

United States Court of Appeals for the Federal Circuit

04-1135

C.R. BARD, INC. and DAVOL INC.,

Plaintiffs-Appellants,

v.

UNITED STATES SURGICAL CORP.,

Defendant-Appellee.

Claire Laporte, Foley Hoag LLP, of Boston, Massachusetts, argued for plaintiffs-appellants. With her on the brief was Peter B. Ellis.

Drew M. Wintringham, III, Clifford Chance US, LLP, of New York, New York, argued for defendant-appellee. With him on the brief was Mark W. Rueh.

Appealed from: United States District Court for the District of Delaware

Judge Kent A. Jordan

United States Court of Appeals for the Federal Circuit

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v.

UNITED STATES SURGICAL CORP.,

Defendant-Appellee.

DECIDED: October 29, 2004

Before NEWMAN, MICHEL, and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge MICHEL. Opinion concurring-in-part and concurring in the result filed by Circuit Judge PROST.

MICHEL, Circuit Judge.

C.R. Bard, Inc. and its subsidiary, Davol Inc., (collectively, “Bard”) appeal from the December 10, 2003, final judgment of non-infringement of claim 20 of U.S. Patent No. 5,356,432 (“432 patent”) in favor of United States Surgical Corp. (“U.S. Surgical”). The appeal was submitted for decision following oral argument on September 8, 2004. Because the district court did not err in construing the mesh surgical plug of claim 20 as requiring a pleated surface, we affirm.

BACKGROUND

This patent case involves a device used to repair hernias. As explained by the district court, “[a] hernia is a relaxation or weakening of the muscle wall, usually in the lower abdomen, which permits tissue to protrude through the muscle wall defect.”

C.R. Bard, Inc. v. United States Surgical Corp., 102 F. Supp. 2d 199, 201 (D. Del. 2000) (“Claim construction order”). Put simply, a hernia defect is a hole in the muscle wall and the invention in this case is a device used to plug the hole. Indeed, devices such as the invention in this case are commonly called “plugs” in the art.

Traditionally, hernias were repaired by suturing together separated strands in the weakened muscle wall. Id. Prior to the '432 patent, the use of cylindrical plugs made of surgical mesh to repair hernias was known in the art. These mesh plugs filled at least some portion of the hernia defect and became fixed in place through “fibroblasting,” wherein the muscle tissue attaches itself to the mesh.” Id. Other mesh plugs were also known in the art, including a mesh plug rolled into a conical, rather than a cylindrical, shape and a mesh plug formed by suturing a square piece of mesh into a conical, four-lobed configuration. In addition to plugs, a method of repair in which a flat piece of surgical mesh was stapled or sutured over the hernia defect was also known.

On January 22, 1992, Drs. Ira Rutkow and Alan Robbins disclosed to Bard employees the invention that culminated in the device claimed in the '432 patent. See Claim construction order, 102 F. Supp. 2d at 202 (“Bard’s project notebook shows that Rutkow and Robbins contemplated using a 3-layered design, comprising an exterior, pleated layer, and two interior layers for support.”). Although the exact relationship between Bard and Drs. Rutkow and Robbins does not appear to be in the present record, Bard claims, the district court stated, and U.S. Surgical does not dispute that Bard prosecuted the patent application that matured into the '432 patent on behalf of Drs. Rutkow and Robbins. See id.

The device claimed in the '432 patent is an implant that includes a mesh plug with a conformable surface and mesh filler material inside the plug. '432 patent, Abstract. The conformable surface allows the plug to fill irregularly shaped hernia defects more completely than other plugs. The mesh filler material provides bulk and stiffness to the implant.

The only claim at issue in this appeal is claim 20 of the '432 patent as amended during reexamination, which recites:

20. An implantable prosthesis for repairing a tissue or muscle wall defect, comprising:

a hollow plug, formed of a surgical mesh fabric having openings therein for tissue ingrowth, constructed and arranged to securely fit within and occlude the tissue or muscle wall defect and which is radially compressible upon insertion into the defect from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect, the surface of said hollow plug being conformable to irregularities in the tissue or muscle wall defining the defect upon insertion of said hollow plug into the defect, said hollow plug being extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect.

