UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MDL NO. 13-2432-RGS

In re: NEUROGRAFIX ('360) PATENT LITIGATION

MEMORANDUM AND ORDER
ON CLAIM CONSTRUCTION

August 19, 2016

STEARNS, D.J.

This is the second wave in a Multidistrict Litigation (MDL) involving U.S. Patent No. 5,560,360 (the '360 patent), directed to "[a] neurography system [] for generating diagnostically useful images of neural tissue [] employing a modified magnetic resonance imaging [(MRI)] system." '360 patent, Abstract. In 2012, plaintiffs NeuroGrafix, Neurography Institute Medical Associates, Inc., Image-Based Surgicenter Corporation, and Dr. Aaron G. Filler, launched an armada of lawsuits against MRI equipment manufacturers and university and hospital end-users, accusing them of infringing the '360 patent. With one exception, the nine cases originally consolidated by the MDL Panel in this district for pretrial proceedings resolved before reaching claim construction.[1] In 2015, plaintiffs filed six new

[1] Prior to the MDL consolidation, plaintiffs sued two groups of defendants in the Central District of California for alleged infringement of the '360 patent. *See Neurografix v. Siemens Med. Sols. USA, Inc.*, 2011 WL

lawsuits. These too were consolidated with this MDL proceeding.[2] Before the court are the parties' competing briefs on claim construction. Pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), the court received tutorials in the underlying technology and heard argument on August 18, 2016.

THE '360 PATENT

The '360 patent, entitled "Image Neurography and Diffusion Anisotropy Imaging," was issued on October 1, 1996. It lists as its inventors Aaron G. Filler,[3] Jay S. Tsuruda, Todd L. Richards, and Franklyn A. Howe. The '360 patent sets out 66 claims.

The '360 patent discloses methods and apparatus for generating "diagnostically useful" images of peripheral nerves (the term includes

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3439324 (C.D. Cal. May 5, 2011); *Neurografix v. Regents of Univ. of California*, 2012 WL 8281409 (C.D. Cal. Jun. 13, 2012). Judge Mariana Pfaelzer presided over both cases and issued lengthy memoranda construing contested claim terms.

[2] This court stayed the action against the end-user defendants, pending the outcome of the litigation involving the manufacturer defendants. *See* Dkt. # 187. Since completing claim construction briefing, Hitachi Medical Systems America, Inc., and Hitachi Medical Corporation have reached a settlement agreement with plaintiffs. *See* Dkt. ## 330, 331. The end-user and Hitachi defendants did not participate in the claim construction hearing.

[3] Dr. Filler, who has taken an active role in the litigation, presented plaintiffs' tutorial at the hearing.

peripheral, autonomic, and cranial nerves) using MRI technology. ’360 patent, Abstract. These nerves

> commonly travel through and along bone, muscle, lymphatics, tendons, ligaments, intermuscular septa, collections of fatty tissues, air and fluid spaces, veins, arteries, joints, skin, mucous membranes and other tissues. The relatively small size of peripheral nerves, as well as their close proximity to other tissue of comparable size and shape, makes them difficult to locate and identify.

Id. col. 1, ll. 32-38. The complex structure of neural plexus (where bundles of nerve fibers “may join together, separate, rejoin, intermix, and resegregate, forming intricate three dimensional patterns”) also complicates the examination of peripheral nerves. *Id.* col. 1, ll. 39-51.

Prior to the invention of the ’360 patent, MRI technology had been used to image peripheral nerves with only limited success. By way of a brief background,

> MRI involves the exposure of tissue to a variety of different magnetic and radio-frequency ([RF]) electromagnetic fields. The response of the specimen’s atomic nuclei to the fields is then processed to produce an image of the specimen.

Id. col. 2, ll. 5-9. The patient is first exposed to a polarizing magnetic field that causes hydrogen protons’ axes to align themselves with the field. When additional energy in the form of an RF electromagnetic wave pulse is applied, the protons change the alignment of their axes. When the RF pulse is switched off, the protons reorient their alignment with the magnetic field, causing them to emit detectable resonance (also in the form of radio waves). Receiver coils detect the radio signal, which is converted by a computer using Fourier analysis into a visual image. Various RF pulse sequences can be used to emphasize or suppress different types of tissues within the body.

Prior to the '360 patent, MRI was used in conjunction with injectable contrast agents to image peripheral nerves. This technique requires two-part contrast agents – one part to promote neural uptake of the dye, and the other to enhance the imageability of the nerve. The technique has several limitations. In addition to being invasive, only a single nerve or nerve group can be imaged at one time, and the contrast agent typically reduces the intensity of the imaged nerve.

MRI had also been used to successfully image non-peripheral white matter nerve tracts in the brain without the use of contrast agents. White matter nerve tracts, in comparison to the surrounding gray matter, exhibit a relatively high diffusion anisotropy, that is, water mobility in the direction along the white matter tracts is relatively high, while water mobility perpendicular to the tracts is low.

> [T]his process involves the use of a pair of field gradient pulses (hereinafter referred to as diffusion gradients), oriented perpendicular and parallel to the white matter tracts to be imaged. . . . [G]iven the anisotropic nature of the tracts, water will diffuse freely along a tract, but is restricted in it[s] motion perpendicular to the tract. When the diffusion gradient is

> aligned with the tract there is thus a greater reduction in signal than when the diffusion gradient is aligned perpendicular to the tract. Because this phenomenon is not exhibited by the surrounding gray matter tissue, the white matter tracts can be identified.

