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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

GENSCI ORTHOBIOLOGICS, INC.

Plaintiff and Counterclaim Defendant,

v.

OSTEOTECH, INC.

Defendant and Counterclaim Plaintiff.

CASE No. CV 99-10111 MRP

MEMORANDUM OF DECISION RE: CLAIM CONSTRUCTION

Osteotech Inc. ("Osteotech") and Gensci Orthobiologics, Inc. ("Gensci") filed Cross-Motions for Claim Construction of United States Patent Nos. 5,290,558 ("the '558 patent") and 5,284,655 ("the '655 patent") under Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995). The Motions came before this Court on October 24, 2000. The Court heard oral argument and conducted an evidentiary hearing at which both parties presented witnesses.

INTRODUCTION

Both Osteotech and Gensci make compositions for use in the surgical repair of bone defects. The products at issue in this case are demineralized bone compositions that enable surgeons to implant demineralized bone at a bone defect site. ~~Osteotech alleges that~~ two

527

of Gensci's demineralized bone products, Dynagraft Gel and Dynagraft Putty, infringe Osteotech's '558 and '655 patents.

While this litigation began as a patent infringement lawsuit filed by Osteotech against Gensci in the District of New Jersey, Gensci filed its own patent claims against Osteotech in the Central District of California, and the New Jersey litigation was transferred to this Court. Subsequently, after discovery, Gensci dropped its allegations of patent infringement by Osteotech, leaving for disposition only Osteotech's infringement allegations and Gensci's defenses of noninfringement and invalidity.

ANALYSIS

At the Markman hearing, the Court heard evidence and considered the Parties' arguments regarding the following five claim terms:

"POLYHYDROXY COMPOUND"

"LIQUID SOLUTION OF SOLID POLYHYDROXY COMPOUND"

"ACYCLIC POLYHYDRIC ALCOHOL"

"POLYALKYLENE GLYCOL"

"SWELLING AGENT"

The Court focuses on these five disputed terms because they are potentially dispositive of the central infringement issue in the case: whether the carrier used in Gensci's products - a block copolymer compound called Pluronic F127 - falls within the scope of these terms.

I. "POLYHYDROXY COMPOUND"

Gensci argues that the proper construction for the term "polyhydroxy compound" has three subparts: 1) that a "polyhydroxy compound" is limited to having two to about eighteen carbon atoms; 2) that a "polyhydroxy compound" is limited to having three or more hydroxy groups in the individual molecules; and 3) that a "polyhydroxy

compound" is limited to a group of compounds with similar functional characteristics based on multiple adjacent hydroxy groups. Osteotech, in opposition, argues that the term "polyhydroxy compound" simply defines a class of compounds having two or more hydroxy groups and is not limited to any specific size or particular set of functional characteristics.

Given that both the specification and claims of the patents-in-suit provide numerous examples of compounds that the patentee considered to be "polyhydroxy compounds," the Court determines that this term can be construed by the intrinsic evidence alone. While the Court does not rely upon extrinsic evidence in arriving at its construction, the interpretation applied by the Court does not conflict with any clear usage of "polyhydroxy" within the relevant art.

Having considered the intrinsic evidence and the arguments offered by the parties at the Markman hearing, the Court holds that the term "polyhydroxy compound," as used in the relevant claims of the patents-in-suit, shall mean "an organic molecule having two or more hydroxyl (-OH) groups."

A. Intrinsic Evidence

As used in the claims and specification of the patents-in-suit, "polyhydroxy" is not ambiguous and does not require that the Court resort to the use of extrinsic evidence. It is undisputed that the prefix "poly" means "many"; it follows that the word "polyhydroxy" refers to something having "many hydroxy groups." While this does not resolve the issue of whether "many hydroxy groups" includes "two hydroxy groups," it does narrow the necessary inquiry to the context

of the patents themselves: what kinds of compounds are classified in the patents as having "many hydroxy groups"?