'432 Reexamination Certificate, col. 2, ll. 10-24 (original emphases and alteration noting deletion omitted; emphases added).

In the intrinsic record, the claimed plug is consistently described as having pleats. The Summary of the Invention states that “[t]he present invention is an implantable prosthesis” and that “[t]he implant includes a pleated surface which increases the pliability of the implant, allowing the prosthesis to conform to irregularities in the tissue or muscle wall surrounding the opening.” '432 patent, col. 1, ll. 37 (first quotation); id. at col. 1, ll. 51-55 (second quotation; emphasis added). The Abstract describes “[a]n implantable prosthesis including a conical mesh plug having a pleated

surface which conforms to the contours of the defect being repaired.” Id., Abstract (emphasis added). Statements in latter sections in the specification describing preferred embodiments all refer to a pleated plug. E.g., id. at col. 2, ll. 56-60 (“The surface of the conical plug is pleated 18 which enhances the flexibility and pliability of the implant, allowing the device to conform to irregularities in the shape of the hernia without kinking.”) (emphasis added); id. at col. 4, ll. 39-43 (“The resulting implant includes a hot molded conical plug with a pleated surface . . .”) (emphasis added); id. at col. 5, ll. 37-40 (“The pleated surface is extremely pliable . . .”) (emphasis added). Finally, the prosecution history includes a number of arguments in which the claimed plug is distinguished on the basis that the claimed plug is pleated. In particular, during the reexamination, Bard stated that “the surface of the inventive plug is pleated.” (Emphasis added.)

Bard brought suit against U.S. Surgical, claiming that U.S. Surgical made and sold a mesh plug that infringed claim 20 and induced surgeons to infringe method claim 21 of the '432 patent. In its claim construction order, the district court concluded that the plug in claim 20 must contain “pre-formed pleats.”¹ 102 F. Supp. 2d at 217. This conclusion was based alternatively on an examination of the specification and a conclusion that claim 20 contained means-plus-function limitations requiring pre-formed pleats. Id. at 215-17. Because the accused device admittedly did not include a pleated plug, the district court granted summary judgment that U.S. Surgical did not infringe claim 20 literally or under the doctrine of equivalents. C.R. Bard, Inc. v. United States

¹ Although Bard contends that the plug in claim 20 does not need to be pleated, Bard does not dispute that the term “pleated” refers to pre-formed, permanent folds, rather than spontaneous pleat-like folds formed upon insertion of unpleated conical plugs.

Surgical Corp., 107 F. Supp. 2d 489, 491-94 (D. Del. 2000) (“Summary judgment order”). The district court, however, denied U.S. Surgical’s motion for summary judgment on claim 21. Id. at 494. After Bard prevailed at a jury trial and in post-trial motions on claim 21, the parties settled their dispute involving claim 21. Bard timely appealed the final judgment as to claim 20, and we have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Applicable Law

“Determination of patent infringement requires a two-step analysis: (1) the scope of the claims must be construed; and (2) the allegedly infringing device must be compared to the construed claims.” Mars, Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1373 (Fed. Cir. 2004). We review the district court’s claim construction de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc). The district court’s grant of summary judgment of non-infringement is also reviewed without deference. Mars, Inc., 377 F.3d at 1373.

A long line of cases indicates that the intrinsic record is the primary source for determining claim meaning. E.g., Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); Autogiro Co. of Am. v. United States, 384 F.2d 391, 397-98 (Ct. Cl. 1967). The intrinsic record includes the specification and the prosecution history. Masco Corp. v. United States, 303 F.3d 1316, 1324 (Fed. Cir. 2002). Under this approach to claim construction, evidence extrinsic to the patent document “can shed useful light on the relevant art,” but is less significant

than the intrinsic record in determining the “legally operative meaning of disputed claim language.” Vanderlande Indus. Nederland BV v. Int’l Trade Comm’n, 366 F.3d 1311, 1318 (Fed. Cir. 2004). Particularly, our caselaw suggests that extrinsic evidence cannot alter any claim meaning discernible from intrinsic evidence. See, e.g., Intel Corp. v. VIA Techs., Inc., 319 F.3d 1357, 1367 (Fed. Cir. 2003) (“When an analysis of intrinsic evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained.”).

