United States District Court,
D. New Jersey.

DATASCOPE CORP,
Plaintiff.
v.
ARROW INTERNATIONAL, INC,
and Arrow International Investment Corp. Defendants.

No. CIV A 00-3200 DRD

Aug. 17, 2001.

John R. Nelson, Roy H. Wepner, Robert B. Cohen, Lerner, David, Littenberg, Krumholz & Mentlik, Westfield, NJ, for Plaintiff.

Murray J. Laulicht, Pitney, Hardin, Kipp & Szuch, Florham Park, NJ, Kenneth P. George, Amster, Rothstein, & Ebenstein, New York, NY, for Defendants.

OPINION

DEBEVOISE**, Senior J.**

Plaintiff, Datascope Corporation ("Datascope"), instituted this action against defendant Arrow International, Inc. and Arrow International Investment Corp. (collectively, "Arrow"), alleging that claims 22-41 of Arrow's U.S. Patent No. Re. 34,993 FN1 ("the '993 patent") are invalid, and that the remaining claims of the '993 patent (claims 1-21) are not infringed by Datascope.FN2

FN1. Patent No. Re. 34,993, entitled "Method of Inserting an IAB Device Into The Body," dated July 4, 1995.

FN2. Datascope's notice of motion sought only a judgment of invalidity of claims 22-41 of the '993 patent. In its briefs and at oral argument it expanded its motion to include a declaration that its intra-aortic balloon device that does not use a hemostasis sheath does not infringe claims 1-21 of the '993 patent. No objection was raised to the expanded motion.

The '993 patent relates to methods of inserting intra-aortic balloon devices ("IADs") into an artery. The nub of Datascope's argument is that during the prosecution of U.S. Patent No. 4,897,077 ("the '077 patent"), which later was reissued as the '993 patent, Arrow initially sought claims that did not require a hemostasis sheath (a plug-like device that prevents bleeding). When Arrow failed to obtain allowance of such claims because of the prior art, it made amendments to its patent claims and asserted arguments in favor of

patentability that limited its claims to methods that employ a hemostasis sheath. Datascope does not use a hemostasis sheath or its equivalent. In order to assert its patent against Datascope Arrow obtained reissuance of the '077 patent as the '993 patent, obtaining claims that omitted any limitation requiring a hemostasis sheath. Arrow pursued a reexamination certificate as to the '993 patent and obtained more claims that omit any requirement of a hemostasis sheath. Original claims 1-21 all require the use of a hemostasis sheath; claims 22-41, which were added during the reissue and reexamination proceedings, do not.

Datascope contends that by initially seeking claims that did not require a hemostasis sheath, and by then narrowing its claims in the face of the prior art and arguing patentability over the prior art predicated on the presence of a hemostasis sheath, Arrow irrevocably surrendered the right to cover methods that do not employ a hemostasis sheath.

Datascope moved for summary judgment on claims 1-21 because those claims require a hemostasis sheath, which Datascope does not use. Datascope moved for summary judgment declaring claims 22-41 of the '993 patent invalid because they improperly broaden the patent to cover methods that omit the essential requirement of a hemostasis sheath, unlawfully recapturing subject matter that had previously been surrendered. For the reasons that follow Datascope's motion will be granted.

FACTS

Arrow specializes in the development and manufacture of, among other things, medical devices and instruments related to heart surgery and treatment. The original patent application that led to the '077 patent, was filed with 12 claims, of which claims 1 and 5 were independent. U.S. Patent Application Serial No. 53,178 Claim 1 read as follows:

1. A method for inserting an intra-aortic balloon apparatus into a patient's body through the patient's skin and into the patient's artery, wherein said intra-aortic balloon apparatus includes a balloon catheter having a proximal end and distal end, and an inflatable and deflatable balloon bladder means sealidly attached at the distal end of the balloon catheter and a hollow stylet means passing through the length of the intra-aortic balloon, the method comprising the steps of:

(a) puncturing the patient's skin into the patient's artery to create an opening in the skin and artery;

(b) inserting a guide wire into the artery and passing the guide wire up to the patient's aorta;

(c) dilating with dilating means the opening to achieve a diameter sufficient to permit insertion of the intra-aortic balloon apparatus into the artery;

(d) removing the dilating means;

(e) inserting the intra-aortic balloon bladder in a wrapped configuration directly through the opening over the guide wire and passing it up to the aorta; and

(f) removing the guide wire.

(Nelson Decl. Ex. D. at 18.) Claim 1 did not require use of a hemostasis sheath; nor did dependent claims 2-4.

