

United States District Court,
E.D. Texas, Lufkin Division.

CANDELA CORPORATION and the General Hospital Corporation d/b/a Massachusetts General Hospital,
Plaintiffs.

v.

PALOMAR MEDICAL TECHNOLOGIES, INC,
Defendant.

Civil Action No. 9:06-CV-277

Aug. 6, 2008.

Samuel Franklin Baxter, McKool Smith-Marshall, Marshall, TX, Craig N. Tolliver, John Shumaker, Laura A. Handley, Pierre Jean Hubert, Steven John Pollinger, Travis Gordon White, McKool Smith-Austin, Austin, TX, Julie S. Turner, Law Office of Julie Turner, Palo Alto, CA, Mara Jill Bindler, Scott Robert Jacobs, McKool Smith, Dallas, TX, for Plaintiffs.

***MEMORANDUM OPINION AND ORDER CONSTRUING CLAIM TERMS OF UNITED STATES
PATENT NOS. 5,810,801; 6,120,497; AND 6,659,999***

KEITH F. GIBLIN, United States Magistrate Judge.

Plaintiff Candela Corporation FN1 filed suit against Defendant Palomar Medical Technologies, Inc. claiming infringement of United States Patent Nos. 5,810,801 ("the '801 patent"); 6,120,497 ("the '497 patent"); and 6,659,999 ("the '999 patent"). The court conducted a *Markman* hearing to assist the court in interpreting the meaning of the claim terms of the patents-in-suit.

FN1. After suit was filed here, Massachusetts General Hospital ("MGH"), a co-assignee of the patents in suit, was joined as a Plaintiff. *See* Order Granting Motion for Leave to File Amended Complaint [Doc. # 15].

Having carefully considered the patents, the prosecution history, the briefs, and the arguments, the court now makes the following findings and construes the disputed patent terms.FN2

FN2. The transcript of the hearing contains a number of representations and agreements of the parties and their answers to technical questions from the court, all of which will not be repeated here, but which assisted the court in reaching the conclusions set out in this Order. This Order governs in the event of any conflict between the Order and the court's preliminary analysis at the hearing. The transcript will be cited as Tr. at p. ----, ll. __.

I. CLAIM CONSTRUCTION STANDARD OF REVIEW

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) ("*Markman II*"). "The duty of the trial judge is to determine the meaning of the claims at issue, and to instruct the jury accordingly." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed.Cir.1995) (citations omitted), *cert. denied*, 518 U.S. 1020, 116 S.Ct. 2554, 135 L.Ed.2d 1073 (1996).

" [T]he claims of the patent define the invention to which the patentee is entitled the right to exclude.' " *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed.Cir.2005) (*en banc*) (citation omitted), *cert. denied*, 546 U.S. 1170, 126 S.Ct. 1332, 164 L.Ed.2d 49 (2006). "Because the patentee is required to 'define precisely what his invention is,' it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.' " *Phillips*, 415 F.3d at 1312 (quoting *White v. Dunbar*, 119 U.S. 47, 52, 7 S.Ct. 72, 30 L.Ed. 303 (1886)).

The words of a claim are generally given their ordinary and customary meaning. *Phillips* 415 F.3d at 1312. The "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." *Id.* at 1313. Analyzing "how a person of ordinary skill in the art understands a claim term" is the starting point of a proper claim construction. *Id.*

A "person of ordinary skill in the art is deemed to read the claim term not only in context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* Where a claim term has a particular meaning in the field of art, the court must examine those sources available to the public to show what a person skilled in the art would have understood the disputed claim language to mean. *Id.* at 1414. Those sources "include 'words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art .'" *Id.* (citation omitted).

"[T]he ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* In these instances, a general purpose dictionary may be helpful. *Id.*

However, the court emphasized the importance of the specification. "[T]he specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). A court is authorized to review extrinsic evidence, such as dictionaries, inventor testimony, and learned treatises. *Phillips*, 415 F.3d at 1317. But their use should be limited to edification purposes. *Id.* at 1319.

The intrinsic evidence, that is, the patent specification, and, if in evidence, the prosecution history, may clarify whether the patentee clearly intended a meaning different from the ordinary meaning, or clearly disavowed the ordinary meaning in favor of some special meaning. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed.Cir.1995); *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated "clear intent" to deviate from the ordinary and accustomed meaning of a claim term by redefining the term in the patent

specification. *Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed.Cir.1999).

The "'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Phillips*, 415 F.3d at 1321. However, the patentee may deviate from the plain and ordinary meaning by characterizing the invention in the prosecution history using words or expressions of manifest exclusion or restriction, representing a "clear disavowal" of claim scope. *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed.Cir.2002). If the patentee clearly intended to provide his own definitions, the "inventor's lexicography governs." *Phillips*, 415 F.3d at 1316.

