United States District Court,
D. Massachusetts.

AMERICAN MEDICAL SYSTEMS, INC. and Laserscope,
Plaintiffs.
v.
BIOLITEC, INC,
Defendant.

Civil Action No. 07-30109-MAP

July 31, 2008.

Background: Patentee brought action against competitor, alleging infringement of patent for method and system for photoselective vaporization of the prostate, and other tissue. Parties sought claim construction.

Holdings: The District Court, Ponsor, J., held that:
(1) term "comprising" meant including but not limited to;
(2) term "spot size" meant the cross-sectional area of the laser beam, without further qualification; and
(3) phrase "the laser radiation being absorbed substantially completely by the tissue within about 1 mm of the surface" meant at least 63 percent of the laser radiation is absorbed by the tissue within about 1 millimeter of the surface.

Claims construed.

6,986,764. Construed.

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MEMORANDUM AND ORDER REGARDING CONSTRUCTION OF PATENT CLAIMS

PONSOR**, District Judge.**

I. *INTRODUCTION*

Plaintiffs American Medical Systems, Inc. ("AMS") and Laserscope brought suit against Defendant Biolitec, Inc. ("Biolitec") on June 14, 2007, charging infringement of U.S. Patent No. 6,986,764 ("the '764 patent"). (Dkt. No. 1.) The parties submitted briefs on the construction of the claims contained in the patent, and on May 8, 2008, the court heard oral argument on the disputed terms. The task before the court now is to "determin[e] the meaning and scope of the patent claims asserted to be infringed." Markman v. Westview

Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995).

II. *BACKGROUND*

Generally, the '764 patent teaches a "Method and System for Photoselective Vaporization of the Prostate, and Other Tissue." Plaintiff's invention is useful as a treatment for Benign Prostatic Hyperplasia, a condition in which an enlarged prostate compromises functioning of the bladder and urethra. Vaporization, or ablation, of some of the prostate tissue allows reduction of the prostate to a more suitable size.

A typical claim of Plaintiffs' patent describes:

A method for photoselective vaporization of tissue, comprising: delivering laser radiation to a treatment area on a surface the tissue [sic], the laser radiation being absorbed substantially completely by the tissue within about 1 mm of the surface, and having average irradiance in the treatment area greater than 10 kiloWatts/cm ^{2} in a spot size at least about 0.05 mm ^{2}.

'764 patent col. 17, ll.34-41. Other independent claims cite variations on this method or particular systems for accomplishing the desired results, while the dependent claims add details such as appropriate laser wavelengths or the use of an irrigant.

III. *CLAIM CONSTRUCTION*

[1] The analysis of Plaintiffs' infringement charge requires the court to determine preliminarily "the meaning and scope of the patent claims asserted to be infringed"-in this case, claims 1-3, 7-12, 16-18, 22-27, 31, 35-36, 40-43, and 63-64 (of which claims 1, 16, 31, 36, 40, 42, and 63 are independent claims while the rest are dependent). Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995). This interpretation must be based on the meaning the patent claims would have to "a person of ordinary skill in the art at the time of the invention." Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1116 (Fed.Cir.2004).

[2] [3] In construing patent claims, "[i]t is well-settled that ... the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Extrinsic evidence should be used only where intrinsic evidence is insufficient to resolve the meaning or scope of technical terms. Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed.Cir.1995).

Plaintiffs and Defendant have put forward conflicting interpretations of certain words and phrases in the patent. Set forth below is the court's construction of the terms disputed by the parties.

A. "*Comprising*" *(claims 1, 16, 31, 36, 40, 42, 63).*

[4] The court finds that "comprising" is a term of art that means "including but not limited to." *See* Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1327 (Fed.Cir.1999). Although this is a well-known term in the field of patent law, this construction will clarify its definition for the lay jury.

B. "*Spot size*" *(claims 1, 16, 31, 35).*

[5] The parties agree that this term refers to the cross-sectional area of the laser beam, but Biolitec urges the court to limit the definition to the cross-sectional area as measured on the *surface* of the tissue. However, adding that qualification to the definition of the term would result in the duplication of language in the claims and specification, as where the Detailed Description speaks of "spot size on the surface of the tissue." '764 patent col. 15, l.52; col. 16, l.33. Similarly, the claims where necessary refer to the spot size as being "in the treatment area," which seems most reasonably to mean on the surface of the tissue being treated.

See, e.g., id. col. 17, ll.39-41. Therefore the construction of the term spot size should not itself include any limitation as to where the spot size is measured. The court finds that the term "spot size" means "the cross-sectional area of the laser beam" without further qualification.

C. "*Irradiance*" *(claims 1, 16, 31, 36, 40, 42, 63).*

There appears to be no dispute that irradiance is properly defined as "laser power divided by the cross-sectional area of the laser beam," and the court so finds. As with the term spot size, the patent specifies where along the beam irradiance is to be measured and thus a limitation to that effect need not be read into the term itself.