Language in some of our recent cases, however, suggests that the intrinsic record, except for the claims, should be consulted only after the ordinary and customary meaning of claim terms to persons skilled in the pertinent art is determined. See, e.g., Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002), cert. denied, 538 U.S. 1058 (2003). The language in these cases emphasizes technical and general-usage dictionaries in determining the ordinary meaning. Id. Under this approach, where the ordinary meaning of a claim term is thus evident, the inventor’s written description of the invention, for example, is relevant and controlling insofar as it provides clear lexicography or disavowal of the ordinary meaning. See id. (“[T]he presumption in favor of a dictionary definition [of a claim term] will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning. Further, the presumption also will be rebutted if the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.”).

Bard cites these cases in a failed attempt to contend that dictionary definitions somehow trump or override the intrinsic record in determining the meaning of a claim term. Like the many other litigants who have advanced such a position, Bard extracts dicta from these cases that is taken out of context. Bard's reliance on Texas Digital Systems is a good example. Bard block quotes language from Texas Digital Systems, which advises that dictionaries might be more objective and reliable than other sources for determining the meaning of claim terms. Bard, however, fails to quote language from that opinion emphasizing the need to consult the intrinsic record, such as the following: "The objective and contemporaneous record provided by the intrinsic evidence is the most reliable guide to help the court determine which of the possible meanings of the terms in question was intended by the inventor to particularly point out and distinctly claim the invention." Tex. Digital Sys., Inc., 308 F.3d at 1203. Furthermore, Bard fails to recognize that the holding of Texas Digital Systems is narrow. The Texas Digital Systems court construed nine claims but used dictionary definitions in only two of its constructions. In those two constructions, the Texas Digital Systems court concluded that the dictionary definition and intrinsic record were consistent with one another. Thus, Texas Digital Systems cannot be read as holding that a dictionary definition trumps the intrinsic record.

Despite Bard's contentions to the contrary, cases such as Texas Digital Systems do not require, or even allow, the Court to disregard the intrinsic record. Instead, these cases merely suggest a methodology that emphasizes the use of dictionaries and claim that if courts adopt this methodology, claim terms "will be more accurately determined" and improperly narrow constructions "will be more easily avoided." Id. at 1205.

In any event, we need not decide in this case the precise relationship between ordinary and customary meaning, dictionary definitions, and the intrinsic record,² because the district court's claim construction must be affirmed even under Bard's preferred methodology. As demonstrated below, both the specification and the prosecution history require that the plug in claim 20 be pleaded.

II. Ordinary and Customary Meaning

Because we conclude that the district court's claim construction must be affirmed under either methodology offered by the parties, we begin by consulting the ordinary and customary meaning of the claim terms as requested by Bard.

Bard argues that the ordinary and customary meanings of the terms "conformable" and "pliable" do not require pleading. Bard proffers general-usage dictionary definitions for the terms "conformable" and "pliable." One representative definition of the term "conformable" is "corresponding; similar." American Heritage Collegiate Dictionary 292 (3d ed. 1993). A definition from the same dictionary for the term "pliable" is "easily bent," with synonyms including "flexible" and "supple." Id. at 1050-51.

Bard's dictionary definitions are largely unhelpful. First, even under the cases Bard cites, the ordinary and customary meaning of a term does not govern if the intrinsic record contains clear lexicography or disavowal of claim scope. Tex. Digital Sys., Inc., 308 F.3d at 1204. Because we conclude below that the intrinsic record demonstrates that the plug in claim 20 must be pleaded, the ordinary and customary

² Resolution of this question may be approaching. See Phillips v. AWH Corp., 376 F.3d 1382 (Fed. Cir. July 21, 2004) (granting petition for en banc rehearing to address broadly the law of claim construction).

definitions of “conformable” and “pliable” are not controlling. Second, because claim scope in this case turns most directly on the term “plug,” the proffered dictionary definitions of “conformable” and “pliable” are largely inapposite. Finally, we question the need to consult a dictionary to determine the meaning of such well-known terms. Courts, including the Texas Digital Systems court, regularly forgo detailed dictionary analyses if the term is as commonplace as “conformable” or “pliable.” See, e.g., Tex. Digital Sys., Inc., 308 F.3d at 1207 (determining the ordinary meaning of “controlling the durations” without referring to a dictionary). Indeed, Bard itself “submits that merely rephrasing or paraphrasing the plain language of a claim by substituting synonyms does not represent genuine claim construction.”