Id. col. 5, ll. 19-39.

This technique, however, does not transfer easily to the imaging of peripheral nerves even though these nerves are also diffusionally anisotropic. Peripheral nerves are considerably smaller than white matter tracts and their return signals are too weak for effective imaging. In addition to fat (which is isotropic and distinguishable from the nerves when imaged), peripheral nerves are also surrounded by muscle, which is also diffusionally anisotropic and not easily distinguished.

To solve the problem of effectively imaging peripheral nerves without the use of contrast agents, the inventors discovered

> novel ways of assembling complex pulse sequences, wherein even though the simple components of the sequence decrease the signal-to-noise ratio of nerve or decrease the signal strength of nerve relative to other tissues, the fully assembled complex sequence actually results in the nerve signal being more intense than any other tissue.

Id. col. 6, ll. 39-45. More specifically, "[t]he combined use of fat suppression [pulses] and diffusional weighting has [] been found to be extremely effective in providing the desired nerve image enhancement" and has the "synergistic benefit . . . [of] an actual increase in neural signal anisotropy . . . with the conspicuity of the neural component of the image increasing by roughly 250 percent when the fat component is removed." *Id.* col. 22, ll. 32-35; 58-64.

The patent describes two nerve imaging approaches depending on the diffusion-weighted gradients used. Subtraction neurography is appropriate where the diffusion-weighted gradients match the nerve axes.

> [I]n one currently preferred embodiment, the analysis involves the application of pulsed magnetic field gradients to the polarizing field in two or more directions to produce images in which the peripheral nerve is enhanced or suppressed, depending upon the "diffusion weighting" resulting from the particular pulsed gradient axis chosen. Discrimination of water diffusion anisotropy is then achieved by subtracting the suppressed image from the enhanced image, in the manner described in greater detail below, producing an image depicting only the peripheral nerve.
>
> Most preferably, the magnetic field gradients are applied in mutually substantially orthogonal directions. For example, with gradients approximately perpendicular and parallel to the axis of the peripheral nerve at the particular point being imaged, the parallel gradient image can be subtracted from the perpendicular gradient image to produce the desired "nerve only" image.

Id. col. 15, ll. 40-57. However, where the gradients do not align with the nerve(s) to be imaged, vector processing is used to obtain the image.

> [I]f the axis of the peripheral nerve is not known, or if many nerves having different axes are being imaged, the neurography system must employ a system of gradient orientations suitable for imaging nerve having substantially any axial alignment. For example . . . a full three-dimensional vector analysis can be used to characterize the diffusion coefficient and provide a nerve image by construction based upon a fixed arrangement of diffusion weighting gradients.

Id. col. 15, l. 63 – col. 16, l. 4.

Claim 36 is a representative method claim.

> 36. A method of utilizing magnetic resonance to determine the shape and position of a structure, said method including the steps of:
>
> (a) exposing a region to a magnetic polarizing field including a predetermined arrangement of diffusionweighted gradients, the region including a selected structure that exhibits diffusion anisotropy and other structures that do not exhibit diffusion anisotropy;
>
> (b) exposing the region to an electromagnetic excitation field;
>
> (c) for each of said diffusion-weighted gradients, sensing a resonant response of the region to the excitation field and the polarizing field including the diffusionweighted gradient and producing an output indicative of the resonant response; and
>
> (d) vector processing said outputs to generate data representative of anisotropic diffusion exhibited by said selected structure in the region, regardless of the alignment of said diffusion-weighted gradients with respect to the orientation of said selected structure; and
>
> (e) processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy.

Claim 54 is a representative apparatus claim.

54. A magnetic resonance apparatus for determining data representative of the diffusion anisotropy exhibited by a structure, said apparatus including:

(a) excitation and output arrangement means for exposing a region to a suppression sequence of electromagnetic fields that suppresses the electromagnetic responsiveness of structures in the region that do not exhibit diffusion anisotropy, so as to increase the apparent diffusion anisotropy of structures in the region that exhibit diffusion anisotropy, said suppression sequence of electromagnetic fields not including diffusionweighted magnetic gradients;

(b) polarizing field source means positioned near said excitation and output arrangement means for exposing the region to a predetermined arrangement of diffusionweighted magnetic gradients chosen to:

i) emphasize a selected structure in the region exhibiting diffusion anisotropy in a particular direction; and

ii) suppress other structures in the region exhibiting diffusion anisotropy in directions different from said particular direction, said excitation and output arrangement means further for sensing a resonant response of the region to the diffusion-weighted gradient and producing an output indicative of the resonant response, for each of said diffusionweighted gradients; and

(c) processor means coupled to said excitation and output arrangement means for processing said outputs to generate data representative of the diffusion anisotropy of the selected structure.

