United States District Court,
E.D. Virginia, Richmond Division.

LIFENET, INC,
Plaintiff/Counterclaim-Defendant.
v.
MUSCULOSKELETAL TRANSPLANT FOUNDATION,
Defendant/Counterclaim-Plaintiff.

Civil Action No. 3:06CV387-HEH

June 21, 2007.

Craig Thomas Merritt, Nichole Buck Vanderslice, Rowland Braxton Hill, IV, Christian & Barton LLP, Richmond, VA, Anthony Roth, Corinne A. Niosi, David Michael Morris, Jennifer Lynn Scism, Nathan Wayne McCutcheon, Robert William Busby, Jr., William Jackson Matney, Jr., Morgan Lewis & Bockius LLP, Washington, DC, Kell M. Damsgaard, Morgan, Lewis & Bockius, LLP, Philadelphia, PA, for Plaintiff/Counterclaim-Defendant.

Dana Johannes Finberg, Leclair Ryan PC, Richmond, VA, Thomas Gerard Rowan, Brian Michael Poissant, Daniel Lawrence Malone, Eric Stops, Jones Day, New York, NY, Michelle Karen Fischer, Thomas Robert Goots, Jones Day, Cleveland, OH, for Defendant/Counterclaim-Plaintiff.

MEMORANDUM OPINION

(Claim Construction)

HENRY E. HUDSON**, United States District Judge.**

This is a patent infringement action filed by Plaintiff LifeNet, Inc. against Defendant Musculoskeletal Transplant Foundation ("MTF"). It is before the Court for the construction of the disputed claim terms in the patents-in-suit. Both parties have filed memoranda of law in support of their respective positions, and the Court conducted a claim construction hearing on May 31, 2007. The Court's construction of the disputed terms follows.

I. Background

There are four patents-in-suit. United States Patent Nos. 5,797,871 ("the ' 871 patent") and 5,976,104 ("the '104 patent") (collectively, "the Bone Cleaning Patents") describe a process for cleaning bone grafts using an ultrasonic cleaning device to produce bone grafts that are free from bone marrow and free from bacterial, fungal, and viral contamination. United States Patent Nos. 6,189,537 ("the '537 patent") and 6,305,379 ("the '379 patent") (collectively, "the Demineralization Patents") describe a process for demineralizing bone to produce an optimally osteoinductive bone, which is a bone having a certain optimal range of residual calcium.

The '871 patent issued on August 25, 1998, and the '104 patent issued on November 2, 1999. The '871 patent application is a continuation-in-part of, and incorporates by reference, the '104 patent application. The Bone Cleaning Patents describe a process of cleaning bone in one or more solvents to remove bone marrow, bacteria, viruses, fungi, and other contaminants from the bone. The process varies based on the cleaning method used during each step, the type of solvent used during each step, the processing temperature, and the sequence and number of the cleaning steps. The various steps may include using an ultrasonic cleaning device with solvent, agitating the solvent, or inducing a flow of the solvent through the bone. The types of solvents include water, detergents, decontaminating agents, as well as antibacterial, antimycotic, and antiviral agents. One of the central inventive aspects of the Bone Cleaning Patents is the ultrasonic cleaning, by itself and in combination with inducing a flow of solvent through the bone.

The '537 patent issued on February 20, 2001, and the '379 patent issued on October 31, 2001. The '379 patent application is a continuation of the ' 537 patent application, and thus, the patents have identical specifications. The Demineralization Patents describe a process of demineralizing bone, i.e., subjecting the bone to an acid bath for a certain period of time in order to remove calcium from the bone. The object of the invention is to create an optimally osteoinductive bone, which, according to the specification, is a bone demineralized to between 1 wt % and 4 wt % residual calcium, or most preferably between 2 wt % and 2.3 wt %. The process includes contacting the bone with an acidic solvent and optionally contacting the bone with a detergent. A linear relationship exists between the pH of the eluent acidic solvent and the amount of residual calcium in the bone, and therefore, the process may also include measuring the pH of the eluent acidic solvent as a way of monitoring the residual calcium level.

