United States Court of Appeals for the Federal Circuit

EDWARD TOBINICK,
Appellant,

v.

KJELL OLMARKER AND BJORN RYDEVIK,
Appellees.

2013-1499

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Interference No. 105,866.

Decided: May 19, 2014

ROBERT HAHL, Neifeld IP Law, PC, of Alexandria, Virginia, argued for appellant. With him on the brief was RICHARD A. NEIFELD.

TODD R. WALTERS, Buchanan, Ingersoll & Rooney PC, of Alexandria, Virginia, argued for appellees. With him on the brief was ERIN M. DUNSTON.

Before LOURIE, REYNA, and WALLACH, *Circuit Judges.*

REYNA, *Circuit Judge*.

This appeal arises out of an interference proceeding before the Patent Trial and Appeal Board ("Board") at the United States Patent and Trademark Office ("PTO") relating to drug treatments for spinal nerve injuries. The Board construed "administered locally" as administering the claimed therapeutic compound "directly to the site where it is intended to act, that is, to the location where the nucleus pulposus is causing the symptoms of the nerve disorder." Based on this construction, the Board found that Edward Tobinick's ("Tobinick") patent application did not contain written description support for the interference count. Without written description support for the count, Tobinick lacked standing to bring the interference, and the Board dismissed. *See* 37 C.F.R. § 41.201(2)(ii).

On appeal, the parties dispute the meaning of "administered locally" and whether Tobinick's patent application contains written description support for this claim limitation. We agree with the Board's claim construction but reverse its written description decision and subsequent dismissal. We find that Tobinick's application contains sufficient written description support for local administration because it describes administering the relevant therapeutic compound to the epidural space adjacent to a herniated spinal disc, which is the site where the compound "is intended to act" and "the location where the nucleus pulposus is causing the symptoms of the nerve disorder." We therefore reverse.

BACKGROUND

The technology at issue relates to drugs for treatment of spinal nerve injuries, such as those associated with herniated discs. Between spinal vertebrae are soft discs, referred to as "spinal discs," that permit the spine to flex and move by absorbing and distributing compressive forces. A spinal disc becomes herniated when tissue

surrounding it tears. As a result, nucleus pulposus, a substance normally inside the disc, leaks out into the epidural space of the spine. Nucleus pulposus secretes a molecule called tumor necrosis factor-α ("TNF-α"), a powerful signaler of inflammation and other injuries. The nerve roots that extend from the spinal cord to various parts of the body pass through the epidural space. When TNF-α comes into contact with nerve roots, it injures the nerves and may cause back pain or numbness. The nerve root injuries may be reduced or eliminated by "inhibiting" the activity of TNF-α. The patents and application at issue here disclose methods of inhibiting TNF-α via the local administration of a monoclonal antibody (the TNF-α inhibitor) to the site of an affected nerve.

Kjell Olmarker and Bjorn Rydevik (collectively "Olmarker") are the named inventors on the following related patents, each of which claims priority from an application filed on September 25, 1998:

U.S. Patent No.	Involved Claims	Issue Date
7,708,995	12, 13	May 4, 2010
7,811,990	13, 22, 31, 40, 45, 48, 49, 51	Oct. 12, 2010
7,906,481	2, 20, 22, 32	Mar. 15, 2011
8,057,792	10, 11, 23, 24	Nov. 15, 2011
6,649,589	8, 18, 27, 34	Nov. 18, 2003

On December 15, 2011, Tobinick requested an interference[1] by copying claims from the '995 and '990 patents

[1] The activities at issue occurred before the enactment of the Leahy–Smith America Invents Act ("AIA"), Pub.L. No. 112–29, § 3, 125 Stat 284, 285–93 (2011), which eliminated interference proceedings. Therefore, the earlier version of the patent statute, 35 U.S.C. § 102(g)(2)

in Tobinick's patent application 12/714,205 ("'205 application"). These claims covered methods of treating spinal nerve injuries by locally or epidurally administering a TNF-α inhibitor. The following claims represent the interference counts:

> Claim 68: A method of treating or alleviating one or more symptoms of a nerve disorder mediated by nucleus pulposus in a mammal in need of such treatment comprising the step of administering a therapeutically effective amount of a TNF-α inhibitor to the mammal, wherein said TNF-α inhibitor is an antibody that blocks TNF-α activity, wherein the antibody is *administered locally*.

'205 application ¶ 36 (emphasis added).

> Claim 69: The method of claim 68, wherein the antibody is *administered epidurally* to the mammal.

'205 application ¶ 37 (emphasis added).

Before the Board, Tobinick filed five motions, and Olmarker filed eleven motions. As relevant here, Olmarker moved the Board to dismiss for lack of standing on the basis that Tobinick's '205 application did not contain written description support for the claim terms "administered locally" and "administered epidurally." According to Olmarker, the '205 application failed to describe local administration of a TNF-α inhibitor and instead only

---

(2006), governs the activities in this case. *See* AIA § 3(n)(1), 125 Stat. at 293 (providing that certain AIA amendments apply to, inter alia, applications, and patents issued thereon, that have ever contained a claim to an invention having an effective filing date of March 16, 2013, or later).

described systemic administration. The Board held an oral argument on December 4, 2012.

