NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

BOSTON SCIENTIFIC CORP., RELIEVANT MEDSYSTEMS, INC.,
Plaintiffs-Appellants

v.

STRYKER CORPORATION,
Defendant-Appellee

2026-1171

Appeal from the United States District Court for the District of New Jersey in No. 2:25-cv-12700-EP-JSA, Judge Evelyn Padin.

Decided: June 17, 2026

MATTHEW WOLF, Arnold & Porter Kaye Scholer LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by NICHOLAS M. NYEMAH.

NATHANIEL C. LOVE, Sidley Austin LLP, Chicago, IL, argued for defendant-appellee. Also represented by MARY T. HANNON, STEPHANIE P. KOH; SHARON LEE, New York, NY.

Before DYK, REYNA, and STARK, *Circuit Judges*.

DYK, *Circuit Judge*.

Boston Scientific Corp. and Relievant Medsystems, Inc. (together, "Boston Scientific") appeal a decision of the United States District Court for the District of New Jersey denying Boston Scientific's request for a preliminary injunction. The requested injunction would restrain Stryker Corporation ("Stryker") from launching its OptaBlate BVN product on grounds that its sale would induce infringement of claims 16 and 21 of U.S. Patent No. 12,303,166 (the "'166 patent"). Because we agree with the district court that there are substantial questions as to whether Stryker induced infringement of the asserted claims, we *affirm*.

BACKGROUND

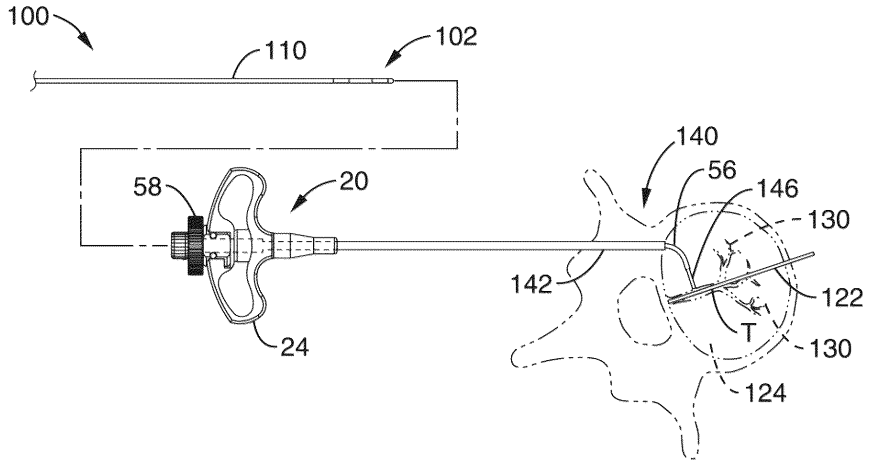
The human spine is made of bony vertebrae separated by discs. Between the vertebrae and the discs are vertebral endplates. When these endplates are damaged, it can lead to chronic low back pain. The basivertebral nerve transmits those pain signals, and the pain can be decreased when that nerve is therapeutically destroyed or disrupted through a process called ablation. As relevant to this case, the '166 patent claims a method of using a radiofrequency probe to ablate the basivertebral nerve in a vertebral body of a patient. *See* '166 patent claims 16, 21.

The basivertebral nerve is difficult to reach because it is located within the interior cancellous (spongy) bone of the vertebral body, which is near and anterior to the spinal cord. Therefore, to expose the basivertebral nerve to the radiofrequency energy, a physician must navigate the radiofrequency probe around the spinal column, through the cortical (dense) bone covering the vertebra, and into the cancellous interior of the vertebral body while also ensuring the probe is not too close to the spinal cord that it risks

damaging the large and important nerves in the spinal cord.

