# United States Court of Appeals for the Federal Circuit

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**AMERICAN MEDICAL SYSTEMS, INC. AND LASERSCOPE,**
*Plaintiffs-Appellants,*

**v.**

**BIOLITEC, INC.,**
*Defendant-Appellee.*

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2009-1323

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Appeal from the United States District Court for the District of Massachusetts in case no. 07-CV-30109, Judge Michael A. Ponsor.

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Decided: September 13, 2010

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LELAND G. HANSEN, McAndrews, Held & Malloy, Ltd., of Chicago, Illinois, argued for plaintiffs-appellants. With him on the brief was SCOTT P. MCBRIDE.

MARK D. GIARRATANA, McCarter & English, LLP, of Hartford, Connecticut, argued for defendant-appellee. With him on the brief were ERIC E. GRONDAHL and CHARLES D. RAY.

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Before BRYSON, DYK, and PROST, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* BRYSON.
Dissenting opinion filed by *Circuit Judge* DYK.

BRYSON, *Circuit Judge*.

In this patent infringement action, plaintiffs American Medical Systems, Inc., and Laserscope appeal an order granting summary judgment of noninfringement to defendant Biolitec, Inc. The patent in suit, Laserscope's U.S. Patent No. 6,986,764 ("the '764 patent"), is entitled "Method and System for Photoselective Vaporization of the Prostate, and Other Tissue." It claims various methods and devices for vaporizing tissue by using laser radiation. The district court based its summary judgment order on its conclusion that Biolitec's accused device does not perform "photoselective vaporization of tissue," a term that is contained only in the preambles of the asserted claims. Because we conclude that the disputed preamble term does not limit the asserted claims, we reverse and remand.

## I

The invention of the '764 patent can be used to treat Benign Prostatic Hyperplasia ("BPH"), a condition in which growth of the prostate gland restricts the passage of urine out of the bladder and through the urethra. Vaporization, or ablation, of some of the prostate tissue reduces the size of the prostate and can relieve bladder outlet obstructions. As described in the patent, this type of BPH treatment generally involves the insertion of a cytoscope into the urethra, the provision of an irrigant such as sterile water, and the application of high-

intensity laser radiation to the target tissue by means of an optical fiber.

According to the specification of the '764 patent, prior art tissue vaporization systems were inefficient when used with continuous irrigation, and they frequently caused side effects including residual tissue coagulation, i.e., the generation of a layer of thermally denatured tissue, which led to swelling, transient urinary retention, and infection. '764 patent, col. 2, ll. 33-41. The ineffectiveness of the prior art systems was due in part to their use of longer wavelengths of laser radiation, such as 2100 or 1064 nanometers ("nm"). At 2100 nm, the specification explains, laser radiation is "strongly absorbed by water in the prostate tissue" and there is "essentially no selective absorption by blood." When combined with the pulse energies and pulse durations used in the prior art devices, the use of radiation of that wavelength led to violent tissue disruption and "poor hemostasis" (stoppage of bleeding). *Id.*, col. 2, ll. 17-20, 28-32. At 1064 nm, the radiation is hemostatic when used at high power levels, but has low absorption in blood and prostate tissue that "leads to inefficient ablation and a large residual layer of thermally denatured tissue several millimeters thick." *Id.*, col. 2, ll. 36-38. By contrast, the specification explains, laser radiation at a wavelength of 532 nm "is selectively absorbed by blood, leading to good hemostasis," and when sufficient power is used at that wavelength, the process leaves behind a layer of denatured tissue less than 1 millimeter thick, which reduces swelling and painful urination. *Id.*, col. 2, ll. 49-56. The specification adds, however, that even when using a wavelength of 532 nm, prior art techniques were inefficient and caused significant residual coagulation. *Id.*, col. 2, ll. 59-65.

The inventors of the '764 patent determined that the use of high "volumetric power density," i.e., a high amount of energy delivered to a given volume of tissue, would result in increased vaporization efficiency while minimizing residual coagulation. The patent is directed to various methods and devices for achieving high volumetric power density for tissue vaporization, by manipulating variables such as wavelength, output power, beam quality, irrigant composition, and distance between the optical fiber and the tissue. Those variables in turn affect the resulting irradiance level, spot size, and absorption depth.