II. PATENT BACKGROUND AND TECHNOLOGY

The '801 patent is directed at a method and apparatus used to treat skin wrinkles using radiation. Specifically, this method involves the use of a laser beam or other incoherent radiation to thermally injure collagen in a targeted dermal region of the skin to elicit a healing response that results in substantially fewer wrinkles. The '497 patent is a continuation of the '801 patent, and the '999 patent is a continuation of the '497 patent. FN3

FN3. With a few typographical errors (*see, e.g.*, '497 patent, col. 3, l. 39, where "Brief Description of the Drawings" in the '801 specification has become "Brief of the Drawings"), the specifications of the '497 and '999 patents are the same as the specification of the '801 patent. For ease of understanding, the court will refer to the '801 patent when citing to the specification unless otherwise specified.

One of Ordinary Skill

Candela suggests that a "person of ordinary skill in the art would have a graduate degree in science or engineering and at least two years of research experience in cutaneous laser medicine or surgery." Pl. Claim Const. Br. at 4 [Doc. # 69]. Palomar argues that this individual would be a "person with a graduate degree in a biological science, such as a dermatologist or plastic surgeon, with a working knowledge of laser-tissue interaction in skin and wrinkle removal using skin resurfacing techniques obtained by *either* clinical or research activities." Def. Claim Const. Br. at 2 [Doc. # 70](emphasis in original). The parties agreed at the *Markman* hearing that a graduate degree is necessary, Tr. at p. 9, ll. 3-4, but disagree over whether the person of skill can be a clinician, rather than a purely research scientist, and over whether the individual could have a more general science and engineering background, rather than in just the biological sciences.

Based on the patents and their cited references, and the representations of the parties and their experts, the court finds that "one of ordinary skill in the art" covered by the patents-in-suit is someone with the equivalent of a graduate degree in a field of science or engineering, with courses covering the biological sciences and the properties of various forms of energy. In addition, this individual will have at least two years of clinical or research experience in cutaneous laser medicine or surgery.

III. CLAIM CONSTRUCTION

1. "A beam of radiation." Used in the '801 patent, claims 1-6, 8-14; '497 patent, claims 1-10; '999 patent, claims 1-10.

An exemplar use of this term is seen in claim 1 of the '801 patent, stating in part, with the disputed term in bold:

1. A method for treating a wrinkle in human skin, comprising:

generating **a beam of radiation....**

Candela initially suggested "one or more rays of electromagnetic radiation" while Palomar initially proposed ordinary meaning. In the event the court did construe the term, Palomar suggested "a stream of light." However, the parties agreed at the *Markman* hearing that the construction for this term would be the plain meaning. Tr. at p. 116, ll. 2-10.FN4

FN4. The transcript is somewhat ambiguous on this point. Candela's counsel stated that, after conferring, Candela "has agreed to adopt the plain meaning proposed by Palomar for that term." Tr. at p. 116, ll. 5-7. The court interpreted this to mean that the parties agreed on plain meaning (i.e., a "beam of radiation" means a beam of radiation), not that the parties agreed to Palomar's alternate construction, "a stream of light."

2. Various terms related to "a beam of radiation" (wavelength only). Used in the '801 patent, claims 1-6 and 8-14; '497 patent, claims 1-10.

An exemplar use of the term is seen in claim 1 of the '801 patent, stating in part, with the disputed term in bold:

1. A method for treating a wrinkle in human skin, comprising:

generating **a beam of radiation having a wavelength of between 1.3 and 1.8 microns and a fluence of between 10 and 150 joules per square centimeter....**

Candela argues that none of these phrases require further construction, in light of the ordinary meaning of "a beam of radiation" and the parties' agreed constructions of "wavelength," "fluence," and "power density." Palomar suggests various constructions FN5 for these terms; for example, Palomar proposes "a beam of radiation having a wavelength within a range of 1.3 and 1.8 microns and a fluence within that wavelength range of between 10 and 150 joules per square centimeter," for the above-quoted term in claim 1 of the '801 patent.

FN5. "Construction" is perhaps not the correct word, as Palomar does not dispute the meaning of any word or phrase in the terms. Rather, it seeks to insert additional words and limitations into the claim language.

