IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

KYPHON'S OPPOSITION TO DOT'S PROPOSED CLAIM CONSTRUCTION OF DISPUTED CLAIM TERMS OF U.S. PATENT NOS. 4,969,888; 5,108,404; 6,235,043 B1 AND U.S. PATENT NOS. 6,241,734 B1 & 6,613,054 B2

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Dated: April 14, 2005

"Specifications teach. Claims claim."

The text and figures of a patent's specification explain the particular approach that the patentee believes is the best mode of practicing the invention, and provide sufficient detail to teach others how to practice the best mode of the invention. The claims, however, are what actually define the invention. DOT's proposed claim constructions ignore this fundamental tenet of patent law in an effort to avoid infringement. For example, DOT insists that the "compacting" step in the claims of the '888 and '404 patents – claims that do not even mention any type of expandable body – must nonetheless be performed with an "inflatable device," such as a balloon. With regard to the '043 patent – where the claims generically reference the use of "expandable bodies" – DOT again insists that the claims can only be satisfied with an "inflatable device," such as a balloon. Likewise, with respect to the bone filler device claims of the '734 and '054 patents – where the claims describe certain ***devices*** without any limitation regarding how the devices must actually be used – DOT insists that the claims require that the devices must be used in the particular ***method*** described in the specification. DOT's approach is a direct rebuff to decades of case law from the Supreme Court:

> We may take it that, as the statute requires, the specifications just detailed show a way of using the inventor's method and that he conceived that particular way described was the best one. But he is not confined to that particular mode of use since the claims of the patent, not its specifications, measure the invention.

Smith v. Snow, 294 U.S. 1, 11 (1935) (citations omitted). DOT's approach also ignores the more recent pronouncements of the United States Court of Appeals for the Federal Circuit:

> The specification "set[s] forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112. This one embodiment of the invention does not restrict the claims.

SRI Int'l v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1122 (Fed. Cir. 1985) (*en*

banc) (quoting *Adams v. United States*, 330 F.2d 622, 165 (Ct. Cl. 1964), *aff'd* 383 U.S. 39 (1966)). Or, as Chief Judge Markey of the Federal Circuit has simply put it: "Specifications teach. Claims claim." *Id.*, at 1121 n.14. Yet, DOT's claim constructions uniformly seek to change the plain meaning of the claim terms by adding limitations chosen by DOT from the detailed descriptions in the specifications that set forth the best modes for practicing the claimed inventions. As such, DOT disregards the basic roles played by the specification vis-à-vis the claims, and its proposed claim interpretations must be rejected.

I. SUMMARY OF ARGUMENT

With regard to the '888, '404 and '043 patents, DOT uses four tactics to import limitations from the specification into the plain terms of the claims.

1. DOT disregards the plain, ordinary meaning of the claim terms, and reads limitations into the claims from the specification. DOT's proposed "balloon" claim construction – which it did not rely on in opposing Kyphon's preliminary injunction motion, and which it advances now only after losing on what "marrow" means in the context of that motion -- would render meaningless a dependent claim that specifically requires the "inflating of an inflatable device" for performing the basic procedure set forth in claim 1.

2. DOT's reliance on prosecution history is also misplaced. DOT can point to no evidence in the prosecution history that shows the required disavowal by the inventors of the plain meaning of the claims. Not even the statements cherry-picked by DOT come close to showing that the inventors acted as their own lexicographer and departed from the plain, ordinary meaning of the claim terms, or otherwise made statements that are both so clear and so unmistakable that they could constitute a relinquishment of the plain and ordinary meaning of the claims issued by the U.S. Patent & Trademark Office.

3. DOT's attempt to use extrinsic evidence, both its own expert witnesses' declarations and carefully segregated inventor-testimony, to contradict the plain, ordinary meaning of the claim terms must also be rejected. DOT again is asking the Court to disregard a well-established principle of claim construction: extrinsic evidence may not be used to vary or contradict the plain and ordinary meaning of the claims.

4. Desperate to avoid infringement, DOT in many instances simply takes complete license and rewrites the claims without any effort to proffer evidence, intrinsic or extrinsic, that supports a departure from the plain meaning of the claim terms. Simply put, DOT is telling the Court that the plain meaning of the claim terms should be interpreted in a different way because DOT says so. This runs afoul of yet another basic canon of claim construction: courts (and litigants) do not have the ability to rewrite claims.

5. Lastly, with regard to the bone filler device claims of the '734 and '054 patents, DOT again seeks to limit the claimed inventions to the best mode described in the specification. DOT's claim construction arguments primarily boil down to an insistence that the inventions in the bone filler device claims must utilize a method that ends in material being pushed into a bone via ***one*** tube. DOT, not surprisingly, insists upon this approach because DOT's bone filler device utilizes a method of pushing material into a bone via ***two*** tubes (one resting concentrically inside the other).[1] However, none of the terms of the asserted claims requires that the devices be used in the particular manner set forth in DOT's proposed claim construction. Thus, DOT's effort to avoid the plain meaning of the asserted bone filler device claims should be rejected.

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[1] While DOT seeks to impose a "one tube" approach for purposes of avoiding infringement liability, DOT takes the opposite approach to the asserted claims in an effort to invalidate them. Specifically, DOT asserts that prior art that purportedly shows the introduction of material into the body via two tubes anticipates every aspect of various claims of the '734 patent. See Kyphon's Opening Claim Construction Brief [*hereinafter* Kyphon's Opening Brief], D.I. 145, at 22; D.I. 147, Ex. W.

