

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MDL NO. 13-2432-RGS

In re: NEUROGRAFIX ('360) PATENT LITIGATION

MEMORANDUM AND ORDER ON BRAINLAB'S MOTION FOR
SUMMARY JUDGMENT OF NO INFRINGEMENT

May 25, 2018

STEARNS, D.J.

This circling of the wagons by defendant Brainlab against the Neurografix plaintiffs¹ is the final skirmish in this drawn-out multidistrict patent litigation. In a nutshell, Neurografix alleges that Brainlab, through the use of its FiberTracking software, directly and by inducement, infringes U.S. Patent No. 5,560,360 (the '360 patent). Fact and expert discovery now complete, Brainlab moves for a brevis judgment of noninfringement.

“To support a summary judgment of noninfringement it must be shown that, on the correct claim construction, no reasonable jury could have found infringement on the undisputed facts or when all reasonable factual inferences are drawn in favor of the patentee.” *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1353 (Fed. Cir. 2001). “To establish literal

¹ These are NeuroGrafix, Neurography Institute Medical Associates, Inc., Image-Based Surgicenter Corporation, and Dr. Aaron G. Filler.

infringement, all of the elements of the claim, as correctly construed, must be present in the accused system.” *Id.* Patent law also holds “[w]hoever actively induces infringement [to be] liable as an infringer.” 35 U.S.C. § 271(b). “[I]nducement requires evidence of culpable conduct, directed to encouraging another’s infringement” *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part). “[L]iability for inducing infringement attaches only if the defendant knew of the patent and that ‘the induced acts constitute patent infringement.’” *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015), quoting *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011).

The ’360 patent is directed to, inter alia, obtaining “diagnostically useful images of neural tissue,” ’360 patent Abstract, by vector processing the output of magnetic resonant imaging (MRI) using certain diffusion-weighted pulse sequences.² The patented method distinguishes nerve tracts, including peripheral nerves,³ which are anisotropic (water diffuses freely along a tract, but diffusion perpendicular to the tract is restricted) from surrounding tissue. Neurografix asserts claims 36-37, 39-42, 44, 46-47, and

² The technology of the ’360 patent is described more fully in the court’s *Markman* opinion. See *In re Neurografix (’360) Patent Litig.*, 201 F. Supp. 3d 206, 209-211 (D. Mass. 2016).

³ As used in the patent, the term “peripheral nerves” encompasses “peripheral, autonomic, and cranial nerves.” ’360 patent, col. 1, ll. 29-31.

49. Of these, claim 36 is an independent claim upon which the remaining asserted claims depend.

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 diffusion-weighted 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.

Brainlab contends that its FiberTracking software does not directly infringe claim 36 because (1) the software does not allow a user to target a “selected structure that exhibits diffusion anisotropy” as the subject of imaging prior to performing diffusion tractography, and (2) because FiberTracking does not “distinguish[the] selected structure from other structures in the region that do not exhibit diffusion anisotropy,” as required by step (e).

FiberTracking instead “allows [the user] to track fiber structures in a defined region of interest [(ROI)], based on diffusion-weighted MR image [(DTI data)].” FiberTracking Manual § 11.1, Def.’s Ex. K (Dkt # 459-12). The user first defines a 3-dimensional ROI from anatomical images fused with DTI data. *Id.*, see also *id.* § 11.2.1. The user then sets two parameters – the FA Threshold and Minimum Length. *Id.* § 11.2.2. “The FA threshold is the minimum value of diffusion that will be considered for tracking fibers.” *Id.* “The Start Tracking function allows the software to track all fibers that intersect with the active regions of interest and meet the defined criteria (FA Threshold and Minimum Length).” *Id.* § 11.2.3. “Once the process is completed, the software displays the fibers in different colors according to the diffusion direction” *Id.*

According to Brainlab, FiberTracking does not satisfy the “selected structure” limitation for two reasons. First, Brainlab argues that because the ’360 patent is directed to improved imaging of peripheral nerves, “selected structure” is correspondingly so limited. In support, Brainlab points to dependent claims 64 and 66, which narrow “the selected diffusion anisotropic structure” to “a member of the group consisting of peripheral nerves, cranial nerves number three through twelve, and autonomic nerves.” Because FiberTracking only images white matter neural tracts within the brain and not peripheral nerves, it does not image “selected structure[s]” as claimed. Second, Brainlab argues that because FiberTracking “is focused on *finding* patient specific anisotropic structures that are *not* previously known,” it does not permit the user to select a structure prior to imaging. Def.’s Mem. (Dkt # 456) at 4 (emphasis in original).