The patents-in-suit, in disclosing the use of polyhydroxy compounds in the claimed inventions, include a representative listing of members of this class. The specifications and claims of both the '558 and '655 patents offer numerous examples of polyhydroxy compounds that include not only those with three or more hydroxy functional groups, but also those having only two hydroxy functional groups. ('558 patent at col.3, ln.66-col.4, ln.14; '655 patent at col.4, lns.20-36.)

If the Court were to construe the term "polyhydroxy compound" to include only those compounds possessing three or more hydroxy groups, the Court's construction would be at odds with many of the polyhydroxy examples disclosed in the '558 patent specification, including, among others, ethylene glycol, diethylene glycol, triethylene glycol, 1,2-propanediol, and the polyalkylene glycols. ('558 patent at col.3, ln.66-col.4, ln.14; '655 patent at col.4, lns.20-36.) A three-hydroxy construction would also eliminate some of the examples enumerated in the relevant claims of the '558 and '655 patents, such as some acyclic polyhydric alcohols,[1] all of the polyalkylene glycols, and some of the ester derivatives of those types of compounds. In light of this intrinsic evidence, the Court holds that even an organic compound with only two hydroxy groups may be characterized, within the context of the patents, as a "polyhydroxy compound."

Although Gensci additionally argues that the scope of "polyhydroxy compound" should be limited to compounds having only from

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[1] The Court construes the claim limitation "acyclic polyhydric alcohol" in section III, below.

two to about eighteen carbon atoms, the Court finds such a construction unwarranted. First, this proposed construction conflicts with the express examples of polyhydroxy compounds disclosed and claimed by the patentees. Similar to the effect that a three hydroxy limitation would have within the patents, a low carbon number limitation would eliminate many compounds cited in the specifications, including, among others, carrageenan, agar, alginic acid, guar gum, gum arabic, xanthan gum, gum tragacanth, and locust bean gum. ('558 patent at col.4, lns.9-14; '655 patent at col.4, lns.33-36.) This limitation would also eliminate certain claimed compounds, including many of the acyclic polyhydric alcohols, oligosaccharides, and polyalkylene glycols, and all of the polysaccharides.

Second, apart from a single statement in which the patentees state that "useful polyhydroxy compounds possess from 2 to about 18 carbons," ('558 patent at col.3, lns.64-66; '655 patent at col.4, lns.18-20.), nothing in the patents or the prosecution history reveals any intention by the patentees (or any understanding by the Examiner) that a carbon number limitation should be incorporated into the meaning of "polyhydroxy compound." Without a clear indication that the patentees intended to limit their invention to a preferred embodiment, it would be improper for the Court to import such a limitation into the claims. See Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.3d 855, 865 (Fed. Cir. 1988) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations.").

The prosecution history cited by Gensci in support of a carbon number limitation is inapposite. Gensci argues that the patentees added a Markush group to the claims to overcome a prior art rejection

based on polyhydroxy molecules with a higher number of carbons. To the contrary, the prosecution history demonstrates that the Examiner directed the patentees to claim specific polyhydroxy compounds to exclude "agents that are merely considered carriers having no direct effect, such as saline." ('458 App., 5-25-1993 Office Action at p.3-4.) When the patentees followed this suggestion, they directed the Examiner to the polyhydroxy examples mentioned in the specification, carefully citing to the "polyhydroxy" examples but avoiding the limiting language regarding the size of the compounds. ('458 App., 8-25-1993 Amendment and Remarks at p.4-5.) Because there is no evidence that the patentees included (or that the Examiner understood them to intend to include) the carbon limitation in the recited Markush group, the Court will not read this limitation into the claims.

The Court finds no evidence in the specifications, claims, or prosecution histories of the patents-in-suit that the term "polyhydroxy" should be limited to compounds with any particular set of functional characteristics. The "polyhydroxy" examples cited by the patentees cover thousands of compounds, all of which can widely vary in molecular weight, solubility, tertiary structure, melting point, freezing point, etc. To add a limitation based on functional characteristics, particularly solubility, would be improper and unjustified.

B. Extrinsic Evidence

While the Court does not find it necessary to look to extrinsic evidence to construe "polyhydroxy compound," the Court notes that, had it considered the extrinsic evidence, the Court would have arrived at the same construction as that which it now finds based upon the intrinsic evidence.