Palomar argues that its constructions clarify the requirement in the specification that the chosen fluence be of the specified wavelength to achieve the desired result, and points to col. 4, ll. 27-37 FN6 and col. 6, ll. 4-20 of the '801 patent to support this position. However, despite Palomar's suggestions to the contrary, these passages do not actually state that the fluence or power density must be within the specified wavelength range. Palomar's construction would, without support in the specification, exclude the scenario in which the beam of radiation has a fluence outside the claimed wavelength range.FN7

FN6. "In particular, the wavelength of the radiation beam has been chosen to maximize absorption in the targeted region of the dermis, and the fluence or power density, depending on the type of radiation, has been

chosen to minimize erythema ... Within this wavelength range, radiation energy applied through the surface of the skin is deposited predominantly in the dermal region of the skin ."

FN7. While Palomar argues that the specification does not teach a specific range of fluence, it does not necessarily follow that the fluence must therefore be within the specified wavelength range. Any theories of invalidity based on lack of enablement or written description are more appropriate on a motion for summary judgment or at trial than in a claim construction brief.

Claims are generally read in accordance with the precepts of English grammar, *In re Hyatt*, 708 F.2d 712, 714 (Fed.Cir.1983), and the plain meaning of the exemplar term stated above is that beam of radiation has (a) a wavelength within a certain range and (b) a fluence within a certain range. Palomar's suggestion that the fluence must be within the wavelength range is contrary to that plain meaning and finds little, if any, support in the specification. For the same reasons, the court rejects Palomar's argument as it relates to power density.

As with several other claim terms, Palomar does not seek to construe any word in these phrases; rather, Palomar attempts to limit the terms as much as possible by inserting additional words. While the court recognizes that the recent Federal Circuit holding in *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 524 F.3d 1351 (Fed.Cir.2008) seemingly requires the court to construe a disputed term whenever claim scope might be implicated, the purpose of claim construction is to construe those terms that might be unfamiliar or confusing to the jury, or which are unclear or ambiguous in light of the specification and patent history. See *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed.Cir.1997). Claim construction is an exercise in interpreting, not rewriting, claim language. The court will therefore decline to add Palomar's extraneous limitations to these claim terms.

3. Various terms related to "a beam of radiation" (tissue absorption coefficient and wavelength). Used in the '999 patent, claims 1-10.

An exemplar use of the term is seen in claim 1 of the '999 patent, stating in part, with the disputed term in bold:

1. A method for treating a wrinkle in human skin, comprising:

generating a beam of radiation having a wavelength within a range of which a tissue absorption coefficient is in the range of between 1 and 20 cm⁻¹ and a fluence of between 10 and 150 joules per square centimeter....

Candela again argues that none of these phrases require further construction, in light of the ordinary meaning of "a beam of radiation" and the parties' agreed constructions of "wavelength," "tissue absorption coefficient," and "power density." Palomar suggests various constructions for these terms; for example, Palomar proposes "a beam of radiation having a wavelength within a range of 1.3 and 1.8 microns and a fluence within that wavelength range of between 10 and 150 joules per square centimeter," for the above-quoted term in claim 1 of the '999 patent.

The parties' dispute is two-fold. First, Palomar again seeks to import the limitation that fluence or power

density must be within the specified wavelength range. For the reasons discussed above, the court rejects this argument. Second, Palomar argues that radiation with a tissue absorption coefficient of between 1 and 20 cm^{-1} includes only wavelengths within the specified range of 1.3 to 1.8 microns. Candela argues that Palomar, in effect, seeks to import a limitation found only in a preferred embodiment into the '999 patent claims. *See* '999 patent, col. 4, ll. 36-39 (the wavelength of the radiation beam "has a tissue absorption coefficient preferably in the range of about 1 to 20 cm^{-1} . Thus, the beam preferably has a wavelength of between about 1.3 and 1.8 microns in one embodiment.").

It is axiomatic that courts should avoid importing limitations from the specification into the claim terms, absent a clear disclaimer of claim scope. *Phillips v. AWH Corp.* 415 F.3d 1303, 1323 (Fed.Cir.2005); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1375 (Fed.Cir.2005). Only where the specification uses language of requirement, rather than preference, will the specification describe an essential step or element of the claim rather than merely a preferred embodiment. *See Andersen Corp. v. Fiber Composites, Inc.*, 474 F.3d 1361, 1372-73 (Fed.Cir.2007), *Honeywell Int'l v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed.Cir.2006). As noted above, the specification uses "preferably" and "in one embodiment," rather than "required" or "necessary," when discussing the tissue absorption coefficient.

To support its argument that the two phrases are interchangeable, Palomar points out that, with the substitution of the phrase "having a wavelength within a range at which a tissue absorption coefficient is in the range of between 1 and 20 cm^{-1} " in claims 1 and 6 of the '999 patent for "having a wavelength of between 1.3 and 1.8 microns" in claims 1 and 6 of the '497 patent, claims 1-10 of these two patents are identical. In fact, the '999 patent was initially rejected for obvious-type double patenting and only issued after the patentees submitted a terminal disclaimer to the Patent and Trademark Office.