LifeNet is currently asserting eight claims in the '871 patent-claims 1, 3 (dependant on claim 1), 10 (dependant alternatively on claims 1, 8, and 9), 11, 19 (dependant on claim 11), 20 (dependant on claim 19), 24, and 25-and three claims in the '104 patent-claims 10, 13, and 15 (dependant alternatively on claims 1, 3, 10, 12, and 13). LifeNet is asserting claims 1, 2 (dependant on claim 1), 4, 9, 12 (dependant alternatively on claims 9 and 11), 13 (dependant on claim 9), and 16 of the '537 patent and claims 3, 6, 11 (dependant alternatively on claims 5 and 6), 14, 15, 17 (dependant on claim 16), 19, 21, 26, 35 (dependant alternatively on claims 29-32 and 33), and 37 (dependant on claim 36) of the '379 patent.

II. Statement of the Law

Claim construction is a question of law for the court to decide. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996). Generally, claim terms are given their "ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (internal quotation marks omitted). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1313. Construing the disputed terms begins with a review of the intrinsic evidence, including the language of the disputed claim, the other claims, the specification, and the prosecution history. *Id*. Courts may also consider extrinsic evidence, which includes all other evidence, such as expert testimony, dictionaries, and learned treatises. *Id*. at 1317.

The specification has been characterized as the "single best guide to the meaning of a disputed term" and is usually "dispositive." *Id*. at 1315 (internal quotation marks omitted); *see* United States v. Adams, 383 U.S. 39, 49 (1966) ("[I]t is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention."). Thus, " '[t]he construction that stays true to the

claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.' " Phillips, 415 F.3d at 1316 (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998)). "A claim construction that excludes a preferred embodiment, moreover, 'is rarely, if ever, correct.' " SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1285 (Fed.Cir.2005) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed.Cir.1996)).

Although considered less reliable than intrinsic evidence, extrinsic evidence can help the court determine what a person of ordinary skill in the art would understand claim terms to mean, but it should not be used to support a construction that contradicts the intrinsic evidence. Phillips, 415 F.3d at 1318-19.

III. Analysis

With the above principles in mind, the Court will now turn to the terms in dispute. Some of the terms are edited to reflect the true nature of the parties' disagreement, primarily by removing superfluous words that are not in dispute.

A. The Bone Cleaning Patents

1. "sonicating"

LifeNet suggests that "sonicating" means "applying ultrasonic sound energy," while MTF proposes that it means "the use of an ultrasonic cleaning device to create high frequency sound waves in a solution which causes the formation and collapse of microscopic cavities (cavitation) to clean bone." The Court finds that MTF's proposed construction is cumbersome and overly narrow. For example, in addition to reciting "sonicating," claim 1 of the '871 patent also recites "an ultrasonic cleaner" and "to produce cleaned bone ." Thus, it would be improper to include those limitations in the definition of "sonicating."

The specification appears to use sonication interchangeably with "ultrasonic cavitation" and "ultrasonic energy." *See* '871 Patent, col. 3, line 1, col. 4, line 9. LifeNet's definition is consistent with the claims, the specification, and at least two technical dictionaries. *See* Dorland's Illustrated Medical Dictionary 1664 (29th ed.2000) ("sonication" defined as "exposure to sound waves"); Taber's Cyclopedic Medical Dictionary 1787 (18th ed.1997) ("sonication" defined as "[e]xposure to high frequency sound waves"). Accordingly, the Court will adopt LifeNet's construction. "Sonicating" means "applying ultrasonic sound energy."

2. "agitating"

The next term in dispute is "agitating." LifeNet proposes the definition "to move back and forth, stir, or shake," while MTF proposes "agitation achieved through the use of a gyrator shaker, commercial paint shaker, pulsatile lavage, or means to achieve similar result." MTF's construction is based on two terms defined in the specification of the '871 patent, as follows:

Mild Agitation. By the term "mild agitation" is intended agitation achieved through the use of a gyrator shaker or means to achieve a similar result, including, for example: pulsatile lavage wherein induced currents in the solution impact the surface of bone and annoited [sic] soft time [sic].

Vigorous Agitation. By the term "vigorous agitation" is intended agitation achieved through the use of a commercial paint can shaker or other means which achieve a similar result including, for example, high pressure pulsatile lavage wherein induced currents in the solution impact the surface of bone and annoited

[sic] soft tissue.

