

Keywords: prosecution history estoppel; claim construction; doctrine of claim differentiation; disclaiming through negative statements; broadening amendments

General: The Federal Circuit concludes that a district court was correct in construing various claim terms as having the same meaning, in spite of apparent claim differentiation and broadening amendments made with respect to some of the terms during prosecution.

Edwards Lifesciences v. Cook, Inc.

Nos. 2009-1006 (Fed. Cir. 2009)

Decided September 22, 2009

I. Facts

Edwards appeals a judgment granting summary judgment of non-infringement of several claims of a series of related patents. Edwards owns four patents which relate to intraluminal grafts for treating aneurysms without open surgery. Each of the patents-in-suit includes a common specification. As described in the specification, an aneurysm is a weakness in a blood vessel that can cause enlargement or dilation of the vessel. If the aneurysm is not repaired the vessel can rupture, resulting in serious injury or death. To avoid the adverse consequences of open surgery, techniques have been developed to repair aneurysms endovascularly (or “intraluminally”), allowing surgeons to make small incisions and guide a delivery catheter through the arteries to apply a graft reinforced with metal framework to the affected area. The graft is generally compressed onto the delivery catheter and once at the location, the graft is expanded into position against the walls of the blood vessel. Stent-grafts are classified as two types: either self-expanding or balloon expandable. A self-expanding stent-graft will automatically expand to the size of the vessel upon release from the catheter, while a balloon expandable stent-graft is expanded using an inflatable balloon, once it reaches the target site.

The specification describes a method of treating aneurysms using two overlapping grafts, whereby the degree of overlap can be adjusted to change the overall length of the graft. Each of the claims at issue in each of the four patents recites two of the following structures: a “graft”, a “graft body”, a “graft structure”, a “bifurcated base structure”, and a “bifurcated base graft structure.” Further, each of the independent claims recites that the two structures are “anchored”, “attached”, “attachable”, or “dockable,” to each other while they are inside the vessel. The District Court found that graft, graft structure, bifurcated base structure, and bifurcated base graft structure were used interchangeably throughout the specification and claims, at least with respect to the further limitations attributable to the terms, discussed further below. On appeal, Edwards asserts that the District Court erred in its constructions of these terms, all of which were construed: (1) to be intraluminal, (2) to require wires, (3) to require that those wires be malleable, and (4) to preclude any resilience from such malleable wires. Edwards contended that the Court should not have imposed any of those meanings on the claims.

II. Issues

- A. Should the devices have been construed to be intraluminal?
- B. Should the devices have been construed to require wires?
- C. Must the wires in intraluminal devices be malleable?
- D. Are malleable wires and resilient wires mutually exclusive?

III. Discussion

- A. Yes. Edwards argued that the Court erred in requiring that all of the claimed devices were necessarily intraluminal. According to Edwards, the specification modifies the word “graft” with the word “intraluminal,” showing that not all grafts are necessarily intraluminal. Edwards also argued that some but not all the claims include an “intraluminal” limitation, so those without the modifier cannot be so limited, and that the construction renders redundant those with the modifier. Further, Edwards asserted that during prosecution, the modifier “intraluminal” was deleted from some of the original claims, thus broadening them. Finally, according to Edwards, the prosecution history demonstrates that the inventors intended the claims to cover surgically implanted graft combined with an intraluminal graft.

The Federal Circuit found that the recited “graft” must be “an intraluminal graft,” for a number of reasons. The Court noted that although the construction of a claim term is usually controlled by its ordinary meaning, the Court will adopt an alternative meaning “if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention.” The Court noted that the specification consistently used the words “graft” and “intraluminal graft” interchangeably, including referring to the same element number by each of the two terms. The Court further noted that the only devices described in the specification were in fact intraluminal. The Court further noted that the specification frequently described an “intraluminal graft” as “the present invention” or “this invention,” indicating an intent to limit the invention to intraluminal devices. Finally, the Court found that the claim language itself supported the District Court’s construction of the recited graft necessarily being an intraluminal graft. The Court noted that certain claims reciting “graft bodies” required that the two graft bodies be attachable “while inside a vessel,” necessitating the interpretation that the graft body, which is a piece of a graft, be intraluminal. The Court also found that Edwards’ prosecution history arguments were unpersuasive. The Court notes that while Edwards points out that, during prosecution, certain independent claims were amended to delete the word “intraluminal,” modifying “graft,” from the claim that the accompanying remarks continued to support the construction that the claim defined an intraluminal graft. (Noting that after removal of the word intraluminal, Applicants still stated that the claim at issue defined “an intraluminal graft”). Accordingly, the Federal Circuit agreed that the inventors’ statements urged a change in the claim language that did not affect the breadth of the claim, and thus the Court would not allow the claim to now be broadened.