D. "*The laser radiation being absorbed substantially completely by the tissue within about 1 mm of the surface*" *(claim 1).*

[6] Plaintiffs propose that this phrase should be construed as meaning that "at least about 63% of the laser radiation is absorbed by the tissue within about 1 mm of the surface." Contending that the specification of the patent correlates the term "substantially completely absorbed" with "optical penetration depth," Plaintiffs rely on a reference defining "optical penetration depth" as the depth at which the concentration of light decreases to about 37% of its original concentration. (Dkt. No. 32, Ex. 15, at 4.)

The correlation cited by Plaintiffs occurs in the patent's description of Figures 8 and 9, which depict the "optical penetration depth" of a laser with a 532 nm wavelength versus a prior art laser with a 1064 nm wavelength. '764 patent col. 15, ll.26-60. The patent notes that Figure 8 depicts an "optical penetration depth" of 0.8 mm for the 532 nm wavelength laser, and goes on to state that "[t]he 532 laser beam ... is substantially completely absorbed within less than about 1 mm of the surface of prostatic tissue." Id. col. 15, ll.30-34, 45-47. The patent specification thus does appear to treat the two terms ("substantially completely absorbed" and "optical penetration depth") as closely related. Although the patentees could have been more explicit, the specification does clearly, albeit implicitly, indicate that "substantially complete absorption" and "optical penetration depth" refer to the same thing. Thus, the court finds that "the laser radiation being absorbed substantially completely by the tissue within about 1 mm of the surface" means "at least 63% of the laser radiation is absorbed by the tissue within about 1 mm of the surface."

E. "*A volume of residual coagulation of tissue*"/"*a volume of residual coagulated tissue*" *(claims 16, 31, 36, 40, 42, 63).*

[7] Plaintiffs would have the court interpret these terms to refer to "thermally denatured" tissue, a condition that occurs once tissue is heated to a temperature above 60 (deg.)C and suffers protein denaturation. (*See* Dkt. No. 32, Ex. 14, R. Steiner, *Thermal and Non-Thermal Laser Dissection,* 2 End. Surg. 214, 215 tbl. 2 (1994).) Defendant Biolitec, on the other hand, suggeststhat this language encompasses all "thermally damaged" tissue, whether "denatured" or not.

Plaintiffs' approach is supported by several portions of the patent. At one point the specification states outright that "[t]issue coagulation occurs where the tissue temperature rises above approximately 60 (deg.) C." '764 patent col. 16, ll.46-48. Additionally, the Detailed Description regarding Figures 8 and 9, comparing the effects of a 532 nm and a 1064 nm laser, notes that with the latter "only a small portion of tissue gets vaporized ... [b]ut a huge volume of tissue gets coagulated." Id. col. 15, ll.38-40. With respect to the latter category, coagulated tissue, the patent then specifically refers the reader to the portion of Figure 9 depicting tissue "between 100 (deg.) C. and 60 (deg.) C. isotherm" (where the figure contains isotherms for 100 (deg.) C, 80 (deg.) C, 60 (deg.) C, and 40 (deg.) C). Id. col. 15, ll.40-41. This description would exclude thermally damaged tissue from the definition of coagulated tissue where it is not heated to a temperature of 60 (deg.) C or above.

Supporting this reading, the Background of the Invention equates coagulated tissue with thermally

denatured tissue:

Although 1064 nm light is hemostatic at high power levels its low absorption in blood and prostate tissue leads to inefficient ablation and a large residual layer of thermally denatured tissue several millimeters thick. After surgery, the coagulated, thermally denatured tissue swells ....

'764 patent col. 2, ll.34-39.

The patent does also discuss "thermal damage characterized by tissue coagulation." Id. col. 5, l.9; col. 16, l.61. However, this phrasing does not bear out Biolitec's argument that tissue coagulation is the same as thermal damage; if anything, it describes coagulated tissue as a subset of all thermally damaged tissue.

Therefore, the best interpretation of "a volume of residual coagulated tissue," as used in the '764 patent, is "a volume of residual thermally denatured tissue," where "thermally denatured tissue" means tissue that has been heated to 60 (deg.) C or above. The court need not refer to the outside sources cited by the parties for further confirmation.

F. "*A method for photoselective vaporization of tissue*"/"*An apparatus for photoselective vaporization of tissue*" *(claims 1, 16, 31, 36, 40, 42, 63).*

[8] [9] The patent specification describes "photoselective vaporization" as

based upon applying a high intensity radiation to prostate tissue using a radiation that is highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant during the operation, at power densities such that the majority of the energy is converted to vaporization of the tissue without significant residual coagulation of adjacent tissue.