Even though Hawley's Condensed Chemical Dictionary, defining a "polyol" as having three or more hydroxy groups, might arguably provide indirect support for a "three hydroxy" interpretation of "polyhydroxy," other references demonstrate that "polyhydroxy" (as well as "polyol") is also used to denote compounds having only two hydroxy groups. (Exh. 1664) Both Webster's Dictionary and the Dictionary of Biochemistry and Molecular Biology, for example, define "polyhydroxy" as having two or more hydroxyl groups. (Exhs. 321 and 319.)

The testimony of Dr. O'Leary, a named inventor on both of the patents-in-suit, is of limited value in these circumstances. Inventor testimony, which is extrinsic evidence, is given little weight in claim construction. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 985 (Fed. Cir. 1995)("The subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim (except as documented in the prosecution history)."). Moreover, O'Leary's testimony is ambiguous, as it is impossible to determine from his testimony what he meant when he stated that the patentees did not "pop to poly," but instead were "talking about poly, many hydroxy compounds." (Grant Decl., Exh. 21, O'Leary Depo. at p.96-97.) The uncertainty as to O'Leary's motives cast a shadow over all his testimony. See Bell & Howell Document Management v. Altek Sys., 132 F.3d 701, 706 (Fed.Cir.1997) ("The testimony of an inventor is often a self-serving, after-the-fact attempt to state what should have been part of his or her patent application...."). O'Leary's testimony does not aid the Court in determining how one of skill in the art might understand the term in context, and will not be used to create ambiguity where none exists.

II. "LIQUID SOLUTIONS OF SOLID POLYHYDROXY COMPOUNDS"

The linchpin of the claim term "liquid solution of solid polyhydroxy compound" is the limitation "solution." Gensci argues that the plain meaning of "solution" is technical and narrow, excluding any mixture in which the molecules are not evenly distributed throughout the solvent. Osteotech, in contrast, argues that the plain meaning of "solution" is broad, encompassing both homogenous mixtures (so called "true" solutions) and other types of mixtures, such as dispersions and colloidal suspensions.

The Court determines that this term can be construed by the intrinsic evidence alone. While not based on extrinsic evidence, the Court's construction nevertheless does not conflict with the meaning of "solution" as used by those of ordinary skill in the relevant art.

Having considered the intrinsic evidence and the arguments offered by the parties, the Court holds that the term "liquid solutions of solid polyhydroxy compound," as used in the relevant claims of the patents-in-suit, shall mean "liquid solutions, including true solutions, colloidal solutions, and all other solutions, suspensions and dispersions, of solid polyhydroxy compound."

A. Intrinsic Evidence

While it is generally improper to read limitations into the claims from examples cited in the specification, see Laitram Corp., 863 F.3d at 865, it is critically important to compare these cited examples to the patent claims to confirm that the disputed terms are used consistently between them. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996) (holding that claims should be construed so as to maintain consistency with the specification and the preferred embodiments described therein).

The specification lists numerous examples of polyhydroxy compounds that are solids at room temperature and therefore must be mixed with water to create "liquid solutions of solid polyhydroxy compound." Many of these solid polyhydroxy compounds in water do not form true solutions, but instead form colloidal suspensions. In the '655 patent, for instance, Examples 4 and 5 disclose using a solution of dextran as a carrier for the composition. ('655 patent at col.7, ln.60-col.8, ln.8.) Dextran, a large molecule that is solid at room temperature, is not evenly dispersed when mixed with water to form a true solution, but actually forms a colloidal suspension. The same is true for other large molecules disclosed in the specifications of the patents-in-suit, such as agar, gums, carrageenan, etc. ('558 patent at col.4, lns.9-14; '655 patent at col.4, lns.33-36.) To interpret "solution" to exclude suspensions would therefore contradict the disclosure in the specification that certain polyhydroxy compounds can be made into solutions.