II. DOT'S PROPOSED INTERPRETATIONS VIOLATE THE BASIC RULES GOVERNING CLAIM CONSTRUCTION

As detailed below, the case law governing claim construction requires a straight-forward two-step approach: the claims are first given their plain and ordinary meaning, and then, the specification and prosecution are examined to determine whether there has been a clear disavowal of claim scope that rebuts the "heavy presumption" that claims mean what they say. DOT, however, simply jumps straight to the specification and seeks to define the claims as being limited to the best mode of practicing the invention that is described in the patent's specification.

A. DOT's Proposed Constructions Are Inconsistent With The Heavy Presumption in Favor of the Ordinary Meaning of Claim Language

The construction of disputed claim terms focuses primarily on the intrinsic evidence, which includes the claim itself, the specification, and the prosecution history of the patent. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves." *Texas Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1201 (Fed. Cir. 2002) (quoting *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001)). Moreover, a review of other claims in the same patent can aid in determining the scope of a particular claim. *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 986 (Fed. Cir. 1988).

There is a "heavy presumption" in favor of the ordinary meaning of claim language as understood by one of ordinary skill in the art to which the invention pertains. *Texas Digital*, 308 F.3d at 1202; *Specialty Composites*, 845 F.2d at 986. To determine the ordinary meaning of a term, courts may consider and rely on technical treatises and dictionaries, which "hold a special place in claim construction." *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1178 n.4 (Fed. Cir. 2002).[2]

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[2] *See also Texas Digital*, 308 F.3d at 1202 ("Dictionaries are always available to the court to aid in the task of determining meanings that would have been attributed by those of skill in the relevant art to any disputed terms used by the inventor in the claims.");

B. DOT's Importation of Limitations From the Specification Is Expressly Prohibited

The heavy presumption that the ordinary meaning of a claim term controls can only be overcome by an express intent of the patentee to impart a novel meaning to the claim term, as evidenced by the intrinsic record. *Texas Digital*, 308 F.3d at 1204; *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). That is, to overcome the presumption, the intrinsic record must show that the patentee has either acted as his or her own lexicographer and "clearly set forth an ***explicit definition*** of the term different from its ordinary meaning" or used "words or expressions of ***manifest exclusion or restriction***, representing a clear disavowal of claim scope." *Texas Digital*, 308 F.3d at 1204 (citing *Teleflex*, 299 F.3d at 1324) (emphasis added); *see also Nystrom*, 374 F.3d at 1111.

The Federal Circuit has, clearly and repeatedly, instructed courts to exercise due care to avoid importing limitations from the specification when using the specification to determine the context for a disputed term. *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 906 (Fed. Cir. 2005).[3] Courts "must use the written description for enlightenment and ***not*** to read a limitation from the specification" because "claims, not the specification embodiments, define the scope of protection." *Playtex*, 400 F.3d at 906 (emphasis added).

It is axiomatic that limitations unintended by the patentee cannot be imported from examples, figures, or preferred embodiments.[4] This is true even if a patent describes only

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Vitronics, 90 F.3d at 1578 n.6 (noting that "technical treatises and dictionaries . . . are worthy of special note" and that courts may "rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents").

[3] *See also, e.g., Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 & 906 (Fed. Cir. 2004); *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1369 (Fed. Cir. 2004); *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1327 (Fed. Cir. 2003); *Interactive Gift Express*, 256 F.3d at 1333; *Am. Permahedge, Inc. v. Barcana, Inc.*, 105 F.3d 1441, 1444 (Fed. Cir. 1997); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988).

[4] *See, e.g., Playtex*, 400 F.3d at 907 (finding that the district court erred in importing limitations from the figures); *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361,

one single embodiment.[5] For example, in *Brookhill-Wilk 1, LLC. v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003), the written description of the patent at issue only described performing the surgical procedure without the surgeon present in the same room as the patient. However, the court interpreted the term "remote" broadly to include surgical procedures performed with the surgeon present in the same room as the patient because, "[n]o statement in the written description ... constitute[d] a limitation on the scope of the invention."

Importation of limitations from statements in the specification that generally describe the invention (such as statements from the abstract or the summary of invention), ***as DOT urges this Court to do***, also constitutes reversible error. *Liebel-Flarsheim Co. v. Medrad, Inc*, 358 F.3d 898, 908-909 (Fed. Cir. 2004). In *Liebel-Flarsheim*, the district court construed the term "syringe receiving opening" of the claimed front-loadable powered injectors to require the use of pressure jackets, based on the fact that every powered injector described in the patents at issue contained a pressure jacket. *Id.* at 901, 904. On appeal, to buttress its argument that the "pressure-jacketed injector" is the only subject matter described in the specification and therefore constituted the invention itself rather than just a preferred embodiment, *id.* at 904, the alleged infringer pointed to descriptions of the "pressure-jacketed injectors" in the ***abstract*** and the ***summary of invention*** sections of the patents, and to language that described the use of the powered injectors with pressure jackets as one of the ***objectives of the invention*** and in accordance with the ***principles of the invention***. *Id.* at 908. The Federal Circuit found that the district

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1369 (Fed. Cir. 2004) (same); *Laitram*, 863 F.2d at 865 ("References to a preferred embodiment . . . are not claim limitations."); *Specialty Composites*, 845 F.2d at 987 ("What is patented is not restricted to the examples[.]").