"Obvious-type double patenting" is a "judicially created doctrine adopted to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *In re Metoprolol Succinate Patent Litigation*, 494 F.3d 1011, 1016 (Fed.Cir.2007) (internal quotation omitted). A terminal disclaimer filed with the PTO in response to a non-statutory obvious-type double patenting rejection may restrict the later-filed application to the term of the original patent, thus curing the rejection and permitting the later application to issue. *Geneva Pharma., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1372, 1378 (Fed.Cir.2003). However, filing a terminal disclaimer will not permit a patent to issue over a statutory "same invention" double patenting rejection. This type of rejection occurs when identical subject matter is being claimed, *Application of Buehler*, 515 F.2d 1134, 1141 (C.C.P.A.1975), and is based on 35 U.S.C. s. 101. *Application of Driscoll*, 562 F.2d 1245, 1248 (C.C.P.A.1977).

The distinction between statutory and non-statutory double patenting is important in this case, since the PTO initially rejected the claims under the latter theory. This means that, despite Palomar's assertion to the contrary, the tissue absorption coefficient and wavelength phrases were not considered by the PTO to be exactly the same: if they were, the rejection would have been for statutory, rather than non-statutory, double-patenting. Therefore, the court will again decline to adopt Palomar's limitations for these claim terms and, beyond the adoption of the ordinary meaning for "beam of radiation," will not further construe these terms.

4. "Along the wrinkle" and "adjacent the wrinkle." Used in '801 patent, claims 3, 8; '497 patent, claims 3, 8; '999 patent, claims 3, 8.

An exemplar use of the term "along the wrinkle" is seen in claim 3 of the '801 patent, stating in part, with the disputed term in bold:

The method of claim 1 further comprising the step of stretching the skin **along the wrinkle...**

Candela proposes "beside the wrinkle" for "adjacent to the wrinkle" and "through an axis of a wrinkle" for "along the wrinkle." Palomar suggests the same construction for both terms: "longitudinally in the direction of the wrinkle so that only the collagen fibers across the wrinkle will be subjected to thermal injury and collagen fibers in the direction of the wrinkle will not be damaged."

Palomar first argues that "along" and "adjacent" mean the same thing, largely because the patent specification never mentions the word "adjacent." Candela points to a preliminary amendment made during prosecution of the '497 patent in which the applicants changed the word "along" to "adjacent" to support its theory that the two words have different meanings. Although Palomar is correct that this change was not done in response to an office action or other communication from the PTO, the fact that the applicants deliberately changed "along" to "adjacent" strongly indicates that the two words mean different things.FN8 The fact that the Examiner apparently considered the two words interchangeable, *see* Def. Cl. Const. Br., Ex. L at para. 5 [Doc. # 70], does not compel a different conclusion.

FN8. Palomar argues in a footnote that because the word "adjacent" is not mentioned in the '801 patent specification, there is no support for a meaning of the word different from "along" and cites *Chiron Corp. v. Genetech, Inc.*, 363 F.3d 1247, 1255 (Fed.Cir.2004) for the proposition that the written description requirement prevents an applicant from using the process of amending claims to "update" the claims or specification. While this may be true, whether or not the specification sufficiently enables or describes the claim term "adjacent" is a validity, rather than a claim construction, argument.

Palomar cites to several portions of the specification to support its somewhat long-winded construction of these terms. *See, e.g.*, '801 patent, col. 3, ll. 28-33 and col. 6, ll. 21-29. These sections describe the end result of stretching the skin "along the wrinkle," but Palomar provides absolutely no support for the proposition that these results should be incorporated into the meaning of the term. In fact, neither side points to any spot in the specification that indicates these terms were intended to have anything other than their plain, ordinary meaning. *See, e.g., The American Heritage Dictionary* 11, 25 (4th ed.2001) ("along" means "on a course parallel and close to" and "adjacent" means "close to, lying near"); *Merriam-Webster Collegiate Dictionary* 14, 32 (10th ed.2002) ("along" means "in a line parallel with the length or direction of" and "adjacent" means "to lie near"). The court will therefore construe these terms as follows:

"Along the wrinkle" means **"close to and parallel with the length of the wrinkle."**

"Adjacent to the wrinkle" means **"close to or lying near the wrinkle."**

5. "Thermal injury" and "causing thermal injury." Used in '801 patent, claims 1-14; '497 patent, claims 1-10; '999 patent, claims 1-10.