The '166 patent claims methods for accessing and ablating the basivertebral nerve. A needle trocar—essentially a long, straight, and narrow tube for inserting instruments into the body—establishes a straight path from the outside of the body to the cancellous interior of the vertebral body. To allow the trocar to enter the body, a straight stylet with a sharp tip that pierces bone is inserted into the trocar such that the sharp point extends beyond the distal tip of the trocar. The assembly of the trocar and the stylet enter the patient's back at an angle and is "advanced through soft tissue to the surface of the [vertebral] bone" and then "through the cortical shell of [the] pedicle [a bony protrusion from the vertebra] and into the cancellous interior . . . of the bone." '166 patent, col. 7 ll. 43–48. The straight stylet is then removed, and a curved cannula is inserted into the trocar with the aid of a straightening stylet. With the aid of a curved stylet, the curved cannula is advanced beyond the tip of the trocar to generate a curved path through the cancellous bone. Then, a channeling stylet is used to create a working channel from the tip of the curved cannula to the target treatment zone in the center of the vertebral body. The radiofrequency probe is then delivered to the treatment site where it ablates the nerve by heating it.

Figure 4F illustrates this probe at the treatment site within the vertebra, labeling the trocar (20) and the cancellous region of the bone (124).



J.A. 61.[1]

Claim 16 is exemplary and recites in relevant part:

A method of ablating a basivertebral nerve in a vertebral body of a patient, the method comprising:

inserting an introducer through a pedicle of the vertebral body such that an opening at a distal tip of the introducer reaches a cancellous portion of the vertebral body,

the introducer having a handle coupled to a shaft defining a central channel in communication with the opening,

wherein inserting the introducer comprises inserting a stylet into the central channel of the introducer such that the stylet extends beyond the opening at the distal tip of the introducer and advancing the introducer and stylet simultaneously such that the stylet pierces bone as the introducer

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[1] Citations to the "J.A." refer to the corrected confidential joint appendix filed by the parties. Dkt. No. 34.

> is delivered through the pedicle of the vertebral body;
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> delivering an instrument through the central channel of the introducer, the instrument comprising a proximal portion, a distal deflectable section, and a rotatable element at the proximal portion of the instrument,
>
> wherein the distal deflectable section of the instrument is configured to penetrate the cancellous portion of the vertebral body to form a curved path;
>
> initiating a first rotation of the rotatable element;
>
> advancing the distal deflectable section of the instrument past the opening at the distal tip of the introducer to a target area proximal to a junction of the basivertebral nerve,
>
> wherein a second rotation of the rotatable element occurs when the distal deflectable section of the instrument is deployed at an angle of 5 degrees to 90 degrees;
>
> and applying bipolar radiofrequency energy between a first electrode and a second electrode of a bipolar RF probe disposed in the curved path at a treatment location immediately adjacent to the basivertebral nerve in the target area to ablate at least a portion of the basivertebral nerve.

'166 patent, claim 16 (emphasis and line breaks added). The parties agree the claimed "introducer" refers to the described trocar.

Stryker's OptaBlate BVN device is designed to ablate the basivertebral nerve to treat chronic low back pain, and Stryker sought FDA approval using Boston Scientific's previously approved product as a predicate device. Boston Scientific filed this action after Stryker announced FDA

clearance for its product and commenced plans to market the product.

Boston Scientific moved for a preliminary injunction, arguing that it was likely to succeed on the merits of its theory that Stryker's planned activities would make it liable for induced infringement of claims 16 and 21 of the '166 patent. Boston Scientific's theory was that the OptaBlate BVN's "access cannula" corresponded to the claimed "introducer." Stryker argued that it did not induce infringement of that limitation because Stryker did not instruct physicians to place the access cannula so that it "reaches" the cancellous portion of the bone. Although the parties disputed the meaning of the term "reaches," neither party in their briefs presented any substantive argument or identified intrinsic or extrinsic evidence as to the proper construction. The district court concluded that the "reaches" limitation required that the distal tip of the introducer "touch[] or extend[] to" the cancellous portion of the vertebral body and that the evidence did not sufficiently demonstrate that Stryker instructed physicians using its device to extend the access cannula to reach the cancellous bone. J.A. 12–14. The district court therefore denied the preliminary injunction, concluding that Boston Scientific had not demonstrated a likelihood of success on the merits or that an injunction would be in the public interest.

