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

Bruce N. SAFFRAN, Ph.D., M.D,
Plaintiff.
v.
BOSTON SCIENTIFIC CORPORATION,
Defendant.

Civil Action No. 2-05-CV-547 (TJW)

Sept. 28, 2007.

Gary M. Hoffman, James W. Brady, Jr., Jeremy Adam Cubert, Paul R. Taskier, Ryan Holbrook Flax, Dickstein, Shapiro, Morin & Oshinsky, Washington, DC, for Plaintiff.

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MEMORANDUM OPINION AND ORDER

T. JOHN WARD**, United States District Judge.**

After considering the submissions and the arguments of counsel, the court issues the following order concerning the claim construction issues:

I. Introduction.

Plaintiff Bruce Saffran, M.D., Ph.D. ("Saffran") accuses Defendant Boston Scientific Corporation ("Boston Scientific") of infringing United States Patent No. 5,653,760 (the "'760 Patent") titled "Method and Apparatus for Managing Macromolecular Distribution." FN1 This opinion resolves the parties' various claim construction disputes.

FN1. Saffran asserts all claims of the '760 Patent except for claim 5.

II. Background of the Technology

The body generates macromolecules as a result of injury and these macromolecules heal the affected area. The '760 Patent discloses an invention that acts like a bandage attached to a bone (or any other damaged tissue) and retains macromolecules to facilitate natural healing of damaged tissues. The invention prevents macromolecules from leaving the proximity of damaged tissue while allowing smaller particles to freely

travel to and from the affected area.

III. General Principles Governing Claim Construction

"A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." Burke, Inc. v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334, 1340 (Fed.Cir.1999). Claim construction is an issue of law for the court to decide. Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

To ascertain the meaning of claims, the court looks to three primary sources: the claims, the specification, and the prosecution history. Markman, 52 F.3d at 979. Under the patent law, the specification must contain a written description of the invention that enables one of ordinary skill in the art to make and use the invention. A patent's claims must be read in view of the specification, of which they are a part. *Id*. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. *Id*. "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." Watts v. XL Sys., Inc., 232 F.3d 877, 882 (Fed.Cir.2000).

Nonetheless, it is the function of the claims, not the specification, to set forth the limits of the patentee's claims. Otherwise, there would be no need for claims. SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed.Cir.1985) (en banc). The patentee is free to be his own lexicographer, but any special definition given to a word must be clearly set forth in the specification. Intellicall, Inc. v. Phonometrics, 952 F.2d 1384, 1388 (Fed.Cir.1992). And, although the specification may indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into the claims when the claim language is broader than the embodiments. Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994).

This court's claim construction decision must be informed by the Federal Circuit's decision in Phillips v. AWH Corporation, 415 F.3d 1303 (Fed.Cir.2005) (en banc). In *Phillips,* the court set forth several guideposts that courts should follow when construing claims. In particular, the court reiterated that "the *claims* of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d at 1312 (emphasis added) (*quoting* Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004)). To that end, the words used in a claim are generally given their ordinary and customary meaning. *Id*. 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, i.e., as of the effective filing date of the patent application." Id. at 1313. This principle of patent law flows naturally from the recognition that inventors are usually persons who are skilled in the field of the invention. The patent is addressed to and intended to be read by others skilled in the particular art. *Id*.

The primacy of claim terms notwithstanding, *Phillips* made clear that "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id*. Although the claims themselves may provide guidance as to the meaning of particular terms, those terms are part of "a fully integrated written instrument." *Id*. at 1315 (*quoting* Markman, 52 F.3d at 978). Thus, the *Phillips* court emphasized the specification as being the primary basis for construing the claims. *Id*. at 1314-17. As the Supreme Court stated long ago, "in case of doubt or ambiguity it is proper in all cases to refer back to the descriptive portions of the specification to aid in solving the doubt or in ascertaining the true intent and

meaning of the language employed in the claims." Bates v. Coe, 98 U.S. 31, 38, 25 L.Ed. 68 (1878). In addressing the role of the specification, the *Phillips* court quoted with approval its earlier observations from Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998):

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Consequently, *Phillips* emphasized the important role the specification plays in the claim construction process.

The prosecution history also continues to play an important role in claim interpretation. The prosecution history helps to demonstrate how the inventor and the PTO understood the patent. Phillips, 415 F.3d at 1317. Because the file history, however, "represents an ongoing negotiation between the PTO and the applicant," it may lack the clarity of the specification and thus be less useful in claim construction proceedings. *Id*. Nevertheless, the prosecution history is intrinsic evidence. That evidence is relevant to the determination of how the inventor understood the invention and whether the inventor limited the invention during prosecution by narrowing the scope of the claims.