The application also included independent claim 5, which read as follows:

5. A method of inserting an intra-aortic balloon apparatus into a patient's body through the patient's skin and into the patient's artery, wherein said intra-aortic balloon apparatus includes a balloon catheter having a proximal end and distal end, and an inflatable and deflatable balloon bladder means sealidly attached at the distal end of the balloon catheter and a hollow styllette means passing through the length of the intra-aortic balloon, the method comprising the steps of:

(a) puncturing the patient's skin into the patient's artery to create an opening in the skin and artery;

(b) inserting a guide wire into the artery and passing the guide wire up to the patient's aorta;

(c) dilating with dilating means the opening to achieve a diameter sufficient to permit insertion of the intra-aortic balloon apparatus into the artery;

(d) inserting the intra-aortic balloon bladder in a wrapped configuration directly through the opening and over the guide wire and passing it up to the aorta;

(f) removing the guide wire; and

(g) sliding the hemostasis sheath into the opening and partially into the artery to control bleeding from the opening.

(Nelson Decl. Ex. D. at 19-20.) Claim 5 differed from Claim 1 in that its preamble recited that the IAB apparatus further included a hemostasis sheath slidably coupled with the balloon catheter, it did not recite a step of "removing the dilator", and it added step (g) calling for "sliding the hemostasis sheath into the opening and partially into the artery to control bleeding from the opening."

Claims 1 and 5 as originally filed in the application were rejected as unpatentable under 35 U.S.C. s. 103 (along with all the other claims). (Nelson Decl. Ex. D. at 38-41.) Arrow then filed an amendment to the application. In the amended application, claims 1 and 5 and dependent claims 2-4) were cancelled, and claim 13, which largely corresponded to original Claim 5, was submitted as the only independent claim. It read as follows:

13. A method for inserting an intra-aortic balloon apparatus through a patient's skin and into the femoral artery, wherein said intra-aortic balloon apparatus includes a balloon catheter having a proximal end and a distal end, and inflatable and deflatable balloon bladder means sealidly attached at the distal end of the balloon catheter and a hollow stylette means passing through the length of the intra-aortic balloon, said intra-aortic balloon apparatus further including a hemostasis sheath slidably coupled with the balloon catheter, said hemostasis sheath having a distal end adjacent to the balloon bladder means and a proximal end opposite from the balloon bladder means having a larger outside diameter than that at the distal end, said intra aortic balloon apparatus also including sealing means releaseably coupled to said hemostasis sheath, the method comprising the steps of:

(a) puncturing the patient's skin and femoral artery to create an opening in the skin and artery;

(b) inserting a guide wire into the opening in the artery and passing the guide wire up to the patient's aorta;

(c) dilating with dilating means the opening to achieve a diameter sufficient to permit insertion of the intra-aortic balloon bladder means in a wrapped configuration into the femoral artery;

(d) removing the dilating means;

(e) without the use of sheath, directly inserting the intra-aortic balloon bladder means in a wrapped configuration over the guide wire and through the opening and passing it up to the aorta; and

(f) sliding the hemostasis sheath along the balloon catheter, through the insertion site and into the femoral artery far enough to control bleeding from the puncture opening in the femoral artery, yet permit blood flow along the femoral artery.

(Nelson Decl. Ex. D at 53-55). Thus at this point in the application process the only independent claim (and thus every claim) required the use of a hemostasis sheath.

In remarks accompanying the amended application, Arrow stated, *inter alia,* that in prior inventions, intra-aortic balloons (IAB's) had been designed to be inserted using an insertion sheath through the dilated opening and into the femoral artery, and that in all prior art attempts to insert IAB's percutaneously, sheaths had always been used. (Nelson Decl. Ex. D at 57-58.) Arrow added that this technique was the first time that intra-aortic balloons have been inserted percutaneously without passage through a sheath. (Nelson Decl. Ex. D at 58). Arrow concluded its remarks by stating that:

[n]owhere[ ] does the prior art show that, *in combination* with this sheathless insertion technique, subsequently a hemostasis sheath then is passed along the balloon catheter through the insertion site and into the femoral artery far enough to control bleeding from the puncture in the femoral artery yet permit blood flow along the femoral artery to the lower extremities. *It is Applicant's recognition that the sheathless insertions are possible with intra-aortic balloons combined with the use of the hemostasis sheath which gives rise to Applicants' inventive method.*

(Nelson Decl. Ex. D at 58-59 (emphasis added)). The "Remarks" section also noted that one of the cited references (Vallancourt) did not disclose or suggest the combination of a sheathless insertion of an IAB balloon with a hemostasis sheath, and that another reference (Wolvek) did not describe an IAB device with a hemostasis sheath. Similar arguments were made with respect to other references. It is Datascope's contention that the amendment and the remarks constituted an irrevocable surrender of patent coverage for methods that do not include the use of a hemostasis sheath.