- B. Yes. Edwards asserted that even if the claimed devices are required to be intraluminal, such intraluminal devices need not have wires. According to Edwards, certain claims require wires, and others do not. The Court disagreed and found that the claimed graft devices must have wires because they are intraluminal and because each of the claims recites an attachment that requires wires. The Court noted that the parties agreed at trial that intraluminal devices require wires. The Court further noted that every embodiment described in the specification and shown in the drawings includes wires. Further, every claim also includes a requirement that the two graft devices be “anchored,” “attached,” “attachable,” or “dockable” to each other while they are inside the vessel. The parties agreed that only wires perform this function. Because the parties agreed that such an attachment relationship requires wires, the Federal Circuit concluded that the claimed “graft” devices must also include wires. Finally, the Court noted that while Edwards attempted to use claim differentiation to broaden the independent claim by pointing out that a dependent claim added “a wire structure” to the graft of the independent claim, claim differentiation is a rule of thumb that does not trump the clear import of the specification. “While claim differentiation may be helpful in some cases, it is just one of

many tools used by courts in the analysis of claim terms.” Here, the specification and the parties’ agreement in the District Court make clear that the claimed graft devices require wires.

- C. Yes. Edwards next argued that even if all the claimed graft devices require wires, that those wires need not be malleable, but instead may be resilient. Edwards noted that the word “malleable” does not appear in any of the claims. Edwards further asserted that in the specification, the word “malleable” only describes three particular embodiments and does not limit the whole invention and that an alleged disclaimer in the specification disparaging the prior art’s lack of precise control of the grafts expansion is not limited to resilient wires. Finally, Edwards argued that malleable wires were removed from some claims during prosecution, showing the intent for a broader definition of “wires.”

The Court disagreed and found that the claimed wires must be malleable, as the inventors disclaimed the use of resilient, or self-expanding wires. The Court noted that the inventors disparaged the prior art resilient wires in their “background art” section of the specification. Specifically, the specification states that “[i]t is known to form ... an intraluminal graft of a sleeve in which is disposed a plurality of self-expanding stents ... there are a number of problems associated with such known grafts.” The problems that the specification then discusses including a “lack of precise control of the expansion of the graft in the lumine.” The specification then describes the wires of the invention as malleable and states that the device is expanded by the use of balloons. The Court held that where the general summary or description of the invention describes a feature of the invention and criticizes other products that lack the same feature, this operates as a clear disavowal of these other products. Thus, the Court found that a person of ordinary skill in the art would clearly understand that this invention requires malleable, as opposed to resilient, wires. Further, the Court noted that during prosecution, the inventors canceled claims requiring “malleable wires,” and replaced them with claims requiring only “wires,” but then conducted the prosecution as if the wires were required to be malleable. For instance, in attempting to distinguish claims without an express malleable wire limitation over certain prior art, Edwards stated that the written description “expressly teaches that the wire forms are malleable, deformable, non-springy material” and that they are not “self-expanding.” The Court then noted that this change again does not affect the breath of the claims because the inventors’ statements indicated that the claims remained narrow, and thus Edwards cannot now reclaim what is disclaimed during the prosecution and throughout the specification (i.e., resilient wires).

- D. Yes. Finally, Edwards argued that “malleable” wires may still display some resilience. The Court disagreed relying primarily on the specification which defines “malleable” as “not resilient to any substantial extent” and that this definition overrides any ordinary meaning of the word “malleable” that might allow for substantial resilience.

Based on these relevant claim interpretations, the Federal Circuit affirmed the District Court’s finding of non-infringement since the accused devices do not contain malleable wires, but instead contain self-expanding wires.

IV. Notable citations

- Although the construction of a claimed term is usually controlled by its ordinary meaning, we will adopt an alternative meaning “if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention.” *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed. Cir. 2002).
- “Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.” *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001).
- Moreover, “when the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment.” *Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1379 (Fed. Cir. 2005).
- “When different words or phrases are used in separate claims, a difference in meaning is presumed. However, simply noting the difference in the use of claim language does not end the matter. Different terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading of the terms or phrases is proper.” *Id. Nystrom v. TREX Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005).
- However, claim differentiation is a rule of thumb that does not trump the clear import of the specification. (“While claim differentiation may be helpful in some cases, it is just one of many tools used by courts in the analysis of claim terms.”) *See Netcraft Corp. v. eBay, Inc.*, 549 F.3d 1394, 1400 n.1 (Fed. Cir. 2008).
- “Where the general summary or description of the invention describes a feature of the invention ... and criticizes other products ... that lack that same feature, this operates as a clear disavowal of these other products” *Astrazeneca AB v. Mut. Pharm. Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004).