The Board first construed the term "administered locally." Tobinick argued that the term should encompass all localized forms of drug administration, whereas Olmarker argued that the term should require administration "directly to" the site of injury, and exclude any form of administration that involves travel or diffusion of the inhibitor. Based on the '995 patent specification, expert testimony, and medical dictionary definitions, the Board adopted Olmarker's construction, namely administering a TNF-α inhibitor "directly to the site where [the TNF-α inhibitor] is intended to act, that is, to the location where the nucleus pulposus is causing the symptoms of the nerve disorder."

Based upon its construction, the Board then found that the '205 application lacked adequate written description support for the construed term because it did not sufficiently delineate between local and non-local administration. The Board noted that the '205 application described "local" as including administration of medication near the site of injury followed by diffusion or travel of the medication to the site of injury. Because this technique of administration would not fit within the Board's construction, the Board concluded that the '205 application lacked written description support for "administered locally." Accordingly, the Board granted Olmarker's motion to dismiss and did not consider the other pending motions. Tobinick appealed and we have jurisdiction under 35 U.S.C. § 1295 (2006).

On appeal, Tobinick argues that the Board's claim construction is improperly narrow and, in the alternative, that the '205 application provides adequate written description support for the interference count. We agree with the Board's claim construction but reverse its written description decision.

CLAIM CONSTRUCTION

We review claim construction de novo. *Lighting Ballast Control LLC v. Philips Elecs. N. Am.*, 744 F.3d 1272, 1276-77 (Fed. Cir. 2014) (en banc); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-15 (Fed. Cir. 2005) (en banc). In interference proceedings, a disputed claim is construed in the context of its originating disclosure rather than the interfering application. *Robertson v. Timmermans*, 603 F.3d 1309, 1312 (Fed. Cir. 2010) ("When a party challenges written description support for an interference count or the copied claim in an interference, the originating disclosure provides the meaning of the pertinent claim language.") (internal citations omitted). Here, the claim limitation "wherein the antibody is administered locally" is construed in light of the '995 and '990 patent specifications, not the '205 application.

The Board first considered the intrinsic evidence. The '995 patent[2] discloses "a method for treating nerve disorders . . . by administering . . . a TNF inhibitor." Col. 1 ll. 21-24. The goal of the method is to treat back pain caused by TNF-α's irritation of nerve endings. *See id.* at col. 2 ll. 1-3; col. 18 ll. 4-7. The '995 patent contrasts local and systemic administration. Regarding local administration, the patent provides an example in which the inhibitor is applied directly to the nucleus pulposus. *Id.* at col. 20 ll. 16-29 ("[T]he nucleus pulposus was mixed with . . . the anti-TNF-alpha antibody."); *see also* col. 17 ll. 42-47 (describing experiments in which a "blocking monoclonal antibody to the TNF-alpha is applied *locally in the nucleus pulposus*") (emphasis added). Apart from this direct application, the patent does not discuss or disclose any

---

[2] While both the '995 and '990 patents are relevant to the construction of "administered locally," we only discuss the '995 patent here because both specifications are essentially the same.

other method of local administration. Regarding systemic administration, the patent discloses the use of a pill taken orally, whereby the TNF-α inhibitor was "not administered locally in the autotransplanted nucleus pulposus, but instead was administered systemically." *Id.* at col. 27 ll. 18-20.

Both parties presented expert testimony to the Board, including similar medical dictionary definitions of "local." Olmarker's witness, Dr. Andersson, relied on dictionary evidence to contrast the definition of "local," as "restricted to or pertaining to one spot; not general," Dorland's Illustrated Medical Dictionary 552 (23d ed. 1957), with that of "general," as "affecting many parts or all parts of the organism, not local," *id.* at 772. Based on these definitions, Dr. Andersson defined "local administration" as administration "directly to the site where the medicine is intended to act," whereas he defined "systemic administration" as administration in which "medicine is broadly distributed before reaching the site of action, such as being carried . . . by the vascular system." Dr. Andersson opined that the '995 patent described the local administration of a TNF-α inhibitor to the affected nerve roots in a manner consistent with these definitions. Specifically, according to Dr. Andersson, the '995 patent is consistent with the definitions because it describes local administration as entailing direct contact of the inhibitor with the nucleus pulposus, and systemic administration as entailing administering a pill.

Tobinick's expert witness, Dr. Richardson, also relied on dictionary evidence, which defined "local" in essentially the same way as Dr. Andersson. *See* Stedman's Medical Dictionary for the Health Professions and Nursing 982 (7th ed. 2012). Dr. Richardson also discussed more remote administration techniques. For example, Dr. Richardson testified that a steroid can be injected up to about ten centimeters away from the site of the nerve injury and still remain effective**.** Dr. Richardson also explained a

type of administration called "transpinal administration," in which medication is delivered to a venous system, remote from the nerve injury, known as the Batson's plexus.