Claim 31 is representative of the method claims. It recites:

> A method for photoselective vaporization of tissue, comprising:
>
> > delivering laser radiation to a treatment area on the tissue, the laser radiation having a wavelength and having 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, wherein the delivered laser radiation has an average irradiance in the treatment area greater than 10 kiloWatts/$cm^2$ in a spot size at least 0.05 $mm^2$.

The apparatus claims are generally similar, except that they also recite a laser and an endoscope having an optical fiber for delivering the laser radiation.

Most of the independent claims do not specify a maximum or minimum wavelength for the laser radiation used in the claimed methods or by the claimed apparatus, although several of them have dependent claims specifying that "the laser radiation has a wavelength in a range from about 650 to about 200 nm." The other independent claims expressly recite "laser radiation having a wavelength in a range of about 200 nm to about 650 nm." With the exception of claims 1 and 16, all of the independent claims contain limitations requiring that the laser radiation have 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." Claim 1 requires that the laser radiation be "absorbed substantially completely by the tissue within about 1 mm of the surface," and that it have "average irradiance in the treatment area greater than 10 kiloWatts/cm$^2$ in a spot size at least about 0.05 mm$^2$." Claim 16 requires the delivery of laser radiation and a flow of transparent liquid irrigant, with the laser "causing vaporization of a volume of tissue greater than a volume of residual coagulation of tissue, and having irradiance in the treatment area greater than 10 kiloWatts/cm$^2$ in a spot size at least about 0.05 mm$^2$."

The plaintiffs filed suit against Biolitec in the United States District Court for the District of Massachusetts, alleging that Biolitec's Evolve™ laser system and method of use infringed a number of the claims of the '764 patent. The accused product is a laser-powered tissue ablation system that uses radiation having a wavelength of 980 nm. It includes an optical fiber probe for administering the radiation by direct contact with the target tissue.

Following a *Markman* hearing, the district court issued an order construing several key terms in the asserted claims. *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 569 F. Supp. 2d 313 (D. Mass. 2008). Most sharply disputed were the terms in the preambles of the asserted claims: "A method for photoselective vaporization of tissue" and "An apparatus for photoselective vaporization of tissue." The plaintiffs argued that the preamble language (particularly the phrase "photoselective vaporization") simply describes the invention as a whole and should not be construed as a limitation of any of the asserted claims. The district court, however, ruled that the repeated use of the phrase "photoselective vaporization" in the specification and claims indicated that "photoselective vaporization" is a "fundamental characteristic" of the invention, albeit not its central innovative feature. *Id.* at 320-22. The court found support for that conclusion in the patent's discussion of the prior art. In particular, the court relied on the patent's criticism of earlier laser systems that used longer wavelengths of 2100 nm or 1064 nm. Those systems, according to the specification, produced "low" or "no" selective absorption of the radiation by blood and tissue; by contrast to those systems, the specification praised a prior art system that used a shorter wavelength of 532 nm that was "selectively absorbed by blood." *Id.* at 321. Accordingly, the court construed the term "photoselective vaporization" to mean "using a wavelength that is highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant." *Id.* at 327.

In light of the district court's claim construction ruling, Biolitec moved for summary judgment of noninfringement, asserting that its Evolve™ laser system operated at a wavelength (980 nm) at which the energy is absorbed to more than "a negligible degree by water or

other irrigant." The district court granted Biolitec's motion. *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 603 F. Supp. 2d 251 (D. Mass. 2009). The court began by noting certain undisputed facts concerning the properties of 980 nm laser light (as in the accused product), as compared with 532 nm laser light (the wavelength of the '764 patent's preferred and commercial embodiment). For example, the absorption coefficient of 980 nm laser energy in water is 0.43, whereas the absorption coefficient of 532 nm laser energy in water is only 0.00036; and 4.2% of 980 nm laser energy is absorbed by water at a distance of 1 mm from prostate tissue, whereas only 0.004% of 532 nm laser energy is absorbed by water at that distance. *Id.* at 255-56. The district court also observed that Biolitec's accused device operates by placing the device in direct contact with the target tissue so as to prevent absorption of the energy by the water irrigant. In light of those facts, the court concluded that "[w]hen compared to 532 nm laser light, 980 nm laser light is more than negligibly absorbed by the water irrigant" and thus did not satisfy the "photoselective vaporization" limitation of the '764 patent, as the district court construed it. *Id.* at 256. The court therefore held that Biolitec's accused device did not literally infringe the '764 patent.