[5] *See, e.g., Liebel-Flarsheim*, 358 F.3d at 906 (citing *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1091 (Fed. Cir. 2003)); *see also, Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1377 (Fed. Cir. 2003); *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1373 (Fed. Cir. 2003); *Texas Digital*, 308 F.3d at 1204-05; *Teleflex*, 299 F.3d at 1327; *SRI*, 775 F.2d at 1121 n. 14.

court erred in its claim construction, finding that the specification did not define the term restrictively. *Id.* at 905. The court also rejected the alleged infringers' misplaced reliance on the abstract, the summary of invention, and other general descriptions of the invention in the patents, noting that although the quoted passages "focus[ed] on the use of the invention in conjunction with pressure jackets, [they did] not disclaim the use of the invention in the absence of a pressure jacket." *Id.* at 908. The court reasoned that although the language quoted from the abstract "can reasonably be understood as constituting a general description of the invention, the quoted passage does not suggest that a pressure jacket is an essential component of the invention, nor is there any language in that passage, or elsewhere in the specification, that disclaims the use of the invention in the absence of a pressure jacket." *Id.* The court also pointed out that "[t]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." *Id.*

Likewise, in *Nystrom*, the district court construed the term "manufactured to have" to mean "a manufacturing process utilizing woodworking techniques," because the specification of the patent stated that "the advantages of the invention" were achieved through "cutting or milling and the like." *Nystrom*, 374 F.3d at 1114-15. The Federal Circuit held that the district court's construction was erroneous: "This claim limitation means exactly what it says, and the district court erred in limiting it to the manufacturing steps used to shape wood." *Id.* at 1114.

Similarly, the Federal Circuit has held that limitations may not be imported from the ***title*** of a patent. In *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999), the word "light" in the title of the patent at issue ("Apparatus and Method for Generating Images by Producing Light Spots of Different Sizes") had been added during prosecution. The district court construed the claim term "spot" to mean "light spot" in view of the amendment and the title. *Id.* at 1311-12. The Federal Circuit held that the

district court erred in its construction, finding that "the district court attached too much weight in its claim construction to the patent title and to the amendment of that title." *Id.* at 1312. The Federal Circuit noted that the "near irrelevancy of the patent title to claim construction" is "demonstrated by the dearth of case law in which the patent title has been used as an aid to claim construction." *Id.* The Federal Circuit pronounced: "[I]f we do not read limitations into the claims from the specification that are not found in the claims themselves, then we certainly will not read limitations into the claims from the patent title." *Id.*

Here, after reviewing essentially the same evidence DOT is now relying on, this Court in its Preliminary Injunction decision has already concluded that "the patent does not state that an inflatable device is an essential element of the invention or that it is the only possible embodiment for achieving the claimed invention of compacting the bone marrow."[6] D.I. 102, at 8-9. Nevertheless, for page after page, DOT cites to the embodiments described in the specification of the patents, the Abstract, the Summary of Invention, and the title of the patents in order to read limitations into unambiguous claim terms. DOT apparently hangs its hat on *C.R. Bard, Inc. v. United States Surgical Corp.*, 388 F.3d 858 (Fed. Cir. 2004). However, DOT's reliance on *Bard* is misplaced.

In *Bard*, the claim at issue was directed to a device comprising a plug with certain recited qualities. *Id.* at 860. The court concluded that the specification required the claimed plug to be pleated (i.e. having pre-formed permanent folds) because the specification, in particular the Abstract and the Summary of the Invention, "explicitly defines the inventive plug as 'having' or 'include[ing] a pleated surface.'" *Id.* at 865 (quoting the patent). However, the *Bard* panel recognized that its holding was limited. *Id.*

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[6] The Court reached this question not in the claim construction context, but in addressing DOT's argument that claim 1 of the '404 patent was invalid due to lack of written description under Section 112. The entire premise of DOT's written description challenge, in the preliminary injunction context, was that the plain meaning of the claim **did** include non-inflatable devices and so was not adequately described in the specification for that reason. Having failed in that attack, DOT has now reversed course 180 degrees.

at 864 (noting that "what import to give language from the specification must, of course, be determined on a case-by-case basis"). The *Bard* panel distinguished the case before it from *Liebel-Flarsheim*, noting that, in *Liebel-Flarsheim*, the specification did not define the claim term "opening" restrictively, and the disputed term was not ambiguous whereas, in the case before it, "[i]n the Summary of the Invention, the phrase 'includes a pleated surface' modifies the word 'implant'" and "[i]n the Abstract, the phrase 'having a pleated surface' modifies the word 'plug.'" *Id.* at 864-65.[7]

Unlike *Bard*, the ordinary meanings of the disputed claim terms in this case are clear of any ambiguity. Also unlike *Bard*, the claim terms (for example, "compacting") that DOT seeks to read limitations into (such as, an "inflatable device") are not ***defined*** as requiring such limitations anywhere in the patents, even under *Bard*'s broad interpretation of what "define" is. For example, nowhere in the patents is the claim term "compacting" unequivocally defined as requiring the use of an "inflatable device."

A patentee may also relinquish the plain meaning of claims through statements made during prosecution. *Southwall Techs., Inc. v. Cardinal IG, Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995). However, for prosecution disclaimers to attach, the Federal Circuit has required "the alleged disavowing statements to be both *so clear* as to show reasonable clarity and deliberateness, and *so unmistakable* as to be unambiguous evidence of disclaimer." *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003) (internal citations omitted) (emphasis added). A disclaimer is "clear and unmistakable" if there is only one reasonable reason for the prosecution statement or amendment so that "it is not suitable to multiple interpretations." *Id.* at 1327-30. The prosecution statements

[7] To the extent *Bard* is inconsistent with *Liebel-Flarsheim* and other Federal Circuit case law before it that prohibit courts from importing limitations from the specification, it is well established that "decisions of a three-judge panel of this court cannot overturn prior precedential decisions." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). *See also Swimways Corp. v. Overbreak, LLC*, 354 F. Supp. 2d 637, 646 (E.D. Va. 2005) (noting that "the holding in *C.R. Bard* is a narrow one").

cherry-picked by DOT do not come close to being such clear and unmistakable disclaimers of the patent claims' plain and ordinary meaning.