Phillips rejected any claim construction approach that sacrificed the intrinsic record in favor of extrinsic evidence, such as dictionary definitions or expert testimony. The *en banc* court condemned the suggestion made by Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed.Cir.2002), that a court should discern the ordinary meaning of the claim terms (through dictionaries or otherwise) before resorting to the specification for certain limited purposes. *Id*. at 1319-24. The approach suggested by *Texas Digital*-the assignment of a limited role to the specification-was rejected as inconsistent with decisions holding the specification to be the best guide to the meaning of a disputed term. *Id*. at 1320-21. According to *Phillips,* reliance on dictionary definitions at the expense of the specification had the effect of "focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of the claim terms within the context of the patent." *Id*. at 1321. *Phillips* emphasized that the patent system is based on the proposition that the claims cover only the invented subject matter. *Id*. What is described in the claims flows from the statutory requirement imposed on the patentee to describe and particularly claim what he or she has invented. *Id*. The definitions found in dictionaries, however, often flow from the editors' objective of assembling all of the possible definitions for a word. *Id*. at 1321-22.

Phillips does not preclude all uses of dictionaries in claim construction proceedings. Instead, the court assigned dictionaries a role subordinate to the intrinsic record. In doing so, the court emphasized that claim construction issues are not resolved by any magic formula. The court did not impose any particular sequence of steps for a court to follow when it considers disputed claim language. *Id*. at 1323-25. Rather, *Phillips* held that a court must attach the appropriate weight to the intrinsic sources offered in support of a proposed claim construction, bearing in mind the general rule that the claims measure the scope of the patent grant. The court now turns to a discussion of the disputed claim terms.

The '760 Patent includes claim limitations that fall within the scope of 35 U.S.C. s. 112 para. 6. Section 112 para. 6 states "[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 ... in support thereof, and such claim shall be construed to cover the corresponding structure ... described in the specification and equivalents thereof." 35

U.S.C. s. 112 para. 6 (2007). The first step in construing a means-plus-function limitation is to identify the recited function. *See* Micro Chem., Inc. v. Great Plains Chem. Co., 194 F.3d 1250 1258 (Fed.Cir.1999). Then, the court must identify in the specification the structure corresponding to the recited function. *Id*. The "structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." Medical Instrumentation and Diagnostics, Corp. v. Elekta AB, 344 F.3d 1205, 1210 (Fed.Cir.2003) (*citing* B. Braun v. Abbott Labs., 124 F.3d 1419, 1424 (Fed.Cir.1997)).

The patentee must clearly link or associate structure with the claimed function as part of the *quid pro quo* for allowing the patentee to express the claim in terms of function pursuant to s. 112 para. 6. *See* id. at 1211; *see also* Budde v. Harley-Davidson, Inc. 250 F.3d 1369, 1377 (Fed.Cir.2001). The "price that must be paid" for use of means-plus-function claim language is the limitation of the claim to the means specified in the written description and equivalents thereof. *See* O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1583 (Fed.Cir.1997).

IV. Agreed Constructions

1. "affixed to a fixation device" (claims 6 and 13)

This phrase means "attached to a device capable of providing support."

2. "the layer is capable of being affixed to a fixation device" (claims 6, 13, and 14)

This phrase means "the layer can be affixed to a fixation device."

3. "small molecules" (claim 9)

This phrase means "molecules having a size on the order of water, bicarbonate, urea, and hydrogen ions."

4. "lysis of a chemical bond" (claim 3)

The parties agree that "lysis" means "breakage." This term is considered an agreed term because the court finds that it is unnecessary to construe "chemical bond," which is the only disputed portion of this term.

V. Terms in Dispute

1. "damaged tissue" (claims 1, 4, 7, 8, 9, 10, 11, 12, 13, and 15)

Plaintiff argues that this term means "injured tissue" while Defendant argues that it means "abnormal tissue." The specification reflects that the invention may be used to heal tissue injured as a result of trauma. *See e.g.,* 1:23-32; 5:61-6:5; 17:4-15; Fig. 5a; 17:17-32; Fig. 5b. For example, the specification addresses wrapping the device around fractures to heal the tissue surrounded by the fracture. *See* 6:26-36; 6:44-49. The '760 patent, however, also encompasses tissue that is "damaged" by some means other than trauma. For example, at col. 6, ll. 5-10, the patent specification shows that the invention can be used to treat tissue affected by infection, disease, or other soft tissue metastases. *See* 6:5-10. Accordingly, the court construes the term "damaged tissue" to mean "tissue that has been injured by trauma as well as tissue that is abnormal because of disease, infection, or other soft tissue metastases."

3. "macromolecules" (claims 1, 4, 8, 15, and 16)

Plaintiff argues that "macromolecules" should be construed as "molecules having a molecular weight of at least 500." Defendant argues that the term should be construed as "molecules larger than about 500 molecular weight." The specification states that the "cardinal feature" of the patent is its ability to restrain macromolecules. *See* 7:39-41. The specification further states that "the precise size of the molecules that the minimally-porous sheet can restrain is not important, for the purposes of this invention, the pores should be small enough to restrain molecules greater than around 500 Daltons." 8:3-6. In light of the intrinsic record, the court defines"macromolecules" as "molecules with a molecular weight of at least approximately 500 Daltons."