The district court also addressed the issue of infringement under the doctrine of equivalents. The court concluded that the "function-way-result" test was ill-suited to evaluating the patent in suit, but it held that under the "all limitations" rule and the corollary "specific exclusion" principle developed by this court, Biolitec's device did not infringe the '764 patent by equivalents. *Am. Med. Sys.*, 603 F. Supp. 2d at 257-58.

On appeal, the plaintiffs contend that (1) the term "photoselective vaporization" in the preamble of each of

the asserted claims should not be construed as a claim limitation; (2) if "photoselective vaporization" is a limitation on the claims, the district court erred in construing that term to require a wavelength that is "absorbed only to a negligible degree by water or other irrigant"; and (3) if the district court's claim construction is correct, the district court erred in its infringement analysis in several respects. We conclude that the preamble phrase "photoselective vaporization of tissue," and particularly the descriptor "photoselective," does not limit the claims of the '764 patent. Therefore, we need not address the plaintiffs' remaining arguments. Because the district court's grant of summary judgment was predicated entirely on its conclusion that Biolitec's accused device "does not violate the 'photoselective vaporization' claim limitation in the '764 patent as construed in the *Markman* Order," *Am. Med. Sys.*, 603 F. Supp. 2d at 256, we reverse and remand for further proceedings.

## II

Whether to treat a preamble term as a claim limitation is "determined on the facts of each case in light of the claim as a whole and the invention described in the patent." *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003). While there is no simple test for determining when a preamble limits claim scope, we have set forth some general principles to guide that inquiry. "Generally," we have said, "the preamble does not limit the claims." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). Nonetheless, the preamble may be construed as limiting "if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002), quoting *Pitney Bowes, Inc. v. Hewlett-Packard*

*Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). A preamble is not regarded as limiting, however, "when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Catalina*, 289 F.3d at 809. If the preamble "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 [prior art] 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). We have held that the preamble has no separate limiting effect if, for example, "the preamble merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth the invention." *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434-35 (Fed. Cir. 2000).

In light of those principles, we conclude that the preamble language in the asserted claims of the '764 patent does not constitute a limitation of the claims. More specifically, we reject the district court's suggestion, implicit in its claim construction and infringement analyses, that the preamble descriptor "photoselective" limits the claims to a particular (albeit unspecified) range of wavelengths at which laser radiation is "absorbed only to a negligible degree by water or other irrigant."

First, there is no suggestion in the prosecution history of the '764 patent that the inventors added the phrase "photoselective vaporization" in order to distinguish their invention from the prior art. Rather, the examiner's primary reason for approval was the claims' use of high power densities to vaporize tissue without causing significant residual tissue damage.

Second, contrary to Biolitec's argument, the preamble term "photoselective vaporization of tissue" does not provide a necessary antecedent basis for the term "the tissue" in the bodies of each of the independent claims. The preamble's reference to "vaporization of tissue" does not specify a particular type or location of tissue being treated. Nor does the generic term "tissue" in the preamble provide any "context essential to understand[ing]" the meaning of "the tissue" in the body of each claim. *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1376 (Fed. Cir. 2005). Thus, the claim drafters did not rely on the preamble language to define or refine the scope of the asserted claims. *See Catalina*, 289 F.3d at 808 ("[D]ependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention.").

Third, and most importantly, the descriptor "photoselective" does not embody an essential component of the invention. Instead, the term "photoselective vaporization" is simply a descriptive name for the invention that is fully set forth in the bodies of the claims. *See Storage Tech.*, 329 F.3d at 831 (preamble term "policy caching method" did not limit claims because it served only as a "convenient label for the invention as a whole"). The bodies of the asserted apparatus claims (claims 63-64) describe a structurally complete device, including a laser adapted to deliver "radiation at a wavelength and irradiance . . . sufficient to cause [tissue] vaporization[.]" The bodies of those claims identify the covered wavelengths by function ("sufficient to cause vaporization"), and nothing in the claim language suggests that the term "photoselective" further limits those wavelengths. The inference that the asserted apparatus claims do not require the use of energy of a particular wavelength is considerably strength-

ened by the fact that a number of other apparatus claims (claims 59-62 and 67-74), which contain the same disputed preamble language, limit the wavelength of the radiation to the range from "about 200 nm to about 650 nm." If the term "photoselective" were deemed independently limiting, it would either be redundant or in conflict with the specific wavelength range set forth in the body of those claims.