An exemplar use of the term "causing thermal injury" is seen in claim 1 of the '801 patent, stating in part, with the disputed term in bold:

1. A method for treating a wrinkle in human skin, comprising: ...

causing thermal injury within the targeted dermal region....

Candela suggests that "thermal injury" be defined as "injury to tissue due to radiation exposure, including partial denaturation of collagen," and argues that "causing thermal injury" requires no further construction. Palomar also proposes the same construction for both terms: "causing mild heating of collagen to not more than 60 (deg.)C to partially change the nature of the collagen in the region, but not to shrink or fully denature the collagen."

The parties agree that the collagen is partially denatured or changed as a result of the heating, and there is ample support in the specification for this conclusion. *See* Abstract; col. 2, ll. 57-61; col. 3, ll. 17-22; col. 4, ll. 5-10. Despite these repeated references to partially denaturing collagen that Candela itself cites, Candela seeks to broadly construe the terms such that injury to any tissue, not just collagen, is included. Candela argues that since the claims encompass thermal injury directed at the dermal region and the dermal region includes things other than collagen (e.g., fibroblasts, connective tissue, glycosaminoglycans, etc.), "tissue" is the more appropriate term. However, Candela points to no place in the specification that even hints that the thermal injury is broadly directed to tissue. On the other hand, as noted *supra*, the specification states that the purpose of the invention is to partially denature collagen or dermal collagen on several occasions.

Palomar's construction would import two limitations into the claim term: (1) a temperature cap of 60 (deg.)C above which the collagen could not be heated and (2) a requirement that the thermal injury not shrink or fully denature the collagen. While Palomar is correct that the specification does state that full denaturation occurs somewhere between 60 and 70 degrees Celsius, adopting Palomar's proposed temperature cap would exclude a preferred embodiment. *See* '801 patent, col. 5, ll. 37-40 (discussing heating the targeted dermal region to between 50 and 70 degrees Celsius). The Federal Circuit has consistently held that a claim construction that excludes a preferred embodiment is "rarely, if ever, correct." *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1583 (Fed.Cir.1996).

Another problem with importing any kind of temperature cap into the construction of "thermal injury" is that the specification itself acknowledges that the temperature at which full denaturation occurs cannot be precisely pinpointed and instead provides a range. Any attempt by the court to pin down the specific temperature at which full denaturation occurs would not be helpful, as the specification points out that denaturation could occur at any temperature within the 60 to 70 degree Celsius range.

As to the second suggested limitation, the passages Palomar points to in order to bolster its position are not as persuasive as Palomar contends. For example, the '801 patent states, in the "Background of the Invention" section, that "A known property of collagen fibers, such as those found in the skin, is that the fibers shrink when elevated to a temperature in the range of 60 to 70 degrees Celsius." Col. 2, ll. 17-19. The patentees then state "[h]owever, this technique cannot be effectively used to remove wrinkles in skin by shrinking dermal collagen. The bulk of the shrunken, thermally denatured, collagen fibers do not remain in the skin after treatment with this technique." Col. 2, ll. 36-39.

While Palomar seeks to inject a negative limitation which excludes any shrunken or fully denatured collagen, there is no language in the specification that indicates a disclaimer of this subject matter. Palomar's construction would exclude the situation in which even one collagen fiber is fully denatured, whether by design or by accident. The court will therefore construe these terms as follows:

"Thermal injury" and "causing thermal injury" mean: "injury to collagen, caused by heating, which partially denatures the collagen."

6. "Epidermal region" and "cooling an epidermal region." Used in '801 patent, claims 4-5, 9-14; '497 patent, claims 1-10; '999 patent, claims 1-10.

An exemplar use of the term "cooling an epidermal region" is seen in claim 4 of the '801 patent, stating in part, with the disputed term in bold:

The method of claim 1, further comprising the step of **cooling an epidermal region** of the skin....

Candela proposes that "epidermal region" be defined as "one or more strata of tissue in the epidermis," and argues that "cooling an epidermal region" requires no further construction. Palomar suggests that "epidermal region" be construed as "the epidermis and upper layers of the dermis," and that "cooling an epidermal region" be defined as "reduce the temperature of the epidermis and upper layers of the dermis to avoid thermal injury to the epidermis and upper layers of the dermis."

While neither side asserts that the claim term is indefinite, the court finds that it must, as part of claim construction, determine the construction of this term from the disclosures in the specification, or lack thereof, as a matter of law. *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 949 (Fed.Cir.2007). Taking this into account, and given the fact that the parties addressed the construction of this term at length during the Markman hearing, the court will now consider whether these claims are indefinite.