The parties dispute the construction of 9 claims terms.[4]

- "processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy" (claim 36)

- "processing said outputs to generate data representative of the diffusion anisotropy of the selected structure" (claim 51)

- "analyzing the data representative of anisotropic diffusion to determine how to relate said data set and said additional data sets describing the shape and position of cross sections of said neural tissue" (claims 39, 46, 49)

- "combining said data set and said additional data sets to generate said further data set that describes the three dimensional shape and position of the segment of said neural tissue, thereby enabling the three dimensional shape and position of curved neural tissue to be described" (claims 39, 46, 49)

- "vector processing" (claim 36)

- "effective vector" (claims 41, 42, 43, 44, 47, 50)

- "excitation and output arrangement means for exposing a region to a suppression sequence of electromagnetic fields that suppresses the electromagnetic responsiveness of structures in the region that do not exhibit diffusion anisotropy, so as to increase the apparent diffusion anisotropy of structures in the region that exhibit diffusion anisotropy, said suppression sequence of electromagnetic fields not including diffusion-weighted magnetic gradients" (claim 54(a))

- "said excitation and output arrangement means further for sensing a resonant response of the region to the diffusion-weighted gradient and

[4] The parties have agreed on the construction of 9 additional terms. *See* Joint Prehearing Statement, Dkt. # 211 at 7-9.

producing an output indicative of the resonant response, for each of said diffusion-weighted gradients" (claim 54(b))

- "near said excitation and output arrangement means" (claim 54)

DISCUSSION

Claim construction is a matter of law. *See Markman*, 517 U.S. at 388-389. Claim terms are generally given the ordinary and customary meaning that would be ascribed by a person of ordinary skill in the art in question at the time of the invention. *Phillips v. AWH Corp.,* 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (en banc) (citations omitted). In determining how a person of ordinary skill in the art would have understood the claim terms, the court looks to the specification of the patent, its prosecution history, and in limited instances where appropriate, extrinsic evidence such as dictionaries, treatises, or expert testimony. *Id.* at 1315-1317. Ultimately, "[t]he 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." *Id.* at 1316 (citation omitted).

"processing said data . . ." (claim 36); "processing said outputs . . . " (claim 51); "analyzing the data . . ." (claims 39, 46, 49); "combining said data set . . ." (claims 39, 46, 49)

Defendants contend that the "processing . . . ," "analyzing . . . ," and "combining . . ." terms of claims 36, 39, 46, 49, and 51 are step-plus-function claims and should be construed as such.[5] Special rules apply to means-plus-function and step-plus-function claim terms by virtue of 35 U.S.C. § 112, para. 6.[6]

> An 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.

Id.[7] Under paragraph 6,

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[5] With the exception of the "processing said outputs . . ." term of claim 51, defendants take the position that the claims do not disclose acts associated with the claimed function and are thus indefinite.

[6] Under the America Invents Act, signed into law after the issuance of the '360 patent, paragraph 6 of Section 112 was renamed subsection (f), without altering its substantive requirements.

[7] Congress enacted paragraph 6 of Section 112 to permit the limited use of functional language in drafting patent claims.

> In *Halliburton Oil Well Cementing Co. v. Walker,* 329 U.S. 1 (1946), the Supreme Court held invalid a claim that was drafted in means-plus-function fashion. Congress enacted paragraph six . . . to overrule that holding. In place of the *Halliburton* rule, Congress adopted a compromise solution, one that had support in the pre-*Halliburton* case law: Congress permitted the use of purely functional language in claims, but it limited the breadth of such claim language by restricting its scope to the structure disclosed in the specification and equivalents thereof.

Greenberg v. Ethicon Endo-Surgery, Inc., 91 F.3d 1580, 1582 (Fed. Cir. 1996).

> [t]he word "means" clearly refers to the generic description of an apparatus element, and the implementation of such a concept is obviously by structure or material. We interpret the term "steps" to refer to the generic description of elements of a process, and the term "acts" to refer to the implementation of such steps. This interpretation is consistent with the established correlation between means and structure. In this paragraph, structure and material go with means, acts go with steps. Of course, as we have indicated, section 112, ¶ 6, is implicated only when means *plus function* without definite structure are present, and that is similarly true with respect to steps, that the paragraph is implicated only when steps *plus function* without acts are present.

O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1582-1583 (Fed. Cir. 1997). If a claim term is within the ambit of Section 112, para. 6, construction is a two-step process. "First, we must identify the claimed function, staying true to the claim language and the limitations expressly recited by the claims. Once the functions performed by the claimed means are identified, we must then ascertain the corresponding structures [(or acts)] in the written description that perform those functions." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1321 (Fed. Cir. 2003) (citations omitted).

In identifying means-plus-function and step-plus-function terms, the signaling phrases, "means for," and "step for" (but not the phrase "steps of") create a rebuttable presumption that Section 112, para. 6 applies. *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998); *Masco Corp. v. United States*, 303 F.3d 1316, 1327 (Fed.

Cir. 2002). The absence of a signal triggers the converse and also rebuttable presumption that Section 112, para. 6 does not apply. *Personalized Media*, 161 F.3d at 703-704. A recent en banc decision of the Federal Circuit, *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015), overruled a line of cases (beginning with *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1358 (Fed. Cir. 2004)) holding that the lack of the signaling phrase "means" creates a "strong" presumption that a claim term is not a means-plus-function term. *Williamson*, 792 F.3d at 1348-1349.