Based on this evidence, the Board construed "administered locally" as administered "directly to the site where it is intended to act, that is, to the location where the nucleus pulposus is causing the symptoms of the nerve disorder." The Board also found that this limitation did not include "systemic administration away from the site where the TNF-α is intended to act."

We agree with the Board. The Board's conclusion that the disputed claims cover the administration of TNF-α inhibitor "directly to" the site of the nerve injury is supported by the specification and the medical definitions of "local" presented by both sides. Contrary to Tobinick's argument, the Board's construction does not exclude administration "adjacent to disc herniation." 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 well be where the inhibitor "is intended to act." Thus, administration "adjacent to disc herniation" may fall within the court's construction, depending upon the precise location of the injury. Accordingly, we affirm the Board's claim construction.

WRITTEN DESCRIPTION

The parties dispute whether the '205 application provides written description support for the term "administered locally." Tobinick argues that the description of epidural administration in the application supports the term. Olmarker responds that the '205 application lacks written description support because the specification includes non-local forms of administration within its description of local administration. We agree with Tobinick and find that the '205 application contains sufficient

written description support because it describes administering an inhibitor to the epidural space adjacent to a herniated disc, which is the location where nucleus pulposus causes nerve injury.

35 U.S.C. § 112 (2006) provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The purpose of the written description requirement is to require an inventor to disclose his invention to the public in such a manner as to allow "a person of skill in the art to recognize that the patentee invented what is claimed." *Synthes USA, LLC v. Spinal Kinetics, Inc.*, 734 F.3d 1332, 1341 (Fed. Cir. 2013) (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)). The written description determination depends on "the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.* (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357-58 (Fed. Cir. 2005)). Accordingly, we must determine whether the disclosure of the '205 application "reasonably conveys to those skilled in the art" that Tobinick "had possession" of the claimed local administration. *Id.* (internal citations omitted).

"Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006) (citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)). We review the Board's written description finding for sub-

stantial evidence and set aside actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. *Id.* (citing 5 U.S.C. § 706).

The '205 application discloses "methods for treating neurological . . . disorders in humans by administering a [TNF-α inhibitor]." '205 application ¶ 31. The specification distinguishes between local and systemic delivery of TNF-α inhibitor and lists several unique benefits of local administration. For instance, the '205 application explains that the "[l]ocal perispinal administration [] has the advantage of providing a depot of therapeutic medication in the surrounding tissue, which will provide therapeutic levels of medication to the treatment site for a prolonged period of time." *Id.* ¶ 34. The application also states that local delivery of TNF-α inhibitor "produces . . . greater efficacy[,] more rapid onset, [and] longer duration of action." *Id.* ¶ 114.

The disclosure lists perispinal administration as a preferred form of localized administration of a TNF-α inhibitor. *Id.* ¶ 49. The specification defines perispinal administration as including a number of different administration techniques. One such technique is an epidural injection adjacent to the site of disc herniation. *Id.* ¶ 47 ("In another preferred embodiment injection of the therapeutic molecule to the anatomic area adjacent to the disc herniation is accomplished by epidural injection.").

A person of ordinary skill in the art would understand this type of epidural injection to be an injection into the location where the TNF-α is injuring spinal nerves. As explained above, nucleus pulposus leaks from an injured spinal disc into the epidural space, where spinal nerve roots are located. The '995 specification recognizes that TNF-α in the epidural space harms adjacent nerve roots. *See* '995 patent at col. 22 ll. 37-44. Thus, an epidural injection adjacent to the site of disc herniation will administer the drug "directly to the site where it is intended to

act, that is, to the location where the nucleus pulposus is causing the symptoms of the nerve disorder."

Olmarker contends that the '205 application does not adequately describe local administration because it mixes local administration techniques with non-local techniques. According to Olmarker, the '205 application teaches that "anatomic proximity" can include an area as far as ten centimeters from the spine. Because that area is "a very large portion of the body," Olmarker argues that this teaching refers to systemic, rather than local, administration. By defining the anatomic proximity so broadly, Olmarker argues, the '205 application redefines non-local methods of administration as local methods of administration. Olmarker supports this argument with expert testimony by Dr. Andersson that administering the medicine to the anatomic area adjacent to the disc herniation is not local administration because it is not administered directly to the nerve root.

We are not persuaded by Olmarker's argument. The specification plainly describes localized, epidural injection of a TNF-α inhibitor. *See* '205 application ¶ 47 ("In another preferred embodiment injection of the therapeutic molecule to the anatomic area adjacent to the disc herniation is accomplished by epidural injection."). Because the epidural space is precisely the area in which the nerve root extends from the spinal cord, the TNF-α administration described in the '205 application is made "directly to the site where it is intended to act, that is, to the location where the nucleus pulposus is causing the symptoms of the nerve disorder." While the "perispinal" administration discussed in the '205 application certainly covers more than just local administration techniques, this does not render all perispinal techniques non-local. Some techniques may be local, others may not. 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 of local admin-

istration. The epidural injection technique is such an embodiment.

For the above reasons, we conclude that the Board's finding of lack of adequate written description is not supported by substantial evidence. Accordingly, we reverse the Board's decision to dismiss the interference and remand for further proceedings.

REVERSED