C. Extrinsic Evidence Cannot Be Used to Contradict the Ordinary Meanings of the Claim Terms Ascertained from the Intrinsic Record

Expert testimony and inventor testimony are considered extrinsic evidence. *Vitronics*, 90 F.3d at 1584. Unless the limitation remains ambiguous after considering the intrinsic evidence, courts may not resort to extrinsic evidence other than to ascertain the ordinary meaning of the claim. *Id.* at 1583. Although extrinsic evidence may be used to assist in understanding the technology, it cannot vary or contradict the claim language, the specification or file history. *Id.*

III. DOT'S CLAIM CONSTRUCTIONS IGNORE THE PLAIN ORDINARY MEANING OF UNAMBIGUOUS TERMS

A. DOT's Proposed Construction of Disputed Claim Terms in the '888 and '404 Patents Must Be Rejected

1. "bone marrow"

DOT asserts that "bone marrow" means "the viscous liquid material contained within the interstices (spaces) of the cancellous bone." As noted in Kyphon's Opening Brief, the Court previously adopted Kyphon's interpretation and rejected DOT's "viscous liquid" construction in its Preliminary Injunction decision. *See* D.I. 102, at 4. The record amply supports that decision. DOT has identified nothing that requires the Court to change its interpretation.

While Kyphon's Opening Brief lays out the support, from both the claims themselves and the specifications, for its construction in great detail, DOT only offers two purported pieces of evidence — Kyphon's training manual and an article published by Kyphon's expert in 1987 — to support a construction that its own, now former expert

admitted would render the claims meaningless. Such extrinsic evidence cannot be used to contradict the meaning ascertained from the intrinsic record. *Vitronics*, 90 F.3d at 1584.

Moreover,

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See D.I. 144, Ex. L, at KY 73082.[8] DOT's reliance upon such materials is misplaced, because Kyphon has readily noted that the term bone marrow has been used by those of ordinary skill in the art to reference various portions of the interior of bone. However, DOT's effort to strictly limit bone marrow to being ***only*** a viscous-liquid runs directly counter to how the term "bone marrow" is used in the patent, and, indeed, as this Court recognized would render the claims "meaningless." D.I. 102, at 4.

Thus, DOT's "viscous liquid" construction must be rejected.

2. "forming a passage in the bone marrow"

It appears from DOT's proposed construction that the dispute with respect to "forming a passage in the bone marrow" lies only in the term "bone marrow." Because DOT's construction of "bone marrow" must be rejected, its construction of "forming a passage in the bone marrow" must also be rejected for the same reasons.

3. "compacting the bone marrow to increase the volume of said passage"

Aside from DOT's proffer of a construction of "to increase ***the*** volume of ***said*** passage" as somehow meaning "to thereby increase ***a*** volume of ***a*** passage" without any explanation or support, DOT also tries to import numerous limitations inconsistent with

[8] Likewise, the portion of the article relied on by DOT that allegedly discussed bone marrow as distinct from cancellous bones only showed a photomicrograph where, according to the figure legend, "bone marrow" was given a different label than the "trabeculae" in the context of bone pathology, and at a microscopic level. Such extrinsic evidence is irrelevant to the construction of the term "bone marrow" as used in the '888 and '404 patents.

the plain, ordinary meaning of the term "compacting." According to DOT, "compacting" is not just compressing, but is "using an inflatable device to form a void in the interior of a bone, by compressing substantially all of the bone marrow away from a central portion of an interior bone volume, towards the walls of bone." But the only added limitation for which DOT offers any alleged support is the "inflatable device" limitation.

DOT cites various pieces of the specifications of the '888 and '404 patents in an attempt to import the limitation "inflatable device." However, as discussed above, the Federal Circuit has expressly, and repeatedly, prohibited this exercise. *See, e.g.*, *Playtex*, 400 F.3d at 907; *Nystrom*, 374 F.3d at 1113-14; *Liebel-Flarsheim*, 358 F.3d at 906; *Liquid Dynamics*, 355 F.3d at 1369; *Brookhill-Wilk 1*, 334 F.3d at 1301; *Pitney Bowes*, 182 F.3d at 1304. Nothing in the specification, including those portions quoted by DOT, ***defines*** "compacting" as requiring the use of an inflatable device, let alone a balloon. And nothing in the specification suggests that either the term "compacting" or the "compacting step" is ambiguous. "The fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." *Liebel-Flarsheim*, 358 F.3d at 908. "This case is therefore governed by the principle that '[a]bsent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the invention is limited to that context.'" *Id.* at 909 (quoting *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346,1355 (Fed. Cir. 2003)).

Moreover, DOT's reliance on *Tate Access Floors, Inc. v. Maxcess Technologies, Inc.*, 222 F.3d 958, 966 (Fed. Cir. 2000), is misplaced. While the abstract of a patent is

part of the intrinsic evidence, and therefore is certainly relevant to the construction of a disputed claim term, *see Vitronics*, 90 F.3d at 1582, *Tate Access Floors* does not offer DOT a license to import limitations from the abstract. In *Tate Access Floors*, the court examined the abstract of the patent at issue, and found that it was ***consistent*** with the ***ordinary meaning*** of the disputed claim term, and thereby rejected a more restrictive interpretation offered by the alleged infringer. *Tate Access Floors*, 222 F.3d at 965.

