Evidence. Allowing evidence of separate patentability of an accused product is likely to lead lay people to believe that the accused product is unique and non-infringing. See Union Carbide Corp. v. Tarancon Corp., 742 F. Supp. 1565, 1577 (N.D. Ga. 1990)("most lay people believe that once they receive a patent, their invention has been held unique and non-infringing. Lay persons are often surprised by the idea of that they can still be responsible for infringing another dominating patent."). In the Court's experience, the likelihood of jury confusion in a complex patent trial is high and, in the Court's view, introducing the issue of separate patentability in this case makes the likelihood of jury confusion even higher. In contrast, the probative value of the separate patentability of the accused product is marginal. Separate patentability represents the Patent and Trademark Office's ("PTO") conclusion regarding the patentability of some aspect of the accused product. However, because separate patentability is merely a conclusion, it is not helpful to the jury. The danger here is that the jury will forgo reaching its own conclusion and adopt the one presented to it.

For the above reasons, the Court sustained Ciena's objection and barred evidence of the separate patentability of Corvis' accused product.

NOW THEREFORE, IT IS HEREBY ORDERED that evidence of the separate patentablility of Corvis' accused product is inadmissible during the infringement phase of trial.

3/19/03
DATE

UNITED STATES DISTRICT JUDGE

3

KYPHON'S MOTION *IN LIMINE* 3 OF 5

Motion *In Limine* to Preclude Admission of, or Reference to, Kyphon's Discussions with the FDA Regarding Kyphon's Commercial KyphX IBT Devices

Kyphon sells devices known as KyphX IBTs ("Inflatable Bone Tamps") that are commercial embodiments of asserted U.S. Patents '888, '404, and '043. To secure approval to market the KyphX IBTs for use in kyphoplasty surgeries to repair vertebrae in the spine, Kyphon submitted information regarding the KyphX IBTs to the Food and Drug Administration (FDA). DOT now seeks to use statements regarding the KyphX commercial device to support DOT's assertions: (i) that various asserted patent claims are anticipated and/or rendered obvious by a reference authored by Sven Olerud, M.D.; and, more specifically, (ii) that an element in various asserted patent claims that requires use of a "flowable material capable of setting to hardened condition" is satisfied by use of bone graft material. Kyphon has no objection to appropriate use of any statements it has made to FDA about the prior art. However, because none of Kyphon's statements to the FDA discusses, much less analyzes, the terms in the asserted patent claims, any statements to the FDA about Kyphon's commercial embodiment of the patent are not relevant to the issues for which DOT wants to use them and should be excluded. Moreover, to the extent the statements are of any conceivable relevance, DOT's use of them would only serve to confuse the jury and distract it from the required comparison of the claims to either DOT's own device or the prior art references. Kyphon, therefore, moves *in limine* to preclude DOT from admitting into evidence, presenting argument regarding, and proffering testimony related to Kyphon's statements to the FDA about its products (including related discussions about those FDA submissions, which occurred within Kyphon).

I. Kyphon's Statements Regarding the Commercial KyphX IBT Device Are Not Relevant

Kyphon accuses DOT of infringing, among other things, U.S. Patents '888, '404, and '043. These three patents cover various surgical procedures that allow a surgeon to repair fractured vertebrae in the spine. Kyphon sells small balloons (KyphyX IBTs) that serve as inflatable bone tamps that can be used, with specialized equipment, to perform the patented methods. As part of the required FDA approval process for marketing the inflatable balloons for use in kyphoplasty surgery, Kyphon submitted a document known as a 510k premarket notification.[1] Kyphon's notification explained to the FDA how various functions and uses of the KyphX IBT are reasonably similar to predicate devices such as standard bone tamps. However, since FDA submissions of course have nothing to do with patents – particularly in this case, where the core kyphoplasty patents at issue (the '888 and '404) issued years before the FDA process was even begun -- ***none*** of Kyphon's statements to the FDA discussed the steps required by the methods in Kyphon's patents. Instead, ***all*** of the statements were made about commercial embodiments and, most critically, ***none*** of Kyphon's statements ever compared the patented methods to the decades-old standard bone tamp technology. DOT nevertheless seeks to use Kyphon's statements and submissions to prove that, because the KyphX IBT was in some ways similar to the old bone tamp technology, various asserted claims in three of the patents-in-suit must be anticipated and/or rendered obvious by such technology.

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[1] As explained by this Court: "A 510(k) submission to the FDA is a 'submittal[ ] of engineering and clinical information which [is] provided to the FDA to permit that agency to assess the safety and effectiveness of a new product with regard to a predicate product which is already on the market.'" *Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F.Supp.2d 638, 667 n.12 (D.Del. 2004) (quoting *Sunrise Med. HHG, Inc. v. AirSep Corp.*, 95 F.Supp.2d 348, 405 (W.D.Pa.2000)).

