United States Court of Appeals for the Federal Circuit

00-1453

BIONX IMPLANTS, INC.,
BIONX IMPLANTS, OY, and DR. SAUL N. SCHREIBER,

Plaintiffs-Appellants,

v.

LINVATEC CORPORATION,

Defendant-Appellee.

Paul M. Richter, Jr., Kenyon & Kenyon, of New York, New York, argued for plaintiffs-appellants. On the brief was Richard L. DeLucia, of New York, New York. Of counsel were Michael D. Loughnane, Jeffrey M. Butler, and Richard L. Mayer of New York, New York; and C. Kyle Musgrove and John R. Hutchins of Washington, DC.

John J. Normile, Pennie & Edmonds LLP, of New York, New York, argued for defendant-appellee. With him on the brief were Bruce J. Barker, John D. Garretson, and Claudia DP Zumbro.

Appealed from: U.S. District Court for the Southern District of New York

Judge Jed S. Rakoff

United States Court of Appeals for the Federal Circuit

00-1453

BIONX IMPLANTS, INC.,
BIONX IMPLANTS, OY, and DR. SAUL N. SCHREIBER,

Plaintiffs-Appellants,

v.

LINVATEC CORPORATION,

Defendant-Appellee.

DECIDED: August 15, 2002

Before NEWMAN, RADER, and BRYSON, Circuit Judges.

BRYSON, Circuit Judge.

Bionx Implants, Inc., and two related parties, Bionx Implants, OY, and Dr. Saul N. Schreiber, (collectively, "Bionx") brought suit against Linvatec Corporation for infringement of United States Patent No. 4,873,976 ("the '976 patent"). The United States District Court for the Southern District of New York granted Linvatec's motion for summary judgment of noninfringement. Based on the court's interpretation of the term "rigid" in the claims of the '976 patent, the court held that the accused device did not infringe the asserted claims. We uphold the district court's claim construction but vacate the order entering summary judgment for the defendant and remand the case for further proceedings.

I

The '976 patent relates to a surgical fastener that is particularly adapted to repairing tears in the meniscus of the knee. The human knee joint contains two

crescent-shaped menisci, which serve as a cushion for the thigh bone. Each meniscus consists of relatively tough fibrous cartilaginous tissue. The meniscus, however, is subject to tearing when subjected to extreme distortion, as in the case of certain sports injuries. Various surgical procedures have been used to hold the torn elements of the injured meniscus in the appropriate position for proper healing. The ’976 patent recites one such procedure and the device employed in that procedure.

The suturing device of the ’976 patent is a rigid barbed shaft that is inserted by pushing it into the meniscus so that it joins the portions of the torn meniscus on either side of the tear. After the shaft is inserted so that it straddles the tear, the two portions of the meniscus are held together by pressure between the barb in the tissue on one side of the tear and the base member that rests on the outer surface of the meniscus on the other side of the tear. The claimed shaft and its use in repairing a torn meniscus are illustrated in Figures 4 and 10 from the ’976 patent, reproduced below. Figure 4 depicts the claimed shaft, and Figure 10 depicts a top view of a torn meniscus with three of the claimed shafts extending across the tear.

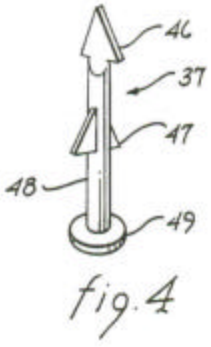

fig. 4

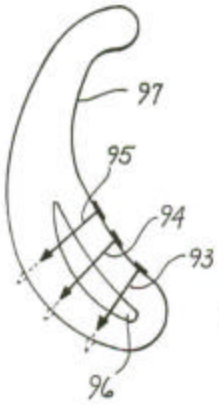

fig. 10

The patent explains that the invention minimizes the risk of damaging neurovascular structures located behind the knee, in contrast to traditional surgical techniques, which are more invasive. Bionx further claims that the suture embodied in

the ’976 patent can be inserted more rapidly than traditional fasteners and that it also reduces patient trauma and healing time.