In addition to the unwarranted importation of a limitation from the specification, DOT cites to prosecution history as support for the "inflatable device" limitation.[9] However, the cited prosecution history does not evidence the requisite "clear and unmistakable" disavowal that would limit "compacting" to the use of an inflatable device.

An applicant does not relinquish the scope of a claim simply by referring to a preferred embodiment having a certain feature and comparing the preferred embodiment to the prior art that has a similar feature. In *Nystrom*, the district court construed the claim term "board" to mean a "piece of elongated construction material made from wood cut from a log," based in part on the statements made by the patentee during prosecution in

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[9] REDACTED *See* D.I. 140, Ex. A-24. At best, the Record of Invention is simply cumulative to DOT's repeated references to balloons being described in the patent's specification.

Moreover, DOT fails to provide any evidence that the document was or is accessible to the public, or to a person of ordinary skill in the art. Indeed, under the Patent Office's normal practice, a disclosure document will be destroyed after two years, unless it is referred to "in a separate letter in a related patent application filed within the two-year period . . . by its title, number, and date of receipt in the USPTO." MPEP 1706.

REDACTED Further, a disclosure document is accepted by the Patent Office as evidence of the date of ***conception***. *Id.* DOT cites to no case, and Kyphon finds none, that holds that evidence of a conception can be used to contradict the plain, ordinary meaning of the claim terms.

arguing against an obviousness rejection. *Nystrom*, 374 F.3d at 1110. The Federal Circuit concluded that the district court erred in its claim construction of the term "board," noting that it "read [the patentee]'s statement that '[the prior art reference] is clearly not concerned with materials made from wood' not as a disavowal or disclaimer that [the patentee]'s claimed invention is limited to wood decking boards, but as an argument against the examiner's obviousness rejection." *Id.* at 1113.

In the present case, the applicants were not even using "inflatable devices," or even "expandable devices,"[10] as the distinguishing feature in arguing against asserted prior art — the asserted prior art also used expandable devices.[11] The distinguishing feature was not what type of expandable device was being used, but rather the very existence of the ***compacting*** step. This point was made clear in a sentence that DOT chooses to omit, a sentence that immediately follows the language quoted by DOT. The applicants stated that the expandable devices described in the *Murray* reference "are not used ***to compact*** bone marrow against the inner surface of the cortical bone." D.I. 143, Ex. G, at 5 (emphasis added). Claim 1 was then amended to include the "compacting" step in order to clearly distinguish the claims over the prior art. *See id.* at 3. And on page 4 of the same

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[10] It is worth noting that even in the prosecution history reference cited by DOT, the applicants discussed the device that embodies the invention in terms of "expandable devices," – a much broader and more generic term than the "balloon" embodiment to which DOT seeks to limit the invention. *See* D.I. 143, Ex. G, at KY228858.

[11] Furthermore, DOT's assertion that "[t]he applicants distinguished ***the balloons*** in the prior art references," DOT Brief, at 19-20 (emphasis added), is misleading, especially when it is immediately followed with the discussion of the *Murray* reference. The *Murray* reference never once mentioned a "balloon" or even an "inflatable device," but only describes devices in terms of being "expandable." *See* U.S. Patent No. 4,627,434, attached hereto as Ex. 7 to Halkowski Declaration. (Unless otherwise specified, "Halkowski Declaration" refers to the Declaration of Thomas L. Halkowski in Support of Kyphon's Inc.'s Oppositions to DOT's Proposed Claim Construction and Motions for Summary Judgment of Non-Infringement and Invalidity].)

document cited by DOT, the applicants also distinguished *Lee*, another prior art reference, as follows:

> Lee shows an inflatable device 32 for closing or sealing one end of a hollow bone 10. However, there is no teaching in Lee of the combination of steps of amended Claim 1 ***because Lee fails to even remotely suggest the compacting of the bone marrow in the bone*** to increase the volume of a recess so that the recess can be filled with a flowable material capable of setting to a hardened condition.

Id. at 4 (emphasis added). Thus, the statements referenced by DOT merely highlight the importance of the "compacting" step; they in no way restrict ***how*** that compacting step must be accomplished in order to enlarge the initial passage-way formed by the surgeon, or what type of expandable body must be used.

DOT also relies on carefully selected portions of inventor testimony as support for its restrictive definition of "compacting."[12] However, inventor testimony is extrinsic evidence, and cannot be used to contradict the ordinary meaning of claim language. *Vitronics*, 90 F.3d at 1584. Moreover, DOT's selective quote is misleading, as DOT has chosen to omit testimony that is ***consistent*** with the ordinary meaning of the claim term. Following is an excerpt of the deposition testimony that immediately precedes the part quoted by DOT:

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[12] On page 20 of its brief, DOT quotes testimony from Dr. Reiley and mistakenly cites to "Exhibit U, Reiley Dep., Nov. 3, 2004, at 22-23." However, DOT's Exhibit U is a copy of the transcript of February 2, 2005 Deposition of Mark Reiley. The quoted statement actually appears on 21:9-22:1 of the transcript of the November 3, 2004 Deposition of Mark Reiley, a copy of the relevant pages are attached hereto as Ex. 9 to Halkowski Declaration.

November 3, 2004 Deposition of Mark Reiley [Halkowski Decl., Ex. 9], at 21:5-8. DOT also chose to omit the following testimony from Dr. Reiley, which, if anything, ascribes an unduly broad definition to the claimed inventions:

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Id. at 25:9-18 (emphasis added).