'871 Patent, col. 8, lines 31-41. "Agitating" clearly includes "mild agitation" and "vigorous agitation," particularly given the fact that two dependent claims in the '871 patent recite "wherein said agitating comprises mild agitation" and "wherein said agitating comprises vigorous agitation." ' 871 Patent, col. 13, lines 58-61. Except for citing the two definitions above, however, MTF provides no further support for limiting "agitating" to only "mild agitation" and "vigorous agitation." Certain claims recite only "agitating," and thus, are properly construed more broadly than MTF's definition. A broader construction is also necessary because "agitating," by itself, does not limit the claim to any particular method or machine to cause the agitation.

MTF's primary concern with LifeNet's definition is that LifeNet may contend that "sonicating" causes the bone to move back and forth, thus eviscerating the distinction between "sonicating" and "agitating," a distinction that LifeNet made to secure allowance of the claims of the '871 patent. In a September 21, 2004 Response to the United States Patent and Trademark Office during a re-examination of the '871 patent, the applicant wrote "agitation of bone grafts is not sonication of such grafts." MTF Rebuttal Br., Ex. 18, '871 Re-exam, Response 8 (Sept. 21, 2004); *see also* MTF Opening Br., Ex. 5, '871 Patent, Response 9 (Oct. 20, 1997) (noting that a prior art patent teaches sonication, but not agitation). Further, the specification of the '871 patent provides that certain processing steps "may include agitation only, sonication only, and agitation and sonication," thus distinguishing between two. Therefore, the Court agrees that it is appropriate to define "agitating" in such a manner as to exclude "sonicating."

LifeNet's definition is sufficiently broad, but does not include sonicating. Thus, the Court construes "agitating" to mean "moving back and forth, stirring, or shaking."

3. "an antibiotic, an antimycotic and an antiviral agent"

Several of the claims in the '871 patent recite "an antibiotic, an antimycotic and an antiviral agent." LifeNet argues that the term means "an agent that destroys or suppresses the growth or reproduction of bacteria or other microorganisms, an agent that destroys or suppresses the growth of fungi or other microorganisms, and an agent that destroys or suppresses the function or reproduction of viruses." LifeNet's proposed construction is based on the general meaning of the terms as defined by several medical dictionaries. *See* LifeNet's Opening Br., Ex. 10, Dorland's Illustrated Medical Dictionary 38, 98, 105, 211, 1965 (29th ed.2000), Ex. 11, Taber's Cyclopedic Medical Dictionary 118, 123, 125 (18th ed.1997), Ex. 16, Stanley Hoppenfeld & Michael S. Zeide, Orthopaedic Dictionary 19 (J.B. Lippincott Co.1994). MTF argues that any construction adopted by the Court should limit the definition, first, to include only "FDA-approved pharmaceutical drugs," second, to exclude "detergents," and third, to exclude "general antiseptics or disinfectants such as alcohols ... and hydrogen peroxide." The Court will address each proposed limitation in turn.

There is no mention of the words "FDA-approved" or "drug" in the '871 patent. MTF concludes that one of skill in the art would interpret "an antibiotic, an antimycotic and an antiviral agent" to be an FDA-approved drug based on the prosecution history, as well as entries in a technical manual and an encyclopedia. While these documents suggest that the term "an antibiotic, an antimycotic and an antiviral agent" includes FDA-approved drugs, which LifeNet does not dispute, nothing cited by MTF requires that the term include *only* FDA-approved drugs. The use of the word "agent," instead of "drug," supports a broader interpretation of the term. *See* LifeNet's Opening Br., Ex. 10, Dorland's Illustrated Medical Dictionary 38 (29th ed.2000)

(defining "agent" to be "any ... substance capable of producing an effect, whether physical, chemical, or biological").