III. Specification of the '432 patent

U.S. Surgical contends that the plug in claim 20 must be pleated because, in various ways and places, the specification defines the claimed plug as including pleats.³ In two places, the patent describes in general terms what it deems to be the invention. In both places, the patent unequivocally defines the claimed plug as having pleats. First, the Summary of the Invention begins by stating that “[t]he present invention is an implantable prosthesis.” '432 patent, col. 1, ll. 36. In the next paragraph, before the embodiments of the invention are described, the patent states that “[t]he implant includes a pleated surface.” Id. at col. 1, ll. 51-52 (emphasis added). Second, the

³ Despite the suggestion to the contrary in the concurrence, this opinion’s use of the term “define” is not intended to invoke the theory that the inventors acted as lexicographers and redefined words differently from their ordinary meaning in the art. Instead, we use the term merely to denote that “the specification makes clear at various points that the claimed invention is narrower than the claim language might imply” based on a reading of the specification as a whole. Alloc, Inc. v. Int’l Trade Comm’n, 342 F.3d 1361, 1370 (Fed. Cir. 2003), cert. denied, 124 S. Ct. 2390 (2004). The term takes on similar meaning when applied in this opinion to the prosecution history.

Abstract describes “[a]n implantable prosthesis including a conical mesh plug having a pleated surface which conforms to the contours of the defect being repaired.” Id., Abstract (emphasis added).

Bard claims that a statement in the specification is not “determinative of claim construction merely because it appears in the ‘Summary of the Invention’ section.” Although a statement’s location is not “determinative,” the location can signal the likelihood that the statement will support a limiting definition of a claim term. Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term. See Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1347 (Fed. Cir. 1998) (relying on “global comments made to distinguish the applicants’ ‘claimed invention’ from the prior art” during the prosecution of the patent in construing a claim term). Statements that describe the invention as a whole are more likely to be found in certain sections of the specification, such as the Summary of the Invention. See Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1348 (Fed. Cir.) (“Those statements, some of which are found in the ‘Summary of the Invention’ portion of the specification, are not limited to describing a preferred embodiment, but more broadly describe the overall inventions of all three patents.”), cert. denied, ___ U.S. ___, 2004 WL 2058375 (Oct. 4, 2004). Accordingly, other things being equal, certain sections of the specification are more likely to contain statements that support a limiting definition of a claim term than other sections, although what import to give language from the specification must, of course, be determined on a case-by-case basis. In this case, the

plug claimed by the '432 patent is defined globally as requiring a pleated surface, which limits claim 20.

Bard further contends that these statements do not limit claim 20 to pleated plugs because the statements are merely “passing reference[s]” and relies for this argument on Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898 (Fed. Cir.), petition for cert. filed, ___ U.S. ___, 2004 WL 1553522 (July 1, 2004). Liebel-Flarsheim involved patents related to powered fluid injectors used in medical procedures. Id. at 900. The trial court construed the claims as requiring the use of a “pressure jacket,” reasoning that the term “syringe receiving opening” was ambiguous and that each of the two embodiments in the specification disclosed the syringe receiving opening being located at the front end of a pressure jacket. Id. at 904. This court rejected the trial court’s reasoning for several reasons, the first of which was that “[t]he specification does not define ‘opening’ restrictively, nor is there anything in the specification that supports the district court’s conclusion that the term is ambiguous.” Id. at 905.