DOT's characterization of co-inventor Arie Scholten's testimony is also misleading. DOT avoids quoting the actual testimony, and instead cites to certain page numbers of the transcript as representing Mr. Scholten's testimony that "only the balloon worked, and that was what they invented." *See* D.I. 139, at 21. However, an examination of the actual testimony reveals that Mr. Scholten made clear that although the balloon was the "best way," it was not the only way.[13] And again, DOT chooses not to include Mr. Scholten's testimony that is ***consistent*** with the ordinary meaning of "compacting":

[13] Following are excerpts of Mr. Scholten's deposition testimony:

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February 15, 2005 Deposition of Arie Scholten [Halkowski Decl., Ex. 8], at 42:14-17.

Therefore, even if resort to inventor testimony were necessary and appropriate, such testimony would offer no help to DOT's claim construction position.

Moreover, DOT's importation of an "inflatable device" limitation into Claim 1 also runs afoul of the doctrine of claim differentiation. The Federal Circuit has aptly explained this doctrine, as follows:

> It is settled law that when a patent claim does not contain a certain limitation and another claim does, that limitation cannot be read into the former claim in determining either validity or infringement.
>
> The reason for the rule is well illustrated here. Non-asserted claim 3 is specifically drawn to the structure of Figure 1. To interpret the asserted claims as though they were also drawn to that structure (or to its manner of operation) would be to render the asserted claims ***superfluous***.
>
> In interpreting the asserted claims in light of the specification, the district court read limitations into them from other claims. That was error as a matter of law.

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February 15, 2005 Deposition of Arie Scholten [Halkowski Decl., Ex. 8], at 42:2-8; 46:2-16. *See also id.* at 58-62.

SRI, 775 F.2d at 1122 (emphasis added) (internal citations omitted).[14] Here, claim 1 of the '888 patent does not contain the "inflatable device" limitation that DOT is trying to add to the claims. Claim 5, however, which depends from claim 1, explicitly requires an inflatable device: "A method as set forth in claim 1, ***wherein said compacting step includes inflating an inflatable device*** in said passage to urge the osteoporotic bone marrow therein." '888 Patent [D.I. 146, Ex. F], at col. 9:41-44 (emphasis added). Similarly, claim 1 of the '404 patent does not contain the "inflatable device" limitation, yet dependent claim 5 explicitly requires such a limitation: "A method as set forth in claim 1, ***wherein said compacting step includes inflating an inflatable device*** in said passage to urge the bone marrow therein." '404 Patent [D.I. 146, Ex. B], at col. 9:53-55.

Thus, DOT's effort to read claim 1 as requiring the use of an "inflatable device" would render unasserted claim 5 "superfluous", and, just as was the case in *SRI*, construing the claims in that manner would constitute "error as a matter of law."[15]

In summary, the Court in its Preliminary Injunction decision has already rejected DOT's attempt to argue that the specification required the use of an "inflatable device" in the invention set forth in claim 1 of the '404 patent. D.I. 102, at 8-9 ("The Court finds that the patent does not state that an inflated device is an essential element of the invention or

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[14] "Where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement." *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574 (Fed. Cir. 1985). And "where the limitation that is sought to be 'read into' an independent claim already appears in a dependent claim, the doctrine of claim differentiation is at its strongest." *Liebel-Flarsheim*, 358 F.3d at 910 (citing *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302-03 (Fed. Cir. 2003)).

[15] DOT also asks the Court to alter the ordinary meaning of the term and add limitations such as "to form a void in the interior of a bone," "substantially all of the bone marrow," and "away from a central portion of an interior bone volume, towards the walls of bone." However, nothing in the intrinsic record supports such a construction, and DOT makes no effort to establish the existence of any such support.

that it is the only possible embodiment for achieving the claimed invention of compacting the bone marrow."). The specifications of the '888 and '404 patents, the Record of Invention, the prosecution history that DOT now quotes, and Dr. Reiley's deposition testimony from November 2004 were ***all*** before the Court. D.I. 84, Exs. F, H, L, U, W. The only piece of evidence DOT now relies on that was not before the Court was deposition testimony of Mr. Scholten, which offers no support to DOT's position, and certainly does not require the Court to change its interpretation of the scope of the claims.

4. "flowable material capable of setting to a hardened condition"

DOT contends that this term should be construed to mean "bone filler material capable of flowing and setting to a hardened condition." DOT's effort to further limit the material as being "bone filler material" simply pulls a term from thin air and invites mischief at trial regarding arguments over what is or is not commonly known to be "bone filler material." Rather than create more uncertainty by importing new terms, Kyphon has urged that the plain and ordinary dictionary meaning of "flow" requires the claimed "flowable material" be defined as "a material that is at some point in a fluid state, i.e., capable of flowing on its own." This approach hews close to the plain meaning of the claim term which simply defines a type of material that is at one point flowable (i.e., fluid) and is, on its own, capable of setting to a hardened condition.[16] Kyphon's Opening Brief, at 20.

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[16] Worthy of note is that the ordinary meaning of the term "flowable material capable of setting to a hardened condition" simply defines the type of flowable material by referring to what it is capable of. It does not state that the material is injected at any particular stage of firmness — paste, slurry, or otherwise. Obviously, the material starts out as a liquid outside the body and hardens on its own into a solid mass within the vertebrae, but the claims say nothing about when the material must be injected and precisely what viscosity, or thickness, the material must be when introduced into the bone.