The next question for the Court is whether "an antibiotic, an antimycotic and an antiviral agent" excludes detergents. MTF argues that it does based on the prosecution history. In an October 20, 1997 Response, the applicant described a prior art patent, U.S. Patent No. 5,095,925 ("Elledge"), as disclosing a "two-step process, where in the first step the article to be cleaned is subjected to a positive pressure stream of sterile water, and in the second step the article is sonicated in water optionally containing surfactant." MTF's Opening Br., Ex. 5, '871 Patent, Response, at 5-6 (Oct. 20, 1997). The Response distinguishes Elledge by stating that "Elledge does not teach after sonicating in a solvent, sonicating the bone segment in an antibiotic, antimycotic and/or an antiviral agent followed by a third sonication step in a third solvent containing one or more decontaminating agents." Id. at 9. Neither this statement, nor any other statements made in the Response, represents the clear and unequivocal disavowal required to constitute prosecution disclaimer. *See* Seachange Int'l, Inc. v. C-Cor, Inc., 413 F.3d 1361, 1373 (Fed.Cir.2005) (requiring a "clear and unambiguous" disclaimer); Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1368 (Fed.Cir.2004) (requiring an "unequivocal[ ]" disclaimer).

MTF argues that, without the disclaimer, Elledge discloses the claimed invention. This argument is best reserved until the question of validity is before the Court. A claim should be interpreted to preserve validity only when "the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous." Phillips, 415 F.3d at 1328. There may be some ambiguity in what the applicant believes distinguishes the invention from Elledge, but there is no ambiguity in the plain meaning of the term "an antibiotic, an antimycotic and an antiviral agent." The '871 patent specifically mentions the antibacterial and antiviral properties of detergents. *See* '871 Patent, col. 2, lines 50-52 ("Alcohol and detergents have been demonstrated to be virucidal towards enveloped viruses such as HIV and hepatitis and certain bacteria...."). Thus, "an antibiotic, an antimycotic and an antiviral agent" may include a detergent, so long as it fits within the definition of the term.

The Court next considers whether "an antibiotic, an antimycotic and an antiviral agent" excludes "general antiseptics or disinfectants such as alcohols ... and hydrogen peroxide." It is MTF's position that, because LifeNet discloses "alcohol ... and hydrogen peroxide" in the specification but does not recite them in the claims, those solvents are excluded from patent protection. Considering first the claims, claim 24 recites three solvents, a "first solvent comprising one or more detergents," a "second solvent comprising one or more members selected from a group consisting of: an antibiotic, an antimycotic and an antiviral agent," and a "third solvent comprising one or more decontaminating agent." '871 Patent, col. 14, lines 35-44. Because there are three separate terms, MTF argues that "an antibiotic, an antimycotic and an antiviral agent" must mean something different than a "detergent" or a "decontaminating agent," which are defined by the specification as follows:

Detergent. By the term "detergent" is intended any agent which through a surface action that depends on it possessing both hydrophilic and hydrophobic properties and/or exerts oil-dissolving (cleansing) and/or antibacterial and/or antiviral effects, and can include but is not limited to: anionic detergents, cationic detergents, acridine derivatives, long-chain aliphatic bases or acids, etc.

....

Decontaminating Agent. By the term "decontaminating agent" is intended one or more agents which remove

or inactivate/destroy any infectious material potentially present in the bone marrow of a bone graft, for example, such materials including but not limited to: bacteria, virus, and/or fungi; with such decontaminating agents including, for example, but not limited to one or more of the following: an antibacterial agent; an antiviral agent; an antimycotic agent; an alcohol for example, methyl, ethyl, propyl, isopropyl, butyl, and/or t-butyl; trisodium phosphate; sodium hydroxide; hydrogen peroxide; and/or any detergent.

'871 Patent, col. 5, lines 55-60, col. 6, lines 11-16. Clearly, the terms overlap, but even if the Court were to accept LifeNet's definition, the terms would mean something different. For example, an antibiotic, an antiviral, or an antimycotic agent with no surface acting properties may be considered a decontaminating agent (and of course an antibiotic, antimycotic, or antiviral agent) but would not be considered a detergent. As another example, a substance that removes bacteria, but does not destroy or suppress the bacteria's growth, may be considered a decontaminating agent (and a detergent if it also has surface acting properties), but not an antibiotic agent.