Boston Scientific appeals. We have jurisdiction under 28 U.S.C. §§ 1292(c)(1), 1295(a)(1).

DISCUSSION

We review the denial of a preliminary injunction for abuse of discretion. *Incyte Corp. v. Sun Pharm. Indus., Ltd.*, 135 F.4th 1381, 1383 (Fed. Cir. 2025). It is an abuse of discretion for a district court to base its ruling upon an error of law or a clearly erroneous factual finding. *Id.*

"A preliminary injunction is a 'drastic and extraordinary remedy that is not to be routinely granted.'" *Nat'l Steel Car, Ltd. v. Can. Pac. Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004) (quoting *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir.1993)); *accord High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1554 (Fed. Cir. 1995). Before a preliminary injunction may be granted, the moving party must establish a likelihood of success on the merits. *BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1398 (Fed. Cir. 2022). In a patent case, this requires demonstrating there is no substantial question as to infringement of the asserted claims. *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1364 (Fed. Cir. 2017); *accord Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 866 (Fed. Cir. 2017) ("A preliminary injunction should not issue if the accused infringer 'raises a substantial question concerning validity or infringement.'" (quoting *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001))).

On appeal, Boston Scientific argues the district court applied an incorrect claim construction; under the correct construction, Stryker would induce infringement. It also argues that even under the district court's construction, it had shown that it was likely to succeed on the merits.

I

The claims require that the "opening at [a/the] distal tip of the introducer reaches a cancellous portion of the vertebral body." '166 patent, claims 16, 21. The parties dispute the meaning of the term "reaches." The district court concluded that to "reach[]" the cancellous portion, the opening at the distal tip of the introducer must "touch[] or extend[] to" the cancellous portion, which both parties view as requiring the tip to physically touch the cancellous bone. Boston Scientific argues this was legal error and that under the proper construction of "reaches," the distal tip of

the introducer need only approach near, or create access to, the cancellous portion of the vertebral body and does not need to touch the cancellous bone.

Claim construction is a question of law that potentially contains underlying questions of fact. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331–32 (2015). We review the district court's findings of fact relating to extrinsic evidence for clear error and its ultimate claim construction de novo. *Id.* In this case, the district court has yet to conduct formal claim construction, and given the preliminary nature of the district court's construction, we need not decide the ultimate proper construction of the claims ourselves. *See Jack Guttman, Inc. v. Kopykake Enters.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) ("[W]e will not lightly intrude upon a district court's discretionary decision to issue only a tentative claim construction and to base its resolution of a preliminary injunction motion upon that tentative claim construction.").

In their briefing before the district court, the parties made no substantive arguments as to the proper construction of "reaches" and did not identify any extrinsic or intrinsic evidence bearing on this issue. As the district court described it, they "barely address[ed]" the issue, did not "identify any intrinsic evidence," and their experts did not "suggest that the term 'reaches' has any special meaning in the art." J.A. 12. Instead, they implicitly construed "reaches" in arguing for and against infringement. Boston Scientific bore the burden to demonstrate that it was likely to succeed on the merits, which here required demonstrating that its construction was likely correct or that it was likely to prove infringement even under the district court's construction. On this sparse record, we see no abuse of discretion in the district court's conclusion that Boston Scientific failed to meet its burden. *See Int'l Commc'n. Material, Inc. v. Ricoh Co.*, 108 F.3d 316, 318 (Fed. Cir. 1997) (finding no abuse of discretion in denial of preliminary injunction where district court determined that "'there are

substantial open issues and questions that must be litigated' pertaining to claim construction and has made a determination that the movant is unlikely to succeed on the merits (prove infringement)").