The apparatus claims make clear that one can practice the invention without using wavelengths in the 200 to 650 nm range described by the '764 specification as having "strong oxyhemoglobin absorption" and "relatively weak water absorption," as long as the energy applied is sufficient to "cause vaporization of a substantially greater volume of tissue than a volume of residual coagulated tissue." That point is underscored by the fact that the apparatus claims reciting the 200 to 650 nm range also require a lower minimum irradiance, which indicates that the purpose of the claims is to maximize volumetric power density through different combinations of variables; the '764 patent thus contemplates that with an increase in the laser's wavelength, more power will be necessary to vaporize the tissue and minimize coagulation.

Likewise, the bodies of the asserted method claims contain all the steps necessary to practice the invention. Independent claims 16, 31, 36, 40, and 42 require the delivery of radiation "causing" or "sufficient to cause" vaporization "of a substantially greater volume of tissue than a volume of residual coagulated tissue." Independent claim 1 does not explicitly require vaporization, but it requires that the laser radiation be "absorbed substantially completely by the tissue within 1 mm of the surface." Thus, in each of the asserted method claims, as in the apparatus claims, the invention is recited in func-

tional terms; as long as the stated objective is achieved, through the various recited combinations of wavelength, irradiance, output power, spot size, irrigant type, and distance between the optical fiber and the tissue, it is irrelevant whether a particular wavelength is used that would satisfy an independent requirement of being "photoselective." While, as a practical matter, use of a wavelength of laser radiation that is selectively absorbed by tissue to at least some degree will likely be necessary to satisfy the functional requirements, the claim language does not require any particular wavelength range (or upper limit).

As in the case of the apparatus claims, other claims among the method claims provide strong support for the plaintiffs' argument that the asserted method claims are not limited to wavelengths having a prescribed degree of differential absorption in tissue and water. Method claims 1, 16, and 31 each have dependent claims that recite the use of wavelengths "from about 200 nm to about 650 nm." Under the doctrine of claim differentiation, those dependent claims give rise to a presumption that the broader independent claims are not confined to that range. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc). Thus, in every asserted claim of the '764 patent, the language in the body of the claims recites a complete invention for achieving the stated purpose of applying laser radiation in a high volumetric power density. Removal of the duplicative preamble language would neither alter the scope of the claims nor introduce ambiguity as to their coverage.

The specification of the '764 patent further confirms that "photoselective vaporization" is a label for the overall invention and not a limitation on the claims. Although the phrase "photoselective vaporization" appears in the

title, in the abstract, and six times in the rest of the written description, it is consistently used in reference to the entire invention's emphasis on improved vaporization efficiency through high power densities. The broad recitation in the "Field of Invention," which states that "[t]he present invention relates generally to laser treatment of soft tissue, and more particularly to photoselective vaporization of the prostate PVP, and to photoselective vaporization of other tissue," supports the plaintiffs' position that the phrase is meant to serve as a label for the invention as a whole. The other references to the term, including those in the abstract and in a key passage cited by the district court, also indicate that the phrase "photoselective vaporization" describes the overall invention.

The district court based its claim construction largely on the following sentence in the specification ('764 patent, col. 3, line 66, through col. 4, line 6):

> 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.

As the court acknowledged, 569 F. Supp. 2d at 322, the use of the words "based upon," rather than "means" or "is," undermines the suggestion that the term "photoselective vaporization" is used as a definition or limitation of

the claim terms. In any event, however, to the extent that the sentence describes "photoselective vaporization," it is not limited to describing radiation with wavelengths that are absorbed to a substantially greater degree by tissue than by water, but also describes other key aspects of the overall invention. Those include the use of high irradiance levels to achieve high "power densities" and efficient vaporization of tissue, which the district court deemed the "central innovative feature" of the invention as a whole. Moreover, the sentence's reference to absorption "during the operation" alludes to the principle, expressed elsewhere in the patent, that in practice the irradiance delivered to a treatment area can be increased and the absorption of the laser energy in the irrigant correspondingly decreased not only by selecting an appropriate wavelength for the laser output, but also by reducing the distance between the optical fiber and the tissue, thereby minimizing the amount of liquid through which the laser energy must pass. *See* '764 patent, col. 5, ll. 52-59. Thus, we conclude that the quoted sentence, read in context, does not use the term "photoselective vaporization" to confine the invention to the use of particular wavelengths but is better understood as a description of the overall process described and claimed in the '764 patent.