'764 patent col. 3, l.66-col. 4, l.6. The parties disagree as to whether this term, when used in the patent claims, is non-limiting preamble language, or whether it substantively confines the scope of the '764 patent claims to cover laser wavelengths that are strongly absorbed by tissue but *only weakly* absorbed in water or other irrigants used during an ablation procedure. FN1

FN1. This issue has particular significance, since Biolitec's allegedly infringing invention uses a wavelength that, according to Defendant, is strongly absorbed in water and thus would not fit within Biolitec's preferred definition of a "photoselective wavelength."

[10] Preamble language is not automatically considered to be a substantive part of a patent's claims:

In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim.... Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention."

Catalina Mktg. Int'l, Inc. v. Coolsavings, com, Inc., 289 F.3d 801, 808 (Fed.Cir.2002) (citations omitted); *see also* On Demand Mach. Corp. v. Ingram Indus., Inc., 442 F.3d 1331, 1343 (Fed.Cir.2006) ("In considering whether a preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim.").

[11] Indications that a preamble is intended to limit the scope of a claim may include "dependence on a particular disputed preamble phrase for antecedent basis," "when the preamble is essential to understand

limitations or terms in the claim body," "when [the preamble] recit[es] additional structure or steps underscored as important by the specification," or where there is "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." Catalina, 289 F.3d at 808. The Federal Circuit has recently reaffirmed that if preamble language "is reasonably susceptible to being construed to be merely duplicative of the limitations in the body of the claim (and was not clearly added to overcome a rejection), we do not construe it to be a separate limitation." Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1288-89 (Fed.Cir.2008).

The patent clearly does not depend on photoselective vaporization to distinguish its invention from prior art. The Background of the Invention acknowledges that patented devices such as the frequency doubled Nd:YAG laser had already achieved selective absorption, facilitating good hemostasis. But according to the '746 patent, such prior art lasers still resulted in significant volumes of residually coagulated tissue, the cause of many of the adverse side effects of prostate ablation procedures. '764 patent col. 2, ll.34-38, 63-65. The patent's key innovation is therefore to avoid this flaw by applying laser light at "high power densities," or levels of irradiance, that efficiently vaporize prostate tissue without causing inordinate residual coagulation. *See* id. col. 2, ll.66-67; col. 3, l.53-col. 4, l.13; col. 5, ll.3-19. In approving the '764 patent, the primary reason cited by the patent examiner was the claims' use of high levels of irradiance to vaporize tissue without causing significant residual damage. (Dkt. No. 32, Ex. 3, at 208-12.) The central, unique feature of the patented invention is thus its employment of lasers with high power densities or irradiance, not selective absorption of wavelengths in hemoglobin over water. *Compare* On Demand Mach. Corp. v. Ingram Indus., Inc., 442 F.3d 1331, 1343-44 (Fed.Cir.2006) (limiting claim to "high speed manufacture of a single copy" where that was the basic purpose of the invention, implemented by "the entirety of the claim").

[12] Recognizing that the application of high density laser light is the core of the invention, the court must still wrestle with the question whether "photoselective vaporization" confines the scope of the patent. The patentees' liberal usage of the term "photoselective vaporization" throughout the '764 patent, including in the title, the abstract, the preamble to each independent claim, and the Background of the Invention, suggests it does have considerable significance. *See* '764 patent, Abstract; col. 1, ll.33-36; col. 2, ll.28-32; col. 3, l.66-col. 4, l.6; col. 5, ll.20-22; col. 12, ll.16-34; col. 14, ll.35-36. First, the prominent position of "photoselective vaporization" in the title of the patent stresses its significance. It is true that the Federal Circuit disfavors reference to a patent's title in interpreting its claims. *See* Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1311-13 (Fed.Cir.1999); *see also* Biogen, Inc. v. Berlex Lab., Inc., 113 F.Supp.2d 77, 99 (D.Mass.2000). However, the presence of a term in the title may reinforce its importance where it also appears repeatedly throughout the rest of a patent. *Cf.* Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1310 (Fed.Cir.2004) (noting presence of preamble term "blown-film" in title as well as in description of preferred embodiments, summary of invention, and preamble of each of patent's claims, in holding that term constituted limitation on claims of patent); United Techs. Corp. v. PerkinElmer, Inc., 537 F.Supp.2d 392, 395 n. 7 (D.Conn.2008) (citing presence of term in title as confirming its role in defining patented invention).

In this case, the use of "photoselective vaporization" continues throughout the specification and claims. As in Poly-America, it is also centrally mentioned in the Summary of the Invention, as the very first paragraph of that section, in a passage that connects selective absorption with the patent's subject matter of high power densities:

Photoselective vaporization of tissue, such as the prostate for treatment of BPH, is based upon applying a high intensity radiation to prostate tissue using a radiation that is highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant during the operation, at power densities such that the majority of the energy is converted to vaporization of the tissue without significant residual coagulation of adjacent tissue.