An overly narrow construction for "solution" would also void many of the liquid polyhydroxy solutions expressly claimed in the patents. Claim 4 of the '558 patent, exemplary of all other relevant claims of the patents-in-suit, lists a number of polyhydroxy compounds that do not form "true" solutions, but can only be suspended or dispersed in water. The polysaccharides, for example, when dissolved in water, form colloidal suspensions. The same is true for polyalkylene glycols such as polyethylene glycol or Pluronic F127 - they tend to form suspensions, not truly homogenous mixtures in which each molecule is spread evenly throughout.

That "solutions" should encompass a broader class of mixtures than simply "true" solutions is made apparent from the Markush group

in which the patentees claim compositions that include polyhydroxy solutions composed of "water-dispersible oligosaccharides." ('558 patent at claim 4 - emphasis added) Any construction that does not include dispersions within the broader class of mixtures called "solutions" would render meaningless the recitation of these particular Markush group members.

There is nothing in the prosecution history that imposes an additional limitation on the patentees' use of the word "solution." While Gensci attempts to argue that the patentees distinguished their invention from gels and pastes, a closer examination of the portions of the prosecution history cited by Gensci reveals that the patentees' statements dealt exclusively with the carrier components, not the consistency, of the claimed "flowable composition." ('458 App., 1-26-1993 Amendment and Remarks at p.4-8.) Whether any prior art compound was a gel or a paste was not relevant to the communications with the Examiner. (Id.) Indeed, based on the patentees express definition for "flowable," consistency is not relevant to determining whether a mixture can be classified as a solution.[2]

B. Extrinsic Evidence

Gensci incorrectly asserts that "solution," as used in the patents-in-suit, requires a more technical definition than that derived from ordinary meaning and context. Gensci apparently bases this construction on a mistaken position as to who should be

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[2] "The term 'flowable' in this context applies to compositions whose consistencies range from those which can be described as shape-sustaining but readily deformable, e.g., those which behave like putty, to those which are runny. Specific forms of flowable bone powder compositions include cakes, pastes, creams, and fillers." ('558 patent at col.3, lns.57-63.)

considered one of ordinary skill in the art. Gensci's expert, Dr. Eisch, testified at the Markman hearing that "solution" should be interpreted as it would be understood by one of ordinary skill in the art of physical chemistry. Dr. Eisch considers physical chemistry to be the relevant art for this invention, and one of ordinary skill in the art to be a Ph.D. level physical chemist. Dr. Eisch is mistaken.

The Court finds that the relevant art is that of making bone graft materials, and concludes that this term must therefore be defined with the same degree of specificity that one skilled in the art of making bone graft materials would use to define the term.[3]

As used in the field of bone graft materials, "solution" is a broad term encompassing "true" solutions, colloidal solutions, and other suspensions and dispersions. Osteotech provides evidence that persons of ordinary skill in the art of making bone graft materials use the term "solution" to include mixtures that are more technically classified as colloidal suspensions. For example, Gensci's Standard Operating Procedure classifies Pluronic F127 in water, undisputedly a colloidal suspension, as simply a "solution." (Exhs. 23 and 410.) The same broad usage can also be seen in the research notebook of Dr. Coulson, a Gensci inventor. (Exh. 25.)

Use of the term "solution" to encompass colloidal suspensions is also supported by general references outside the relevant art. Hawley's Condensed Chemical Dictionary, for example, explains that

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[3] Even if the Court were to agree with Gensci's incorrect characterization of the relevant art, extrinsic references demonstrate that persons of ordinary skill in the physical chemistry field often use the term "solution" to identify mixtures falling outside the hyper-technical definition that Gensci proffers. (See, e.g., Exh. 1666, J. Phys. Chem. and Exh. 36, J. Biomed Mat. Res.)

"[a] liquid colloidal dispersion is often called a solution." (Exh. 710 at 1034.) Dr. Hunter's treatise, Foundations of Colloid Science, also uses the term expansively, describing polysaccharide in water as a "colloidal solution or dispersion." (Exh. 1549 at 441.)

III. "ACYCLIC POLYHYDRIC ALCOHOL"

While both parties agree that the term "acyclic polyhydric alcohol" refers to an open chain compound, the central dispute is whether the compound has two or three hydroxyl groups. Relying on extrinsic evidence, Gensci and Osteotech both consider the term "polyhydric alcohol" to be synonymous with "polyol." Although Gensci argues that a polyol has three or more hydroxyl groups and Osteotech contends that it has only two or more, the experts of both parties admit that Pluronics have been often classified as polyols.