> That characterization is unwarranted, is uncertain in meaning and application, and has the inappropriate practical effect of placing a thumb on what should otherwise be a balanced analytical scale. It has shifted the balance struck by Congress in passing § 112, para. 6 and has resulted in a proliferation of functional claiming untethered to § 112, para. 6 and free of the strictures set forth in the statute. Henceforth, we will apply the presumption as we have done prior to *Lighting World,* without requiring any heightened evidentiary showing and expressly overrule the characterization of that presumption as "strong." We also overrule the strict requirement of "a showing that the limitation essentially is devoid of anything that can be construed as structure."

Id. at 1349. Rather,

> [t]he standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. When a claim term lacks the word "means," the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to "recite sufficiently definite structure" or else

> recites "function without reciting sufficient structure for performing that function." The converse presumption remains unaffected: "use of the word 'means' creates a presumption that § 112, [para.] 6 applies."

Id. at 1349 (citations omitted).

In the absence of the signal "step for," disputed claim terms are presumed not to be step-plus-function terms. "[W]here a method claim does not contain the term 'step[s] for,' a limitation of that claim cannot be construed as a step-plus-function limitation without a showing that the limitation contains no act." *Masco*, 303 F.3d at 1327. While defendants acknowledge that the language of the disputed terms can be parsed into an act and a function (as illustrated by the table below, *see* Defs.' Opening Claim Construction Br. at 15-19), defendants assert that the terms do not specify "sufficient acts" to avoid the application of a step-plus-function analysis.

Act	Function
processing said data representative of anisotropic diffusion	to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy
processing said outputs	to generate data representative of the diffusion anisotropy of the selected structure
analyzing the data representative of anisotropic diffusion	to determine how to relate said data set and said additional data sets describing the shape and position of cross sections of said neural tissue

combining said data set and said additional data sets	to generate said further data set that describes the three dimensional shape and position of the segment of said neural tissue, thereby enabling the three dimensional shape and position of curved neural tissue to be described

Relying on Judge Rader's observation in *Seal-Flex, Inc. v. Athletic Track & Court Const.*, 172 F.3d 836 (Fed. Cir. 1999), that means-plus-function and step-plus-function terms are authorized by the same statute, defendants argue that *Williamson* overruled *Masco* by analogy to means-plus-function terms. *See id.* at 848 (Rader, J. concurring) ("The statute's format and language suggest a strong correlation between means and step-plus-function claim elements in both their identification and interpretation."). Defendants cite *GoDaddy.Com, LLC v. RPost Commc'ns Ltd.*, 2016 WL 212676, at *56-57 (D. Ariz. Jan. 19, 2016) as an example of what they deem a correct application of *Williamson*. In *GoDaddy*, the court ruled that the claim term "processor" did not sufficiently denote a definite structure supporting the function of "associating the content data with dispatch record data" in patents directed to electronic message transmission and delivery. Hence, a mean-plus-function analysis was required. Defendants maintain that by the same logic, the "processing," "analyzing," and "combining" steps of the '360 patent do not specify sufficient acts because they do not explain *how* the steps achieve the recited functions.

Plaintiffs respond, and the court agrees, that the holding of *Williamson* does not have the broad sweep that defendants attempt to give it. Although the Federal Circuit backed away in *Williamson* from giving undue weight to the presumption that attaches to the absence of signal phrases, the "sufficient structure" standard for means-plus-function terms is nothing new. "We have [] *traditionally* held that when a claim term lacks the word 'means,' the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Williamson*, 792 F.3d at 1348 (emphasis added), *citing Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000).

Although both means- and step-plus-functions terms share a statutory source, the Federal Circuit has not applied an identical analysis to the two types of terms. In *O.I. Corp.*, defendants made a similar "parallelism" argument that if language in an apparatus claim is drafted as a means-plus-function term, the identical language in a method claim directed to the same invention (but omitting the word "means") is necessarily a step-plus-function term. *Id.*, 115 F.3d at 1583. The Court disagreed.

> Each claim must be independently reviewed in order to determine if it is subject to the requirements of section 112, ¶ 6. Interpretation of claims would be confusing indeed if claims that are not means- or step-plus-function claims were to be

> interpreted as if they were, only because they use language similar to that used in other claims that are subject to this provision.

Id. at 1583-1584. Although the Court noted that the specification failed to indicate a structure supporting the apparatus claim term of "means for passing the analyte slug through a passage," *id.* at 1580, the method claim "step[] of" "passing the analyte slug through a passage" was not held to be a step-plus-function term. *Id.* at 1583.

> Merely claiming a step without recital of a function is not analogous to a means plus a function. We note that the *Halliburton* case concerned an apparatus claim, not a process claim, and we must be careful not to extend the language of this provision to situations not contemplated by Congress. If we were to construe every process claim containing steps described by an "ing" verb, such as passing, heating, reacting, transferring, etc. into a step-plus-function limitation, we would be limiting process claims in a manner never intended by Congress.

Id.