'764 patent col. 3, l.66-col. 4, l.6. *Cf.* MBO Labs., Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1330

(Fed.Cir.2007) (citing Summary of the Invention as indicating that the preamble term "immediately" limited the patent claims where that section stated that patented safety syringe should operate "simultaneously with [the needle's] removal from the donor"); C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 864 (Fed.Cir.2004) (holding that claimed invention must include pleats in part because the Summary of the Invention described it so).

The Field of the Invention furthermore states that "[t]he present invention relates generally to laser treatment of soft tissue, *and more particularly to photoselective vaporization PVP, and to photoselective vaporization of other tissue*." *Id*. col. 1, ll.33-36 (emphasis added). It is difficult to read this statement in any manner other than as limiting the patent by restricting its overall scope. *Cf*. On Demand Mach. Corp. v. Ingram Indus., Inc., 442 F.3d 1331, 1343 (Fed.Cir.2006) (determining preamble language to state limitation on claims where it "states the framework of the invention").

The multiple mentions of photoselective vaporization and repeated emphasis on its benefits in achieving minimal residual tissue coagulation indicate that it is necessarily part of the framework for AMS's patent claims. The '764 specification is notably similar to that considered by the Federal Circuit in Poly-America, L.P. v. GSE Lining Technology, Inc., where the court read the preamble phrase "blown-film" liner as a substantive limitation on the claimed landfill liner. 383 F.3d 1303, 1310 (Fed.Cir.2004). That patent similarly used "blown-film" throughout the specification in a manner indicating that it was a "fundamental characteristic" of the invention, even if it was not the inventor's key innovation:

[T]he phrase "blown-film" is a limitation of the claims of the '047 patent. The specification is replete with references to the invention as a "blown-film" liner, including the title of the patent itself and the "Summary of the Invention." The phrase is used repeatedly to describe the preferred embodiments, and the entire preamble "blown-film textured liner" is restated in each of the patent's seven claims.

Id.

Plaintiffs note that an earlier proposed version of the patent specifically stated in *dependent* claims that the wavelength used is "better absorbed by human tissue than by a substance in an intermediate position between the tissue and a device used to deliver" the light, suggesting that such selective absorption might be a characteristic of some claimed embodiments, but cannot be construed as an innate limitation on *all* claims. (Dkt. No. 32, Ex. 5, October 24, 2001 Application 3308, 3312, 3315, 3319, 3322, 3327.) Those earlier references, however, occurred before the language regarding "photoselective vaporization" was included throughout the patent. If anything, the deletion of those particular dependent claims once the phrase "photoselective vaporization" was added to each preamble suggests that the latter term operated as a substitute for their content, as well as extending the notion of photoselectivity to all of the asserted claims.

Moreover, the term "photoselective vaporization" cannot be dismissed as simply a repetition of the patent's purpose or intended use, a non-binding introduction to the general field of the claim, or a label for the invention. *See* Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1288-89 (Fed.Cir.2008); On Demand Mach. Corp. v. Ingram Indus., Inc., 442 F.3d 1331, 1343 (Fed.Cir.2006); Storage Tech. Corp. v. Cisco Sys. Inc., 329 F.3d 823, 831 (Fed.Cir.2003). Plaintiffs themselves contend that the innovation in the '764 patent was the utilization of high power density radiation to minimize tissue denaturation. In light of that premise, the central role of the term "photoselective vaporization" cannot be passed off as simply a repetition or description of the subject matter of the patent. Given that "preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure," the fact that "photoselective vaporization" is neither the primary use or purpose of this invention suggests that it must be treated as a separate limitation instead. Catalina Mktg. Int'l, Inc. v. Coolsavings, com, Inc., 289 F.3d 801, 809 (Fed.Cir.2002); *see also* Apple Computer, Inc. v. Articulate Sys., Inc., 234 F.3d 14, 22 (Fed.Cir.2000).

In drafting the specification, Plaintiffs were under a statutory mandate to describe their invention in "full, clear, concise, and exact terms." 35 U.S.C. s. 112. Their failure to offer any description of the claimed patent outside of the context of photoselective vaporization despite that directive indicates that their invention is confined by that term. *See* Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed.Cir.2001) ("[T]he claims [do not] enlarge what is patented beyond what the inventor has described as the invention."). The Detailed Description even states outright that "[t]he wavelength used according to the present invention ... should be strongly absorbed in the prostate tissue.... The wavelength also must be minimally absorbed by the irrigant it [sic] used during the procedure, typically water." '764 patent col. 12, ll.16-21. *Cf.* Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318 (Fed.Cir.2006) (holding that a patent covered only fuel filters, not all fuel injection system components, where the specification posited that "[a]ccording to the present invention, a fuel filter for a motor vehicle is made"); *see also* SuperGuide Corp. v. DirecTV Enters., Inc., 358 F.3d 870, 888 (Fed.Cir.2004) (finding that description of a particular figure applied to patent as a whole where specification stated it was a diagram "according to the present invention"); Astrazeneca AB v. Mut. Pharm. Co., 384 F.3d 1333, 1339 (Fed.Cir.2004) (interpreting statement in Description of the Invention that "[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents" to limit scope of the term "solubilizer").