The Court agrees that extrinsic evidence must be used to construe the term. After considering this evidence, the Court finds that the term "acyclic polyhydric alcohol" shall be construed to mean "an open chain polyol, including any member of the class of Pluronic polyols."

A. Intrinsic Evidence

Analyses of the claims, specifications, and prosecution histories fail to provide an express construction or offer guidance in the construction of this term. Unlike the disputed claim terms above, the patentees did not list examples of acyclic polyhydric alcohols. Therefore, to construe this term, the Court must look to extrinsic evidence. See Vitronics Corp., 90 F.3d at 1584 (holding that a court may use extrinsic evidence when "intrinsic evidence is insufficient to enable the court to determine the meaning of the asserted claims").

B. Extrinsic Evidence

The parties have provided extrinsic evidence demonstrating that

the meaning of the term "polyhydric alcohol" is open to more than one interpretation. While neither party has provided a reference explicitly defining the term, both parties agree that the term "polyol" is synonymous with "polyhydric alcohol."

In support of its position, Gensci relies solely on Hawley's Condensed Chemical Dictionary, which defines "polyol" as a compound "containing three or more hydroxyl groups." (Exh. 52) Osteotech, however, points to a multitude of industrial and academic reference materials that characterize compounds with two hydroxyl groups as "polyols." Osteotech refers to the text Nonionic Surfactants (Exh. 317 at p.309-11; Exh. 475 at p.313), a BASF technical data sheet (Exh. 70), and a Gensci internal document on Dynagraft products (Exh. 32), all of which repeatedly refer to Pluronics (compounds with two hydroxy groups) as "PLURONIC polyols." The FDA apparently does the same in its documents. (Exh. 31 at p.6) Osteotech also presents the reference text Polyhydric Alcohols, which classifies dihydric alcohols as a subset of polyhydric alcohols. (Exh. 697)

In addition, Osteotech provides a number of patents that use the terms "polyol" or "polyhydric alcohol" to refer to compounds having two hydroxy groups. For example, Osteotech offered U.S. Patent No. 3,887,601, which equates the terms "polyhydric alcohol" with "organic polyol" and offers examples of compounds containing only two hydroxyl groups that it classifies as "polyhydric alcohols." (Exh. 656 at col.22); Osteotech provides U.S. Patent No. 4,963,555 (Exh. 703), which classifies a glycol as a polyhydric alcohol and U.S. Patent No. 4,980,108 (Exh 699), which presents examples of compounds with two hydroxyl groups that are classified as polyhydric alcohols.

The parties have demonstrated that terms "polyhydric alcohol" and "polyol" are interchangeable. While Gensci has provided only a single dictionary reference defining "polyol" as having three or more hydroxyl groups, Osteotech has provided persuasive, authoritative evidence of usage of the term to encompass those compounds containing only two hydroxyl groups. Most relevant to this action were the multiple references characterizing Pluronic compounds as polyols. Gensci's single dictionary definition notwithstanding, it is clear from the reference materials that "two hydroxy"-compounds, such as the Pluronic compounds, can be classified as polyhydric alcohols.

IV. "POLYALKYLENE GLYCOL"

The central issue is whether the generic term "polyalkylene glycol" necessarily refers to a homopolymer, that is, a polymer in which all of the alkylene subunits are identical. While Gensci argues that the term must refer to homopolymers exclusively, Osteotech contends that the term is broad, including both homopolymers and copolymers (compounds containing different alkylene subunits).

After considering the intrinsic and extrinsic evidence on this term, the Court construes the term "polyalkylene glycol" to mean "any homopolymer or copolymer of alkylene or oxyalkylene units terminated at both ends by a hydroxyl (-OH) group."