In 1996, under a license from Dr. Schreiber, Bionx began marketing and selling the Bionx Meniscus Arrow, a commercial embodiment of the invention of the ’976 patent. In 1998, Linvatec introduced a competing suture called the BioStinger. Like the Meniscus Arrow, the BioStinger suture has a barbed shaft, but it is made of more flexible material. The BioStinger also differs from the Meniscus Arrow in that it has a bore running lengthwise through its shaft. Before use, a guide needle is advanced through the bore of the BioStinger so that it protrudes through a hole in the tip of the shaft. A pusher rod is then used to advance the suture into the damaged tissue through a channel cut by the guide needle. When the suture is fully implanted, the needle is withdrawn, and shaft remains to hold the torn portions of the tissue together for proper healing.

Bionx filed suit charging that the BioStinger and the method of using it infringed the ’976 patent. Linvatec moved for summary judgment, arguing that its device was not “rigid” within the meaning of the asserted claims. The district court agreed and granted Linvatec’s motion. First, the court construed the term “rigid” to mean rigid enough “to be pushed directly through the semi-hard cartilage of a meniscus without any precutting.” The court then held that Bionx’s evidence was insufficient to raise a genuine issue of material fact as to whether the BioStinger was capable of being pushed through uncut meniscal tissue.

II

Bionx argues that the district court erred in its claim construction and that even under the claim construction the court adopted, it erred by granting summary judgment to Linvatec. We disagree with Bionx on the first point, but agree on the second.

A

As to the claim construction issue, Bionx argues that the district court adopted too restrictive a construction of the term "rigid," which is used in each of the asserted claims. The district court construed the term to require that the claimed suture be sufficiently rigid to be pushed through meniscus tissue without a pre-cut channel for the suture to follow. Bionx disagrees and argues that the term "rigid" should be construed to apply to any shaft that is capable of being pushed through tissue, regardless of whether the tissue is pre-channeled. Thus, in Bionx's view, the term "rigid" is used to distinguish the claimed suture from ordinary flexible sutures that are wholly lacking in rigidity and cannot be pushed through any kind of tissue, whether pre-channeled or not.

Claims 1 and 19 of the '976 patent are representative. They provide as follows (emphasis added):

> 1. A single unit suture for body tissue repair comprising:
>
> a solid base member for seating against an exterior surface of said tissue;
>
> a single rigid shaft portion upstanding from and integrally connected to said base member adapted for insertion into said tissue; and
>
> barb means integrally connected to said portion to aid in insertion of said shaft portion into said tissue and to lock said shaft portion into said tissue.
>
> 19. A method for repairing a tear in a meniscus which comprises the steps of:
>
> providing a single unit suture having a solid base member, a single, rigid shaft portion upstanding from and integrally connected to said base member, and barb means located on and integrally connected to said shaft portion;
>
> preparing the medial surface of said meniscus for insertion of said suture; and
>
> inserting said suture into said meniscus, through said prepared surface and through said tear to join together opposing edges of said tear for repairing said tear and leaving said base member external to said meniscus.

The claim language itself offers no real guidance as to the proper construction of the term "rigid," so the district court turned to the specification and prosecution history of the

patent. As the district court noted, the relevant portion of the written description states that "[s]utures, in accordance with the invention, . . . are formed of a material having sufficient rigidity to allow the sutures to be pushed through the tissue to be repaired." '976 patent, col. 2, l. 66, to col. 3, l. 1. Bionx, however, reads "tissue to be repaired" to refer not only to uncut tissue, but also to tissue that has been pre-channeled with a cutting device such as the needle used with Linvatec's BioStinger. Bionx reaches that conclusion based on the statement at the end of the written description that one embodiment of a suture insertion device may be equipped with a "blade end . . . for creating or initiating a channel in the tissue for the suture to pass through." Id., col. 4, ll. 7-9. In Bionx's view, that statement requires the "tissue to be repaired" language at column 3, line 1 to be construed to mean "either uncut or pre-cut tissue to be repaired."