Not surprisingly, this Court has previously rejected an identical attempt to invalidate patents with the aid of statements made in a 510k submission to the FDA. See *Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F.Supp.2d 638, 667 (D.Del. 2004). The statements at issue in *Arthrocare*, just as Kyphon's statements here, concerned commercial embodiments of the patents-in-suit and certain pre-existing devices. However, the Court precluded admission of any such evidence, and explained as follows in ruling upon the alleged infringer's post-trial motions:

> **Anticipation is determined by comparing the limitations of the asserted claims, *not of commercial embodiments* as described in 510(k) submissions, to the disclosure found in a single piece of prior art.** Enablement is evaluated based on the teachings found in the specification, not on those present in 510(k) submissions. **Therefore, since the 510(k) submissions are not relevant to the substantive issues at bar, the exclusion of these documents and corresponding testimony was not in error.**

Here, DOT's assertions of invalidity will require the jury to consider the specific steps in the patented methods and to then compare those particular steps with the prior art references. The jury must then determine if one of ordinary skill at the time of the inventions would have concluded that the references anticipated the patented methods and/or rendered them obvious. The only relevant comparison is between the series of steps required by the patented methods versus what the references would have taught to someone of ordinary skill at the time of the inventions.

What Kyphon said many years later to the FDA is irrelevant. The statements that DOT seeks to use concern the similarity in intended use and therapeutic results of the KyphX IBTs and conventional bone tamps. These general observations were presented to the FDA to permit the agency to assess the safety and effectiveness of the KyphX IBT commercial device vis-à-vis standard metallic bone tamps that had been in use for

decades. For example, DOT's summary judgment briefing quotes the following language from different documents related to the FDA's consideration of the KyphX IBT commercial device:

> The [Kyphon] Inflatable Bone Tamp is intended for the same use as a conventional bone tamp for the reduction of fractures and/or creation of a void to be filled with approved bone void fillers. (Exhibit Y, KY 004440)
>
> The Kyphon Inflatable Bone Tamp is intended to be used as a conventional bone tamp to reduce fractures and/or create a void to be filled with an approved filler by compressing cancellous bone and/or moving cortical bone in open or percutaneous procedures. (Exhibit A-27, KY 004845)
>
> The results of these tests demonstrated that the Kyphon Inflatable Bone Tamps can reduce fractures, and create voids in cancellous bone, in the same manner and with the same results as predicate conventional bone tamps. (Exhibit T, KY 4451)[2]

See DOT Brief (D.I. 181) at 10. Since these statements do not relate to the patent claims or even to any specific prior art reference relied on by DOT, they are irrelevant.

There is one limited respect in which a portion of Kyphon's FDA submission may have some relevance: how Kyphon characterized certain prior art which is sufficiently related to art now asserted by DOT, that DOT asserts it is substantially the same thing. In particular, DOT wants to use portions of the following quote about the Karlstrom reference, which DOT does not rely on in the litigation but which has much of the same disclosure as another reference (Olerud) on which DOT does rely:

> Fig. 7-1 below illustrates the similarities in intended use between the Kyphon Inflatable Bone Tamp and conventional bone tamps in reducing fractures and/or creating voids. [figure omitted] In Fig. 7-1A, a fractured vertebral body (in the anterior spine) is being reduced with a conventional bone tamp placed through a drill channel in each pedicle (from Karlstrom

[2] This letter from Kyphon proceeds to explain that, "Kyphon Inc. has determined, based on these tests, that the device conforms to its specifications and is at least as safe and effective as the predicate devices for tamping cancellous bone and/or elevating cortical bone." *Id.* at KY 4451.

> et al, Section 6.0 Appendix G). (The instrumentation in the vertebral bodies above and below treats the posterior spinal instability and is not related to the bone tamping.) The illustration shows a conventional bone tamp being rotated in various directions **to compact the cancellous bone** and push the endplates apart, to achieve the desired reduction. Fig. 7-1B is a sample X-ray image from the Vertebral Body Testing reported in Section 6.2.2 of the submission. It illustrates how two Inflatable Bone Tamps inserted into a vertebral body in the same manner as the conventional bone tamps of Fig. 7-1A achieve the same intended result as illustrated in Fig. 7-1A. Thus, the Kyphon Inflatable Bone Tamp and conventional bone tamps have the same intended uses.