In *Masco*, the Court rejected the argument that the phrase "transmitting a force" in the context of a patent directed to electronic dial combination locks was "too amorphous to be interpreted as an act" in the claim limitation of "transmitting a force applied to the dial to the lever." *Id.*, 303 F.3d at 1326. The Court applied the distinction drawn between acts and functions by Judge Rader in his *Seal-Flex* concurrence. "[T]he 'underlying function' of a method claim element corresponds to *what* that element ultimately accomplishes in relationship to what the other elements of the claim and the claim as a whole accomplish. 'Acts,' on the other hand, correspond to *how* the function is accomplished." *Masco*, 303 F.3d at 1327, quoting *Seal-Flex*, 172 F.3d at 849-850. "The underlying function of the 'transmitting a force' limitations, or in Judge Rader's formulation, what those limitations ultimately accomplish in relation to what the other limitations and each claim as a whole accomplish, is to drive the lever into the cam." *Masco*, 303 F.3d at 1327. Looking to dictionary definitions of "transmit" as meaning to "cause [something] to pass through a medium," the Court concluded that "'[t]ransmitting a force' describes how the lever is driven into the cam. In other words, "transmitting" in the sense of causing a force to be conveyed through a medium by mechanical parts is an act, since it describes how the function of the "transmitting a force" limitation is accomplished." *Id.* at 1328. The Court did not raise the issue of whether "transmitting a force" was a "sufficient act."

It is true that in *Williamson*, the Court disapproved of extending *Masco*'s holding to means-plus-function terms and expressly overruled the requirement of *Flo Healthcare Sols., LLC v. Kappos*, 697 F.3d 1367, 1374 (Fed. Cir. 2012), of "a showing that the limitation essentially is devoid of anything that can be construed as structure." *Williamson*, 792 F.3d at 1349.

As for *Masco* itself, however, the Court recognized the disparate standard applicable to step-plus-function terms and commented only that *Masco* involved "the unusual circumstances in which § 112, para. 6 relates to the functional language of a method claim." *Id.* Nothing in *Williamson* suggests that *Masco* is no longer the governing law for identifying step-plus-function terms. *See Word To Info Inc. v. Facebook, Inc.*, 2016 WL 3690577, at *25-27 (N.D. Cal. Jul. 12, 2016) (applying *Masco* post-*Williamson* and rejecting the proposition that an act must be contain "sufficient detail" to avoid step-plus-function analysis); *see also Syncpoint Imaging, LLC v. Nintendo of Am. Inc.*, 2016 WL 55118, at *5 (E.D. Tex. Jan. 5, 2016) (citing *Masco* post-*Williamson* for the proposition that paragraph 6 "does not apply when the claim includes an 'act' corresponding to 'how the function is performed.'"). Under *Masco*, because the disputed terms each recites an act that describes how the stated function is accomplished, they are not step-plus-function terms as defined in Section 112, para. 6.[8]

[8] Whether the claimed acts are sufficient for performing the stated functions, as Judge Pfaelzer observed in *Regents*, are "analyze-the-fact question[s], appropriate for determining if a claim element is valid under the enablement, written description, and definiteness inquiries under 35 U.S.C. § 112 ¶¶ 1-2." *Regents*, 2012 WL 8281499, at * 6. Defendants, however, have not made an enablement argument, at least at this stage.

"vector processing" (claim 36)

The parties agree that "vector processing" is the "analysis of the data set to determine direction and magnitude of a given point (or voxel)." They disagree whether this term is limited to "vector analysis (not tensor analysis)" (defendants) or if it more broadly encompasses "mathematical analysis" (plaintiffs). Defendants rely on Judge Pfaelzer's understanding in *Siemens* that because a tensor is a different mathematical concept than a vector, "vector processing" by definition excludes tensor analysis. Defendants further argue that under the principle of *stare decisis*, this court owes deference to Judge Pfaelzer's ruling.

The claim construction of a respected judge of another district court may be persuasive, but it is not binding. As the Federal Circuit has instructed, a district court has a duty to perform its own analysis independent of another court's claim construction. *See Lexington Luminance LLC v. Amazon.com Inc.*, 601 F. App'x 963, 969 (Fed. Cir. 2015) (vacating a district court's adoption of another district court's claim construction "without performing its own analysis"). Here, I respectfully part company with Judge Pfaelzer and agree with plaintiffs that the term "vector processing" does not necessarily exclude tensor analysis.

The term "vector processing" appears only once in the specification of the '360 patent, namely, in the heading of the section, "Vector Processing and Three-Dimensional Image Generation." *Id.* col. 19, l. 28-29. The section itself describes techniques for producing a three-dimensional image of a neuron from two-dimensional images based on the anisotropic direction of the nerve.

> As a preferred alternative [to an informed approximation based on known neural anatomy], requiring less mechanical complexity and faster processing speed, a technique has been developed for observing diffusional anisotropy, independent of its degree of alignment with any individual gradient axes. This process involves the combination of information from anisotropy measurements obtained along three standard orthogonal axes or using information from multiple fixed axes. For example, in the preferred embodiment, a vector analysis is used to produce interpolated images and directional information from the three orthogonal diffusionweighted images described above.
>
> In that regard, image information is collected from, for example, four "multi-slice" sets using a zero diffusion gradient B_0 and diffusion gradients B_x, B_y, B_z, in the x-, y-, and z-orthogonal directions, respectively. For each pixel in the image to be produced, information concerning the corresponding pixels in the four diffusion gradients images is combined to produce a diffusion vector, representative of water molecule movement along the nerve fiber in either direction. This vector has a magnitude representative of the image intensity of the pixel and a direction representative of an "effective" diffusion gradient associated with the pixel.