Candela argues that "epidermal region" and "epidermis" are essentially interchangeable terms, while Palomar suggests that the region in question includes some portion of the dermis as well. The court has some difficulty with this term, as the patentees clearly knew the difference between the epidermis and dermis FN9, yet chose to use the somewhat vague term "epidermal region" (as well as the similarly vague term "dermal region" elsewhere in the patent). The conflicting clues littered throughout the specification do much to compound this problem.

FN9. *See, e.g.*, '801 patent, col. 1, ll. 27-27 ("Human skin consists mainly of two layers: the top layer of skin known as the epidermis; and the layer beneath the epidermis known as the dermis.").

For example, Figure 3 identifies the "epidermal region 22" as the location where radiation pulses are directed toward. The specification then goes on to state that the radiation pulses "are preferably directed to a targeted dermal region between 100 microns and 1.2 millimeters below the surface of the skin." This indicates that the "epidermal region," despite its name, contains part of the dermis. Candela argues that these two radiation pulses are directed at different regions (the epidermal and dermal), but that is far from clear. Candela's position also begs the question why, if the inventors knew the difference between the epidermis and the dermis, why they would use a different term ("epidermal region") to describe a subset of the epidermis. The word "region," as it is commonly understood, means an area somewhat larger than the precise object being referenced.FN10

FN10. For example, the abdominal "region" is not part of the abdomen; rather, it is the area surrounding the abdomen. The New York City "region" is understood to encompass some surrounding towns, not merely

Fifth Avenue.

Palomar offers a citation to what it terms an "express definition" of the term, in the '801 patent at col. 4, l.64-col. 5, l.15. In this passage, a preferred embodiment is detailed in which thermal injury to the "epidermis and the upper layers of the dermis" is minimized by cooling the epidermal region of the skin receiving the beam of radiation. Palomar then cites to claims 11 and 14, where the cooling system "minimize[s] injury to the epidermal region." Col. 8, ll. 25-28, 57-59. The only conclusion, according to Palomar, is that the "epidermal region" has to be the epidermis and upper layers of the dermis.

While the passage Palomar cites to is a preferred embodiment, it is also the only hint the specification provides as to what an "epidermal region" is. As noted *supra*, the court should avoid importing limitations from the specification into the claim terms, absent a clear disclaimer of claim scope. Phillips, 415 F.3d at 1323. Here, the specification uses language of requirement and describes an essential element of the claim, rather than merely a preferred embodiment. *See* Andersen, 474 F.3d at 1372-73; Honeywell, 452 F.3d at 1318.

The court also agrees that "cooling" means reducing the temperature of something. This is the common, everyday meaning of the word, and neither side points to any passage in the specification that would indicate otherwise. However, Palomar's suggestion that the construction of "cooling an epidermal region" include the limitation that the cooling "avoid[s] thermal injury to the epidermis and upper layers of the dermis" is redundant as the requirement that injury to epidermal region is minimized is already present in the claims using that term.FN11 The court will therefore construe these terms as follows:

FN11. *See, e.g.*, '801 patent, claim 11: "a cooling system for contact cooling an epidermal region of the skin above the targeted dermal region, to thereby minimized injury to the epidermal region." Col. 8, ll. 25-27.

"Epidermal region" means "the epidermis and upper layers of the dermis" and "cooling an epidermal region" means "reducing the temperature of the epidermis and upper layers of the dermis."

7. "Directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin." Used in the '801 patent, claims 1-14; '497 patent, claims 1-10; '999 patent, claims 1-10.

An exemplar use of this term is seen in claim 1 of the '801 patent, stating in part, with the disputed term in bold:

1. A method for treating a wrinkle in human skin, comprising: ...

directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin....

Candela suggests that this term does not need further construction, in light of the ordinary meaning of "a beam of radiation." Palomar proposes "directing the previously generated beam of radiation to the dermis at a depth between 100 microns and 1 .2 millimeters underneath a wrinkle to be treated to avoid injury to the epidermis, upper layers of the dermis and tissue beneath the dermis."

Palomar again seeks to insert extraneous language into the claim term regarding the results generated by performing the action recited in the term. For instance, Palomar cites col. 4, ll. 22-27 of the '801 patent for the proposition that the parameter range for the beam of radiation recited in the claim term has been "specifically selected to cause thermal injury to the dermis while avoiding injury to the epidermis and upper layers of the dermis." The court recognizes that this passage exists in the specification, and that it purports to explain why the targeted dermal region was selected. As with several other claim terms, Palomar is again attempting to limit the term as much as possible by inserting additional words directed toward the results achieved by performing the method or apparatus recited in the claims. However, Palomar can give no reason, and cites no authority, for including this explanation in the construction of the claim term.