Arrow abandoned the application in favor of a combination application, Serial No. 275,593. A Preliminary Amendment added 16 new claims to the seven claims that remained from the original application. Only two independent claims were added, claims 15 and 24, both of which had specific limitations relating to the use of a hemostasis sheath or hemostasis means.

In remarks accompanying the continuation, Arrow stated that:

[n]owhere [ ] does the prior art show that in combination with the sheathless insertion technique, a hemostasis sheath means such as a hemostasis sheath [ ] then is passed along the balloon catheter through

the opening and into the femoral artery for controlling bleeding. *It is Applicant's recognition that sheathless insertions are possible with percutaneous intra-aortic balloons combined with the use of the hemostasis sheath means for controlling bleeding from the opening, which give rise to Applicants' inventive method.*

(Nelson Decl. Ex. E at 14-15) (emphasis added)). In response to subsequent official actions Arrow reiterated its position that sheathless insertions are possible when combined with the use of a hemostasis sheath to control bleeding and that this combination gave rise to Arrow's inventive methods.

The continuation issued as U.S. Patent No. 4,897,077 with 21 claims ("the '077 patent"). (Nelson Decl. Ex. B.) Each of the 21 claims in the '077 patent required expressly or by dependency FN3 that the IAB catheter be inserted directly in a sheathless manner with a hemostasis sheath. Id.

FN3. Claims 1, 9, and 17 were independent claims.

Within the two-year period prescribed by 35 U.S.C. s. 251, Arrow filed Application Serial No. 826,868 seeking reissuance of the '077 patent. (Nelson Decl. Ex. F.) The application sought to add new claims 22-29, none of which referred to the hemostasis sheath requirement, but all of which required sheathless insertion of the IAB catheter. (Nelson Decl. Ex. A.)

The reissue declaration alleged that the original patent was wholly or partly inoperative or invalid by reason of claiming less than the patent applicants had a right to claim. In particular the reissue declaration asserted that the patent applicants had failed to obtain claims directed to a method for inserting an intra-aortic balloon apparatus wherein the apparatus does *not* include a hemostasis sheath, and the method does *not* include a step of placing a hemostasis sheath at the insertion site. New claims 22-29 were asserted to correct the defect. Asserting reliance on Arrow's attorney at the time, the declaration stated that the error in claim scope was discovered when Arrow investigated the possibility of an infringement of the patent and realized that the claims obtained were narrower in scope than what could have been obtained. Seeking to comply with the requirements of s. 251, the declaration went on to recite that acceptance of the narrower claims was due to an error on applicants' part, as well as on the part of the attorney handling the prosecution, and that the error was made without any deceptive intent.

The new claims sought to be added substantially correspond to claims 22-29, which were eventually issued in the '993 patent. The new claims also substantially correspond to independent claims 1 and 9 and dependent claims 4-6 of the '077 patent except that the new claims omit any reference to a hemostasis sheath. In particular independent claim 22 corresponded to claim 1 of the '077 patent, except that all reference the hemostasis sheath was deleted from the preamble, and the last step (f), reciting use of the hemostasis sheath was deleted from the claim. New independent claim 26 generally corresponded to claim 9 of the '077 patent, except that all references to the hemostasis sheath were eliminated. New dependent claims 23-25 and 27-29 were dependent on independent claims 22 and 26, respectively. None added a requirement of a hemostasis sheath.

The application proceeded through several office actions and responses. Datascope has pointed to several instances in which Arrow's responses relating to the inclusion of a hemostasis sheath were less than fully candid. For example, when trying to explain the "error" of failing to recognize that claims to the "disclosed embodiment" for insertion without a hemostasis sheath could be obtained, Arrow stated:

At that time, it was learned that the patent disclosure included insertion without the need for a hemostasis sheath *but that no claims for such an embodiment were presented*. It was concluded then that error had arose because of the failure to realize that such claims [*sic,* could] have been obtained but were not obtained.

(Exh F at 89 (emphasis added).). The underlined statement was untrue, because claim 1 as originally "presented" was broad enough to encompass methods that did not include the use of a hemostasis sheath. In any event, after a series of office actions the '993 patent issued on July 4, 1995.