A. Intrinsic Evidence

As was the case with the term "acyclic polyhydric alcohol," the claims provide no representative examples to guide the Court in the construction of this term. The specification of the '558 patent, however, provides one example of a polyalkylene glycol; namely, polyethylene glycol, which is a homopolymer of ethylene subunits. ('558 at col.4, ln.5) While this statement in the specification

provides definitive evidence that polyalkylene glycols cover homopolymers of alkylene subunits, it does not speak directly to the issue before the Court: whether the term "polyalkylene glycol" excludes copolymers. Though Gensci cites to this portion of the specification to support construing the term narrowly, there is no express statement excluding copolymers that would justify reading such a limitation into the claims. See Laitram Corp., 863 F.3d at 865.

B. Extrinsic Evidence

Having determined that intrinsic evidence is inadequate to ascertain the proper construction for this term, the Court takes into account extrinsic evidence to decide whether the term "polyalkylene glycol" embraces both homopolymers and copolymers. See Vitronics Corp., 90 F.3d at 1584. Gensci presents evidence of patents, including those of Osteotech, in which all of the examples of polyalkylene glycols are homopolymers. Gensci fails to show, however, that the classification of the homopolymer examples as "polyalkylene glycols" necessarily precludes the use of the term to encompass copolymers.

To bolster the characterization that the term "polyalkylene glycols" necessarily excludes from its scope copolymers, Gensci performed a somewhat questionable search of the files of the United States Patent and Trademark Office to demonstrate that the terms "Pluronic" and "polyalkylene glycol" rarely appeared together in the same patent. Rather than providing affirmative references that support its limited proposed construction, Gensci instead emphasizes the paucity of references that apply Osteotech's broader definition.

Despite the fact that a search of the terms "polyalkylene glycol" and "copolymer" would have been more probative in ascertaining the

meaning of the term, Gensci's search nevertheless illustrates that "Pluronic" and "polyalkylene glycol" have been used together in the same patents. Though Gensci only found this correspondence in about two percent of the patents searched, the results show that the term "polyalkylene glycol" can be applied to a Pluronic compound.

Osteotech, in addition, offers numerous academic and industrial reference texts and patents supporting its inclusive construction. First, Osteotech points to the Kirk-Othmer Encyclopedia of Chemical Technology, which elucidates the term "polyalkylene glycol," describing it as a polymer that "can be formed by the polymerization of any alkylene oxide," and "is usually prepared either from propylene oxide" or "copolymers of propylene oxide and up to 50% ethylene oxide..." (Exh. 324) Also, Osteotech finds support for its construction in Ashford's Dictionary of Industrial Chemicals (Exh. 681 at p.724), which discusses the production of polyalkylene glycol using propylene oxide and ethylene oxide.[4]

Next, Osteotech relies on the resource text Nonionic Surfactants, which discusses "polyalkylene oxide block copolymers." (Exh. 475 at p.301) The Court finds that if polyalkylene oxide referred to homopolymers exclusively, it would be contradictory to classify it as a copolymer. Also, the same text identifies Pluronic polyols as polyalkylene oxide block copolymers, which contradicts Gensci's proposed construction limiting polyalkylenes to homopolymers. (Exh. 317 at p.309-10).

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[4]A number of references use the term "polyalkylene glycols" interchangeably with "polyoxyalkylene glycols," including Gensci's expert. (Trial Transcript, p. 46, l.1-17). See Osteotech brief, p.27-28, Exh. 476 ('073 patent); Exh. 484; and Exh. 485.

In addition, Osteotech offered many patents containing copolymer examples that had been classified as polyalkylene or polyoxyalkylene glycols. (See Exhs. 273; 275; 336; 340; 347 (showing that the terms polyethers, polyalkylene glycols, polyoxyalkylene glycols, and Pluronics can be interchangeable); Exh. 393 at col.2, lns.8-28 and col.3, lns.55-60 (describing polyalkylene glycols as copolymers); Exh. 318 at col.4, ln.53; and Exhs. 392 and 394 (providing Pluronics as an example of a polyalkylene glycol)).

Finally, Osteotech focuses on the pioneering patent for preparation of Pluronics, U.S. Patent No. 2,674,619, which classifies Pluronics as polyoxyalkylene compounds (Exh. 395). After reviewing numerous sources that define and use the term "polyalkylene glycols" to include copolymers, as well as finding no references that limit the term solely to homopolymers, the Court construes the term "polyalkylene glycol" to include both homopolymers and copolymers.