Contrary to Bard’s characterization, the holding of Liebel-Flarsheim did not depend on the number of times the term “pressure jacket” was used or on details of preferred embodiments. Instead, the Liebel-Flarsheim court rejected the trial court’s reasoning because, inter alia, the specification did not clearly define the term in question, even implicitly. In this case, however, the specification explicitly defines the inventive plug as “having” or “includ[ing] a pleated surface.” See '432 patent, Abstract (first quotation); id. at col. 1, ll. 52 (second quotation). Accordingly, Liebel-Flarsheim provides no support for Bard’s position.

Bard finally contends that these statements do not define the terms “conformable” and “pliable” as requiring pleating. Even if true, this argument is irrelevant because the statements define the words “implant” or “plug.” In the Summary of the Invention, the phrase “includes a pleated surface” modifies the word “implant.” See '432 patent, col. 1, ll. 51-55 (“The implant includes a pleated surface which increases the pliability of the implant”). In the Abstract, the phrase “having a pleated surface” modifies the word “plug.” See id., Abstract (describing “[a]n implantable prosthesis including a conical mesh plug having a pleated surface which conforms to the contours of the defect being repaired”). Accordingly, whether or not the patent describes pleating as the only way to achieve conformability or pliability is irrelevant because the patent requires the “implant” or “plug” to have a pleated surface.

This point can also be made from another perspective. Claim 20 covers a specific structure, namely the surface of a mesh plug. Whether or not the patent states that pleating is the only structure that could achieve certain effects, such as conformability or pliability, is irrelevant because the patent defines the claimed structure as including pleats. In other words, because the language requiring pleating applies to the structure, not to the effects produced by the structure, Bard’s contention that the patent does not state that pleats are the only way to achieve conformability and pliability is simply beside the point.

Both parties also point to the preferred embodiments. Under our precedent, a patentee’s choice of embodiments can shed light on the intended scope of the claim, but a patent claim term is not limited merely because the embodiments in the specification all contain a particular feature. See Liebel-Flarsheim, 358 F.3d at 907-08.

On the other hand, a construction that excludes a preferred embodiment “is rarely, if ever, correct.” Vitronics Corp., 90 F.3d at 1583.

Bard points to language in the specification that does not use the term “pleated” to argue that a construction in which the plug in claim 20 must have a pleated surface would exclude a preferred embodiment. That language states in pertinent part, “In another embodiment of the invention, a filler body is positioned in a mesh cone and packs the implant when the plug is compressed by placement in the narrow hernia opening, providing the bulkiness believed to be essential for non-recurrent repair of abdominal wall hernias.” ’432 patent, col. 2, ll. 3-8 (emphasis added). Bard contends that construing claim 20 to require a pleated plug would improperly exclude this preferred embodiment, which describes a “mesh cone” without mentioning pleating.

We find this argument unpersuasive for two reasons. First, the “embodiment” to which Bard refers is merely a description of one aspect of the claimed implant, namely the filler body. That the patent does not explicitly mention the pleated structure of the plug’s outer surface is unsurprising given the focus in that paragraph on the filler body, which is contained inside the surface of the plug. Second, because the patent globally defined the plug as having a pleated surface, the term “pleated” need not be repeated each time a term describing some other aspect of the plug is used. Accordingly, the failure to recite the term “pleated” before “mesh plug” does not mean that the patent discloses an embodiment with a non-pleated plug.

U.S. Surgical argues that the plug in claim 20 must be pleated because neither the embodiments nor the drawings describe a non-pleated plug. It is true that many of the descriptions of the plug in the specification explicitly require pleating and are

strikingly similar to the language employed in claim 20. For example, the language of claim 20 -- “said hollow plug being extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect” -- can be compared with the following language describing a preferred embodiment -- “The pleated conical plug is extremely pliable, allowing localized portions of the implant to adapt to the irregular contour 40 of the defect.” ’432 Reexamination Certificate, col. 2, ll. 22-24 (first quotation); ’432 patent, col. 4, ll. 45-48 (second quotation). The only significant difference between these two quotations is an explicit description of pleating. Similarly close comparisons can be made between other descriptions of preferred embodiments and the disputed terms in claim 20. Id. at col. 1, l. 66 to col. 2, l. 2; id. at col. 2, ll. 56-60; id. at col. 3, ll. 16-18; id. at col. 4, ll. 39-43; id. at col. 5, ll. 37-40; see also id. at col. 3, ll. 22-32 (describing multiple pleat configurations).

