United States District Court,
D. Massachusetts.

DIOMED, INC,
v.
ANGIODYNAMICS, INC.

No. Civ.A.04-CV-10019-RG

April 12, 2005.

James J. Foster, Jason M. Honeyman, Michael A. Albert, Wolf, Greenfield & Sacks, PC, Boston, MA, for Diomed, Inc.

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MEMORANDUM AND ORDER ON CLAIMS CONSTRUCTION

STEARNS**, J.**

On January 6, 2004, Diomed, Inc., a company specializing in "minimally invasive endovascular laser" technology used in the treatment of swollen or "varicose" veins, sued a competitor, AngioDynamics, Inc., alleging infringement of Diomed's U.S. Patent No. 6,398,777 (the '777 patent). On March 4, 2004, Diomed sued another competitor, Vascular Solutions, Inc., for allegedly infringing the same patent (*Diomed, Inc. v. Vascular Solutions, Inc.,* Civil Action No. 04-10444-RGS). The two cases were then consolidated for purposes of claim construction under Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). FN1 Diomed alleges that AngioDynamics and Vascular Solutions have each infringed independent Claims 9 and 21 and dependent Claims 10-14 and 16-19 of the '777 patent. The parties seek construction of certain terms contained in Claim 9 of the '777 patent (several of which are imported into Claim 21, as well as into some of the dependent claims). They also look for a construction of the phrase "emptying the blood vessel" as it is used in Claim 10. FN2 The hearing on claim construction was held on March 17, 2005.

FN1. Diomed subsequently brought similar suits against Total Vein Solutions, Inc. (Civil Action No. 04-10686-RGS), and New Star Lasers, Inc. (Civil Action No. 04-12157-RGS). The parties to these cases have agreed to await the court's decision on claim construction in this case before proceeding with the separate litigation.

FN2. The parties also seek construction of certain terms in dependent Claims 11, 12, 16, 17, 18, and 19, that do not simply replicate language in Claim 9. None of the nominated terms seem sufficiently material or ambiguous to warrant examination for present purposes. *See* U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed.Cir.1997) ("The *Markman* decisions do not hold that the trial judge must repeat or restate

every claim term....Claim construction is a matter of resolution of disputed meaning and technical scope, to clarify and when necessary to explain what the patentee covered by the claims...."). Finally, AngioDynamics seeks construction of Claim 1, arguing that Claim 1 is relevant to its counterclaims. Given that the court has agreed to the parties' joint request to address the *Markman* issues common to all four Diomed cases in one hearing, the court will defer construction of any claim that relates solely to an individual defendant's counterclaims to a more appropriate stage of the proceedings.

PRIOR ART

According to the '777 patent, certain veins in the leg, including the "greater saphenous" vein, can become varicose when a valve located in the vein does not close properly, allowing blood to "reflux" and pool. Col. 4, II. 22, 23-26. In addition to a malfunctioning valve, varicose veins can be traced to failed or incompetent blood vessels connecting a vein to other portions of the venous system. Id., Col. 6., II. 26-32.

Treatment for varicose veins traditionally involved ligation and stripping, that is, the surgical removal of the vein from the leg-or sclerotheraphy, the injection of an irritant chemical into the vein causing the vein to seal itself. Neither technique was hugely successful, prompting researchers to turn to laser technology in the quest for a superior method of treatment. As originally developed, laser-based techniques involved the irradiation of the outer surface of the skin with sufficient energy to cause the blood vessels in the vein to coagulate. However, the high dosages of energy required to treat large veins augmented the risk of side effects such as scarring or skin discoloration. On January 14, 1986, Leon Goldman was issued U.S. Patent No. 4,564,011 (the Goldman patent) teaching a new laser treatment method in which a fiber optic line was inserted "into a blood vessel" to form a blood clot "causing the vessel to shrink in size and at least partially disappear from view."