Turning to the “distinguishing” limitation, Brainlab notes that FiberTracking displays all neural tracts within the ROI meeting the user-defined FA Threshold and Minimum Length requirements. The default FA Threshold value is .3, and FiberTracking does not permit the user to enter an FA Threshold value of zero (corresponding to no anisotropy). Thus, while FiberTracking distinguishes structures exhibiting greater or lesser degrees of

anisotropy, it does not distinguish anisotropic structures from those “that do not exhibit diffusion anisotropy.”⁴

Firing back, Neurografix challenges Brainlab’s constructions of “selected structure” and “do not exhibit diffusion anisotropy.” With respect to the former, Neurografix notes (accurately) that nothing in the specification of the ’360 patent compels Brainlab’s restriction of “selected structure” to the class of peripheral nerves. That the invention described in the ’360 patent was motivated by a desire to improve peripheral nerve imaging does not restrict the scope of application of the invention’s disclosed solution. Moreover, Brainlab’s importing of a limitation disclosed in the dependent claims turns the principle of claim differentiation upside down. *See Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) (“[C]laim differentiation’ refers to the presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim.”). Neurografix also finds support in the specification for its contention that by claiming “distinguishing . . . from other structures . . . that do not *exhibit* diffusion anisotropy,” the ’360 patent is concerned

⁴ Brainlab also notes that “[a]n FA threshold of zero, *i.e.*, exhibiting no anisotropy, would result in many small irrelevant fibers being tracked and would obscure the image with low anisotropy noise.” Def.’s Reply (Dkt # 471) at 9.

with levels of anisotropy that are insignificant for purposes for imaging, rather than with an absolute absence of anisotropy. *See* '360 patent, col. 5, ll. 11-12 (characterizing gray matter as not exhibiting diffusion anisotropy even though gray matter can possess some degree of anisotropy).

Although it has the more persuasive claim constructions, Neurografix ultimately loses the battle. In response to Brainlab's contention that "the existence and location of patient specific white matter neural tracts are not known and cannot be selected in advance," Def.'s Mem. at 1, Neurografix tenders the argument that FiberTracking infringes when the user images a known structure in the brain – specifically, the pyramidal tract (Neurografix uses this term interchangeably with corticospinal tract). According to Neurografix,

without any MRI imaging, a neurosurgeon or neuroradiologist knows that there is a cortico-spinal tract that starts along the motor strip in the cerebral cortex, travels through a large white matter area to reach the area of the "internal capsule" between the globus pallidus and thalamus – where it is readily identified and isolated. It then descends to reach the crus cerebri in the midbrain, perforates through the pons, and then forms the pyramids in the anterior surface of the medulla oblongata before reaching the exterior white matter of the spinal cord to descend in the lateral and anterior corticospinal tracts.

Pl.'s Opp'n (Dkt # 463) at 20.

[I]f a neurosurgeon has identified these pyramidal tracts as the selected structure to image with tractography in order to be able to know and determine its precise, exact shape and position, he

will know that the head must be imaged. Thus, he will, in claim step 36 (a), assure that this selected structure is in the region to be exposed to the magnetic fields and will assure in 36 (b) will assure that this selected structure is exposed to an electromagnetic excitation field by assuring that the head is being imaged. Further, after step 36 (c) is completed, he will be able to direct that step 36 (d) is performed so that data representative of this selected structure – the pyramidal tract’s anisotropic diffusion data – is subject to vector processing. The gradients used to create this data will not need to be aligned with any part of the selected structure – the pyramidal tract. Finally, in Step 36 (e) he will be able to generate a data set that at least distinguishes that selected structure from isotropic areas such as at least the spinal fluid.

Id. at 20-21. In further support of its infringement theory, Neurografix reproduces two excerpts from Brainlab’s marketing materials. The first is an illustration showing a tractographic image of the pyramidal tract, Pl.’s Opp’n at 9, while the second illustrates, by highlighting blue bands against the contours of a brain, positions the pyramidal tract. The second excerpt also states that “[i]t is possible to delineate major white matter tracts, such as the pyramidal tract, by applying fiber tracking algorithms . . . [to] user defined-seed volumes.” *Id.* at 10.