This reading of the patent is reinforced by the inventors' description of prior art that used wavelengths *not* selectively absorbed by tissue. In discussing a prior art 2100 nm laser, the patent notes that at that wavelength, which is highly absorbed in water, half the light is absorbed within 0.2 mm of water, resulting in poor hemostasis. '764 patent col. 2, ll.28-32. The specification also notes that a prior art 1064 nm laser failed to achieve efficient ablation, due to low absorption in blood. Id. col. 2, ll.33-38. By contrast, the patent praises a laser operating at 532 nm because the "light from these lasers is selectively absorbed by blood leading to good hemostasis" and beams at that wavelength "are better absorbed by the tissue, and promote more efficient tissue ablation," though suggesting that using the patent's key innovation of high power densities will further improve the results obtained at that wavelength. Id. col. 2, ll.49-50, 63-65; col. 3, ll.53-59; col. 7, ll.45-46.

Those references are perhaps not so explicitly critical as to constitute binding disavowal of non-photoselective wavelengths on their own. *See* SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340-45 (Fed.Cir.2001) (and cases cited therein). However, in combination with the specification's and claims' discussion of the benefits of using photoselective wavelengths, *see, e.g.,* '764 patent col. 12, ll.16-21, they indicate that the patentees were focused on building upon the then-best practice of using photoselective wavelengths and were aware of the disadvantages of other wavelengths. *See* Catalina Mktg. Int'l, Inc. v. Coolsavings, com, Inc., 289 F.3d 801, 808 (Fed.Cir.2002) ("[W]hen reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation."); *cf.* Gen. Elec. Co. v. Nintendo Co., 179 F.3d 1350, 1361-62 (Fed.Cir.1999) (limiting patent to particular type of display device where the "specification makes clear that the inventors were working on the particular problem of displaying binary data on a raster scan display device and not general improvements to all display systems"); Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed.Cir.1989) ("[The] specification makes clear that the inventors were working on the particular problem of an effective optical communication system not on general improvements in conventional optical fibers. To read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality.").

In sum, a review of the patent at issue and analysis of the applicable authorities must lead to a conclusion that the attribute of *photoselective* vaporization limits the scope of the patent, even though its central innovative feature is the use of high power densities in the application of laser light.

The next step is to determine the meaning of the term "photoselective vaporization." Although the sources available to the court in interpreting that phrase are limited,FN2 there is one extended discussion of "photoselective vaporization" in the Summary of the Invention:

FN2. The extrinsic sources offered by Biolitec in support of its definition-two articles regarding laser ablation of tissue-are irrelevant, as both are dated after the effective filing date of the 764 patent, October 23, 2002. (Dkt. No. 34, Exs.3, 6.) The court may only consider how a patent's claims would have been understood at the time of its effective filing date. *See* PC Connector Solutions LLC v. SmartDisk Corp., 406 F.3d 1359, 1363 (Fed.Cir.2005). In any case, the cited literature discusses the workings of particular commercial embodiments of the contested patent rather than the '764 patent itself. (Dkt. No. 34, Ex. 3, Reza S. Malek & Kester Nahen, *Photoselective Vaporization of the Prostate,* 23 AUA Update Series 153, 154 (discussing 532 nm laser and other specific embodiments); Dkt. No. 34, Ex. 6, A.E. Te, *The Development of Laser Prostatectomy,* 93 B.J.U. Int'l 262, 263-64 (2004) (also describing 532 nm laser).)