Id. col. 20, ll. 24-46. The specification also discloses equations for computing S_n, the length of a vector representing the intensity of a particular pixel, and θ_{xy}, θ_{xz}, and θ_{yz}, the three directional components of the effective gradient associated with the pixel image. *Id*. col. 20, ll. 36-65. In addition to the preferred form of vector analysis,

> [a]lternative forms of vector analysis can also be applied, for example, as described in Basser et al., *Fiber Orientation Mapping in an Anisotropic Medium with NMR Diffusion Spectroscopy,* SMRM BOOK OF ABSTRACTS 1221 (1992). Similarly, tensor analyses employing tensors of various ranks, as described in Basser et al., *Diagonal and Off Diagonal Components of the Self-Diffusion Tensor: Their Relation to an Estimation from the NMR Spin-Echo Signal,* SMRM BOOK OF ABSTRACTS 1222 (1992), can be used to treat, or transform the coordinates of, MR diffusional anisotropy data. Suitable alternative processing techniques have been developed for use in the evaluation of magnetic, thermal, and structural anisotropy data.

Id. col. 21, ll. 35-47.

I begin with the patentee's choice of words. Defendants' expert witness, Professor Michael Moseley, is of the view that the term "vector processing" did not have a plain meaning to a person of ordinary skill in the MRI field when the '360 patent was filed in 1993. Moseley Decl. ¶ 27. The specification reflects that while the patentees were familiar with vector analysis, having described a preferred form, they elected to claim the concept of "vector processing." This choice suggests that "vector processing" is not intended as an equivalent to vector analysis. Moreover, the word *processing* has a broader meaning than the term *analysis*.

This distinction is borne out by the different methods of data processing disclosed in the specification. In addition to the vector analysis embodied within the four equations, the specification discloses "[a]lteranative forms of vector analysis" and "[similarly,] tensor analysis." Nothing in the specification or the claims suggests that "vector processing" includes only some, but not all, of the listed alternatives.

Defendants' focus on the use of the word *vector* in "vector processing" is also unconvincing. Although tensors and vectors are different mathematical constructs, they are correlative. A vector is a quantity with both a magnitude and a direction. A tensor is a higher-order construct that can represent more complex quantities with more than one direction and one magnitude. The complexity of a tensor is specified by its rank. Vectors are rank-one tensors. A rank-two tensor is a linear operator that transforms one vector to another vector through a dot product.

The use of the word *vector* in "vector processing," consistent with the specification, refers to the object of the processing and not necessarily the type of *processing*. The patent specifies that each pixel of the three-dimensional image may be represented by a "diffusion vector." '360 patent, col. 20, ll. 38-44. "This vector has a magnitude representative of the image intensity of the pixel and a direction representative of an 'effective' diffusion gradient associated with the pixel." *Id.* col. 20, ll. 44-46. The agreed-upon portion of the definition confirms this understanding – the purpose of "vector processing" is to "determine direction and magnitude of a given point."

Tensor analysis may be applied to process the vector representation of diffusional image information. "[T]ensor analyses employing tensors of various ranks . . . can be used to treat, or transform the coordinates of, MR diffusional anisotropy data." *Id.* col. 21, ll. 39-45. Since the specification explicitly describes tensor analysis as a method of analyzing diffusional data represented as a vector, a person of ordinary skill in the art at the time of the invention would not understand the term "vector processing" to exclude tensor analysis. The court therefore adopts plaintiffs' proposed construction. "Vector processing" means "mathematical analysis of the data set to determine direction and magnitude of a given point (or voxel)."

"effective vector" (claims 41-44, 47, 50)

The term "effective vector" does not appear in the specification. The parties agree, however, that the term describes vector representation of the "effective" diffusion at a given point in the image.

> For each pixel in the image to be produced, information concerning the corresponding pixels in the four diffusion gradients images is combined to produce a diffusion vector, representative of water molecule movement along the nerve fiber

> in either direction. This vector has a magnitude representative of the image intensity of the pixel and a direction representative of an "effective" diffusion gradient associated with the pixel.

Id. col. 20, ll. 38-46. Although the parties initially proposed conflicting constructions,[9] through briefing they have more or less come to an agreement on the essence of the term – that the "effective vector" is a vector, that is, a direction and a magnitude, of diffusion at a given point, and that this vector is computed from "the combination of information from anisotropy measurements obtained along . . . multiple fixed axes." *Id.* col. 20, ll. 28-31; *see* Pls.' Reply Br. at 9; Defs.' Reply Br. at 5.[10] The court will therefore construe the "effective vector" to mean: "at a given point (voxel), the direction and magnitude that provides the combined representation of diffusional measurements along multiple axes."

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[9] Plaintiffs originally proposed "direction and magnitude that represents the data at a given point (or voxel)," while defendants proposed "a vector that provides a composite representation of diffusion parallel to the neural tissue and diffusion perpendicular to the neural tissue."

[10] At oral argument, plaintiffs continued to object to defendants' use of the word "composite" because it is not a term used in the specification. As noted, the specification uses the term "combination." The court will thus substitute the word "combined" for "composite" in the approved construction.

