

TOBINICK v. OLMARKER, Appeal No. 2013-1499 (Fed. Cir. May 19, 2014). Before Lourie, Reyna, and Wallach. Appealed from the Patent Trial and Appeal Board.

Background:

Tobinick amended claims of his '205 application to copy claims of the '995 and '990 patents by Olmarker. The claims covered methods of treating spinal nerve injuries by locally or epidurally administering a TNF- $\alpha$  inhibitor. Tobinick then filed an interference with the Patent Trial and Appeal Board (PTAB). Olmarker moved to dismiss for lack of standing on the basis that the '205 application did not contain written description support for the claim terms "administered locally" and "administered epidurally" and instead only had support for systemic administration. The PTAB agreed, and held that the term "administered locally" requires administering directly to the site where TNF- $\alpha$  is intended to act, that is, the location where the nucleus pulposus is causing the symptoms of the nerve disorder. This definition excluded any form of administering that involves travel or diffusion of the inhibitor. The PTAB then found that the '205 application lacked adequate written description support for the terms.

Tobinick appealed, arguing that the PTAB's claim construction was too narrow and, alternatively, the '205 application provides adequate written support for the interference count.

Issue/Holding:

Did the PTAB err in its claim construction and its finding of inadequate written description support? No, for the claim construction; yes, for the written description. Reversed.

Discussion:

In the assessment of claim construction, the Federal Circuit interpreted the claims in light of the '995 and '990 specifications. The Federal Circuit also relied on intrinsic evidence, expert testimony and dictionary definitions. Based on the evidence, the Federal Circuit agreed with the PTAB's construction, stating that the evidence supported the interpretation to include only administration directly to the site of the nerve injury. However, because leakage of nucleus pulposus from a herniated disc affects the nerve roots of adjacent discs, a site of nerve injury adjacent to disc herniation may be where the TNF- $\alpha$  is intended to act. Thus, the claim construction for local application is not limited only to application directly on the nerve roots.

With regard to the assessment of the '205 application's written description support, Olmarker argued that the '205 application lacked support because the specification includes non-local forms of administration within the description of local administration. According to Olmarker, because the '205 application teaches that "anatomic proximity" can include an epidural space as far as 10 cm away from the spine, the administration to the epidural space is to be considered systemic, rather than local. The Federal Circuit disagreed, stating that because the epidural space is precisely the area in which the nerve root extends from the spinal cord, the TNF- $\alpha$  administration described in the '205 application is made "directly to the site where it is intended to act, that is, the location where the nucleus pulposus is causing the symptoms of nerve disorder," as recited in the claim construction. Moreover, the '205 application need only reasonably convey to one skilled in the art that Tobinick had possession of at least one embodiment that meets the Board's construction. The epidural injection technique is one such embodiment.