Arrow filed a request for reexamination on December 31, 1996. Original claims 1-21-all of which required use of a hemostasis sheath-were confirmed as to their patentability from the outset of the proceedings. After proceedings before the examiner and the PTO's Board of Patent Appeals and Interferences a Reexamination Certificate Issued on November 2, 1999. In addition to confirming claims 1-21, the certificate states that independent claims 22 and 26, both of which had been added during reissue, were determined to be patentable as amended. Also, dependent claims 23-25 and 27-29, as dependent on amended independent claims, were determined to be patentable. New independent claims 32 and 36 recite essentially the same method of claims 22 and 26 and omit any reference to a hemostasis sheath. The new dependent claims 30 and 31 are dependent on claims 22 and 26, respectively; new claims 33-35 and claim 40 are dependent on claim 32; new claims 37-39 and 41 are dependent on claim 36. None makes reference to a hemostasis sheath.

Thus each of claims 22-41 of the reissued and reexamined '993 patent is broader in scope than independent claims 1, 9 and 17 of the '077 patent in that none of them require the provision of a hemostasis sheath or a step of sliding the hemostasis sheath into the opening in the artery. These are the claims that Arrow has asserted against Datascope.

SUMMARY JUDGMENT STANDARD

Pursuant to Fed.R.Civ.P. 56(c), a motion for summary judgment will be granted if the pleadings, depositions, answers to 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. *See* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

Whether the statutory requirements of 35 U.S.C. s. 251 have been met is a question of law, Hester Indus., Inc. v. Stein, Inc., 142 F.3d 1472, 1479 (Fed.Cir.1998). Deciding this legal question may involve questions of fact. *Id*. If a moving party satisfies its initial burden of establishing a prima facie case for summary judgment, the opposing party "must do more than simply show that there is some metaphysical doubt as to material facts." Matsushita Elec. Indus, Co., v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Instead, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial'." Id. at 587 (quoting Fed R. Civ. P. 56(e)). In a case, such as the present one, that involves application of the recapture rule, there are less likely to be material issues of fact, because to a large extent the case turns upon an indisputable record before the Patent Office.

DISCUSSION

Under the patent law a patentee is free to seek reissue of a patent if the patentee believes that his patent claims more or less than he had a right to claim, due to an error made without deceptive intent. 35 U.S.C. s. 251. If the patentee wants to pursue claims that are broader in scope than the original patent claims, then the

reissue must be sought within two years of the grant of the patent. The statute reads in pertinent part as follows:

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue

* * *

No reissued patent shall be granted enlarging the scope of claims of the original patent unless applied for within two years from the grant of the original patent.

Arrow's reissue application was filed within the two year period, but Datascope challenges the validity of the reissued patent on the basis of the recapture rule that bars the patentee from acquiring, through reissue, claims that are of the same or of broader scope then those claims that were cancelled from the original application. Mentor Corp. v. Coloplast, Inc., 998 F.2d 992, 995 (Fed.Cir.1993) (quoting Ball Corp. v. United States, 729 F.2d 1429, 1436 (Fed.Cir.1984)). The recapture rule "prevents a patentee from regaining through reissue the subject matter that he surrendered in an effort to obtain allowance of the original claims." In re Clement, 131 F.3d 1464, 1468 (Fed.Cir.1997). Any limitations that are added to a claim in order to overcome a prior art objection cannot later be deleted from the claims in a subsequent reissue proceeding.

In the present case Datascope contends that the addition of a hemostasis sheath to sheathless insertion was an element added during the original prosecution to distinguish over the prior art. Arrow, on the other hand, contends that "the evidence is overwhelming that the sheathless insertion requirement was the critical requirement added to distinguish over the prior art and that use of a hemostasis sheath was simply a secondary embodiment that was not germane to any prior art rejection." (DB at 15).

In re Clement, 131 F.3d, prescribes the steps to determine the applicability of the recapture rule: i) "The first step in applying the *recapture* rule is to determine whether and in what 'aspect' the *reissue* claims are broader than the patent claims", at 1468. ii) "The second step is to determine whether the broader aspects of the reissue claims relate to surrendered subject matter", at 1468-69. This requires a finding that the applicant's amendment was an admission that the scope of that claim was not in fact patentable. iii) "Once we determine that an applicant has surrendered the subject matter of the canceled or amended claim, we then determine whether the surrendered subject matter has crept into the reissue claim", at 1469.