"excitation and output arrangement means for exposing a region . . ." (claim 54(a)); "said excitation and output arrangement means further for sensing . . ." (claim 54(b))

The parties agree that claim elements 54(a) and 54(b) are means-plus-function terms governed by 35 U.S.C. § 112, para. 6. The parties also concur that the respective functions of the terms are: *exposing a region to a suppression sequence of electromagnetic fields that suppresses the electromagnetic responsiveness of structures in the region that do not exhibit diffusion anisotropy, so as to increase the apparent diffusion anisotropy of structures in the region that exhibit diffusion anisotropy* (54(a)); and, *sensing a resonant response of the region to the diffusion-weighted gradient and producing an output indicative of the resonant response, for each of said diffusion-weighted gradients* (54(b)). The dispute concerns the extent of the corresponding structures.

With respect to the claim 54(a) term, the parties agree that the corresponding structure includes *excitation coil 62, gradient coil pairs 64 and 66, and computer 72 and front-end circuit 74 (including RF pulse generator 84),*[11] *wherein the computer 72 is programmed with the CHESS pulse* and their equivalents. Plaintiffs argue for, and defendants argue

[11] Although defendants object to the explicit inclusion of RF pulse generator 84, they agree that it is included as part of front end circuit 74. *See* Defs.' Br. at 22, n.4.

against, the additional inclusion of the Dixon technique, and STIR and FLAIR pulse sequences for fat suppression.

Although the specification describes the CHESS pulse sequence in some detail, *see* '360 patent, col. 13 ll. 12-24 & Fig. 11, it mentions the alternatives only by reference to prior art articles.

> As an alternative to the use of CHESS for fat suppression, the desired suppression may be effected by selective water stimulation. Other suitable alternatives include the Dixon technique for fat suppression described in, for example, Dixon et al., *Simple Proton Spectroscopic Imaging,* 153 RADIOLOGY 189-194 (1984) and also STIR (short tau inversion recovery) described in *Improved Fat Suppression in STIR MR Imaging: Selecting Inversion Time through Spectral Display*, 178 RADIOLOGY 885-887 (1991).

Id. col. 13, ll. 32-40.

> Finally, carefully adjusted water suppression techniques can be used to limit the contribution of the blood vessels and cerebrospinal fluid (CSF) to the neural image generated by system 14. One such technique is fluid-attenuated, inversion recovery (FLAIR), described in, for example, Bydde et al., *Comparison of FLAIR Pulse Sequences with Heavily* T2 *Weighted SE Sequences in MR Imaging of the Brain,* 185 RADIOLOGY SUPP. 151 (1992).

Id. col. 24, ll. 54-61.

As a general rule, "[t]rial courts cannot look to the prior art, identified by nothing more than its title and citation in a patent, to provide corresponding structure for a means-plus-function limitation." *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1317 (Fed. Cir.

2010). The Federal Circuit carved out a small exception in *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374 (Fed. Cir. 1999), when "essentially unrebutted" expert testimony establishes that the prior art's "title alone was sufficient to indicate to one skilled in the art the precise structure of the means recited in the specification." *Id.* at 1382.

Plaintiffs rely on the declaration of Dr. Filler (one of the named inventors) for the proposition that the Dixon technique, and the STIR and FLAIR pulse sequences, were well-known to persons of ordinary skill in the art (POSITA) at the time of the invention, such that the mere invocation of their names would point to the corresponding structure. Dr. Filler recites as supporting evidence the number of article hits containing the disputed algorithm names in conjunction with the term "MRI" that appear from 1986 to 1992 on Google Scholar. Filler Decl. ¶ 66. Although the number of references suggests that the algorithms (or at least their names) were known in the contemporary art, this does not persuade defendants' expert, Professor Moseley, that a POSITA would have had sufficient familiarity with the precise steps of the algorithm to recognize the corresponding structure. *See* Moseley Decl. ¶¶ 62, 64, 68. Given the competing opinions of two persons of superior skill in the art, the court cannot conclude that a POSITA would have known the corresponding structure from the mere recitation of prior art reference titles.

With respect to the claim 54(b) term, plaintiffs propose that the structures include *external return coil; return coil; return field coils; coils identified as corresponding structures in claim 54(a)*, and their equivalents, while defendants propose *excitation coil 62, duplexer 88, preamplifier 90, mixer 92, low pass filter 96, and analog-to-digital converter 98 (not including external return coil, return coil, and return field coils described in the '360 patent Background)*; and their equivalents.

In support of their position, plaintiffs largely rely on portions of the background section of the specification.

> An external return coil is used to sense the field associated with the transverse magnetic moment, once the excitation field is removed. The return coil, thus, produces a sinusoidal output, whose frequency is the Larmor frequency and whose amplitude is proportional to that of the transverse magnetic moment. With the excitation field removed, the net magnetic moment gradually reorients itself with the polarizing field. As a result, the amplitude of the return coil output decays exponentially with time.

'360 patent, col. 2, ll. 31-40. While there is no categorical rule that the background section of a patent cannot provide the requisite structure,

> 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. This duty to link or associate structure to function is the *quid pro quo* for the convenience of employing § 112, ¶ 6.