THE '777 PATENT

On June 4, 2002, the '777 patent was issued. The '777 patent teaches a procedure for inserting a fiber optic line inside the vein to enable the laser energy source to cause fibrosis of the blood vessel. Independent Claim 9 of the '777 patent describes

[a] method of treating a blood vessel using laser energy, comprising the steps of:

inserting means for emitting laser energy into the blood vessel at a punctuate site, wherein said emitting means has a laser emitting section;

placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel at a treatment site; and

emitting said laser energy into the blood vessel through said laser emitting section of said emitting means, thereby decreasing the diameter of the blood vessel.

According to Diomed, the procedure described for treatment of the greater saphenous vein is representative of the treatment of the lesser saphenous and other veins. FN3

FN3. *See* '777 patent, Figs. 9-14, Col. 5, I. 58-Col. 6, I. 25; and Figs. 15-20, Col. 6, II. 26-57.

-> The treatment areas is (sic) anesthetized with a local anesthetic.
-> Access is gained to the blood vessel, typically by insertion of a standard entry device such as an angiocatheter or by incision and insertion of the fiber.

-> A fiber optic line with an exposed portion such as an uncoated tip (for emission of laser energy) is inserted into the interior lumen of the vessel. The non-emitting portion of the fiber optic line is coated with a known substance for mechanical protection and to prevent emission of the laser energy in undesired locations.

-> The fiber optic line is advanced to the desired portion of the vessel, in this case just shy of the incompetent valve. (Positioning of the fiber optic line may be achieved, for example, with an ultrasound imager or with a visible aiming beam.)

-> The laser is fired through the fiber optic line as the fiber optic line is withdrawn within and along the vessel lumen. The primary wavelength of the laser light is between 500 and 1100 nanometers.

-> Contact occurs between the emitting section of the fiber and the wall of the blood vessel, facilitating the desired transfer of laser energy to the vessel wall. Contact may result from any number of a variety of factors, individually or in combination-what actually brings about contact is of no moment. The patent discloses, without limitation, several techniques for ensuring contact between the emitting section and the inner vein wall (e.g., lifting the patient's leg to drain blood from the vessel, or applying external pressure to it.).

-> As the fiber is withdrawn, sufficient laser energy is delivered to the wall of the vessel to lead to a decrease in the diameter thereof.

Diomed's Claim Construction Memorandum, at 5. Defendants argue that Diomed's proffered description omits several key limitations contained in the claims of the '777 patent. According to defendants, the patent requires the touching of the tip of the fiber optic line against the interior wall of a vessel that has been drained and compressed to insure the direct contact with the wall that is taught in Claim 9. The laser is then fired, while contact with the interior wall is maintained by continued compression. AngioDynamics' Claim Construction Motion, at 1-2. Defendants' argue that Diomed's proposed construction of the patent seeks to sweep into Claim 9 any contact between the uncoated tip of a fiber optic line and any part of the blood vessel, including the blood itself. Defendants argue that this reading of the patent is totally at odds with what Diomed told the Patent Office in its effort to distinguish its invention from Goldman's. Independent claim 1 recites a blood vessel treatment device including means "adapted for intraluminal contact with a wall of a blood vessel, for emitting laser energy to cause a decrease in the diameter of said blood vessel." Thus the device according to the claimed invention is arranged inside the vein to be treated and then the laser is directed against a wall of the vein to thereby cause fibrosis of the vein leading to a decrease in the diameter of the vein. (See specification p. 8, lines 16-28). It is respectfully submitted that a close review of the Goldman reference reveals that the device disclosed therein is not adapted to deliver energy to the vein wall in an intraluminal manner to thereby decrease the diameter of the vein.

Goldman discloses a laser optic device 11 which includes a needle 27. As shown in Fig. 3 and discussed at column 3, line 44 through column 4, line 32 the needle may be inserted within the vein. However as discussed in the specification of Goldman the laser energy is not directed into the wall of the blood vessel

but rather is used to create a blood clot in the vessel. Accordingly, unlike the claimed invention, there is no intraluminal contact with the blood vessel nor any delivery of laser energy to the vessel wall to thereby cause a decrease in the size of the vessel. Rather in Goldman a blood clot is generated to thereby cause a stoppage of flow in the vessel which in turn causes a decrease in the diameter of the vessel.