As Candela does not request construction of this term, and Palomar seeks only to add extraneous words to the term, the court will not further construe it.

8. "Minimize injury." Used in '801 patent, claims 11-14.

An exemplar use of this term is seen in claim 11 of the '801 patent, stating in part, with the disputed term in bold:

... a cooling system for contact cooling an epidermal region of the skin above the targeted dermal region, to thereby **minimize injury** to the epidermal region.

Candela suggests "mitigate damage" while Palomar proposes "avoid injury." Palomar, somewhat fantastically, suggests that the ordinary meaning of "minimize" ("reduce to ... the smallest possible amount or degree," according to Palomar) is consistent with the word "avoid." Palomar cites passages of the specification like col. 2, ll. 57-61 and col. 6, ll. 16-20 of the '801 patent to support its argument. While the court does agree that the '801 patent specification confuses the issue somewhat by using a variety of words to describe the injury FN12, the use of different words indicates that the patentees knew and understood the difference between them. As Palomar points out, the patentees used the word "avoid" in the specification elsewhere. Their choice of the word "minimizes" therefore strongly indicates that they meant something other than "avoid."

FN12. *See, e.g.*, col. 2, ll. 60-61 ("avoiding injury"); col. 6, ll. 2-3 ("protecting the upper layers from thermal injury"); col. 6, ll. 9-10 ("spared from injury"); col. 6, ll. 18-19 ("substantially or completely sparing injury").

At the same time, the specification consistently characterizes the injury as greatly or substantially reduced as a result of practicing or using the claimed method or apparatus. Candela's suggestion that "minimize" means "mitigate" is somewhat inconsistent with this theme in the specification. The ordinary meaning of minimize, i.e., to reduce to the least quantity or amount possible FN13, is therefore consistent with the specification and claims.

FN13. *Merriam-Webster*, at p. 739; *The American Heritage Dictionary*, at p. 540.

Finally, while Candela's construction would substitute "damage" for "injury," Candela neither addresses this issue in its brief nor provided the court with any reason whatsoever why "injury" is somehow confusing to

the jury or affects claim scope. The court will construe this term as follows:

"Minimize injury" means "reduce injury to the least quantity or amount possible."

9. "Substantially unwrinkled skin" and "produces substantially unwrinkled skin." Used in '801 patent, claims 1-6, 8-14; '497 patent, claims 1-10; '999 patent, claims 1-10.

An exemplar use of these terms is seen in claim 1 of the '801 patent, stating in part, with the disputed term in bold:

... causing thermal injury within the targeted dermal region to elicit a healing response that **produces substantially unwrinkled skin.**

Candela proposes "skin having a reduction in the number or sizes of wrinkles" for "substantially unwrinkled skin" and argues that "produces substantially unwrinkled skin" needs no further construction. Palomar suggests "skin from which substantially all of the wrinkle has been removed to produce smooth skin" for "substantially unwrinkled skin" and "removes substantially all of the wrinkle to produce smooth skin" for "produces substantially unwrinkled skin."

Neither party's construction is particularly satisfactory, as Candela's construction of these terms more or less reads the "substantial" limitation out of the claims and Palomar's essentially equates "substantial" with "total" by adding the requirement that smooth skin be produced. As neither side points to any portion of the specification which limits the construction of the term to one extreme or the other, the court once again turns to the its trusty dictionary in order to come up with the ordinary meaning of substantial: "considerable or large." *See, e.g., The American Heritage Dictionary*, at p. 819; *Merriam-Webster*, at p. 1170. The court also notes that the Federal Circuit has stated that the ordinary meaning of the word is "considerable in extent" or "largely but not wholly that which is specified." *York Products v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1572-73 (Fed.Cir.1996). The court will therefore construe these terms as follows:

"Substantially unwrinkled skin" means "skin from which the wrinkles have been considerably or largely reduced or removed."

"Produces substantially unwrinkled skin" means "produces skin from which the wrinkles have been considerably or largely reduced or removed."

10. "To elicit a healing response" and "sufficient to elicit a healing response." Used in '801 patent, claims 1-6, 8-14; '497 patent, claims 1-10; '999 patent, claims 1-10.

An exemplar use of the term "to elicit a healing response" is seen in claim 1 of the '801 patent, stating in part, with the disputed term in bold:

... causing thermal injury within the targeted dermal region **to elicit a healing response** that produces substantially unwrinkled skin.