See DOT Appendix to Claim Construction and Summary Judgment Filings, (D.I. 140-144) Exh. A 27, at KY 4841-42; *see also* DOT Brief (D.I. 181) at 11-12 (quoting a portion of this excerpt, and asserting that the Karlstrom reference discussed by Kyphon purportedly contains the same disclosure as the prior art Olerud reference now being asserted by DOT). DOT has focused upon the bolded portion, in particular, because the actual Karlstrom and Olerud references do not state that the conventional probes shown in fact compact cancellous bone, and as the Court knows that is one aspect of Kyphon's claimed methods. But there is no reason to allow DOT to use Kyphon's otherwise irrelevant and potentially confusing FDA submissions to establish that specific fact. Kyphon does not dispute, and will stipulate if necessary, that the probe shown in Karlstrom does compact cancellous bone to some degree when used as shown. The jury will have a difficult enough time making the legally relevant comparison (patent claims to asserted prior art), without introducing the risk for confusion and prejudice inherent in showing them other irrelevant comparisons (Kyphon's commercial embodiment to unasserted prior art).

Thus, evidence related to the FDA discussions should be precluded pursuant to FRE 402, just as such evidence was precluded by this Court in *Arthrocare*. Moreover, to the extent any arguable relevance exists, the risk of confusing the jury with various

comparisons between the commercial embodiment and certain prior art references substantially outweighs any minimal relevance of Kyphon's statements to the FDA and any evidence related to such statements should be precluded pursuant to FRE 403.

II. Kyphon's Statements Regarding Bone Graft Material Are Not Relevant

DOT also seeks to use FDA-related information to prove that bone graft is a "flowable material capable of setting to a hardened condition" as required by an element that appears in various asserted claims. Specifically, the patented methods in the '888 and '404 patents require that the patented method be completed by filling the cavity made by the surgeon with a "flowable material capable of setting to a hardened condition." The best mode described in the patent references a chemical compound, methyl methacrylate, often referred to as bone cement. Use of quick-hardening bone cement compounds provides an immediate internal cast for the vertebral bone, without the need for metal rods, other fixation devices, or external body supports. Thus, a flowable material capable of setting to a hardened condition was required by the methods in the asserted claims, and bone cement was identified as a preferred flowable material.

The specific FDA evidence that DOT seeks to use here would be an even more substantial detour than Kyphon's statements comparing its device to predicate devices, because the entire exchange between Kyphon and FDA had to do with on-label versus off-label use of various bone filler materials – an arcane and entirely irrelevant topic that, to explain to a jury, would require explanation of the extent to which FDA can and cannot regulate the practice of medicine, and why.

Specifically, during discussions with the FDA, Kyphon was cautioned that the FDA had not formally approved the use of the Kyphon's preferred bone cement chemical

compound for use in the spine. To appease FDA over this potential "off-label"[3] use, and as a part of the on-going discussions with the FDA, Kyphon at one point was willing to recognize that standard bone grafts could be used with Kyphon's inflatable bone tamp devices instead. Kyphon even indicated, at least internally, that it would be willing to formally include the use of bone graft as part of Kyphon's formal "Instructions for Use", if that would be necessary to secure FDA approval for the underlying device.[4] Again, ***nothing*** in any of Kyphon's statements to the FDA or its internal discussions cited by DOT on this subject, however, discusses Kyphon's patents, particularly the last step required by the asserted claims of the '888 and '404 patents – "filling the cavity with a flowable material capable of setting to a hardened condition." Moreover, nothing in any of the materials cited by DOT ever states that bone graft may be defined as a "flowable material capable of setting to a hardened condition." In other words, the commercial embodiment of Kyphon's invention, the KyphX IBT could be used with either: (i) bone graft; or (ii) bone cement (*i.e.,* one type of "flowable material" actually required by the patented method and described in the patent's specification). However, the fact that either material could possibly be used with Kyphon's commercial device has nothing to do with whether bone graft qualifies as a "flowable material" as required in the methods of the asserted claims in the '888 and '404 patents. Thus, once again, the FDA-related evidence on which DOT seeks to rely is simply irrelevant to the invalidity analysis of the actual claims that the jury will need to perform, and it has the potential to confuse the

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[3] "Off-label" refers to use by physicians of medical devices or compounds in ways other than as specifically approved by FDA. The practice is exceedingly common and, because FDA does not regulate the practice of medicine, entirely legal. But it will sound shady to a jury.

[4] Of course, use of the slow-healing bone graft material would require the addition of either internal or external support structures while new bone material would be knit into the bone to heal the fracture. *See* D.I. 175 at ¶¶ 5-6.

jury in a way which would be prejudicial to Kyphon. It should therefore be excluded under FRE 402 and 403.