In support of its argument that the term "photoselective" is a limitation on the claims, Biolitec also points to a portion of the "Detailed Description" section of the specification, which states, "The wavelength used according to the present invention for BPH treatment should be strongly absorbed in the prostate tissue to help initiate and maintain tissue vaporization. . . . The wavelength also must be minimally absorbed by the irrigant . . . used during the procedure, typically water." '764 patent, col. 12, ll. 16-21. That language indicates that using radiation

of certain wavelengths may increase the effectiveness of the invention, but it does not suggest that the invention is limited to particular wavelengths regardless of the values of the other variables in a particular device. Although the quoted passage expresses a preference for using wavelengths of 200 to 650 nm, other portions of the '764 specification discuss embodiments using radiation with wavelengths up to 1000 nm. '764 patent, col. 4, ll. 28-29. Moreover, as noted, the presence of claims reciting wavelengths of 200 to 650 nm gives rise to the inference that the remaining claims, which do not contain that express wavelength limitation, read on processes and devices using wavelengths outside that range. In addition, the specification refers to wavelengths in the 200 to 1000 nm range (a range that includes Biolitec's device, which uses radiation of 980 nm wavelength) as the "preferabl[e]" wavelengths for use in practicing the invention. '764 patent, col. 4, ll. 28-29.

The dissent argues that, while 200 to 1000 nm wavelengths are described as preferred "for some embodiments," the "photoselective vaporization embodiment" is a "separate embodiment" that "is consistently described as having a wavelength in the 200-650 range." However, the '764 specification does not support that interpretation. In the sole instance in which an "embodiment" is specifically described as involving "photoselective vaporization," the subsequent description expresses no preferred wavelength range. Instead, it provides the following general explanation: "According to this embodiment, the method includes delivering laser radiation to the treatment area . . . wherein the laser radiation has a wavelength and irradiance in the treatment area on the surface of the tissue sufficient [to cause] vaporization of a substantially greater volume of tissue than a volume of residual coagulated tissue caused by the laser radiation." '764 patent,

col. 5, ll. 22-29. Here, as in the patent's claims employing nearly identical language, "photoselective vaporization" (the descriptor for the invention as a whole) is expressed in functional terms; i.e., as long as the selected wavelength and irradiance together result in "vaporization of a substantially greater volume of tissue than a volume of residual coagulated tissue," no particular wavelength range is required. The specification does not delineate a particular wavelength range until later, when it addresses a more specific embodiment: "In other embodiments, the delivered laser radiation has a wavelength in a range of about 200 nm to about 650 nm." *Id.*, col. 5, ll. 41-42. The passages cited by the dissent, most of which refer to the invention as a whole, do not support the existence of a separate "photoselective vaporization embodiment"; they merely suggest, but do not require, the use of certain wavelengths as a means of increasing the invention's overall effectiveness in conjunction with other variables.[1] Accordingly, the specification as a whole indicates that while wavelength is one of the variables employed in the invention, the claims (other than those specifically limited to 200 to 650 nm) are not limited to particular wave-

[1] The dissent asserts that the language discussing use of wavelengths greater than 650 nm is a remnant of an earlier parent patent and was retained in order to support additional claims (claims 77-80), which did not recite "photoselective vaporization" and were abandoned after being rejected as anticipated by prior art. The references to longer wavelengths all appeared in the initial application for the '764 patent, however, while claims 77-80 were not added until a later amendment. That sequence of events suggests that the longer-wavelength references were included because the original "photoselective vaporization" claims were intended to encompass longer wavelengths.

lengths exhibiting particular levels of differential absorption in tissue and water.