Neurografix, however, is forced to acknowledge, at least implicitly, that some aspects of the brain neural anatomy of a particular patient are unknown and therefore cannot be selected prior to performing tractography. “If a physician wishes to know, for instance, exactly where the corticospinal fibers of the pyramidal tracts are as they pass through other white matter

regions in the [sic] then only tractography can show this in a living person.” *Id.* at 20. In other words, depending on the physician’s purpose and objective, FiberTracking is capable of both infringing uses and non-infringing uses.

Here, however, is the crux of the matter. That an accused product is capable of an infringing use is insufficient to establish infringement liability. “Unless the claim language only requires the capacity to perform a particular claim element, we have held that it is not enough to simply show that a product is capable of infringement; the patent owner must show evidence of specific instances of direct infringement.” *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1329 (Fed. Cir. 2010). Similarly, “liability for inducement must be predicated on direct infringement.” *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014). “[T]he plaintiff has the burden of showing that the alleged infringer’s actions *induced infringing acts* and that he knew or should have known his actions would induce actual infringements.” *DSU Med.*, 471 F.3d at 1304 (emphasis added). Fatal to Neurografix’s battle plan is the absence of any evidence of actual infringement. Neurografix musters nothing in the record showing that either

Brainlab or any of its customers actually uses FiberTracking in the manner hypothesized by Neurografix.⁵

This is also not a case where direct infringement might reasonably be inferred from instructions for accomplishing an infringing use packaged by Brainlab with its FiberTracking product. *Cf. Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006) (instruction sheets taught an infringing configuration). To authorize such an inference, instructions must not only describe an infringing mode, but teach or encourage it. In *Fujitsu*, the patentee argued that because defendant's accused wireless routers offered a message fragmentation function that necessarily infringed when deployed, it should be permitted to infer that instances of direct infringement occurred. 620 F.3d at 1328-1329. The Federal Circuit demurred. It held that because the infringing mode had to be activated by a customer and there was no evidence that any such thing had ever happened, manuals and expert testing demonstrating that the accused routers *could* operate in an infringing manner were insufficient to

⁵ Neurografix asserts without citation that it is "critical" for brain tumor surgeons to ascertain the precise location of the pyramidal tract in order to "avoid injuring any part" during surgery. Pl.'s Opp'n at 10. There is no evidence in the record, however, that surgeons use FiberTracking to extract this kind of information. Neurografix's neurosurgeon expert, Dr. Filler (also a plaintiff and a patentee), conceded that he himself had never used FiberTracking. Filler Dep. Tr. (Dkt # 459-14) at 120-121.

raise a genuine issue of material fact regarding direct infringement. 620 F.3d at 1329. Conversely, in *Toshiba Corp. v. Imation Corp.*, the Federal Circuit agreed that evidence of user manuals and marketing materials for DVD recorders that recommended use of the infringing mode over the non-infringing mode was sufficient to raise a fact question regarding direct infringement. 681 F.3d 1358, 1364 (Fed. Cir. 2012).

Unfortunately for Neurografix, this case is more aligned with *Fujitsu* than *Toshiba*. FiberTracking is not designed to track a specific structure – the software “track[s] *all fibers* that intersect with the actives regions of interest and meet the defined criteria.” FiberTracking Manual § 11.2.3 (emphasis added). Although the excerpted marketing material states that it is “possible” to use FiberTracking to delineate the pyramidal tract, it does not teach a means of selecting a particular ROI and FA Threshold and Minimum Length values to accomplish this, nor does it recommend this as a superior or even commensurate mode of use. As Neurografix acknowledges, how a physician/neurosurgeon uses FiberTracking depends on his or her reasons for performing tractography. Given the absence of evidence of any instances of actual infringement, the siege is over and Brainlab wins.⁶

⁶ Neurografix’s inducement claim also falters because, for the same reason that a reasonable factfinder cannot infer instances of direct infringement from the FiberTracking marketing materials and manual, the

ORDER

For the foregoing reasons, Brainlab’s motion for summary judgment of noninfringement is ALLOWED. Brainlab’s motions for summary judgment of no lost profit damages and to exclude damages expert opinions are MOOT.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE

“instructions [do not] teach an infringing use of the device *such that* we are willing to infer from those instructions an affirmative intent to infringe the patent.” *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (emphasis in original), quoting *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009).