* * *

Independent claim 9 recites a method in which laser emitting means is placed in intraluminal contact with a blood vessel and laser energy is directed into the blood vessel wall to thereby decrease the diameter of the vessel. As discussed above with respect to the claim 1 the Goldman reference fails to teach any such method. Accordingly it is submitted that Goldman fails to anticipate the claimed invention according to claim 9.

File History, at 83-85. (Emphasis in original).

DISCUSSION

The construction of patent claims is a question of law for the court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-971 (Fed.Cir.1995). The court's task is to determine the meaning of claim terms as they would be understood by persons of ordinary skill in the relevant art. Bell Atlantic Network Serv., Inc. v. Covad Comm. Group, Inc., 262 F.3d 1258, 1267 (Fed.Cir.2001).

Claim 9 specifies three component steps. Step 1 describes an:

inserting means for emitting laser energy into the blood vessel at a punctuate site, wherein said emitting means has a laser emitting section.

Defendants correctly point out (Diomed does not disagree) that because Step 1 is written in a "means plus function" format, it is presumptively governed by 35 U.S.C. s. 112, para. 6, which provides that:

[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Construing a "means-plus-function" limitation under s. 112, para. 6, is a two-step process. First, the court must identify the claimed function. Second, the court must identify the corresponding structure (and any equivalent) set out in the written description that is necessary to perform that function. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1321 (Fed.Cir.2003); Micro Chem., Inc. v. Great Plains Chem. Co., Inc., 194 F.3d 1250, 1258 (Fed.Cir.1999). A disclosed structure is corresponding "only if the specification or the prosecution history clearly links or associates that structure to the function recited in the claim." B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1424 (Fed.Cir.1997). In essence, s. 112, para. 6, "allows a patentee to recite a function to be performed as a claim limitation rather than reciting structure or materials performing that function." Omega, 334 F.3d at 1321.

Defendants first argue persuasively that the function identified in Step 1 is the means for "emitting laser

energy into the blood vessel." Vascular Solution's Claim Construction Memorandum, at 8. Defendants next contend that the corresponding structure disclosed in the '777 patent is "a fiber optic line having an uncoated rounded tip or equivalent structure" from which laser energy is emitted. AngioDynamics' Claim Construction Motion, Exhibit 2, at 2. For support, defendants point to language in the specification describing a "[f]iber optic line 40 [that] has a tip 41 that is uncoated so as to allow emittance of laser energy.... The tip of fiber optic line 40 is preferably rounded in shape, although other shapes are contemplated. A rounded tip 41 is preferred because it enables the operator to more easily control the amount of vein to be treated ...." '777 patent, Col. 4, II. 52-62.

Diomed argues that defendants improperly import limitations from the specification that are not present in the claim language, because the "means for emitting laser energy into the blood vessel" does not "require [that] the means emitting section ... be located at any particular part of the fiber." Diomed's Claim Construction Memorandum, at 14. In other words, Diomed contends that the structure disclosed in the specification requires only that the optic fiber have an uncoated section in order to "allow emittance of laser energy." According to Diomed, the actual location of the uncoated section is of no significance so long as a section exists that is capable of emitting laser energy. FN4 Finally, Diomed maintains that there is no requirement that the tip be rounded.

FN4. At the hearing, Diomed submitted drawings of fibers where the exposed section emitting laser energy is located in the middle of the fiber or at either end. Defendants properly note that such depictions are not part of the patent specification or the prosecution history.

In support, Diomed argues that its proposed construction comports with the dictates of s. 112, para. 6, because the language of a "means plus function" claim requires the disclosure of only the "necessary" structure, and therefore, only those components of the structure that are essential can be considered as limiting. *See* Micro-Chem., 194 F.3d at 1258 ("The statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim. Nor does the statute permit incorporation of structure from the written description beyond that necessary to perform the claimed function."). Diomed argues that because the structure identified in the specification does not require that the laser emitting section be located at the tip of the fiber or that the tip be rounded, these features of the preferred embodiment of the invention should not be imported as limitations.