Accordingly, the specification demonstrates that Bard clearly defined the terms “implant” and “plug” in claim 20 as requiring a pleated surface. Statements of general applicability clearly define the claimed plug as “having” or “includ[ing] a pleated surface.” See ’432 patent, Abstract (first quotation); id. at col. 1, ll. 52 (second quotation). Further, statements describing preferred embodiments of the surface of the plug universally describe a “pleated conical plug.” E.g., ’432 patent, col. 4, ll. 45-48 (located in the Description of the Preferred Embodiments).

Although the statements in the specification suffice by themselves to demonstrate that the plug in claim 20 must be pleated, we also consider the prosecution history of the ’432 patent, which confirms the analysis of the specification.

III. Prosecution History of the '432 patent

A. Initial Examination

The prosecution history of the '432 patent equally supports our conclusion that the plug in claim 20 requires a pleated surface. We begin with the initial examination.

On February 5, 1993, Bard filed a patent application with respect to the present invention by Drs. Rutkow and Robbins. The examiner rejected a number of the claims in the initial application that matured into the '432 patent, including claim 20 (application claim 21), on a variety of grounds. In response, Bard's attorney conducted an interview with the examiner and, thereafter, submitted an amendment and accompanying remarks. Of the amendments and arguments made by Bard, three merit discussion because they explicitly or implicitly address pleating.⁴

First, the examiner rejected claim 20 (application claim 21) based on U.S. Patent No. 5,147,374 ("Fernandez"). Fernandez disclosed a device used in hernia repair in which (1) surgical mesh was rolled into a tight cylinder, (2) one end of the cylinder was slit to produce flaps, (3) the non-slit portion of the cylinder was inserted into the hernia defect, and (4) the flaps along with a flat sheet of surgical mesh were stapled to tissue adjacent to the hernia defect. To overcome Fernandez, Bard argued that "the implant disclosed in Fernandez does not contain pleats, is not conformable to an irregular shaped defect, is not compressible into a reduced configuration which approximates the

⁴ The examiner also rejected claim 20 (application claim 21) based on U.S. Patent No. 2,836,181 ("Tapp"). Tapp disclosed a device that employed axial compressibility in repairing a damaged vein or artery. To overcome Tapp, applicants argued, inter alia, that "the pleated surface allows radial compression of the claimed device." Applicants also amended claim 20 (application claim 21) to include a claim limitation that the device be "radially compressible." '432 patent, col. 8, l. 18.

shape of the defect upon insertion therein and does not contain a filler body or freely moveable mesh petals as is claimed.” (Emphasis added.)

Second, to overcome the examiner’s rejection based on the indefiniteness of the claim language on compressibility, Bard argued that “the claims do not recite that the surgical mesh fabric is compressible but, rather, that the implant formed from such material is compressible from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect.”

Third, in the interview, Bard demonstrated the difference in pliability and flexibility of the claimed device as compared to prior art devices. Bard later described this interview, arguing:

The claimed device easily assumed the shape of the irregular opening while the stiffer prior art devices left gaps around the boundary of the opening. It was also pointed out to the Examiner that the Fernandez plug does not contain pleats as is found in the preferred embodiment of the claimed device and as is expressly required by certain of the pending claims. It was further explained to the Examiner that it is the texturing of the implant which permits the claimed plug to conform to irregularities in the shape of the defect without kinking or buckling.

(Emphasis added).

Pleating is implicated in each of the responses to the examiner’s rejections described above. In distinguishing Fernandez and describing the interview, Bard explicitly relied on pleating as a material distinction over the prior art. Further, Bard argued that compressibility is based on the configuration of the mesh surface, not the nature of the mesh fabric itself. The emphasis on the configuration of the mesh implicates pleating. Such an implication is also supported by Bard’s argument that “it is the texturing of the implant which permits the claimed plug to conform to irregularities in the shape of the defect.”