Photoselective vaporization of tissue, such as the prostate for treatment of BPH, is based upon applying a high intensity radiation to prostate tissue using a radiation that is highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant during the operation, at power densities such that the majority of the energy is converted to vaporization of the tissue without significant residual coagulation of adjacent tissue.
'764 patent col. 3, l.66-col. 4, l.6. As Defendant Biolitec argues, this passage indicates that photoselective vaporization is vaporization accomplished using wavelengths that are "highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant." Indeed, the most intuitive reading of the phrase " *photoselective* vaporization" is that it confines the '764 patent to such selectively absorbed wavelengths.
Plaintiffs contend that describing photoselective vaporization as "based upon" the characteristic of selective absorption does not bind them to a particular definition, a position that admittedly does carry some weight. The inventors' use of the words "based on," rather than terms such as "means" or "is," may indicate a somewhat looser relationship between the term and the following description than that usual in a dictionary definition. *Compare* Sinorgchem Co. v. Int'l Trade Comm'n, 511 F.3d 1132, 1136 (Fed.Cir.2007) (relying on use of quotation marks to set off term and employment of word "is" as indications that patentee intends to set out express definition). In particular, at least one portion of this passage, the reference to power densities sufficient to vaporize tissue without causing significant residual coagulation, is clearly not a characteristic of photoselective vaporization itself but rather the separate innovation claimed in the '764 patent. Additionally, as Plaintiffs point out, if this full excerpt were used as the definition of photoselective vaporization in the claims, it would result in duplicative language when juxtaposed with certain dependent claims. *See* Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed.Cir.2005) ("[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.").

While it is clear that this purported definition to some extent incorporates other aspects of the patented invention, to disregard it entirely would be inconsistent with the plain meaning of the phrase "based upon." Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp., 493 F.3d 1358, 1362 (Fed.Cir.2007) ("A claim term may be defined in a particular manner for purposes of a patent even 'without an explicit statement of redefinition.' ") (citation omitted). To "base" means "to make or form a ... foundation for." *Random House Webster's College Dictionary* 114 (1992). Therefore, though the court will disregard the portions of the paragraph that duplicate other aspects of the invention, the narrower excerpt "based upon applying a high intensity radiation to prostate tissue using a radiation that is highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant during the operation" must serve as the basis for the court's construction of the term "photoselective vaporization."

Plaintiffs next turn to the phrase "during the operation," asserting that it allows them to claim embodiments using wavelengths that are not preferentially absorbed by tissue but nevertheless escape absorption by the irrigant through the surgical technique of putting the laser in direct contact with tissue and avoiding the need to pass the laser light through the irrigant at all.FN3

FN3. As noted above, this is in fact how Biolitec's allegedly infringing device operates.

However, that argument is undermined by the lack of any explicit language in the patent claims, specification, or prosecution history that would support a belief that the patentees intended the '764 patent to encompass such a technique.FN4 It is true that the specification mentions the benefits of "close placement" of the laser in one embodiment:

FN4. The only other description of selective absorption in the specification favors neither party. The Detailed Description provides that "[t]he wavelength used according to the present invention .... must be minimally absorbed by the irrigant it [sic] used during the procedure, typically water." '764 patent col. 12, ll.16-21. Putting aside the clear typographical error in the text, "minimally absorbed by the irrigant ... used during the procedure" can only be read as a reference to which irrigant is employed during the procedure, rather than to how much absorption by the irrigant occurs during the procedure. The rest of the paragraph, describing the use of a 532 nm wavelength (which is more strongly absorbed by tissue than by water), refers to a particular embodiment of the patent and is not a binding limitation. *See* Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1374 (Fed.Cir.2008) (refusing to import limitations into the claims based on language referring to specific embodiments of the patent more narrow than the invention as generally described).

The side firing tip, which causes a diverging beam to be directed out of the optical fiber, is placed close to the tissue, within about 1 mm from the side of the side firing tip to contacting the side of the tip. Close placement increases the irradiance delivered to the treatment area so that higher irradiance is available with solid-state lasers generating a 60 to 80 watts average output power.
'764 patent col. 5, ll.52-56. However, this reference is clearly tied to the patent's separate goal of achieving high power radiation, not photoselective vaporization, as it nowhere mentions the issue of absorption by the irrigant. Moreover, if this discussion and the patent's other references to placing the laser beam "less than 1 mm from the tissue" were meant to endorse *contact* with the tissue as a method for reducing irrigant absorption, they would say so outright rather than focusing on close placement and its relationship to irradiance. *See* id. col. 18, ll.1-2, 59; col. 20, ll.11-13; col. 21, ll.51-52; col. 23, ll.8-9; col. 24, ll.30-31.
The prosecution history is similarly unavailing, despite Plaintiffs' arguments to the contrary. The patent examiner briefly referred to the term "photoselective vaporization" in rejecting certain of Plaintiffs' patent claims. (Dkt. No. 32, Ex. 3, at 174-75.) He noted that the patentees had failed to distinguish their invention from U.S. Patent No. 5,776,127 ("the Anderson patent"), which according to him also disclosed a method for "photoselective vaporization" of tissue using similar levels of irradiance. The Anderson patent describes a process whereby absorption of radiation by irrigants during prostate ablation would be minimized by using a laser pulse to create a vapor bubble in the liquid through which a second laser pulse could travel relatively unhindered to vaporize the tissue. (Dkt. No. 32, Ex. 8, Anderson patent col. 1, ll.45-56.)

