



McKELVIE, District Judge

This is a patent case. Plaintiff C.R. Bard, Inc. is a New Jersey corporation with its principal place of business in Murray Hill, New Jersey. Bard owns U.S. Patent No. 5,356,432, as reexamined (“the ’432 patent”). Plaintiff Davol Inc., a wholly owned subsidiary of Bard, is a Delaware corporation with its principal place of business in Cranston, Rhode Island. Davol markets and sells products that practice the ’432 patent. Defendant United States Surgical Corp. is a Delaware corporation with its principal place of business in Norwalk, Connecticut.

On April 10, 2000, U.S. Surgical moved for summary judgment of noninfringement of claim 20 of the ’432 patent and no inducement of infringement of claim 21 of the ’432 patent.

On June 2, 2000, the court held a trial in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), to construe disputed claims of the ’432 patent. On June 15, 2000, the court issued an opinion construing claim 20 and claim 21 of the ’432 patent.

On June 22, 2000, the court heard oral argument on U.S. Surgical’s motion for summary judgment. Subsequent to the oral argument, both parties submitted supplemental briefing on the motion.

This is the court’s decision on U.S. Surgical’s motion for summary judgment.

## I. FACTUAL AND PROCEDURAL BACKGROUND

The court takes the following facts from the prosecution history of the '432 patent and from the affidavits submitted by the parties.

### A. The Parties' Hernia Plugs

Bard manufactures and sells a hernia plug, called the Perfix plug, which it acknowledges is an embodiment of the '432 patent. The plug has a pleated outer surface, and has several interior mesh petals that may be removed by a surgeon to vary the stiffness of the plug.

U.S. Surgical manufactures and sells a hernia plug called the Hernia-Mate. The Hernia-Mate is a pre-formed mesh plug consisting of a semicircle of mesh joined at the seam. The Hernia-Mate has no pre-formed pleats. The Hernia-Mate has petals that impart bulk to the plug.

U.S. Surgical has prepared marketing and instructional materials that explain how to use the Hernia-Mate. A package insert created by U.S. Surgical states that “[i]f the overall bulk of the SURGIPRO HERNIA-MATE is deemed excessive, then some of the inside ‘petals’ may be trimmed.” A brochure designed by U.S. Surgical illustrates the plugs, and under the caption “Removable Petals for Bulk Reduction,” states that “[p]lug internal bulk is adjustable by petal removal, to conform to expansion or contraction guaranteeing a true tension free repair.”

B. Claim Construction

In its claim construction opinion, the court determined that the language of claim 20 referring to the “surface of said hollow plug being conformable” invokes 35 U.S.C. § 112, ¶ 6, and requires pre-formed pleats which render the plug “extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect.”

The court also determined that trimming a portion of the petals recited in claim 21 is not covered by the literal scope of the claim.

C. U.S. Surgical’s Motion for Summary Judgment

In its supplemental briefing on its motion for summary judgment, U.S. Surgical contends that the court’s claim construction precludes a finding of literal infringement of claim 20 because the Hernia-Mate plug lacks pre-formed pleats. U.S. Surgical argues, moreover, that there is no genuine issue of material fact as to noninfringement under the doctrine of equivalents, because Bard surrendered its claims to an unpleated structure during the prosecution history, and because U.S. Surgical’s Hernia-Mate unpleated plug is substantially different from Bard’s pleated plug. As to claim 21, U.S. Surgical claims that summary judgment is proper, because Bard has produced no evidence that the instructional materials created by U.S. Surgical actually reach doctors and induce them to detach entire petals of the plug to vary its stiffness and bulk.

Bard argues that U.S. Surgical literally infringes claim 20, because the Hernia-Mate is equivalent to the claimed invention under § 112, ¶ 6. Bard argues, moreover, that genuine issues of fact preclude granting summary judgment as to infringement under the doctrine of equivalents. Bard contends that the instructional materials prepared by U.S. Surgical create a question of fact as to whether U.S. Surgical has induced infringement of claim 21, precluding summary judgment.

## II. DISCUSSION

### A. Legal Standards for Granting Summary Judgment

The court may grant summary judgment “if the pleadings, depositions, interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). Summary judgment is appropriate under the doctrine of equivalents where the evidence is such that no reasonable jury could find equivalency. *See, e.g., Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1349-50 (Fed. Cir. 1998).

### B. Claim 20

The Federal Circuit has explained the standard for determining literal infringement under § 112, ¶ 6 as follows:

Under § 112, ¶ 6, an accused device with structure not identical to the structure described in the patent will literally infringe the patent if the device performs the identical function required by the claim with a structure equivalent to that described in the patent. Prosecution history is relevant to the construction of a claim written in means-plus-function form. Indeed, just as prosecution history estoppel may act to estop an equivalence argument under the doctrine of equivalents, positions taken before the PTO may bar an inconsistent position on claim construction under § 112, ¶ 6. Clear assertions made in support of patentability thus may affect the range of equivalents under § 112, ¶ 6. The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter.

Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1457 (Fed. Cir. 1998) (en banc) (citations omitted); accord Alpex Computer Corp. v. Nintendo Co. Ltd., 102 F.3d 1214, 1221-22 (Fed. Cir. 1996). Under this standard, a patentee may not claim equivalents under § 112, ¶ 6 when a competitor would reasonably believe that the applicant surrendered its claims to the allegedly equivalent structure during the prosecution of the patent.

Prosecution history estoppel limits infringement by otherwise equivalent structures, by barring recapture by the patentee of scope that was surrendered in order to obtain allowance of the claims. Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1218 (Fed. Cir. 1995). Prosecution history estoppel normally arises when a change of claim scope is made in order to overcome an examiner's rejection based on prior art. Id. at 1219. Thus, a patentee is estopped from recovering through equivalency that which was deemed unpatentable in view of the prior art. Id.

Because prosecution history estoppel may preclude a finding of infringement of the '432 patent by statutory equivalence under § 112, ¶ 6, and by the doctrine of equivalence, the court will consider the parties' positions as to whether Bard surrendered claims to an unpleated structure during the prosecution history.

U.S. Surgical asserts that Bard made numerous statements during the prosecution of the '432 patent that serve to limit the scope of its coverage to a pleated structure. U.S. Surgical notes that the examiner rejected claim 20 during the reexamination proceedings in light of a prior art publication by Ermanno Trabucco, which disclosed a hernia plug made by suturing a square piece mesh into a conical, four-lobed configuration. U.S. Surgical contends that Bard attempted to overcome this reference by stating: “[I]t is the integrally formed pleats, and not additional fastening mechanisms (such as the sutures or clips disclosed by Trabucco), which allow the prosthesis to conform to the contours of the defect merely upon placement in the tissue or muscle wall opening.” U.S. Surgical also notes that, after the examiner proposed amending claim 20 to insert means-plus-function language into claim 20, Bard stated: “In accordance with the Examiner’s suggestion, claims 19 and 20 have been amended to clearly distinguish the arrangement shown in the Trabucco article.” U.S. Surgical contends that it was reasonable for it to rely on this statement as limiting the scope of claim 20 to a pleated structure. U.S. Surgical asserts that this court’s determination that claim 20 is written in means-plus-function language demonstrates that it was

reasonable to rely on Bard's statement as an indication that Bard surrendered its claims to an unpleated structure.

Bard argues that it is not estopped from claiming equivalents of a disclosed structure unless it unequivocally and unmistakably surrendered the equivalent structures. See Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996) (rejecting district court's decision that remarks effected an estoppel because remarks were "equivocal," not "unmistakable"). Bard asserts that it did not "unmistakably" surrender its claims to an unpleated device, and so prosecution history estoppel does not preclude it from arguing that the Hernia-Mate is equivalent to the claimed invention. Bard contends that, at most, it surrendered claims to a structure containing clips and sutures, like that disclosed in Trabucco.

The touchstone of prosecution history estoppel is that a patentee is unable to reclaim through the doctrine of equivalents what was surrendered or disclaimed in order to obtain the patent. Loral Fairchild Corp. v. Sony Corp., 181 F.3d 1313, 1322 (Fed. Cir. 1999). Because Bard limited its claims in order to distinguish its claimed invention from Trabucco, prosecution history estoppel applies. See id. The crux of the present dispute is whether the scope of the estoppel triggered by Bard's statements to the examiner is limited to the device disclosed in the Trabucco publication, or whether Bard is also estopped from claiming that the unpleated Hernia-Mate is an equivalent of the claimed structure.

In Bard's original application, the scope of claim 21, which subsequently issued as claim 20, undisputably extended to hernia plugs with unpleated surfaces. During reexamination proceedings, the examiner rejected issued claim 20 in light of Trabucco. Bard distinguished its claimed invention from Trabucco by stating that "it is the integrally formed pleats, and not additional fastening mechanisms (such as the sutures or clips disclosed by Trabucco), which allow the prosthesis to conform to the contours of the defect merely upon placement in the tissue or muscle wall opening." To overcome the examiner's rejection, Bard amended its claims by stating that its plug is "extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect." For reasons articulated in the court's claim construction opinion, the court has construed this limitation to invoke § 112, ¶ 6, and to refer to the language of the specification discussing pre-formed pleats. Thus, while Bard amended its claims to distinguish its claims from a device with "sutures or clips," the amended claim refers to a plug with pre-formed pleats.