MTF does correctly note that the specification lists the solvents separately in multiple places. For example, in addition to the definition for "decontaminating agent" above, the specification teaches that a solvent "may contain ... an alcohol, ... virucidal agent; bacteriocidal agent; antimycotic agent; ... and hydrogen peroxide." '871 Patent, col. 6, lines 53-63. MTF, however, provides no case law that supports the proposition that merely listing terms in the specification and then including only a subset of the terms in a claim constitutes a clear and unambiguous disclaimer. Further, the specification describes the antibacterial and antiviral properties of alcohol and hydrogen peroxide:

... Alcohol and detergents have been demonstrated to be virucidal towards enveloped viruses such as the HIV and hepatitis and certain bacteria.... Alcohol and detergent solutions also offer advantages of ... inactivating viruses and bacteria.

....

... For example, addition of ethanol or isopropanol ... to the washing solvent would serve to reduce bacterial, fungal, and/or viral contaminants which might be present in the bone graft.....

....

... antiviral agents (for example, peroxide generating agents such as Exact (a trademarked produce marketed by ExOxEmis, Inc....)....

'871 Patent, col. 2, lines 49-57, col. 8, lines 6-10, 30-32. Indeed, MTF does not appear to dispute that alcohols and hydrogen peroxide exhibit antibacterial, antifungal, and antiviral properties. Thus, because the intrinsic evidence contains no clear and unambiguous disclaimer, it would be inappropriate to exclude alcohols and hydrogen peroxide from the claim term "an antibiotic, an antimycotic and an antiviral agent."

Accordingly, "an antibiotic, an antimycotic and an antiviral agent" means "a substance that destroys or suppresses the growth or reproduction of bacteria or other microorganisms, a substance that destroys or suppresses the growth of fungi, and a substance that destroys or suppresses the function or reproduction of viruses."

4. "first," "second," and "third," regarding the steps in method claims

The next dispute involves the terms "first," "second," and "third." Claim 24 recites:

A method for producing a bone graft suitable for transplantation into a human, comprising:

sonicating said bone graft using an ultrasonic cleaning device with *a first solvent* comprising one or more detergents to produce *a first cleaned* bone graft*;*

sonicating *said first cleaned* bone graft using an ultrasonic cleaning device with *a second solvent* comprising one or more members selected form the group consisting of: an antibiotic, an antimycotic and an antiviral agent, to produce *a second cleaned* bone graft, and

sonicating *said second cleaned* bone graft using an ultrasonic cleaning device with *a third solvent* comprising one or more decontaminating agents to produce *a third cleaned* bone graft, wherein *said third cleaned* bone graft is essentially free from bone marrow.

'871 Patent, col. 14, lines 32-47 (emphasis added). As claim 24 shows by example, a number of the claims in the '871 patent include multiple steps. The parties do not dispute that steps may occur before or after the recited steps, FN1 nor do they dispute that the steps must occur in the recited order. Rather, the disagreement centers on whether the steps must follow each other immediately, without any intervening steps. MTF argues that the steps must follow each other immediately and thus intervening steps should be disallowed. The claim language, however, runs contrary to MTF's argument.

FN1. In its proposed claim constructions, MTF argued that a "first solvent" means "the first solvent used in the process to clean the bone graft," which appears to preclude using another solvent in a separate step before the step using the "first solvent." LifeNet's Opening Br., Ex. 7, MTF's Proposed Claim Constructions (May 2, 2007). MTF sets this argument aside, however, asserting in its Rebuttal Brief that it "has never disputed" that "Claim 24 allows steps *before* the three recited steps in the claim." MTF Rebuttal Br. 12. The use of the open-ended transition "comprising," as well as the specification itself, supports an interpretation that allows for steps before and after the recited steps. *See* Medichem, S.A. v. Rolabo, S.L., 353 F.3d 928, 933 (Fed.Cir.2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps." (internal quotation marks omitted)); *see also* '871 Patent, col. 8, lines 46-47 (describing the use of a "water lavage" before applying a "[first] solvent containing one or more detergents").

For example, claims 19 and 20 recite:

19. The method of claim 11, further comprising:

sonicating said first cleaned bone graft using an ultrasonic cleaning device with a second solvent comprising one or more members selected from the group consisting of: an antibiotic, an antimycotic and an antiviral agent, to produce a second cleaned bone graft; and

sonicating said second cleaned bone graft using an ultrasonic cleaning device with a third solvent comprising one or more decontaminating agents to produce a third cleaned bone graft.