The patent examiner considered this to be a form of photoselective vaporization, interpreting the abstract's statement that the patented technique will "allow[ ] a reduction in the attenuation of the radiation by the surrounding liquid," as describing a method whereby radiation "is preferentially absorbed by the tissue rather than a fluid." (Dkt. No. 32, Ex. 3, at 177.) According to Plaintiffs, this application of the term photoselective vaporization indicates that it might encompass techniques that avoid absorption by an irrigant even where the wavelength in use would normally be strongly absorbed in that irrigant.

[13] Yet the passing statement of a patent examiner is far less important than the *patentee's* stance in the patent specification and prosecution history. *See* Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1347 (Fed.Cir.2005) (noting that a patent examiner's unilateral statement may be pertinent, but is not binding for the purposes of claim construction where the patentee remained silent in response). Furthermore, the

specification takes priority over any statements in the prosecution history where the two are inconsistent. *See* Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1319 (Fed.Cir.2006) ("Where ... the written description clearly identifies what his invention is, an expression by a patentee during prosecution that he intends his claims to cover more than what his specification discloses is entitled to little weight.").

Last, Plaintiffs highlight the specification's brief mention that at least one embodiment of the invention preferably uses wavelengths from 200 nm to 1000 nm. '764 patent col. 4, ll.28-29; *see also* id. col. 8, ll.7-12 (stating possibility of using laser systems adapted to produce wavelengths including from 200 nm to 1000 nm). This range encompasses wavelengths that are *not* photoselective, *i.e.,* strongly absorbed in tissue while being weakly absorbed in water, including the 980 nm wavelength that is used by Defendant in its allegedly infringing device.

While these two excerpts undermine Defendant Biolitec's preferred interpretation, there is precedent for ignoring a lone reference regarding a particular preferred embodiment where it is inconsistent with the rest of the specification.FN5 In Sinorgchem Co. v. International Trade Comm'n, the Federal Circuit disregarded a preferred embodiment that relied on a higher level of water than that cited elsewhere in the specification in defining the claim term "controlled amount." 511 F.3d 1132, 1138-39 (Fed.Cir.2007); *see also* N. Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1345-46 (Fed.Cir.2005) (holding embodiment with concave walls not to obviate construction of term "generally convex" to exclude embodiments with concave walls where convexity was means by which patentee distinguished patent from prior art); Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1327 (Fed.Cir.2002) (similar); Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1326 (Fed.Cir.2001) (endorsing district court's interpretation of claims despite the fact that it was inconsistent with certain described embodiments of the patent).

FN5. Defendant argues that these references should not even be considered as preferred embodiments for this patent since they are the remnants of a precursor patent (Patent No. 6,554,824, granted April 29, 2003) of which the '764 patent is a continuation-in-part. However, at least one mention of the 200 to 1000 nm range was added in the '764 patent. *Compare* '824 patent col. 5, l.54 *with* '764 patent col. 8, ll.7-12. Moreover, a continuation-in-part of a prior application, though adding new subject matter, does not discard the original subject matter. *See* PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1304 n. 3 (Fed.Cir.2008) (describing a continuation-in-part as simply a term of "administrative convenience," characterized by the addition of new matter to a prior patent application).

Disregarding the references to non-selectively absorbed wavelengths does not even require the court to completely eliminate those embodiments mentioning a 200 nm to 1000 nm wavelength, since that broad range includes wavelengths that are preferentially absorbed by tissue. Moreover, the claims themselves, where they discuss specific wavelengths, are confined to wavelengths that are absorbed more strongly by tissue than by water or other irrigants. *See* '746 patent col. 17, ll.47, 49-50, 53-54; col. 18, ll.37, 39-40; col. 19, ll.25-26, 29-30, 35-36, 59; col. 22, ll.29, 53; col. 24, l.4 (mostly specifying wavelengths in the 250 nm to 600 nm range).

Admittedly, confining the '764 patent to selectively absorbed wavelengths leaves the phrase "during the operation" without much effect. However, it is worth considering the result if the court were to adopt Plaintiffs' interpretation of that language: "photoselective vaporization" would effectively be vitiated as a limit on the patent, since the claims would then encompass all wavelengths as long as the laser was applied directly to the tissue during surgery. The inclusion of the words "during the operation" in what Plaintiffs themselves admit was not meant to be a dictionary definition of the term "photoselective vaporization" is not enough to justify such an awkward outcome, especially since Plaintiffs muster only isolated, brief excerpts from the patent and prosecution history to support their interpretation. Instead, the court favors the more intuitive construction that renders "photoselective vaporization" a meaningful limitation on Plaintiffs' patent. That term must confine the patent claims to those embodiments using wavelengths that are "highly

absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant."