The district court correctly observed that the brief reference to the possible use of a suture in a device that uses a blade to cut a channel in tissue does not bear on the definition of the term "rigid." The portion of the written description on which Bionx relies merely explains that a suture rigid enough to be pushed through uncut tissue may also be used in a pre-cut channel; it does not suggest that a suture would be "rigid" if it could be pushed through a pre-cut channel but could not be pushed through uncut tissue.

The written description makes clear that, to be "rigid" within the meaning of the claims of the '976 patent, a suture must be sturdy enough to be "pushed through the tissue to be repaired." The use of the term "pushed" implies that the "tissue to be repaired" is uncut, for in referring to tissue that is pre-channeled, the patent describes the suture as "pass[ing] through" the tissue rather than being "pushed" through it. Thus, the primary passage on which Bionx relies actually supports the district court's construction of the claim language.

The prosecution history of the '976 patent confirms that the district court's interpretation is correct. In attempting to distinguish his claims over a prior art patent to Kronenthal, the inventor submitted an affidavit stating that the Kronenthal device "is not a rigid type of suture as I have disclosed and claimed in my above noted patent application, but is a flexible type of filament which cannot by itself be pushed into a body tissue without the use of a needle." Bionx argues that the inventor's statement stands only for a limited proposition: that the "floppy" Kronenthal device is distinguishable from the more rigid device of the Bionx invention. Linvatec, on the other hand, contends that the inventor was making the point that a suture is not "rigid" if it is designed to be inserted with the use of a needle.

Both parties are incorrect. Linvatec reads the prosecution history too broadly. The inventor did not assert that a suture is "non-rigid" simply because it is inserted using a needle. By the same token, Bionx's reading of the prosecution history is too narrow. The significance of the inventor's statement is not the fact that he distinguished his device from the dissimilar Kronenthal device, but the reason he gave for drawing that distinction. In stating that the "flexible" Kronenthal device, unlike the "rigid" claimed suture, "cannot by itself be pushed into body tissue without the use of a needle," the inventor was making clear that he was using the term "rigid" to refer to a suture that was rigid enough to be pushed into uncut tissue, i.e., "without the use of a needle." The district court's claim construction was therefore correct.

B

Bionx makes the alternative argument that even under the district court's definition of "rigid" the BioStinger infringes the '976 patent. At a minimum, Bionx contends, there is a genuine issue of material fact as to that question, making it inappropriate to grant summary judgment to Linvatec.

In the district court, Bionx offered as evidence a videotaped demonstration that showed the BioStinger being pushed into uncut meniscal tissue. The district court discounted the videotape, however, because "the insertion was made possible only by use of a special 'insertion rod' that plaintiffs concede was designed specifically for the videotaped demonstration." Citing this court's decision in High Tech Medical Instrumentation, Inc. v. New Image Industries, Inc., 49 F.3d 1551, 33 USPQ2d 2005 (Fed. Cir. 1995), the district court concluded that the demonstration was insufficient to defeat summary judgment because it ran afoul of "the well-established rule that a device does not infringe merely because it can be altered to make it infringe."

In High Tech, the asserted claim recited a "camera . . . rotatably coupled" to a "body member." The camera in the accused device could be made to rotate, but only if the user loosened two set screws that secured the camera to its housing. The High Tech court noted that the fact that it was possible to alter the camera so that it could be made to rotate was not enough, by itself, to justify a finding of infringement. The court explained that there was no evidence that the device was designed to be altered in that manner, there was no reference to the rotation of the camera in the defendant's manual or promotional materials, and there was no evidence that any user of the camera had loosened or removed the set screws in actual use. For that reason, we held that there was "no reason to disregard the set screws" in the infringement analysis. 49 F.3d at 1556, 33 USPQ2d at 2009.