20. The method of claim 19, further comprising:

sonicating said second cleaned bone graft with sterile water prior to sonicating with said third solvent.

'871 Patent, col. 13, line 62 to col. 14, line 11. Claim 20 inserts an intervening step between the two steps recited in claim 19. In addition, the specification describes an intervening step using water. *See* '871 Patent, col. 9, lines 15-22.

Generally, a claim which "comprises" multiple steps, as here, is open-ended, allowing for additional steps, unless there is "clear intent to limit the claims." *See* Scanner Techs. Corp. v. Vision Sys. Corp., 365 F.3d 1299, 1305-06 (Fed.Cir.2004). MTF shows no such "clear intent." Thus, the use of the transition "comprising" further supports an interpretation that does not preclude intervening steps. *See* Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368 (Fed.Cir.2003).

Accordingly, the terms "first," "second," and "third," as they relate to the steps in the method claims, mean that the steps recited in the claims must be completed in order, but there may be steps before and after, as well as intervening steps in between.

5. "to produce a cleaned bone graft **essentially free from bone marrow" and "wherein said first cleaned** bone graft **is essentially free from bone marrow"**

Next, the parties dispute the meaning of the terms "to produce a cleaned bone graft essentially free from bone marrow" and "wherein said first cleaned bone graft is essentially free from bone marrow." "Bone graft," "essentially free from," and "bone marrow" are all defined in the '871 patent specification. *See* '871 Patent, col. 5, lines 19-30, col. 6, lines 1-5, 34-38. LifeNet takes the position that, because the term is a concatenation of terms defined in the patent, it does not require construction by the Court. The Court substantially agrees.

Claim 1 recites a "method for producing a bone graft ... comprising: sonicating said bone graft with a solvent comprising one or more detergents ... for a time period effective to produce a cleaned bone graft essentially free from bone marrow." In its Opening Brief, MTF essentially argues that the step of "sonicating said bone graft with a solvent" in claim 1 must yield a bone graft with no bone marrow detectable using detection means known in the art at the time of filing of the application. *See* MTF Opening Br. 13. This argument is self evident and appears to be undisputed by LifeNet.

In its Rebuttal Brief, MTF takes it further, arguing that the " 'time period effective' language limits the recited cleaned bone graft to one that has been sonicated in a detergent only." To begin, this argument goes beyond the term in dispute, including terms that were not included in the Joint Stipulation Regarding Disputed Claim Terms submitted by the parties to the Court on May 4, 2007. Nonetheless, while the step of "sonicating said bone graft with a solvent comprising one or more detergents" must yield a "cleaned bone graft essentially free from bone marrow," that step may be preceded by other steps, as the Court already explained above. Further, "comprising one or more detergents" requires that the solvent include "a detergent," but allows for the possibility of other substances being included as well, such as another detergent or a disinfectant. Thus, it would be inappropriate to limit the "cleaned bone graft" in claim 1 to a cleaned bone graft that has been "sonicated in a detergent *only*."

The Court therefore finds that the term "to produce a cleaned bone graft essentially free from bone marrow" means "to produce a cleaned bone graft that contains no bone marrow detectable using detection means known in the art at the time of filing of the application for the '871 patent." "Wherein said first cleaned bone graft is essentially free from bone marrow" means "wherein the first cleaned bone graft contains no bone marrow that is detectable using detection means known in the art at the time of filing the application for the '871 patent."

6. "inducing a pressure mediated flow of solvent"

The parties declare the term "inducing a pressure mediated flow" to be in dispute. According to the specification of the '104 patent, a "pressure mediated flow of solvent" is "a flow of solvent induced by positive or negative pressure." '104 Patent, col. 4, lines 10-13. The specification further defines "positive pressure" and "negative pressure." *See* '104 Patent, col. 4, lines 50-56. Because the parties raise no substantial disagreement regarding the meaning of this term, the Court will adopt the definition from the specification. Thus, "inducing a pressure mediated flow of solvent" means "causing a flow of solvent induced by positive or negative pressure."