G. "*Delivering laser radiation to a treatment area on a surface [of] the tissue*" *(claims 1, 31, 36, 40, 42).*

Biolitec concedes that, given the court's adoption of its position that preamble limits the scope of the patent claims, an interpretation of "laser radiation" to restrict it to photoselective wavelengths would be redundant. (Dkt. No. 37, Def.'s Claim Construction Opp. Mem. 9 n. 4.) Therefore the court need not address this portion of the claims.

H. "*A wavelength and ... irradiance in the treatment area sufficient to cause vaporization of a substantially greater volume of tissue than a volume of residual coagulated tissue caused by the laser radiation*" *(claims 31, 36, 40, 42, 63).*

Including language regarding absorption in tissue versus water in these claims would also simply repeat limitations already implicit in the preamble. As for Defendant's proposed change of "sufficient to cause vaporization of a substantially greater volume of tissue than a volume of residual coagulated tissue" to "such that the volume of tissue that is vaporized by the laser radiation is substantially greater than the volume of thermally damaged tissue remaining after the procedure," in the court's view that construction would add nothing. Biolitec does not explain how the language already used in the claims is inadequate to convey the patent's meaning. No further construction of this phrasing is needed.

I. "*The laser radiation causing vaporization of a volume of tissue greater than a volume of residual coagulation of tissue*" *(claim 16).*

It would violate the principle of claim differentiation to read this claim to require "substantially greater" vaporization of tissue than residual coagulation, as Biolitec suggests. The patent itself specifically uses the word greater, in contrast to other claims requiring "substantially greater" vaporization. *See* AllVoice Computing PLC v. Nuance Communc'ns, Inc., 504 F.3d 1236, 1248 (Fed.Cir.2007) (reasoning that the use of differing language in different terms is presumed to indicate separate meanings). A construction of the phrase that would import the adverb "substantially" is not justified.

J. "*Delivering a flow of irrigant to the treatment area*" *(claims 7, 38).*

Biolitec wishes to alter these claims to read: "Delivering irrigant to the treatment area while applying the laser energy to that treatment area." As Plaintiffs argue, this would improperly limit the timing of the steps described in claims 7 and 38 to require simultaneous performance. *See* Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1371 (Fed.Cir.2003) (refusing to dictate order of steps where patent did not set order and purpose of invention could be accomplished without following proposed sequence); Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1343 (Fed.Cir.2001) (similar). There is no indication that an area subject to irradiation in the course of the operation no longer qualifies as "the treatment area" if laser radiation is not being applied to it at a particular point in the process. Again, no justification exists for Biolitec's proposed narrowing of the claim language.

K. "*Delivering laser radiation and a flow of a transparent liquid irrigant to a treatment area on a surface [of] the tissue*" *(claim 16).*

Defendant also advocates the interpretation of this claim to indicate that the irrigant is delivered to the tissue at the same time as the laser radiation. As noted above, this would import a limitation not supported by the patent. Additionally, there is no need to add language regarding photoselective vaporization where the court has already held that this preamble phrase does independently limit the patent claims.

L. "*An endoscope, including an optical fiber coupled to the laser, adapted to direct laser radiation from the fiber, and a flow of irrigant to a treatment area on a surface of the tissue*" *(claim 63).*

Biolitec again urges the court to require the flow of irrigant and application of laser radiation to occur simultaneously, but cannot identify any language in the claims or specification that would compel that interpretation. The court will not adopt Defendant's proposal.

IV. *CONCLUSION*

For the foregoing reasons, the disputed terms are construed as follows:

1. "Comprising" means "including but not limited to."

2. "Spot size" means "the cross-sectional area of the laser beam."

3. "Irradiance" means "the laser power divided by the cross-sectional area of the laser beam."

4. "The laser radiation being absorbed substantially completely by the tissue within about 1 mm of the surface" means "at least 63% of the laser radiation is absorbed by the tissue within about 1 mm of the surface."

5. "A volume of residual coagulation of tissue"/"a volume of residual coagulated tissue" means "a volume of residual, thermally denatured tissue."

6. "A method for photoselective vaporization of tissue"/"An apparatus for photoselective vaporization of tissue" means "using a wavelength that is highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant."

None of the other claim language disputed by the parties requires construction by the court beyond what has been stated above.

It is possible that the construction of the patent claims set forth above, particularly the interpretation of the term "photoselective vaporization," may be fatal to Plaintiffs' infringement claims and that the next phase of this litigation may be before the Federal Circuit. Counsel will therefore file with the court, on or before August 15, 2008, a joint proposed schedule for further proceedings. If counsel cannot agree on a joint proposal, separate proposed schedules may be filed.

It is So Ordered.

D.Mass.,2008.
American Medical Systems, Inc. v. Biolitec, Inc.

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