To be sure, the specification points out the drawbacks of prior art lasers that use longer-wavelength radiation to perform tissue ablation, noting that 2100 nm radiation results in "essentially no selective absorption by blood" and that 1064 nm radiation has "low absorption in blood and prostate tissue," leading to inefficient ablation. *See* '764 patent, col. 2, ll. 15-41. However, both of those examples lie above the 200 to 1000 nm range that the '764 specification refers to as "preferabl[e]." The discussion of the prior art therefore falls far short of "mak[ing] clear that the invention does not include a particular feature," *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001), and does not rise to the level of a disclaimer of wavelengths between 650 and 1000 nm.

Read as a whole, the '764 patent discloses methods and devices for increasing power density in the application of laser energy, which may be achieved in ways that do not require a specific wavelength range. Other variables (including, e.g., irradiance, spot size, distance between optical fiber and tissue, irrigant type, and output power) are incorporated in various combinations in the independent and dependent claims, which suggests that while selection of an appropriate wavelength is one means by which the objectives set forth in the asserted claims can be achieved, no particular wavelength range is required by the claims.

## III

For the foregoing reasons, we conclude that the district court erred when it construed the phrase "photose-

lective vaporization" as a claim limitation, rather than merely a label for the invention as a whole. We therefore reverse the summary judgment of noninfringement and remand for further proceedings addressing whether Biolitec's accused device meets the remaining claim limitations of the '764 patent.

**REVERSED AND REMANDED**

# United States Court of Appeals for the Federal Circuit

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**AMERICAN MEDICAL SYSTEMS, INC. AND LASERSCOPE,**
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2009-1323

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Appeal from the United States District Court for the District of Massachusetts in case no. 07-CV-30109, Judge Michael A. Ponsor.

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DYK, *Circuit Judge*, dissenting.

I respectfully dissent from the majority's decision that the preamble is not a claim limitation.

I

Under our precedent, a preamble is construed as limiting "if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim," but not if "the claim body describes a structurally com-

plete invention."[1] Over the years our court has struggled to make sense of when a preamble should be construed as limiting. *See Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995) ("Much ink has, of course, been consumed in debates regarding when and to what extent claim preambles limit the scope of the claims in which they appear.").

As the majority itself appears to recognize, we have not succeeded in articulating a clear and simple rule. Majority Op. at 8; *see also* Patrick J. Flinn, *Claim Construction Trends in the Federal Circuit*, 572 PLI/PAT 317, 335-36 (1999) (characterizing the preamble limitations test as "opaque" and without a set framework). As a result of the lack of clarity as to whether a preamble should be construed as limiting, our case law has become rife with inconsistency, both in result and in the articulation of the test.[2] As the leading treatise on patent law

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[1] *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 808-09 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)).

[2] *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006) ("While it is true that preamble language is often treated as nonlimiting in nature, it is not unusual for this court to treat preamble language as limiting, as it is in this case."); *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003) ("Whether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent."); *Catalina Mktg.*, 289 F.3d at 808 (Fed. Cir. 2002) ("No litmus test defines when a preamble limits claim scope."). *Compare DeGeorge v. Bernier*, 768 F.2d 1318, 1322 n.3 (Fed. Cir. 1985) (stating that "[g]enerally, and in this case, the preamble does not limit the claims"), *with Bell Commc'ns*, 55 F.3d at 621 (noting that the observation in *DeGeorge* that the preamble does not generally limit the claims "can only have been *de* scriptive, rather than *pre*

observes, "the decisions are difficult to reconcile." 3 Donald S. Chisum, *Chisum on Patents* § 8.06[1][d] (2010).

It seems to me that a rule recognizing that all preambles are limiting would make better sense and would better serve the interests of all concerned. There is, after all, little to be said in favor of allowing an applicant, in the claim drafting process, to include material in the claims that is not binding. If patentees are allowed to include material in the claim definitions that is not binding, patentees can suggest or imply one position before the U.S. Patent & Trademark Office ("PTO") to secure allowance of the patent on the theory that the preamble is limiting and another, inconsistent position in infringement litigation on the theory that it is not limiting.[3] Principles of fairness thus dictate that the patentee should be required to clearly define the claimed invention's scope. By creating a uniform rule that all preambles are limiting, we would ensure the patentee has the burden of drafting a patent that avoids confusion as to the scope of the claims. As the Supreme Court concluded in *Merrill v. Yeomans*, 94 U.S. 568, 573-74 (1876), "nothing can be more just and fair, both to the patentee and to the public, than that the former should understand, and

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scriptive. . . . [O]ne cannot determine a preamble's effect except by reference to the specific claim of which it is a component").