7. "through said essentially intact bone graft**"**

The next term is "of solvent through said essentially intact bone graft." LifeNet suggests that the term means "solvent enters and exits some portion of essentially intact bone graft." MTF asks the Court to adopt the construction, "pressure mediated flow is used to cause a solvent to flow through the essentially intact bone graft, past a given point, per unit time, throughout the bone cleaning process." The parties' dispute centers on the meaning of "through."

LifeNet suggests that the term requires the solvent to go through "some portion" of the bone graft, and MTF suggest that the term requires the solvent to go through "an entire essentially intact bone graft from one end to the other." MTF does point to several examples in the specification of solvent going through an entire bone graft, but fails to cite a requirement that it *must* go through the entire bone graft. The Court therefore rejects this limitation.

Further, nothing in the claims requires a flow "throughout the bone cleaning process." On the contrary, the specification states that the flow may be "discontinued" during the process. '104 Patent, col. 10, line 65 to col. 11, line 4. Thus, the Court also rejects this limitation. *See* In re Am. Acad. of Sci. & Tech. Ctr., 367 F.3d 1359, 1369 (Fed.Cir.2004) ("We have cautioned against reading limitations into a claim from the preferred embodiment described in the specification, even if it is the only embodiment described, absent clear disclaimer in the specification.").

Because the term itself is consistent with LifeNet's "some portion" characterization and does not include the improper limitations suggested by MTF, the Court finds that no construction is necessary for the term "through said essentially intact bone graft."

8. "wherein said inducing is carried out simultaneously with said sonicating"

With respect to the term, "wherein said inducing is carried out simultaneously with said sonicating," LifeNet and MTF agree that sonication and a pressure mediated flow must occur at "the same time," however, the parties disagree as to whether they have to be "separate actions." LifeNet argues that sonicating itself causes a pressure induced flow. MTF disagrees.

LifeNet apparently asserts that, because the ultrasonic cleaner produces "alternating high and low pressure waves," the cleaner also produces a "pressure mediated flow." In other words, LifeNet contends that "sonicating ... in an ultrasonic cleaner" constitutes "inducing a pressure mediated flow of solvent." LifeNet's argument is without merit.

Claims 10 and 13 recite "inducing a pressure mediated flow of solvent through said essentially intact bone graft" and "sonicating said essentially intact bone graft in an ultrasonic cleaner," wherein the inducing and sonicating are carried out "simultaneously." Thus, for sonication to constitute induction of a flow, sonication would have to cause a flow of solvent *through* the bone graft. It does not appear to the Court that merely applying ultrasonic sound energy can create such a flow, and LifeNet provides no support for such a proposition.

This conclusion corresponds with statements made by the applicant during the prosecution history for the '871 patent application. In the October 20, 1997 Response, the applicant stated:

Regarding claim 9, claim 9 requires *simultaneously* sonicating and subjecting the intact bone graft to a pressure mediated flow of solvent through an opening in the bone shaft. Elledge does not teach or suggest such simultaneous cleaning. Rather Elledge requires a two-step process with the first step being cleaning using a positive pressure stream of water, and the second step being cleaning using sonication.

MTF Opening Br., Ex. 5, '871 Patent Application, Response 7-8 (Oct. 20, 1997).

Accordingly, "wherein said inducing is carried out simultaneously with said sonicating" means "wherein the separate actions of inducing and sonicating are carried out at the same time."

B. The Demineralization Patents

Regarding the Demineralization Patents, the parties' dispute comes down to whether the applicant disclaimed all methods of making demineralized bone other than "a controlled-flow process wherein acid flows continuously into the process container through an inlet, eluent acid flows continuously out through the process container outlet, and the eluent acid solvent is monitored for change in pH or calcium ion concentration." MTF argues that all other methods are disclaimed. LifeNet disagrees.