In response, defendants argue persuasively that Diomed reaches this conclusion by improperly reading the "means emitting section" language in isolation. When Step 1 is read as a whole, it becomes clear that the location of the fiber optic tip is a necessary component of the disclosed structure. Step 1 describes an "inserting means for emitting laser energy into the blood vessel at a punctuate site, wherein said emitting means has a laser emitting section." This language requires that the "means for emitting laser energy" have a "laser emitting section." The only structure disclosed in the specification capable of "emitting laser energy" is "fiber optic line 40 [that] has a *tip* 41 that is uncoated so as to allow emittance of laser energy." (Emphasis added). A "tip" is defined as the "extremity or top end of a thing; *esp*. the pointed or rounded end of anything long and slender; the top, summit, apex, very end." *Shorter Oxford English Dictionary* (3d ed.1944). Consequently, the "means for emitting laser energy" must be construed as a fiber optic line with an uncoated tip at its end capable of emitting laser energy.

Diomed argues that even if the fiber optic line 40 described in the specification has an uncoated tip that emits laser energy, the next two sentences make clear that fiber optic line 40 is a preferred embodiment and

not a "necessary" structure. These sentences state that "[t]he tip of fiber optic line 40 is preferably rounded in shape, although other shapes are contemplated. A rounded tip 41 is preferred because it enables the operator to more easily control the amount of vein to be treated." I agree with Diomed to a point. The rounded tip is only a "preferred embodiment," hence there is no requirement that the tip be "rounded" in shape. But it still remains that the only structure disclosed in the patent that performs the "means plus function" limitation of Step 1 is "fiber optic line 40 [that] has a tip 41 that is uncoated so as to allow emittance of laser energy." Consequently, the fiber optic line must have an uncoated tip, rounded or not.

Step 2 of Claim 9 requires the

placing [of] said laser emitting section of said emitting means into intraluminal contact with the blood vessel at a treatment site.

The parties agree that "intraluminal contact" FN5 requires physical contact between the vessel wall and the laser emitting section of the optic line. The dispute is over what is meant by "placing" the laser emitting section "into intraluminal contact." Diomed argues that it means "contacting the bare tip and the inner wall of the vessel as the fiber optic line is moved within and along the vessel lumen." Diomed's Claim Construction Memorandum, at 16. Defendants contend that it means "[d]eliberately and systematically putting the uncoated tip of the fiber optic line in physical contact with the interior surface of the artery, capillary or vein at a treatment site; this requires drainage of blood and compression of the vein." AngioDynamics' Claim Construction Motion, Exhibit 2, at 2.

FN5. Intraluminal is a synonym for "intratubal," which means "[w]ithin any tube." *Stedman's Medical Dictionary,* (26th ed.1995).

I find defendants' argument the more persuasive as it more closely conforms with the procedure taught in the patent, as well as with the prosecution history. As previously noted, Diomed distinguished its invention in the Patent Office proceedings from Goldman's prior art by emphasizing "contact" with the blood vessel wall.

Independent claim 1 recites a blood vessel treatment device including means "adapted for *intraluminal contact with a wall of a blood vessel,* for emitting laser energy to cause a decrease in the diameter of said blood vessel." Thus the device according to the claimed invention is arranged inside the vein to be treated and *then the laser is directed against a wall of the vein* to thereby cause fibrosis of the vein leading to a decrease in the diameter of the vein. (See specification p. 8, lines 16-28). It is respectfully submitted that a close review of the Goldman reference reveals that the device disclosed therein is not adapted to deliver energy *to the vein wall* in an intraluminal manner to thereby decrease the diameter of the vein.

File History, at 83-84. (Emphasis added).

To explain how this contact with the vessel wall was to be achieved in a manner different from the method taught by Goldman, Diomed directed the examiner to the discussion of compression in the specification.

Fig. 10 shows an application of a compression bandage to the leg of Fig. 9.... Fig. 13 shows a manual finger compression of the lesser saphenous vein at the tip pf the laser energy carrier during delivery of laser energy to the leg of Fig. 9.

File History, at 29.

Figure 13 was further described in the patent as follows.

As illustrated in Fig. 13, leg 10 is then elevated and lesser saphenous vein 50 is drained of blood and compressed. *The drainage of blood is important to insure direct contact of the vessel walls with tip 41 during delivery of laser energy*.... [T]he above described procedure is followed, with compression of lesser saphenous vein 50 maintained around tip 41, while fiber optic line 40 is incrementally withdrawn.