The contested limitation is facially ambiguous as to whether the plain and ordinary meaning of "reaches" means touches or also includes arriving in the proximity of. As the parties recognize, there are multiple recognized meanings of the term "reach," some of which could support Boston Scientific's construction and others that support Stryker's construction. *See Webster's Third New Int'l Dictionary* 1888 (2002) (noting that "reach" can mean "extend to," "arrive at," "come to," or "get up to or as far as"); 13 *Oxford English Dictionary* 251–255 (2d ed. 2004) (noting that "reach" can mean "[t]o succeed in touching," "[t]o come into contact with," "to come to, arrive at," or "to get up to or as far as"). Boston Scientific admits that "'reaches' can also include scenarios involving physical contact." Appellants' Br. 28. While it appears that the most common dictionary definition supports the district court's construction, given the lack of a definitive definition, dictionaries are of limited help in this context. The question is what the plain and ordinary meaning would be to a skilled artisan in light of the intrinsic record. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 1315 (Fed. Cir. 2005) (en banc).

On appeal, Boston Scientific makes additional arguments as to claim construction based on the intrinsic record not presented to the district court. Even considering these arguments, uncertainty as to the construction of the claim language raises a substantial question of infringement in this case.

Where a claim term is capable of multiple meanings, the disclosed embodiments can inform which meaning is intended. *See Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1303–04 (Fed. Cir. 2001); *Monsanto Tech LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336,

1341–42 (Fed. Cir. 2018). In a preferred method, the specification describes the assembly of the trocar and stylet being "advanced through the cortical shell of [the] pedicle and into the cancellous interior of the bone." '166 patent, col. 7 ll. 43–48 (reference numbers omitted). In the summary, the trocar is described as being "inserted through a cortical bone region and into a cancellous bone region of a vertebrae." *Id.* col. 4 ll. 44–48. These aspects of the specification lend support to the district court's construction, but they do not use the word "reaches" to describe the placement of the trocar. Additionally, Boston Scientific argues that achieving the purposes of the method does not require physical touching of the distal tip to the cancellous region so long as the stylet creates a path to the cancellous bone.

The terms "reaches" and "reached" are only used a couple of times in the specification and only to describe the channeling stylet—a different instrument from the introducer and straight stylet—reaching the "target treatment zone." *Id.* col. 8 ll. 61–65, col. 11 ll. 28–31. In these instances, the channeling stylet bores through bone to create "a working channel" through the bone, *id.* col. 8 ll. 61–63, that allows a treatment device to be placed at the appropriate treatment site, *id.* col. 11 ll. 28–31. The abstract also uses the term "reaches" in the same manner as the asserted claims but does not provide additional insight into the term's meaning. *Id.*, at Abstract.

At oral argument, Boston Scientific argued that numbered embodiment 10 in the specification lends support for its construction because embodiment 10 discloses a broader embodiment that does not require the trocar be placed in the cancellous bone, as made clear by the language of embodiment 18. The '166 patent states that "the present invention includes the following inventive embodiments among others," *id.* col. 12 ll. 49–50, including:

> 10. A method for channeling a path into bone to a treatment location in the body of a patient,

> comprising: inserting a trocar into a region of bone near the treatment location . . . .
>
> . . .
>
> 18. A method as recited in embodiment 10, wherein the trocar is inserted through a cortical bone region and into a cancellous bone region of a vertebrae . . . .

Id. col. 13 ll. 45–60, col. 14 ll. 49–54 (emphases added). Because embodiment 18 is differentiated from embodiment 10 based on the requirement that the trocar is inserted into the cancellous bone, Boston Scientific reasons embodiment 10 must not require inserting the trocar "into" cancellous bone. This argument cannot carry Boston Scientific's burden at the preliminary injunction stage. Embodiment 10—unlike claims 16 and 21—is not restricted to methods for accessing the basivertebral nerve in the vertebral body. The mere fact that the specification states that "the present invention includes" embodiments 10 and 18 does not mean that embodiments 10 and 18 are within the scope of the asserted claims. This is particularly so because neither described embodiment uses the term "reaches." This evidence therefore does not establish that Boston Scientific is likely to succeed on its claim construction at this preliminary stage.