Although pleating is explicitly or implicitly described by each of these arguments, limiting claim 20 to require pleating based solely upon amendments and arguments made during the initial examination would likely be improper. Most importantly, because pleating is described in alternative arguments and many claims contain an explicit pleating limitation, the pleating arguments do not necessarily apply to claim 20. For example, Bard argued, “It was also pointed out to the Examiner that the Fernandez plug does not contain pleats as is found in the preferred embodiment of the claimed device and as is expressly required by certain of the pending claims.” (Emphasis added.)

B. Reexamination

Having determined that amendments and arguments made during the initial examination suggest a close connection between pleating and claim 20 but do not necessarily require the plug in claim 20 be pleated, we now turn to the reexamination. Bard requested that the '432 patent be reexamined because of certain art that was submitted to the examiner but not considered during the initial examination.⁵

The reexamination focused on the latter of two articles authored by Ermanno E. Trabucco. See Ermanno E. Trabucco, A New Preperitoneal Plug Technic for Recurrent Groin Hernioplasty (undated manuscript) (“Trabucco”). In the request for reexamination, Bard described two ways in which the claimed device was distinguishable from Trabucco. First, Bard distinguished Trabucco by noting that the plug “disclosed in Trabucco I and II does not include a pleated surface.” Second, the

⁵ The examiner had not considered the art because it was undated, and the examiner initially refused reexamination on the same ground. Thereafter, the Director of the Patent Examining Group granted patentees’ petition for reconsideration of the examiner’s denial of reexamination, determining that patentees had made a binding admission that the art cited was prior art.

Trabucco plug “is stiff as compared to the flexible plug claimed in the ’432 patent.” Like arguments made during the initial examination, this argument describing pleating does not necessarily apply to and limit claim 20. Bard distinguished Trabucco using two alternative arguments, only one of which explicitly required pleating, and the reexamination initially involved all claims in the ’432 patent.

The examiner allowed all device claims that expressly included pleating and rejected claims 19 and 20, which were the only device claims that did not expressly include pleating. The rejection of claims 19 and 20 was based on the examiner’s determination that the Trabucco plug was radially compressible, flexible, and conformable.

In responding to the examiner’s rejection, Bard clearly distinguished the plug claimed in claims 19 and 20 from Trabucco’s plug on the basis of its plug having pleats. Bard began the response by addressing conformability, contending that it was demonstrated in the interview that the Trabucco plug was not radially compressible to the same degree as the claimed device. Next, in addressing flexibility and pliability, Bard stated:

As explained in the specification of the reexamination application, the surface of the inventive plug is pleated with [sic] enhances the flexibility and pliability of the implant, allowing the prosthesis to conform to irregularities in the shape of the hernia without kinking.

(Emphases added.) In the final argument, Bard again addressed conformability, arguing that the claimed device conforms “simply with insertion into the defect,” whereas the Trabucco plug does not so conform.

U.S. Surgical contends, and we agree, that the statement “the surface of the inventive plug is pleated” is an unequivocal statement constituting a clear disclaimer of

scope in claim 20. In the initial examination and early stages of the reexamination, alternative arguments based on pleating could not conclusively demonstrate that the plug in claim 20 must be pleated because other claims were at issue and those other claims expressly required pleating. But the only claims at issue when Bard stated that “the surface of the inventive plug is pleated” were claims 19 and 20, which were virtually indistinguishable from one another and neither of which expressly required pleating.

Bard counters that the statement “the surface of the inventive plug is pleated” referred only to the pleated preferred embodiment demonstrated to the examiner during the interview and contends, therefore, that the statement does not limit claim 20. Bard’s argument is unpersuasive because the statement “the surface of the inventive plug is pleated” referred to the claimed plug in general, not merely to the embodiment demonstrated during the interview. This can be seen by the context of the statement, which was preceded by the words “[a]s explained in the specification” and was located in a different paragraph from the discussion of the interview. Additionally, the statement uses the term “the inventive plug,” whereas the discussion of the interview in the preceding paragraph describes “a plug embodying the claimed invention.”

Bard further argues that the statement “the surface of the inventive plug is pleated” is merely an inaccurate statement. See Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 832 (Fed. Cir. 2003) (“The applicants’ inaccurate statement cannot override the claim language itself, which controls the bounds of the claim.”). Bard, however, provides no evidence demonstrating that its statement was inaccurate or otherwise a mistake. Further, the context of this argument suggests that it was intentionally made to overcome a rejection by the examiner.