Moreover, in addition to its claim construction, DOT's brief attempts to stretch this claim construction issue into a factual inquiry regarding what particular materials are covered by this claim term. DOT seeks to include bone grafts[17] and tri-calcium phosphate as "flowable materials capable of setting to a hardened condition." Kyphon vigorously disputes any such assertion. *See, e.g.*, March 23, 2005 Rebuttal Expert Witness Report of Michael Marks, M.D. [Halkowski Decl., Ex. 3], at 9, 11, 12. More importantly, however, any such assessment of the claims vis-à-vis particular materials is a factual determination that must be made by the Jury.

5. "forcing the bone marrow outwardly of the central portion of the bone"

DOT again claims that this claim term requires the use of an inflatable device. For the reasons discussed above, DOT's construction must be rejected.

Thus, the state of the material when it is used is irrelevant to the construction of the claim language.

17 With regard to bone grafts, DOT claims that Kyphon

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See D.I. 143, Ex. E-7, at KY 4932-56, Ex. E-8, at KY 263535. Moreover, the discussion referenced by DOT was being conducted over 11 years after the filing of the application for the '888 patent. *See id.*,, Ex. E-7, at KY 4932, Ex. E-8, at KY 263533. Thus, DOT's characterization of Kyphon's statement as an acknowledgement by Kyphon about the scope of the claim element is grossly misleading. Furthermore, none of the statements quoted by DOT (which DOT chooses to put in a separate motion, *see* DOT's Invalidity Summary Judgment Brief, D.I. 135, at 12-14) says anything about what is considered "flowable." In fact, the word "flow," "flowable," or any variant thereof is simply absent from the quoted statements.

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DOT cites nothing that says to fill a void, a material must be flowable. Of course, for the reasons explained by Dr. Marks, if bone graft were to be used in a kyphoplasty procedure, other additional steps would be required, such as internal fixation with metal supports, external fixation with a body cast, and/or extensive bed rest following surgery.

6. "wherein said forming step includes drilling said bone marrow to form said passage"

DOT asserts that "[i]n the context of the method of this patent," this claim term means "using a drill to break through the cortical wall of the bone." That is the full extent of DOT's discussion. DOT thus ignores that the claim language requires drilling the *bone marrow*, not just the outer cortical bone, and forming a passage *in the bone marrow*, not merely forming a hole, or fenestration, in the cortical bone. No explanation is ever provided for transforming the claim language as DOT does, to suit its needs. In contrast, Kyphon's Opening Brief offers the dictionary definitions and points to the specifications of the '888 and '404 patents to support its proposed construction. In essence, DOT is asking the Court to ignore the intrinsic record including the plain meaning of the claim language, and rewrite the claims. However, courts may not rewrite claims. *Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1365 (Fed. Cir. 2003). Therefore, DOT's unfounded construction must be rejected.

B. DOT's Proposed Construction of Disputed Claim Terms in the '043 Patent Must Be Rejected

With regard to the disputed claims of the '043 patent, DOT is, in addition to continuing to advance its "invention = balloon" argument, simply taking complete license to rewrite the claims without any effort to hew to the plain meaning of the claims.

1. "a body adapted to be inserted into bone and undergo expansion"

Like its construction of the "compacting" step of the '888 and '404 patents, DOT contends that this claim term requires an "inflatable body." DOT again cites to the title, the Abstract, the introduction, the Summary of Invention, the Background of the Invention, and the figures of the '043 patent. However, as discussed above, absent a clear disavowal by the patentee, DOT simply cannot import limitations from these sources. *Playtex*, 400

F.3d at 907; *Liebel-Flarsheim*, 358 F.3d at 906; *Liquid Dynamics*, 355 F.3d at 1369; *Brookhill-Wilk 1*, 334 F.3d at 1301; *Pitney Bowes*, 182 F.3d at 1304.

Contrary to DOT's implication, the specification does not define the invention as requiring the use of a balloon to provide necessary compression of all the bone marrow. Rather, the inflatable bone tamp is properly described as the best mode of practicing the broader invention of use of an "expandable body," as set forth in the claims. No matter how many times DOT uses the magic word "define," it cannot point to one instance where the patentee acts as his own lexicographer and defines the term "body" to mean "a balloon" or "an inflatable body," not even under the standards of *Bard*.

Likewise, the quoted text from the prosecution history does not evidence a "clear and unmistakable" disavowal to limit the scope of the plain, ordinary meaning of the claim term. Nothing in the quoted statement defines the term "body" to mean "a balloon" or "an inflatable body." Rather, even the language quoted by DOT describes how the invention may be used much more broadly than DOT says: "The present invention is adapted to be used within a bone to compact or compress the inner cancellous bone to form a cavity for receiving the supporting materials which can harden to a solid and relatively rigid condition." D.I. 139 at 28; D.I. 143, Ex. H at 6.[18] Later in the same amendment, the applicants, in discussing the '404 patent, again focus on compacting: "Scholten['s '404 patent] teaches the method for compacting cancellous bone to create a cavity . . . ." *Id.* at 25. The applicants explained this in no uncertain terms later in the prosecution of the '043 patent. After amending certain allowed claims to replace the term "inflatable" with the

[18] Moreover, DOT's reliance on the cited prosecution history, the November 27, 1995 Amendment in Response to First Office Action, is misplaced, because the discussion was limited to the then-pending claims that were drawn to "balloons" or "inflatable devices."

term "expandable," the applicants explained: "The amendments to the allowed claims remove what applicants believe are unnecessary limitations. The amendments also modify terminology to define the nature of applicants' invention with improved clarity." January 23, 1997 Preliminary Amendment, Appl. No. 08/788,786 [Halkowski Decl., Ex. 11], at 5.