RULE 7.1.1 CERTIFICATION

Pursuant to Local Rule 7.1.1, counsel for Kyphon certifies that it has in good faith undertaken reasonable efforts, via email and phone, in an attempt to confer with counsel for defendants to discuss the issues raised in Kyphon's Motion *In Limine* to Preclude Admission of, or Reference to, Kyphon's Discussions with the FDA Regarding Kyphon's Commercial KyphX IBT Devices, but the efforts of Kyphon's counsel have not, to date, been successful.

2

KYPHON'S MOTION *IN LIMINE* 2 OF 5

Motion *In Limine* to Preclude Evidence Regarding Recreation of Prior Art Procedure

DOT alleges that H.G. Edeland, *Open Reduction of Central Compression Fractures of the Tibial Plateau,* Acta Orthop. Scand. 47, 686-89 (1976) ("the Edeland reference") either anticipates or renders obvious each of the asserted claims of the '404 and '888 patents. [Mitchell Invalidity Report at ¶¶ 37, 43, 46, 52; Mitchell Invalidity Report, Ex. 1 at pp. 1-3, 23-29, 30-32, and 52-56; DOT's Motion for Summary Judgment at pp. 17-26.] In response to DOT's argument, Kyphon pointed out several deficiencies of the Edeland reference. [D.I. 172 at pp. 12-23; Marks Invalidity Rebuttal Report at pp. 8-10.] Kyphon noted, for example, that the Edeland reference fails to teach or suggest the "compacting" step, the "filling" step, and the "drilling" step of the asserted claims.

In an attempt to counter Kyphon's position, DOT presented a declaration authored by its expert, Dr. Mitchell. [Declaration of Dr. David Mitchell.] In that declaration, Dr. Mitchell describes a "recreation" of the procedure described in the Edeland reference that he performed in March or April 2005. [*Id.* at ¶ 5.] In particular, Dr. Mitchell explains that the "recreation" of the Edeland procedure involved performing several of those steps that Kyphon previously noted to be missing from the disclosure of the Edeland reference. [*See, e.g., id.* at ¶¶ 6-9].

Kyphon now moves *in limine* for an order excluding evidence and testimony relating to Dr. Mitchell's "recreation" of the Edeland procedure. This recreation is irrelevant to this case under Fed. R. Evid. 402. Moreover, even if testimony relating to Dr. Mitchell's "recreation" were conceivably relevant, such testimony should be excluded under Fed. R. Evid. 403 because it will confuse and mislead the jury.

I. Testimony Relating to the "Recreation" of the Edeland Procedure is Irrelevant

The "recreation" of the Edeland procedure was performed by Dr. Mitchell in March or April 2005, more than 15 years after the date of invention of the subject matter claimed in the '404 and '888 patents. This "recreation" allegedly included several steps and details that are not described in the Edeland reference. For instance, Dr. Mitchell states, "When I performed the procedure shown in Exhibit 1 hereto [slides of his recreation] and in the Edeland article, I fenestrated (created a cortical window) **by drilling** through the cortical bone to form a passage in cancellous bone." [Declaration of Dr. Mitchell at ¶5, emphasis added.] While the Edeland reference discloses fenestration in *cortical* bone, it discloses neither the use of a drill nor the formation of a passage in the interior cancellous bone as required by the claims DOT seeks to invalidate. And DOT has not, and cannot, cite to any portion of the Edeland reference that contains such disclosures.

In order to anticipate a patent claim, every feature of the claim must be disclosed within a single prior art reference. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). The Edeland reference does not disclose all of the elements of the claims-at-issue, and DOT is attempting to have its expert witness "fill in the gaps" with his "recreation." It is impermissible to use expert testimony to fill in gaps within a prior art reference. *Id.; see also, Medical Instrumentation and Diagnostics Corp. v. Elekta AB,* 344 F.3d 1205, 1221 (Fed. Cir. 2003). Expert testimony can be used to explain a reference, but it cannot be used to expand the meaning of a prior art reference. *Biacore, AB v. Thermo Bioanalysis Corp.*, 79 F.Supp.2d 422, 460 (D.Del. 1999).