V. "SWELLING AGENT"

Both Gensci and Osteotech agree that a "swelling agent" is an agent that causes swelling. The point of contention, however, is whether the term excludes aqueous media outside the acidic pH range. The parties rely solely on intrinsic evidence to justify their proposed constructions. Gensci argues that an aqueous swelling agent must be within the acidic pH range from two to six. Osteotech counters, however, that the ordinary meaning of the term "swelling agent" suffices for claim construction.

The Court finds that the intrinsic evidence is sufficient to construe this term. After considering the claims, specification, and prosecution history, the Court construes "swelling agent" to mean: "An agent that causes swelling. In this patent, an aqueous swelling agent

must be acidic unless it is a polyhydroxy compound functioning as a carrier."

A. Intrinsic Evidence

Gensci begins with Example 1B of the '655 patent, which states that it is a "critical requirement" that an aqueous swelling agent must be in the acidic pH range. The specification, however, distinguishes swelling agents that are carriers for the swollen bone particles from those that are not carriers. It defines the carriers as "certain liquid polyhydroxy compounds" and the non-carriers as "aqueous media." Thus, while it may be questionable in common usage whether any difference exists between aqueous polyhydroxy media and liquid polyhydroxy compounds, the specification sets up a clear distinction between the two terms. Since the patentees have defined the limitation as critical, rather than merely "preferred," the Court will read a narrow acidity requirement into the claims.

The specification also states that acidity is preferred for polyhydroxy compounds, as a polyhydroxy swelling agent will provide quicker results if it is acidic. See '655 patent at col.4, lns.53-62 (referring to "[n]on-acidic polyhydroxy component swelling agents"). By stating that a polyhydroxy swelling agent will be more effective when it is acidic, the specification clearly does not require polyhydroxy swelling agents to be acidic. Since the preferred embodiment described in the specification concerning the polyhydroxy swelling agents is not a claim limitation,[5] the acidity requirement applies to all swelling agents except those that are polyhydroxy compounds also functioning as carriers.

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[5]See Markman, 52 F.3d at 979-80; Laitram Corp., 863 F.2d at 865.

Last, Gensci argues that the prosecution history demonstrates that the Examiner required the limitation that all swelling agents be acidic. Osteotech had argued, during prosecution, that the Examiner incorrectly assumed that physiological saline, which has a "nearly neutral" pH, is effective as a swelling agent. Since neutral saline is neither an acidic media nor a polyhydroxy compound, the argument is inapposite. Therefore, the Court determines that the acidity requirement shall not apply to polyhydroxy compounds also functioning as carriers.

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CONCLUSION

Having considered the Motion, the papers filed in support of and in opposition to the Motion, the other pleadings and papers on file, and the evidence presented and the arguments of counsel at the Markman hearing, IT IS HEREBY ORDERED:

1. "Polyhydroxy compound" as used in relevant claims of the patents in suit shall mean: "An organic molecule having two or more hydroxyl (-OH) groups."

2. "Liquid solutions of solid polyhydroxy compound" as used in relevant claims of the patents in suit shall mean: "Liquid solutions, including true solutions, colloidal solutions, and all other solutions, suspensions and dispersions, of solid polyhydroxy compound."

3. "Acyclic polyhydric alcohol" as used in relevant claims of the patents in suit shall mean: "An open chain polyol, including any member of the class of Pluronic polyols."

4. "Polyalkylene glycol" as used in relevant claims of the patents in suit shall mean: "Any homopolymer or copolymer of alkylene or oxyalkylene units terminated at both ends by a hydroxyl (-OH) group."

5. "Swelling agent" as used in relevant claims of the patents in suit shall mean: "An agent that causes swelling. An aqueous swelling agent must be acidic unless it is a polyhydroxy compound that also functions as a carrier."

DATED: December 6, 2000

Mariana R. Pfaelzer

Honorable Mariana R. Pfaelzer
United States District Judge