[3] Of course, if the patentee makes his or her positions explicit, the patentee could be barred by the doctrine of prosecution history estoppel from taking such inconsistent positions. But, in many cases, it is not readily apparent whether the patentee has taken inconsistent positions.

correctly describe, just what he has invented, and for what he claims a patent."

Neither the Supreme Court nor our court sitting en banc has ever addressed the preamble limitation issue. I think the time may have come for us to eliminate this vague and confusing rule.

II

Even under our existing precedent, which is binding on the panel, I believe that the preamble term "photoselective vaporization" should have been construed as a claim limitation. The determination of whether a preamble serves as a claim limitation is "resolved only on review of the entire[ ] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed.Cir. 1989); *see also Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1572-73 (Fed. Cir. 1996) ("Whether a preamble stating the purpose and context of the invention constitutes a limitation of the claimed process is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history."). A preamble generally limits an invention if it recites essential structure or steps or if it is "necessary to give life, meaning, and vitality" to a claim. *Catalina Mktg.*, 289 F.3d at 808 (quoting *Pitney Bowes*, 182 F.3d at 1305).

In my view, the photoselective vaporization language must be treated as a claim limitation. U.S. Patent No. 6,986,764 ("the '764 patent") was a continuation-in-part of U.S. Patent No. 6,554,824 ("the '824 patent"). Neither the '824 application nor the issued '824 patent used the term "photoselective vaporization" in the claims or in the

specification. The addition of the term "photoselective vaporization" in the preamble of the claims of the '764 patent was significant. The applicant took considerable care to add new matter to the specification describing and defining photoselective vaporization. The term appears in the title of the patent (once), the abstract (once), the Field of the Invention section (twice), the Summary of the Invention section (twice), and the Detailed Description section (once). For example, the Field of the Invention section states: "The present invention relates generally to laser treatment of soft tissue, and more particularly to *photoselective vaporization* of the prostate PVP, and to *photoselective vaporization* of other tissue." '764 Patent, col.1 ll.33-36 (emphases added).

The Summary of the Invention section of the specification defines "photoselective vaporization" as follows:

> 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.

*Id.* col.3 l.66-col.4 l.6. In light of this passage, the District Court properly construed "[a] method for photoselective vaporization of tissue"/"[a]n apparatus for photoselective vaporization of tissue" to mean "using a wavelength that is highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, No. 07-30109-MAP,

slip op. at 38 (D. Mass. July 31, 2008). Photoselective vaporization is a product of shortening the wavelengths of the emitted signal.

The majority appears to conclude that reading photoselective vaporization as a clear limitation would be inconsistent with the specification, which contemplates wavelengths up to 1000 nm. In my view, the majority misconstrues the specification and prosecution history.

As the majority points out, the original '824 patent was concerned, among other things, with reducing the wavelength of the laser light over the prior art. As the majority recognizes, the specification repeatedly criticizes the prior art use of "earlier laser systems that used longer wavelengths of 2100 nm or 1064 nm." Majority Op. at 6. The '824 patent reduced the claimed wavelengths to the 200 to 1000 nm range, and the specification stated that the "wavelength of the laser light is preferably between 200 and 1000 nm." '764 Patent col.4 ll.28-29; *see* '824 Patent col.3 ll.44-45.

The continuation-in-part application that became the '764 patent further reduced the claimed ranges. The claims of the '824 patent were amended to eliminate wavelengths in the 650-1000 range and to substitute references to wavelengths in the 200-650 range for the original wavelength range of 200-1000 nm in the claims where a specific range is included. *See* J.A. 893-903. While the specification continued to mention wavelengths in the 200-1000 range as "preferred" for some embodiments, the specification makes clear that the photoselective vaporization embodiment is a separate embodiment, stating that "one embodiment of the invention provides a method for photoselective vaporization of prostate tissue." '764 patent col.5 ll.21-22. The specification states that for that invention "it is desirable to provide a wavelength

between 650 and 200 nm." *Id.* col.16 ll.32-33. The photoselective vaporization embodiment is never described as having a wavelength in the 200-1000 range. Rather, it is consistently described as having wavelengths in the 200-650 range.[4] The specification repeatedly touts the advantages of photoselective vaporization, that is, the "532 nm light from these lasers is selectively absorbed by blood leading to good hemostasis" and more efficient tissue ablation. '764 Patent col.2 ll.49-59.