Candela proposes "to trigger a biological response that leads to remodeling of tissue" for "to elicit a healing response" and "sufficient to trigger a biological response that leads to remodeling of tissue" for "sufficient to elicit a healing response ." Palomar suggests "only sufficient to cause fibroblasts to produce new collagen and not sufficient to cause removal of the thermally injured collagen" for "to elicit a healing response" and

argues that no further construction is needed for "sufficient to elicit a healing response."

Col. 3, l. 65-col. 4, l. 4 of the '801 patent states that the system and method contemplated by the claims removes wrinkles by "caus[ing] sufficient thermal injury in the dermal region of the skin to elicit a healing response to cause the skin to remodel itself." Elsewhere, the specification discusses the result of causing selective thermal injury: "causing selective thermal injury to the dermis activates fibroblasts which deposit increased amounts of extracellular matrix constituents (i.e., collagen and glycosoaminoglycans). These increases in extracellular matrix constituents are responsible for dermal skin rejuvenation and the reduced appearance of wrinkles." Col. 3, ll. 11-16. The healing response, therefore, involves fibroblast activation and the deposition of extracellular matrix components collagen and glycosoaminoglycans in order to rejuvenate skin, reduce wrinkles, and, as noted elsewhere in the specification, remodel said extracellular matrix. Col. 2, ll. 57-58. In short, Candela's suggestion of "a biological response that leads to remodeling of tissue," while perhaps overly broad, finds support in the specification.

Palomar's suggestion, on the other hand, flies in the face of language in the "Background of the Invention" section that collagen and glycosoaminoglycans are produced by fibroblasts and degraded by enzymes. Col. 1, ll. 33-35. Collagen, in particular, is degraded by enzymes called collagenases. Palomar points to another section of the specification in which fully denatured collagen is eliminated by collagenases, col. 2, ll. 36-44, and the fact that the purpose of the invention is to accelerate collagen production, in order to conclude that collagen can never be removed from the skin during partial denaturation. However, there is no suggestion in the patent that partially denatured, thermally injured collagen cannot be removed from the skin. Palomar's construction is not supported by the claims or specification. The court will construe these terms as follows:

"To elicit a healing response" and "sufficient to elicit a healing response" mean "[sufficient] to activate fibroblasts, which deposit increased amounts of extracellular matrix constituents (i.e., collagen and glycosoaminoglycans), that leads to the remodeling of said extracellular matrix."

11. "Within the targeted dermal region." Used in '801 patent, claims 1-10; '497 patent, claims 1-10; '999 patent, claims 1-10.

An exemplar use of this term is seen in claim 1 of the '801 patent, stating in part, with the disputed term in bold:

... causing thermal injury **within the targeted dermal region** to elicit a healing response that produces substantially unwrinkled skin.

Candela argues that the phrase does not require further construction by the court. Palomar proposes "within the previously identified dermis below the epidermis and upper layers of the dermis and excluding tissue beneath the dermis."

The claim step immediately preceding this limitation states that the targeted dermal region is "between 100 microns and 1.2 millimeters below a wrinkle in the skin." '801 patent, col. 7, ll. 33-35. Palomar apparently does not request that the word "within" be construed, as "within" is found both in the claim term and Palomar's proposed construction. Rather, Palomar seeks to import the language from the specification that the range of 100 microns and 1.2 millimeters below the wrinkle was chosen to "avoid injury to the epidermis and upper layers of the dermis." '801 patent, col. 4, ll. 22-27.

As discussed above with respect to "epidermal region," the phrase "dermal region" is not necessarily inconsistent with a region that encompasses areas outside the dermal layer of the skin (such as parts of the epidermis or areas below the dermis). However, the specification clearly states that the parameters for the beam of radiation directed toward the targeted dermal region were chosen with the intent that injury to the epidermis and upper layers of the dermis be avoided. '801 patent, col. 4, ll. 22-27. Despite Candela's contention that the upper layers of the dermis are generally included in the range of 100 microns-1.2 millimeters, a patentee is entitled to be his or her own lexicographer. The patentees in this case specifically excluded the upper layers of the dermis from the targeted dermal region.

Finally, the court rejects Palomar's limitation that the tissue beneath the dermis be excluded from the construction of targeted dermal region. As discussed above, a "region" can encompass areas beyond the border of the dermis, and Palomar is able to point to no place in the specification that would compel the addition of such limitation. The court will therefore construe this term as follows:

"Within the targeted dermal region" means "within the aforementioned targeted region, which is between 100 microns and 1.2 millimeters below a wrinkle in the skin and located below the epidermis and upper layers of the dermis."

IV. CONCLUSION

The jury shall be instructed in accordance with the court's interpretation of the disputed claim terms in the '801, '497, and '999 patents.

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Candela Corp. v. Palomar Medical Technologies, Inc.

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