The parties here also have not mined the prosecution history to address the reason patentee added the term "reaches" to the asserted claims and whether such addition was used to distinguish the prior art.[2]

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[2] The '166 patent shares a specification with several other patents. The first patents issued in the family did not have a "reaches" limitation and instead explicitly claimed inserting the introducer "into . . . cancellous bone" or "into a cancellous region." *E.g.*, U.S. Patent

On this record, we conclude that the district court did not abuse its discretion in tentatively adopting Stryker's construction. We note that the district court has scheduled a claim construction hearing at which the parties may present additional argument and evidence that may bear on the construction of the claims.

II

As to the application of the district court's construction to the facts of this case, we again see no error at this preliminary stage. Boston Scientific contends that even under the district court's construction, it sufficiently demonstrated that Stryker induces infringement of the '166 patent because Stryker instructs physicians to place its access cannula such that it touches the cancellous bone of the vertebral body. Stryker argues that the record establishes that it instructs physicians to place the access cannula short of reaching the cancellous bone. We have reviewed the record and conclude that Stryker has at least raised a substantial question of noninfringement as to this issue.

First, Boston Scientific points to a slide show that Stryker uses to train physicians to use its product. This slide show contains many variations of an illustrated vertebra with the access cannula inserted, but the tip of the access cannula is not clearly touching the cancellous bone. The slide show also contains medical imaging photographs that appear to show the access cannula, but again it is unclear where the cancellous bone region begins in the images, so these are also inconclusive. There is some text on

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No. 8,419,730, claim 20; U.S. Patent No. 9,259,241, claim 10; U.S. Patent No. 10,265,099, claim 13. The "reaches" limitation apparently only arose after a rejection in a subsequent patent application. *See* U.S. Patent Application No. 16/368,453 (Dec. 6, 2023) (Claims).

slides that states, "[f]inal position should be just inside the vertebral body," J.A. 9829, 9840, and Stryker's expert admitted that "[t]he inside of the vertebral body is made of cancellous bone," J.A. 12529. But it is unclear whether the slides are referring to the final position of the distal tip of the access cannula or the tip of the stylet that extends from the access cannula. Similarly, a slide show presented internally to sales personnel instructs "to enter just inside the vertebral body past posterior wall," but it is again unclear whether this is referring to the access cannula or the tip of the stylet. J.A. 9733; *see also* J.A. 9734 (specifying that the stylet tip is placed "just at or just inside posterior wall of the vertebral body"); J.A. 9735 ("It is ok if the access cannula is shy of the posterior wall"). The expert declarations supplied by the parties present conflicting views as to how to interpret these documents. The district court reasonably considered evidence that Stryker instructed that the "stylet tip should barely—if at all—enter the vertebral body," i.e., the cancellous bone, J.A. 17 (emphasis omitted), and concluded that the slides' reference to "[f]inal position should be just inside the vertebral body" could be referring to the final position of the stylet tip rather than the tip of the access cannula. There is no abuse of discretion, or clear error, in the district court finding such ambiguous evidence raises a substantial question of infringement.

Second, Boston Scientific argues that other Stryker publications instruct that the access cannula should be placed "inside the posterior wall of the vertebral body." J.A. 12479, 12866. Boston Scientific appears to contend that by instructing a physician to place the access cannula inside the wall of the vertebral body, Stryker instructs placing the tip of the access cannula through the wall and inside the vertebral body rather than literally inside the wall itself, which is made of cortical bone. As the district court reasonably concluded, this could be read as instructing physicians to place the access cannula such that it reaches the cortical wall rather than the cancellous

portion. This evidence also does not establish a likelihood of success for Boston Scientific.