In this case, Bionx did not modify the BioStinger in the course of conducting its videotaped demonstration, but instead, used a cannula, or hollow rod, to assist in the process of inserting the BioStinger into meniscus tissue. The district court regarded the use of the cannula as a modification of the device that made the videotaped demonstration irrelevant as evidence of infringement.

We do not believe the use of the cannula constituted an impermissible alteration of the accused device analogous to removal of the set screws in High Tech. Applying the rationale underlying the High Tech decision, we determine whether the accused shaft was "rigid" within the meaning of that term as used in the '976 patent by determining whether the shaft is rigid enough to be pushed through uncut meniscal tissue in the same general circumstances in which the patented device was designed to be used. Thus, the accused device would not be shown to be "rigid" if it were frozen in liquid nitrogen before being inserted into the meniscus tissue, or if it were shot as a high-speed projectile into the meniscus. Those conditions would differ too dramatically from the conditions of contemplated use for the patented device; the definition of "rigid" that the district court derived from the text and prosecution history of the patent would not be satisfied in those circumstances.

In this case, however, the use of a cannula to insert the BioStinger into meniscal tissue was within the context in which the patent contemplated that the claimed invention would be used. The written description of the '976 patent describes two methods of inserting the claimed suture. In the first embodiment, the suture is inserted into the tissue to be repaired through a "hollow outer sleeve or cylinder" using a "pusher" sized to fit through the center of the cylinder. '976 patent, col. 3, ll. 50-57. The patent also describes an embodiment in which a pusher mechanism with "spring grasping means" forces the suture through an applicator cylinder into the tissue. Id., col. 4, ll. 1-5.

The '976 patent therefore makes clear that a suture that is inserted into uncut tissue through an applicator cylinder is "rigid." For that reason, the fact that Bionx used an "insertion rod" in its videotaped demonstration presented to the district court does not, by itself, constitute an impermissible alteration of the accused device that renders

the videotaped demonstration an invalid test of whether the accused device is "rigid." Accordingly, we conclude that the district court erred by granting summary judgment to Linvatec based primarily on the fact that Bionx used a cannula in its videotaped demonstration.

Linvatec contends, however, that because the BioStinger is not commercially used with a cannula, Bionx's test is inappropriate as a matter of law, arguing that "the only evidence competent to prove infringement is evidence of how the BioStinger suture is actually inserted." That assertion misses the point. The question before the district court was whether the BioStinger is "rigid" within the meaning of the patent. The patent makes clear that the term "rigid" requires that the suture be able to be pushed through uncut meniscal tissue under the circumstances of use contemplated in the patent, i.e., under circumstances that can include the use of a cannula in the insertion process. For that reason, it is irrelevant whether the BioStinger is ever used with a cannula. What matters is whether it is rigid enough to enter the meniscus without a pre-cut channel under the circumstances outlined in the patent. In short, Bionx's use of a cannula in its videotaped demonstration does not render that test irrelevant as a matter of law, since that method of insertion accords with the method described in the '976 patent. The district court's grant of summary judgment of infringement therefore cannot rest on its stated reasoning.

Linvatec contends that Bionx's videotaped demonstration was flawed in other respects. For example, Linvatec argues that in Bionx's demonstration the BioStinger was inserted into uncut tissue only through the use of clinically inappropriate force. Linvatec is correct that in order for the test to be of evidentiary value the BioStinger must be inserted using a degree of force and method of insertion that would be used in a surgical context. The district court, however, did not rest its summary judgment ruling

on the ground that the BioStinger was forced into the meniscal tissue through the use of a method that would never be used in a surgical context. For that reason, we do not reach the merits of that contention. The district court may choose to address that issue on remand, as well as Linvatec's argument that the BioStinger does not satisfy other limitations of the asserted claims. We vacate the summary judgment because the ground on which the district court did rely—the use of a cannula to insert the BioStinger in the videotaped demonstration—did not render the test invalid on the ground that it constituted an alteration of the BioStinger or the context in which the rigidity of the patented device was to be judged.

VACATED and REMANDED.