DOT may attempt to present the jury with testimony relating to Dr. Mitchell's "recreation" under the guise that it will help the jury to understand the teachings of the Edeland reference. However, as noted above, many of the steps and details described with respect to the "recreation" are completely absent from the Edeland reference. Moreover, the relevant teachings of a reference with respect to a validity analysis are those teachings that would have been understood by persons of ordinary skill in the art at the time of the invention. *See, e.g., Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Dr. Mitchell's "recreation," which was performed more than 15 years after the date of invention of the subject matter claimed in the '404 and '888 patents, and with the knowledge gained by having reviewed the '404 and '888 patents, can hardly be considered to exemplify the level of understanding that a person of ordinary skill in the art would have possessed at the time of the invention. Not only is Dr. Mitchell's scope of knowledge expanded relative to a person of skill in the art at the time of the invention of the '404 and '888 patents, but he also has the knowledge of the methods described in the '404 and '888 patents. Thus, Dr. Mitchell's "recreation" and its deviations from the Edeland reference are the result of 15 additional years worth of knowledge and hindsight, as compared to a person of ordinary skill in the art at the time of the invention of the subject matter claimed in the '404 and '888 patents. Courts have explicitly discouraged such recreation or experimentation. In *Glaxco Group Ltd. V. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), for example, the Federal Circuit noted that the district court had properly discredited expert testimony regarding experiments that involved deviations that were likely the result of impermissible hindsight. *Id.* at 1348-49.

Kyphon requests that the court recognize Dr. Mitchell's "recreation" as a biased interpretation of the Edeland procedure using impermissible hindsight, and exclude all

evidence and testimony relating to Dr. Mitchell's "recreation," as irrelevant under Fed. R. Evid. 402.

II. Testimony Relating to the "Recreation" of the Edeland Procedure Will Mislead and Confuse the Jury

Even if testimony relating to Dr. Mitchell's recreation has some relevance, it should be excluded under Fed. R. Evid. 403. By admitting testimony relating to the "recreation" of the Edeland procedure, there is a substantial risk that the jury will confuse the "recreation" with the information disclosed in the Edeland reference itself. A real danger exists, therefore, that in light of such testimony the jury will mistakenly treat Dr. Mitchell's "recreation" itself as prior art. In particular, the jury will likely be led to believe that the details described in Dr. Mitchell's "recreation," but not taught by the Edeland reference itself, may be used to support a finding of invalidity based on anticipation or obviousness. This, however, would violate the fundamental rule that only information qualifying as "prior art" under 35 U.S.C. §102 can be used to support a finding of invalidity based on anticipation or obviousness. At the very least, the efforts that would be required to counteract testimony relating to Dr. Mitchell's "recreation" would divert the jury's attention from the real issues of the case and it should be excluded on that basis as well.

RULE 7.1.1 CERTIFICATION

Pursuant to Local Rule 7.1.1, counsel for Kyphon certifies that it has in good faith undertaken reasonable efforts, via email and phone, in an attempt to confer with counsel for defendants to discuss the issues raised in Kyphon's Motion *In Limine* to Preclude Evidence Regarding Recreation of Prior Art Procedure, but the efforts of Kyphon's counsel have not, to date, been successful.

5

KYPHON'S MOTION *IN LIMINE* 5 OF 5

Motion *In Limine* to Preclude Reference to Kyphon's Streamlining of Its Infringement Claims

Kyphon initially charged infringement of four patents-in-suit: '888, '404, '043 and '110. Subsequently, Kyphon's amended complaint added allegations of infringement of two other patents: '734 and '054.

In January of this year, Kyphon advised that it anticipated pursuing infringement claims at trial under five of the six patents-in-suit: the '888, '404, '043, '734 and '054. Kyphon also advised that it anticipated pursuing certain specified claims from these patents. More recently, in an effort to further streamline the trial by pursuing an even more limited set of patent claims, Kyphon has committed to promptly assessing the claims it has asserted to date upon receipt of the Court's rulings regarding claim construction and pending summary judgment motions.

Reference to Kyphon's efforts to simplify this case for trial are not relevant to the merits of any issue being presented to the jury, and would only serve to confuse and distract the jury. Moreover, allowing reference by DOT to Kyphon's efforts to simplify this case would deter future plaintiffs from the laudable objective, which the Court properly encourages, of presenting a reasonable number of issues to juries. Thus, to prevent DOT from distracting the jury with issues unrelated to the merits, Kyphon moves *in limine*, pursuant to FRE 401, 402 and/or 403, to preclude DOT from referencing Kyphon's efforts to streamline its infringement claims (*i.e.,* by narrowing the focus of the patents at issue and by limiting the claims being asserted against DOT).

RULE 7.1.1 CERTIFICATION

Pursuant to Local Rule 7.1.1, counsel for Kyphon certifies that it has in good faith undertaken reasonable efforts, via email and phone, in an attempt to confer with counsel for defendants to discuss the issues raised in Kyphon's Motion *In Limine* to Preclude Reference to Kyphon's Streamlining of Its Infringement Claims, but the efforts of Kyphon's counsel have not, to date, been successful.