First, MTF argues that LifeNet disclaimed all previously known methods of demineralizing bone by stating in the specification of the '537 patent that, "[a]lthough it is well known to defat and demineralize bone for implantation purposes, known methods of demineralizing and removing lipids have been extremely tedious, labor intensive, and slow." '537 Patent, col. 1, lines 41-44. Further, MTF notes that the applicant stated in the prosecution history that the "present invention is directed to a process." *See* MTF Opening Br., Ex. 16, '537 Patent Application, Response 5 (June 7, 1999). MTF argues that because the invention is "directed to *a* process," the applicant was stating that the controlled-flow process disclosed in the specification must be used to achieve the desired result.

Claim 1 of the '537 patent provides:

A process for producing osteoinductive bone, comprising the step of:

contacting bone with an acid solvent under conditions effective to demineralize said bone to contain 1.8 wt % to 2.5 wt % residual calcium, wherein osteoinductive bone is produced.

'537 Patent, col. 25, lines 2-7. According to MTF, "under conditions effective to demineralize" must mean the controlled-flow process wherein acid flows continuously and the eluent acid solvent is monitored for change in pH or calcium ion concentration. This construction, however, reads limitations into the claim that do not exist. Claim 2, which depends on claim 1, contradicts MTF's argument because it adds the limitation "wherein said step of contacting comprises: contacting said bone with a continuous flow of one or more acidic solvents." '537 Patent, col. 25, lines 8-11. Under the doctrine of claim differentiation, it is generally improper to construe an independent claim in a way that imports the limitation of a dependant claim. Phillips, 415 F.3d at 1315 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.")

MTF provides numerous examples in the specification describing the invention as a controlled-flow process wherein the pH of the eluent is monitored. Nowhere, however, does the specification prohibit other processes. Thus, without a clear disclaimer, it would be inappropriate to import the limitations of the preferred embodiment into the claims that do not recite such limitations. *See* In re Am. Acad. of Sci. & Tech. Ctr., 367 F.3d at 1369.

In the prosecution history, the applicant distinguished the prior art from the '537 patent by arguing that the prior art "teaches that it is desirable to demineralize bone to the fullest extent possible," whereas "[t]he present invention is directed to a process for producing bone that is optimally osteoinductive by demineralizing the bone to a specific extent in order to leave a residual calcium content of 1.8 wt % to 2.5 wt %." MTF Opening Br., Ex. 16, '537 Patent, Response 5 (June 7, 1999). Thus, according to the applicant, the distinction from the prior art was demineralizing to an optimal range versus demineralizing as much as possible. The distinction was not based on the type of demineralizing process, and therefore, the Response does not constitute a disclaimer of all processes not disclosed in the '537 patent.

Accordingly, because the plain meaning of the terms in dispute-"under conditions effective to demineralize said bone" and "bone demineralized"-do not limit the claims to a particular process, the Court finds that the terms do not require a Court construction.

IV. Conclusion

For the reasons stated above, the disputed terms are construed as follows.

1. "Sonicating" means applying ultrasonic sound energy.

2. "Agitating" means moving back and forth, stirring, or shaking.

3. "An antibiotic, an antimycotic and an antiviral agent" means a substance that destroys or suppresses the growth or reproduction of bacteria or other microorganisms, a substance that destroys or suppresses the growth of fungi, and a substance that destroys or suppresses the function or reproduction of viruses.

4. "First," "second," and "third," regarding the steps in the method claims, mean that the steps recited in the claim must be completed in the recited order, but there may be steps before and after, as well as intervening steps in between.

5. "To produce a cleaned bone graft essentially free from bone marrow" means to produce a cleaned bone graft that contains no bone marrow detectable using detection means known in the art at the time of filing of the application for the '871 patent.

6. "Wherein said first cleaned bone graft is essentially free from bone marrow" means wherein the first cleaned bone graft contains no bone marrow that is detectable using detection means known in the art at the time of filing the application for the '871 patent.

7. "Inducing a pressure mediated flow of solvent" means "causing a flow of solvent induced by positive or negative pressure ."

8. "Through said essentially intact bone graft" does not require construction.

9. "Wherein said inducing is carried out simultaneously with said sonicating" means "wherein the separate actions of inducing and sonicating are carried out at the same time."

10. "Under conditions effective to demineralize said bone" does not require construction.

11. "Bone demineralized" does not require construction.

An appropriate Order will accompany this Memorandum Opinion.

E.D.Va.,2007.
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