B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1424 (Fed. Cir. 1997). Here, the structures disclosed in the background are those of a generic MRI system that does not address the nerve-imaging problem solved by the claimed invention. Moreover, the generic system described in the background does not employ diffusion-weighted gradients as required by the functions performed by the claim term. Consequently, these are not structures that "clearly link" to the function of *sensing a resonant response of the region to the diffusion-weighted gradient and producing an output indicative of the resonant response, for each of said diffusion-weighted gradients.*

Defendants' proposed structures, on the other hand, sense and report the resonant response to the diffusion-weighted gradients within the system contemplated by the invention. "[C]oil 62 is [] responsible for detecting the rf return, or echo, fields generated by the spins, although separate transmit and receive coils may alternatively be used." '360 patent, col. 10, ll. 41-44.

> The output of generator 84 is amplified by a high-power rf amplifier 86 before being selectively applied to the excitation coil 62 by a duplexer 88. The duplexer 88 is also controlled to selectively steer the low level MR returns received by the excitation coil 62 to a preamplifier 90.

> A mixer 92 transforms the high frequency output of preamplifier 90 to a low frequency signal by mixing the amplified MR returns with signals from a digitally controlled rf oscillator 94, which also provides inputs to generator 84. The analog output of mixer 92 is input to a low pass filter 96 before finally being converted to a digital form by an analog-to-digital converter 98. The computer 72 processes the resultant digital inputs, which represent the response of the spins to the applied fields, to generate the desired neurograms.

Id. col. 11, ll. 34-49; *see also* Fig. 8 (illustrating the components of "a neurography system [] constructed in accordance with this invention," *see id.* col. 7, ll. 41-19). Consistent with the patent's description of the components that perform the *sensing* . . . and *generating* . . . functions within the specific invention, the court will construe the corresponding structures of claim 54(b) as: *excitation coil 62, duplexer 88, preamplifier 90, mixer 92, low pass filter 96, and analog-to-digital converter 98.*

"near said exciting and output arrangement means" (claim 54)

Claim 54(b) requires that the "polarizing field source means [be] positioned *near said excitation and output arrangement means*." Defendants contend that, because "near" is a subjective word of degree, the claim term is indefinite under 35 U.S.C. § 112, para. 2, because the specification does not "provide objective boundaries for those of skill in the art" as to the scope of the claim term. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014).

Paragraph 2 of 35 U.S.C. § 112 states that a patent's specification "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention." The Supreme Court has interpreted paragraph 2 to "require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). Defendants must prove indefiniteness, like other grounds of invalidity, by clear and convincing evidence.

The preposition "near" signifies physical proximity and is a term of degree that is susceptible to subjective interpretation.

> When a "word of degree" is used, the court must determine whether the patent provides "some standard for measuring that degree." *Enzo Biochem,* 599 F.3d at 1332; *Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.,* 731 F.2d 818, 826 (Fed. Cir. 1984). Recently, this court explained: "[w]e do not understand the Supreme Court to have implied in [*Nautilus*], and we do not hold today, that terms of degree are inherently indefinite. Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing,* 766 F.3d at 1370.

Biosig Instruments, Inc. v. Nautilus, Inc., 783 F.3d 1374, 1378 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 569 (2015). In *Biosig*, the specification and the figures' description and illustration of the electrodes indicated that the scope of the claim term "spaced relationship," while not explicitly defined, could be "neither infinitesimally small or greater than the width of a user's hands," and was therefore sufficiently certain as to be definite. *Id.* at 1382. In contrast, defendants point out that nothing in the specification and prosecution history provides an objective standard positioning the physical proximity of the polarizing field source means in relation to the excitation and output arrangement means.

Plaintiffs do not identify supporting intrinsic evidence, but rely on the claim language and Dr. Filler's opinion. Dr. Filler opines that a POSITA would understand the term to require the components to be "'near' enough" to accomplish the functional goals stated in the claim.

> [O]ne of skill in the art would thus understand, that "the polarizing field source means" need be positioned "near" enough to the excitation and output arrangement means to (1) "expos[e] the region to a predetermined arrangement of diffusion-weighted magnetic gradients," (2) "emphasize a selected structure in the region," (3) "suppress other structures in the region," (4) allow the excitation and arrangement output means to "sens[e] a resonant response of the region to the diffusion weighted gradients" and (5) produce the required output.

Filler Decl. ¶ 81. Professor. Moseley counters, and the court agrees, that nothing in the patent explains which of the potentially many possible configurations would achieve the stated goals of the invention (as opposed to taking generic MRI images). The court also agrees with Professor Moseley that to read the "near" term to encompass all operable configurations, as proposed by Dr. Filler, would render the proximity requirement superfluous. *See Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1257 (Fed. Cir. 2010) ("Claims must be 'interpreted with an eye toward giving effect to all terms in the claim.'" (citation omitted)). Because nothing in the '360 patent sheds light on the limits of proximity required by the "near" term, the court finds that the term is indefinite as a matter of law.

ORDER

The claim terms at issue will be construed for the jury and for all other purposes in a manner consistent with the above rulings of the court. The parties have until September 2, 2016, to submit a joint proposed schedule for the conclusion of fact discovery, expert discovery, and dispositive motions.

SO ORDERED.

/s/ Richard G. Stearns
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UNITED STATES DISTRICT JUDGE