A patentee that amends its claims during prosecution to overcome a prior art reference "does not necessarily surrender all subject matter beyond the literal scope of the amended claim limitation." Litton Systems, Inc. v. Honeywell, Inc., 140 F.3d 1449, 1455 (Fed. Cir. 1998). Prosecution history estoppel, however, does "bar[] recapture of that subject matter actually surrendered during prosecution." Id. Under prosecution history estoppel, "the patentee is estopped from enforcing the patent against

an equivalent [device] if the inventor surrendered, during prosecution of the patent application, claim scope which included the now-asserted element or its equivalent.” Canton Bio-Medical, Inc. v. Integrated Liner Technologies, Inc., 2000 WL 867593, at \*2 (Fed. Cir. June 30, 2000); see also Merck & Co., Inc. v. Mylan Pharmaceuticals, Inc., 190 F.3d 1335 (Fed. Cir. 1999) (“If claim scope is relinquished during prosecution on grounds of patentability, the doctrine of prosecution history estoppel provides that the relinquished scope can not be recovered by operation of the doctrine of equivalents.”).

The scope of prosecution history estoppel extends to more than the particular prior art device distinguished during prosecution. See Sextant Avionique, S.A. v. Analog Devices, Inc., 172 F.3d 817, 827 (Fed. Cir. 1999). Prosecution history estoppel and the prior art provide independent “policy oriented” limitations on the doctrine of equivalents. Id. Competitors are free to practice the art surrendered during prosecution history, and are free to practice technology disclosed in the prior art. See id. If prosecution history estoppel extended only to the particular prior art devices at issue during prosecution, then the scope of prosecution history estoppel would be no broader than the range of prior art considered by the examiner. The Federal Circuit has held that this is not the case, and that “the limits imposed by prosecution history estoppel can be, and frequently are, broader than those imposed by the prior art.” Haynes Int’l, Inc. v. Jessop Steel Co., 8 F.3d 1573, 1579 (Fed. Cir. 1993), on rehearing, 15 F.3d 1076 (Fed. Cir.

1994); see also Sextant, 172 F.3d at 827 (“If Analog were practicing the prior art, it would have had a complete defense to Sextant’s infringement charge, and prosecution history would be irrelevant.”).

In this case, although Bard attempted only to overcome structures with “sutures or clips” during prosecution history, Bard’s amendment served to surrender more than the structures disclosed by Trabucco. Because the claim scope originally sought extended to unpleated structures, and the final claim language is limited to structures with “pre-formed pleats,” the court finds that the claim scope actually surrendered includes unpleated structures such as the Hernia-Mate. Bard surrendered its claims to unpleated plugs during the prosecution history, and it is consequently estopped from claiming unpleated plugs under the doctrine of equivalents. See Litton, 140 F.3d at 1455.

The court also finds that a reasonable competitor would find that the statements made by Bard during the prosecution history constitute a surrender of its claims to unpleated plugs. Accordingly, the court determines that Bard is precluded from arguing that the Hernia-Mate literally infringes claim 20 as an equivalent under § 112, ¶ 6. See Cybor, 138 F.3d at 1457; Alpex, 102 F.3d at 1221-22.

Bard urges that prosecution history estoppel should not apply because it did not “unmistakably” surrender its claims to unpleated plugs. The Federal Circuit has distinguished between applicants’ statements made in the context of amendments, and

other statements. See Bayer AG v. Elan Pharmaceutical Research Corp., 2000 WL 572705, at \*8 (Fed. Cir. May 12, 2000) (“Prosecution history estoppel can occur as a result of (i) amendments made to overcome patentability rejections or (ii) arguments made during prosecution that show ‘a clear and unmistakable surrender of subject matter.’”) (citations omitted). While a statement made outside the context of an amendment must be “unmistakable” to invoke prosecution history estoppel, this same standard does not apply when the statement is made to overcome patentability rejections. See id.; Texas Instruments Inc. v. International Trade Commission, 988 F.2d 1165, 1174 (Fed. Cir. 1993). Thus, the court finds that, although Bard did not expressly withdraw its claims to an unpleated plug, its statements to the examiner to overcome the Trabucco reference preclude its assertions that the Hernia-Mate is an equivalent of the claimed structure.

Accordingly, the court will grant U.S. Surgical’s motion for summary judgment as to noninfringement of claim 20.

C. Claim 21

U.S. Surgical undisputably prepared training materials for its sales people explaining that the petals of the Hernia-Mate may be “trimmed” to reduce the “bulk” of the devices. The parties dispute whether, and for how long, these instructional materials were disseminated to doctors. The parties also dispute the frequency by which doctors actually trim or remove the petals during surgery. These issues present

material questions of fact which preclude a grant of summary judgment as to U.S.

Surgical's affirmative defense of no inducement of infringement of claim 21.

Accordingly, the court will deny U.S. Surgical's motion for summary judgment of no inducement of infringement of claim 21.

### III. CONCLUSION

The court will enter an Order consistent with this Opinion granting U.S. Surgical's motion for summary judgment of no infringement of claim 20, and denying U.S.

Surgical's motion for summary judgment of no inducement of infringement of claim 21.