It is readily apparent that claims 22-29 of the '993 reissue patent are broader in scope than the claims that had originally issued in the '077 patent in that the reissue claims eliminated any requirement that the IAB apparatus include a hemostasis sheath and eliminated the step of placing a hemostasis sheath at the insertion site. Independent reissue claim 22 was based on claim 1 of the original '077 patent, but eliminated the portion of the claim's preamble reciting that the IAB apparatus further includes a hemostasis sheath and how it is slidably coupled with the balloon catheter, as well as step (f) concerning the operation of the hemostasis sheath along the balloon catheter. Independent reissue claim 26 (which corresponded to claim 9 of the '077 patent) eliminated the same recitations concerning the hemostasis sheath from the preamble and steps (f)

and (g) of claim 9. Dependent reissue claims 23-25 and 27-29 (depending either directly or indirectly on reissue claims 22 or 26) are identical to original dependent claims 4-6 of the '077 patent except that they depend on the newly added reissue claims 22 and 26, respectively, which omit any requirement of a hemostasis sheath. None of the dependent claims add back any reference to a hemostasis sheath. In this manner the reissue claims were broadened.

Turning to the question whether the broader aspects of the reissue claims relate to the surrendered subject matter, the court must look to the prosecution history for arguments and changes to claims made in an effort to overcome prior art rejection.

Arrow argues that the omission of the hemostasis sheath requirement from claims 22-41 in the '993 patent was not critical to patentability and was not necessary to distinguish the invention over the prior art. Arrow further argues that the original claims in the '077 patent were not intended to be limited to sheathless insertion coupled with a hemostasis sheath; that the hemostasis sheath of the first patent '077 was not an essential or integral part of the patentability of its claims; and that its entire invention was for sheathless insertion only. More specifically, Arrow argues that the examiner's rejection of application claim 5, "*which required the hemostasis sheath,* as 'obvious' over the prior art, provides conclusive evidence that this limitation did not distinguish over the prior art and was not critical to patentability ." (DB at 18) (emphasis in original). So too, Arrow points out a second examiner acknowledged in her reasons for allowance that the hemostasis sheath was not a patentable feature of the invention. Id.

The examiners' assertions as to the patentability of an insertion sheath alone, however, are irrelevant to the ultimate question of what the '077 patent actually claimed. An element of a patent can be unpatentable by itself but can become patentable in combination with another element; and a combination of elements can be patentable whether it be composed of elements all new, partly new, or all old. Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546 (Fed.Cir.1984). "That all elements of an invention may have been old (the normal situation), or some old and some new, or all new, is, however, simply irrelevant. Virtually all inventions are combinations and virtually all are combinations of old elements." *Env*. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 698 (Fed.Cir.1983). Therefore, the examiner's determination that a hemostasis sheath alone is not patentable subject matter does not foreclose the possibility that the hemostasis sheath could be combined with other elements-namely, sheathless insertion-to make the whole invention patentable.

It must be determined from the prosecution history of the '077 patent whether the insertion sheath was part of the combination of the original '077 patent. If it was, then the '077 patent must be considered as a whole, with its old and new parts, because all these parts combined to make the '077 patent.

Originally Arrow filed a patent application containing independent claims 1 and 5. Claim 1 did not require use of a hemostasis sheath. Claim 5 called for a hemostasis sheath. The application was rejected by the examiner under 35 U.S.C. s. 103 as being obvious under certain prior art. Consequently, Arrow cancelled claims 1 and 5, and filed a single new independent claim (claim 13) that required both a hemostasis sheath and sheathless insertion.

Arrow argues that because a hemostasis sheath was obvious, its inclusion of the hemostasis sheath limitation in claim 13 was not necessary to distinguish the claims over prior art. If it thought so at the time one questions why it cancelled claim 1 which was broad enough to include sheathless insertion without being limited by the requirement of a hemostasis sheath. One obvious answer is that Arrow had concluded that

either of the two features alone would be barred by the prior art but that the two in combination constituted a patentable invention. The prosecution history supports that conclusion. The language of Arrow's amended claim 13 expressly included in the patent disclosure and the claims *both* the hemostasis sheath *and* the sheathless insertion limitations.