File History, at 35. (Emphasis added). Thus, "placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel" must, as defendants contend, be construed to mean "deliberately putting the uncoated tip of the fiber optic line in physical contact with the wall of the blood vessel, which requires the drainage of blood and compression of the vein."

Step 3 of Claim 9 requires the

emitting [of] said laser energy into the blood vessel through said laser emitting section of said emitting means, thereby decreasing the diameter of the blood vessel.

Diomed argues that this should be construed to mean "emitting sufficient laser energy at the bare tip of the fiber optic line to cause vessel wall tissue damage (e.g.fibrosis) to lead to a decrease in the diameter of the blood vessel." Diomed's Claim Construction Memorandum, at 18. Diomed's argues that the definition of Step 3 is straightforward. The term "thereby" signals how much laser energy should be emitted and the amount that is required is the amount that will "decreas[e] the diameter of the blood vessel." No further limitations are disclosed.

Defendants for their part counter that Step 3 requires:

[e]mitting the amplified monochomatic light or other electromagnetic radiation into the interior surface of the artery, capillary or vein through the uncoated tip of the fiber optic line while maintaining the tip-interior surface physical contact to decrease the diameter of the artery, capillary or vein.

AngioDynamics' Claim Construction Motion, Exhibit 2, at 2. Defendants complain that Diomed's construction would eliminate the limitation requiring that the laser tip deliver energy directly to the wall of the vein, so long as the procedure ultimately succeeded in decreasing the diameter of the blood vessel. Defendants argue persuasively that the method described in the '777 patent requires that the laser emit energy into the cylindric walls of the blood vessel and not merely into the vein's interior or the blood within it. This is true, not only because Diomed said so in differentiating its invention from Goldman's, but also because the steps of Claim 9 are sequential. In the previous Step 2, the tip of the fiber optic line is inserted into the blood vessel and then "plac[ed] ... into intraluminal contact with the blood vessel at a treatment site." Step 3 then requires that laser energy be emitted. It must be emitted into the blood vessel wall because that is where the fiber optic tip is to be placed to decrease the diameter of the vein. Consequently, the court will construe Step 3 to require the maintaining of the tip-interior surface in physical contact with the vessel wall while laser energy is emitted to decrease the diameter of the blood vessel.FN6

FN6. Defendants' attempts to import additional limitations, for example, that the laser energy be "amplified monochomatic light or other electromagnetic radiation," has no support in the patent language.

Finally, the parties seek construction of the term "emptying" as it is used in dependent Claim 10. The claim states in pertinent part: "[t]he method of claim 9, further comprising emptying the blood vessel prior to emitting said laser energy." Defendants argue that this phrase must be construed to mean "making the interior space of the artery, capillary or vein empty." AngioDynamics' Claim Construction Motion, Exhibit 2, at 2. Diomed maintains that the act of emptying is a process that embodies "[r]emoving some or all of the blood from the blood vessel," and does not require, as defendants clam, the application of the laser to an "empty" blood vessel. Diomed's Claim Construction Memorandum, at 19. I find the following observation in Kumar v. Ovonic Battery Co., Inc., 351 F.3d 1364, 1369 (Fed.Cir.2003), to be instructive.

[P]recedent teaches that qualifications such as "completely" or "normally" are to be given significance in interpreting the specification. *See* E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369 (Fed.Cir.2003).... [T]here is [however] no indication in these passages or anywhere else in the specification that the term "completely amorphous" was used synonymously with the term "amorphous." The fact that the '686 patent refers to the "random atomic" structure or orientation of both amorphous and completely amorphous alloys does not indicate that the patent defines the terms interchangeably. The terms "random atomic structure" or "random atomic orientation" can themselves mean completely random or partially random.

In the same vein, the court will construe the term "emptying" in claim 10 to mean "the process of emptying most, but not necessarily all of the blood from the blood vessel," since the term "emptying" is not modified by the term "completely."

ORDER

For the foregoing reasons, the disputed terms of the '777 patent will be construed for the finder of fact in language consistent with that set out in this Opinion.

SO ORDERED.

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