4. "layer having material release means for release of an at least one treating material in a directional manner" FN2 **(claim 1)**

FN2. The court elected to construe the recited function and the corresponding structure for these limitations. The portion of the claim language that recites "when said layer is placed adjacent to damaged tissue" needs no construction by the court.

Both parties agree that this limitation is a means-plus-function limitation. Plaintiff argues that the recited function is "to release a drug preferentially toward the damaged tissue when the layer is placed adjacent to damaged tissue" and that the corresponding structure(s) in the specification is/are "various structures performing the claimed function, including chemical bonds and linkages such as a hydrophobic layer and a hydrophobic drug."

The defendant argues that the recited function is "the release of an at least one treating material in a directional manner from the first major surface when said first major surface of the layer has been placed facing the damaged tissue" and that the recited structure(s) in the specification is/are "the previously described layer (which as manufactured, has pores smaller than an at least one treating material such that the layer is impermeable to that treating material), wherein that treating material is initially affixed to the first major surface."

The court will first address the recited function. The parties disagree about the meaning of "directional." The specification supports construing "directional" to mean toward the damaged tissue. In the Background of the Invention, the patentee states that "the invention can be modified such that a treating material, when affixed to a major surface of the minimally-porous sheet, can be directed preferentially to the site of the injury." 1:24-27. Further, at col. 9, the patent states that "healing macromolecules can be contained at the site of the injury, and medicine can be applied directly and preferentially to an injured wall to promote healing." 9:20-23. Additionally, the patent supports "administering antibiotics in a directional manner ... at the site that they are needed most." 9:36-37; *see* generally 9:33-44.

Defining "directional" to mean "toward the damaged tissue" renders the term synonymous with "unidirectional," a term used in claims 8 and 15 when the sole direction is toward the damaged tissue. The prosecution history, however, supports this view. The patentee overcame the Scott reference by telling the examiner that the invention disclosed in the '760 patent was "directional" delivery, whereas Scott disclosed 'multidirectional' delivery. *See* 9/15/96 amendment at 5. In doing this, the patentee thus disclaimed "multidirectional" delivery in the application process.

Turning to the question of structure, the plaintiff argues that the corresponding structure includes chemical

bonds or linkages. In support, the plaintiff correctly notes that the specification supports this argument. *See e.g.,* 15:6-20, 22:4-17, and 14:58-15:5. For example, chemical bonds are clearly linked to the recited function in the specification at col. 15, ll. 6-20:

This device can be manufactured with several different medicines, each with their own particular release bond. Remarkably, one can implant the device of this invention such that one medicine is released by enzymes from Neutrophils (the first inflammatory cells to arrive), a second medicine released by enzymes from fibroblasts (cells that arrive later), and a third medicine which can be released only by osteoblasts (cells arriving even later). Although I have disclosed the implementation of multiple medicines in my application for the Malleable Fracture Stabilization Device with Micropores, the surprising specificity of medicine release provided by the chemical bond is entirely new and unexpected. The above-described feature of specific drug release is impossible using the prior art, and it represents a major advance in fracture treatment.

15:6-20

Elsewhere, the description states:

The rate of healing can be further accelerated by the attachment of a treating material, either mechanically or by chemical bond, to the inner surface of the device. The method of medicine release by chemical bond is also a method of highly significant improvement over the prior art. Prior art references all rely on the efflux of treating materials from micropores to deliver medicine. The ability to release medicine according to a rate constant, rather than relying on random efflux of molecules from various sized micropores, provide a surprising consistency to drug delivery not before seen in the art. Moreover, the chemical coupling of medicine and device provides for unprecedented specificity of release. The unexpected ability to be able to link medicine release with the specific enzymatic activity of healing cells is a highly significant improvement over the prior art.

22:4-17

Accordingly, the court construes the recited function as "releasing a treating material toward the damaged tissue." Because the patentee used a means-plus-function limitation, the patentee is limited to the structure clearly linked or associated with the claimed function. The court identifies the corresponding structure in the specification that is clearly linked to the claimed function to be chemical bonds and linkages. The court rejects the defendant's proposed structure because, *inter alia,* it recites limitations found elsewhere in the claim.

5. "the layer having material release means for release of an at least one treating material in a unidirectional manner" (claims 8 and 15)

As noted above, "unidirectional" and "directional" within the context of claims 1, 8, and 15 are synonymous. Therefore, the court construes this term as it construed the term in section 4.

VI Conclusion

The court adopts the constructions set forth in this opinion for the disputed terms of the '538 and the "0 patents. The defendant asked the court to construe a number of additional claims. However, the court does not believe that those terms should be construed. The parties are ordered that they may not refer, directly or

indirectly, to each other's claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

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