The examiner maintained the rejection of claims 19 and 20 but suggested that they would be allowed if specific means-plus-function language were inserted at the end of both claims. The examiner cited language from the specification that described a “pleated conical plug” in making this suggestion. In response, Bard stated that “[i]n accordance with the Examiner’s suggestion, claims 19 and 20 have been amended to clearly distinguish the arrangement shown in the Trabucco article,” but Bard failed to add the specific means-plus-function language required by the examiner to claim 20. The examiner then allowed claims 19 and 20, describing both as means-plus-function claims.

It is unclear what import, if any, to draw from Bard’s failure to follow the examiner’s suggestion for claim 20 as it did for claim 19. Although Bard did not add the term “pleated” or explicit means-plus-function language to claim 20, they did adopt language substantially identical to the language suggested by the examiner, which language implicitly required pleating.

C. Conclusion as to the Prosecution History

In examining the prosecution history, we note Bard made a number of arguments distinguishing the prior art on the basis that the prior art did not disclose a pleated plug. Many of these arguments are not necessarily applicable to claim 20 because the arguments related to claims in addition to claims 19 and 20 and were offered in the alternative with other arguments that did not address pleating. But in the only response in which claims 19 and 20 alone were considered, Bard made a clear statement to the examiner that “the surface of the inventive plug is pleated.” This statement, when combined with the rest of the prosecution history, demonstrates that Bard therein clearly

defined the plug of claim 20 as having pleats. Accordingly, the prosecution history provides an independent ground for construing claim 20 as requiring a plug with a pleated surface.

IV. Conclusion as to Claim Construction and Infringement

As described in detail above, Bard clearly defined the plug in claim 20 as having pleats in both the specification and the prosecution history. Accordingly, we affirm the district court's claim construction requiring "pre-formed pleats." Claim construction order, 102 F. Supp. 2d at 217. Because an analysis of the intrinsic record suffices to support this construction, we do not consider, in the alternative, whether the district court properly construed claim 20 as containing means-plus-function limitations requiring pre-formed pleats even though claim 20 did not include the words "means for" or similar language.⁶ We thus need not decide whether the presumption against such a conclusion is overcome by determining whether claim 20, drawn to structure, fails to describe specific structure. We merely note that the district court's opinion contains extensive and careful reasoning to support such a construction.

Bard does not dispute that the district court's judgment of non-infringement must be affirmed if this Court affirms the district court's construction of claim 20. Accordingly, we affirm the district court's judgment of non-infringement of claim 20.

Accordingly, the judgment of the district court is

AFFIRMED.

⁶ U.S. Surgical raises a number of additional arguments that need not be reached. These include whether claim 20 included a "kinking and buckling" limitation and whether statements applicants made during the prosecution of foreign patent applications limited the claims of the '432 patent.

United States Court of Appeals for the Federal Circuit

04-1135

C.R. BARD, INC. and DAVOL INC.,

Plaintiffs-Appellants,

v.

UNITED STATES SURGICAL CORP.,

Defendant-Appellee.

PROST, Circuit Judge, concurring-in-part and concurring in the result.

I concur with the majority's conclusion with regard to the reexamination. In this case, the inventors clearly and deliberately disclaimed any coverage of non-pleated plugs they might otherwise have had when they stated during reexamination that "the surface of the inventive plug is pleated" in an attempt to overcome the prior art-based rejections of claims 19 and 20. Under the theory that the inventors acted as lexicographers, the majority holds that this statement, among others, shows that the inventors "clearly defined the plug of claim 20 as having pleats." Ante, at 21 (emphasis added). The statement, in my view, is a surrender of claim scope, which precludes Bard from recapturing coverage of non-pleated plugs. Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1458 (Fed. Cir. 1998). Because the inventors clearly disclaimed coverage of non-pleated plugs in the reexamination, I believe we may affirm the judgment of the district court on that basis alone; accordingly, I find it unnecessary to reach the remaining grounds for affirmance relied upon by the majority.