The other passage from the prosecution history quoted by DOT also provides no help to DOT's construction. In that passage, the applicants discussed the balloons disclosed as the best mode in the '404 patent. But, as discussed above, an applicant does not relinquish the scope of a claim simply by comparing a preferred embodiment having a certain feature to the prior art that describes a similar feature. *Nystrom*, 374 F.3d at 1110, 1113. The quoted text sets forth statements made by the applicants in overcoming obviousness rejections. *See* D.I. 143, Ex. H, at KY 229178. A statement by the applicants that the prior art is unconcerned with certain features of a balloon device should not be read as a disavowal or disclaimer that applicants' claimed invention is limited to a balloon, but simply "as an argument against the examiner's obviousness rejection." *Nystrom*, 374 F.3d at 1113. If anything, the quoted language shows that "balloon" is ***not*** what distinguishes the '043 from the prior art; the distinguishing feature is, among other things, the use of a restraint to constrain and control an expandable body.

DOT also quotes the inventor's testimony – extrinsic evidence that really has no bearing on how to properly construe the claims – out of context in order to try to inject an unwarranted "balloon" limitation into the unambiguous ordinary meaning of the claim term. The testimony immediately preceding the quoted portion puts it into the proper

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See D.I. 143, Ex. H, at 1-4; Patent Application, Appl. No. 08/188,224 [Halkowski Decl., Ex. 10], at 29-40.

context. In the testimony quoted by DOT, the inventor was ***not*** describing what the full scope of the invention is, but why he decided to file the application:

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> MR. SCHERKENBACH: Objection; calls for a legal conclusion. You can answer.

February 15, 2005 Deposition of Arie Scholten [Halkowski Decl., Ex. 8], at 121:25-122:7. The quote cited by DOT then reflects Scholten's desire to secure patent protection for the invention, including most importantly of course the best mode the inventors had developed as of that time for practicing the invention.

Because DOT has offered no evidence that would require a departure from the unambiguous ordinary meaning of the claim term, the term "a body adapted to be inserted into bone and undergo expansion" cannot be read to require the use of a balloon or an inflatable body.

2. "the body . . . includes an internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone"

Aside from adding the unjustified "inflatable body (balloon)" limitation, DOT contends that: (i) "an internal restraint" means "a structure that is connected to the interior" of the body despite the fact that the claim requires no specific connection as long as it acts as a restraint internal to the expandable body; and (ii) that "to constrain the expansion" means "limits movement of the internal walls of the inflatable body," despite the fact that the claim language merely requires that expansion is constrained in some manner, without reference to internal walls or inflatable bodies DOT even attempts to further limit the

scope of the claim term by including examples. However, the only evidence DOT offers to support its limited construction, which like DOT's other constructions is inconsistent with the plain meaning of the claim language, is a passage from the specification where a preferred embodiment is described. Limitations, of course, cannot be imported from examples or preferred embodiments. *See, e.g., Playtex*, 400 F.3d at 907; *Liebel-Flarsheim*, 358 F.3d at 906; *Liquid Dynamics*, 355 F.3d at 1369; *Laitram*, 863 F.2d at 865; *Specialty Composites*, 845 F.2d at 987; *Brookhill-Wilk 1*, 334 F.3d at 1301. Thus, DOT's efforts to do so with respect to this term should be rejected.

Kyphon submits, therefore, that this term does not in fact require any further clarification or interpretation, and should simply be applied as it has been set forth in the claims of the '043 patent.

3. "causing constrained expansion of the body"

The only argument DOT advances with regard to this claim term is that the term "body" means an "inflatable body." DOT does not offer any additional evidence or support. Therefore, for the reasons stated above, DOT's construction must be rejected.

4. "compacting cancellous bone by the constrained expansion"

DOT contends that "[f]or all the reasons set forth above," this term should be construed to mean "using an inflatable body to form a void in the interior of a bone, where the expansion of the inflatable body is restrained by a structure connected to the interior of the inflatable body that limits movement of the internal walls of the inflatable body." In other words, DOT is again asking the Court to depart from the plain, ordinary meaning of a simple term and adopt DOT's unnecessarily restrictive construction because DOT says so. This language requires no clarification and can be readily applied as written in the terms chosen by the patentee. DOT's construction, therefore, should be rejected.

5. "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"

Here, DOT again offers a convoluted, and unduly restrictive construction to alter the plain, ordinary meaning of a claim. DOT asserts the above claim term should mean: "an inflatable body that can be inserted into bone and expanded, the inflatable body including at least two materials, one of which constrains its expansion by an internal or external structure connected to the inflatable body that limits movement of the walls of the inflatable body." Apart from undertaking a wholesale rewriting of the claim, DOT's interpretation also succeeds in completely ***omitting*** the following limitation — "apply a force capable of moving fractured cortical bone," likely because that is *exactly* how its SKy Bone Expander device works.[19] For the same reasons noted above regarding the impropriety of defining the claims to require the use of an "inflatable" device, as well as the fact that no intrinsic evidence supports DOT's effort to read in the numerous other limitations it seeks to add to this term, DOT's proposed claim construction should be rejected. As with a number of the other claim terms of the '043 that DOT seeks to rewrite, Kyphon does not believe that this term requires further clarification or interpretation; rather it can be applied simply as it is written.

C. Construction of Claim Terms Disputed by DOT re '734 Patent

The claimed inventions concern devices for filling bones with material. The specification of the '734 (and '054) patent emphasizes that the sliding of a tamp to push material into a bone at low pressure "serves to uniformly distribute and compact the

[19] As detailed in Dr. Marks' March 23, 2005, report, the SKy Bone Expander applies an axial compressive force via the metal rod (and nut) to the expandable body of the