If there were any doubt that photoselective vaporization is a claim limitation, it is resolved by the specification's statement that "[t]he wavelength used *according to the present invention* for BPH treatment should be

[4] *See, e.g.*, '764 patent col.12 ll.16-34 ("The wavelength used according to the present invention for BPH treatment should be strongly absorbed in the prostate tissue to help initiate and maintain tissue vaporization without creating deep tissue heating. The wavelength also must be minimally absorbed by the irrigant it used during the procedure, typically water. The 532 nm light produced by the system of FIG.5, is both strongly absorbed in oxyhemoglobin and weakly absorbed in water. . . . In yet other embodiments, wavelengths in the range from 200 nm-500 nm are used, which have strong oxyhemoglobin absorption and relatively weak water absorption . . . ."); *id.* col.14 ll.57-59 ("KTP laser energy will be generated by a high power 532 nm laser capable of delivering 80W of KTP laser power to tissue."); *id.* col.15 ll.25-55 (comparing the 1064 nm wavelength used in the prior art to the 532 nm wavelength and concluding that the 532 laser beam is preferable because it is "substantially completely absorbed within less than about 1 mm of the surface of prostatic tissue. . . . The coagulation zone is very thin because of the small optical penetration depth of the 532 wavelength. . . . Other wavelengths which are substantially completely absorbed within less than about 1 mm of the surface of the prostatic tissue include wavelengths less than about 650 nm, for example between about 200 nm and 650 nm.").

strongly absorbed in the prostate tissue to help initiate and maintain tissue vaporization. . . . The wavelength also *must be minimally absorbed* by the irrigant . . . used during the procedure, typically water." '764 Patent col.12 ll.16-21 (emphases added). While this sentence appears in the Detailed Description section of the specification, we have repeatedly held that "the use of the words 'the present invention' can be read to limit the invention to what is described as such." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1383 (Fed. Cir. 2009) (citing *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006)); *see Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340 (Fed. Cir. 2010) (holding that the reference to the system of the present invention strongly suggests that the claimed re-centering command requires a manual input); *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1379 (Fed. Cir. 2005) (noting that "when the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment"); *Honeywell*, 452 F.3d at 1318 (construing claim term to include fuel filter because "[o]n at least four occasions, the written description refers to the fuel filter as 'this invention' or 'the present invention'"). Minimal absorption by the irrigant and strong absorption by tissue, or photoselective vaporization, are thus mandatory aspects of this particular invention.

I recognize, as the majority points out, that the specification for the '764 patent includes references to wavelengths that are not photoselective because they are not "minimally absorbed." '764 Patent col.8 ll.7-12 ("Other laser systems may be used . . . which are adapted to provide the output power and wavelengths described herein, including wavelengths in the ranges from 200 nm to 1000 nm and from 1100 nm to 1800 nm, for example.").

But as I have noted this language in the specification does not relate to the photoselective vaporization embodiment and is explained by the fact that the '824 patent specification included claims that were directed to longer wavelengths. The fact that such language was retained by the '764 patent specification is explained by a desire to include additional claims in the '764 patent not directed to the "photoselective vaporization" embodiment. Indeed, a preliminary amendment to the '764 application recited seven additional claims (claims 77-80) that did not include the term "photoselective vaporization." Claim 77 explicitly described using lasers with a wavelength in the 200 nm to 1000 nm range. These claims were subsequently abandoned during prosecution after being rejected as anticipated by U.S. Patent Nos. 5,776,175 and 5,776,127. J.A. 369.

Under the circumstances, it seems clear to me that "photoselective vaporization" should be construed as a claim limitation; by adding this terminology during prosecution of the '764 patent, the patentee conceded that the term gave life, meaning, and vitality to the claims.[5]

Therefore, contrary to the majority, I would hold that photoselective vaporization is a claim limitation.

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[5] As the majority points out, the reference to the 200 to 650 nm range in the dependent claims (claims 4-6, 19-21, 32-34, 37, 59-62 and 67-74) suggests that the independent claims are broader. *See* Majority Op. at 11. But this merely suggests that the photoselective vaporization limitation applies to somewhat longer wavelengths than 200 to 650 nm.