Specifically, the language of the amended application reads: "it is the Applicants' recognition that sheathless insertions are possible with intra-aortic balloons combined with the use of the hemostasis sheath which gives rise to Applicants' inventive method." (Nelson Decl. Ex. D at 59). That description of the patent was clearly and faithfully reflected in claim 1 of the '077 patent, which expressly requires a sheathless insertion in paragraph (e) of claim 1 and "sliding the hemostasis sheath" in paragraph (f) of claim 1. (Nelson Decl. Ex. B). As set forth in the Statement of Facts above, Arrow presented this thesis throughout the prosecution of the application. Therefore, contrary to Arrow's arguments, the claims and the prosecution history of the '077 patent show that there was no error by virtue of which the '077 patent could be deemed "wholly or partly inoperative or invalid" under section 251 by reason of "claiming more or less than [Arrow] had a right to claim in the patent." 35 U.S.C.A. s. 251.

Arrow's insistence that sheathless insertion *alone* is the heart of the patent, and that the language of the claims and the disclosures should be read to reflect that centrality, is unsustainable. Indeed, "there is no legally recognizable or protected 'essential,' 'gist,' or 'heart' of the invention." Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 875 (Fed.Cir.1985), *overruled on other grounds,* Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed.Cir.1998). Ultimately, it is the *combination* of elements, not any single element or subset of that combination, that is patented. Porter v. Farmers Supply Serv., Inc., 790 F.2d 882 885 n. 4 (Fed.Cir.1986). The public has the right to rely on the documented claims and prosecution history of a patent. Particularly when patent claims are broadened during reissue, it can affect competitors who previously relied on the original and relatively narrow scope of the patent. *See* Vectra Fitness, Inc. v. TNWK Corp., 162 F.3d 1379, 1384 (Fed.Cir.1998), *cert. denied,* 526 U.S. 1160 (1999).

During reexamination of the '993 reissue patent, independent claims 22 and 26 (which had been added in reissue) were amended to add an additional step. Also new method claims 30-41 were added during reexamination. Of importance for present purposes, all claims 22-41 are broader in scope than the original claims 1-21 of the '077 patent in that, after the reexamination, none of claims 22-41 require that the IAB apparatus include a hemostasis sheath or the step of sliding the hemostasis sheath along the balloon catheter through the insertion site or opening and into the femoral artery. Each of claims 22 and 26 (as amended in reexamination) and new method claims 30-41 (added in reexamination) in the '993 reissue patent remain broader than the original independent claims of the '077 patent in the same manner or aspect as the claims obtained during reissue in that they omit any requirement for a hemostasis sheath. Amended claims 22 and 26 and new claims 30-41 are invalid for violating the recapture rule because the claims are "as broad as or broader in an aspect genuine to a prior art rejection, but narrower in another aspect completely unrelated to the rejection." See Clement, 131 F.3d at 1470.

The present case falls squarely within the recapture rule that "prevents the patentee from regaining through reissue ... subject matter that he surrendered in an effort to obtain allowance of the original claims." In re Clement, 131 F.3d at 1468. "The rule is rooted in the 'error' requirement in that such surrender is not the type of correctable 'error' contemplated by the reissue statute." Hester Indus., 142 F.3d at 1480 (citing Mentor Corp ., 998 F.2d at 995-96). In this case there was a deliberate surrender of the sheathless insertion claim when not in combination with the hemostasis sheath. This is demonstrated both by the amendment deleting original claims 1 and 5 and it is demonstrated by Arrow's argument designed to overcome the prior

art. As recognized in *Hester Industries, id.* at 1481, in a proper case surrender can occur through arguments alone. Anchor's arguments directed to the examiner were alone sufficient to effect a surrender.

In sum, both the hemostasis sheath and sheathless insertion were integral parts of the '077 patent, and were essential limitations upon its scope. Arrow relied heavily and repeatedly upon this combination of elements in prosecuting its patent claims. Further, there is no demonstration of error in the prosecution history of the '077 patent that will justify broadening the scope of the reissued patent by allowing the patent to encompass claims that had been surrendered. Therefore, claims 22-41 of the '993 reissued patent are invalid.

Datascope also moves for summary judgment that claims 1-21 are not infringed for the reason that those claims require a hemostasis sheath and Datascope never uses one or induces others to do so. It follows from the foregoing discussion that these claims of the '993 patent do not read upon Datascope's apparatus and Datascope is entitled to the judgment it seeks in this respect.

CONCLUSION

For the reasons set forth above Datascope's motion will be granted in its entirety and an order will be entered i) declaring that claims 22-41 of the '993 patent are invalid, ii) declaring that Datascope's IAB device does not infringe claims 1-21 of the '993 patent, and iii) granting final judgment in favor of Datascope.

D.N.J.,2001.
Datascope Corp. v. Arrow Intern., Inc.