Third, Boston Scientific relies on an internal Stryker document that describes the access cannula as being "placed within the cancellous bone of the spine." J.A. 12858. While this may well support Boston Scientific's position, it cannot carry Boston Scientific's burden to show no substantial question of infringement exists, as it is an internal document, there is no contention that it was given to users of the OptaBlate BVN, and Boston Scientific has not proven what (if any) impact this or other internal materials have on what Stryker conveys to others. Finally, Boston Scientific points to a diagram in the OptaBlate BVN instructions for use that shows a tube of some kind placed within the cancellous bone. J.A. 12017. Stryker's expert argued that the tube illustrated was not the access cannula, but the curved conduit, a separate tool that Boston Scientific argues maps onto the claimed "instrument" rather than the claimed "introducer". J.A. 8226–27. The district court reasonably concluded that Stryker's interpretation would "not only be consistent with the step-by-step guide and marketing materials discussed above, but it would also be consistent with other disclosures in the same set of instructions." J.A. 18 (emphasis omitted). Thus, whether considering Boston Scientific's evidence individually or collectively, there is a substantial question of infringement under the district court's construction.

III

Boston Scientific alternatively argues that it sufficiently demonstrated a likelihood of success on the merits of its doctrine of equivalents argument. Before the district court, Boston Scientific raised this argument without elaboration in a footnote in its opening brief that cited to a single paragraph in an expert declaration. The district court did not abuse its discretion by concluding that the argument was forfeited because it was only raised in a footnote.

Nonetheless, the district court chose to address it and determined that Boston Scientific had failed to establish its likelihood of success on this issue.

Boston Scientific's expert testified that even if the OptaBlate BVN's access cannula did not literally "reach" the cancellous portion, stopping just short of the cancellous bone would still "create a working channel . . . to access the cancellous portion of the vertebral body," so the difference was insubstantial and the OptaBlate BVN still performed the same function in the same way to achieve the same result as the claimed invention. J.A. 319–20. Stryker has introduced competing evidence that tends to show that varying the location of the final placement of the introducer would be a substantial difference because the tip of the introducer determines the final placement of the radiofrequency probe. For example, Stryker's expert testified that "if the distal opening of Stryker's access cannula were within the cancellous portion of the vertebral body, then the . . . RF probes[] would be located more anteriorly and not in the target ablation zone." J.A. 8236–37. Boston Scientific does not seem to dispute that the depth of the access cannula impacts the placement of the probe but rather argues that the difference is insubstantial because the change in placement can be negated by other adjustments. *See* J.A. 8746 (Boston Scientific's expert agreeing that "the location of the distal opening of the access cannula" is "[t]he main factor that controls where . . .the tip of the probe ends up within the vertebral body"). However, Boston Scientific's own materials warn that if the cannula tip is placed "too deep," then the end point of the probe would be too anterior to reach the treatment site. J.A. 12275.

Doctrine of equivalents infringement is a "highly factual inquiry [that] rarely comes clear on a premature record." *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1384 (Fed. Cir. 2000). To succeed on such an argument, a patentee carries the burden to present "particularized testimony and linking argument" that can allow a factfinder

to discern between infringing equivalents and non-infringing alternatives to the patented invention. *Tex. Instruments v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1566–67 (Fed. Cir. 1996); *NexStep, Inc. v. Comcast Cable Commc'ns, LLC*, 119 F.4th 1355, 1371 (Fed. Cir. 2024). On this record—and given the limited footnote argument in Boston Scientific's opening brief before the district court—Stryker's conflicting evidence as to the substantiality of the differences between the instructions given as to the use of Stryker's product and the claimed invention raises a substantial question of infringement.

Boston Scientific has not carried its burden to establish that it has a likelihood of success on the merits. We therefore conclude that the district court did not abuse its discretion in denying the preliminary injunction.

We have considered Boston Scientific's remaining arguments and find them unpersuasive.[3]

AFFIRMED

COSTS

Costs to Stryker.

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[3] Boston Scientific also argued that a preliminary injunction was warranted based on Stryker's liability for contributory infringement. Because Boston Scientific raises no additional arguments as to contributory infringement, we also affirm the district court's decision in that respect.