

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

GARY A. LAMOUREUX, :
RICHARD A. TERWILLIGER, :
WORLD WIDE MEDICAL TECHNOLOGIES, :
LLC, :
ADVANCED CARE MEDICAL, INC., :
ADVANCED CARE PHARMACY, INC., :
ADVANCED CARE PHARMACY LLC, and :
IDEAMATRIX, INC., :
 :
Plaintiffs-Counterclaim :
Defendants, :
 :
vs. :
 :
ANAZAOHEALTH CORP., f/k/a :
GENESIS PHARMACY SERVICES, INC., :
d/b/a CUSTOM CARE PHARMACY, :
 :
Defendant-Counterclaimant. :
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No. 3:03cv01382 (WIG)

CLAIM CONSTRUCTION OPINION

Plaintiffs Gary A. Lamoureux and Richard A. Terwilliger are the named co-inventors of U.S. Patent No. 6,554,760 (the '760 Patent) (attached hereto as "Appendix A"), issued on April 29, 2003, and entitled "Pre-Loaded Needle Assembly." The '760 Patent claims an invention for a pre-plugged and pre-loaded needle assembly for the implantation of therapeutic elements into the body for the treatment of cancer. On August 11, 2003, they, along with World Wide Medical Technologies, LLC, the then-exclusive licensee of the patent, filed suit against Genesis Pharmacy Services, Inc., doing business as Custom Care Pharmacy, alleging, inter alia, various claims of patent infringement. Plaintiffs

were granted leave to amend their complaint twice,¹ ultimately resulting in the filing of a Corrected First Amended Complaint on October 21, 2005, with owners and/or licensees Advanced Care Pharmacy LLC, Advanced Care Pharmacy, Inc., Advanced Care Medical, Inc., and IdeaMatrix, Inc., named as additional plaintiffs, and AnazaoHealth Corporation, formerly known as Genesis Pharmacy Services, Inc., named as the sole Defendant (hereinafter "AnazaoHealth" or "Defendant").

Plaintiffs Lamoureux, World Wide Medical Technologies, LLC, Advanced Care Medical, Inc., Advanced Care Pharmacy, Inc., and Advanced Care Pharmacy LLC (collectively "the World Wide Plaintiffs") have asserted that Claims 1, 2, 3, 9, 10, 16, 17, 18, and 21 of the '760 Patent have been infringed by Defendant. Plaintiffs Richard A. Terwilliger and IdeaMatrix, Inc., (collectively "the Terwilliger Plaintiffs") have asserted a patent infringement claim relating solely to Claim 9.²

Following the submission of initial and responsive claim construction memoranda by all parties, the Court held a full-day

¹ Plaintiffs never filed an amended complaint after their first motion for leave to amend was granted. Later they filed a second motion for leave to amend, which in part reflected assignments and transfers of interests in the '760 Patent that had taken place since the last motion to amend. This motion was granted, and the Corrected First Amended Complaint was filed.

² Occasionally, the Court also uses the term "Plaintiffs" to refer to one or more groups of Plaintiffs, when it is clear in the context to which group(s) the term refers.

Markman³ hearing, at which the parties were given the opportunity to submit internal and external evidence in support of their proffered claim constructions. Additionally, the Court received supplemental briefs from the World Wide Plaintiffs and Defendant concerning the issuance of a certificate of correction to the '760 Patent subsequent to the filing of the original complaint. After due consideration of all of briefs and evidence, the Court now renders this Claims Construction Ruling.

Background

As an alternative to general surgery, brachytherapy is a method of cancer treatment whereby a pattern of radioactive seeds is implanted in the vicinity of a cancerous tumor to destroy cancer cells with low-dose radiation. ('760 Patent col. 1, ll. 14-17.) Because optimal treatment of the patient depends on the proper spacing and location of the radioactive seeds, physicians must carefully position the radioactive seeds in a patient's body.⁴ This is accomplished by using multiple hollow needles, also referred to as "cannula,"⁵ which act as holders and carriers

³ Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996).

⁴ See Def.'s Ex. 501, A. Van't Riet, "Ultrasonically Guided Transperineal Seed Implantation of the Prostate: Modification of the Technique and Qualitative Assessment of Implants," 24 Int. J. Radiation Oncology Biol. Phys. 555-58 (1992).

⁵ A "cannula" is a small tube made for insertion into a body cavity. Webster's Third New International Dictionary at 327 (1993) ("Webster's").

of the seeds. Id. at col. 1, ll. 18-22. Prior to insertion of the cannula into a predetermined area of the body, a solid wire stylet is axially introduced into the proximal end of the cannula and rests on the stack of seeds and spacers. Id. at col. 1, ll. 52-54. The cannula is then inserted into the body to the proper position. Id. at col. 1, ll. 55-57. The stylet is held firmly and the cannula is moved axially toward the proximal end of the stylet. Id. at col. 1, ll. 56-58. This motion deposits the radioactive seeds and spacers into the body in a predetermined track or line as the cannula is pulled back. Id. at col. 1, ll. 58-60. The seeds remain in the body as the radioactive dose decays over the treatment time. Id. at col. 1, ll. 23-25. As many as 25 needles or more may be used for each procedure. Id. at col. 1, ll. 26-27.

Two principal types of radioactive seeds are used: "free" seeds, which are individual radioactive seeds that are loaded into the cannula with small non-radioactive cylindrical spacers stacked between them, and a pre-manufactured "strand" of radioactive seeds encapsulated in a biodegradable material that spaces the seeds apart from one another. Id. at col. 1, ll. 61-67. Typically, a physicist or the physician had to pre-load the radioactive seeds into the needles prior to the procedure, which was both time-consuming and risked exposure to radiation. Id. at col. 1, ll. 27-29; col. 2, ll. 25-26.

Prior art needle assemblies disclosed a cannula with a sharpened distal tip and an inner solid wire stylet used to push the radioactive seeds into the body. Id. at col. 1, ll. 36-38. The proximal end of the cannula consisted of a plastic or metal hub that allowed the loading of the radioactive seeds into the cannula. Id. at col. 1, ll. 38-40. The proximal end of the stylet was a plastic or metal handle for manipulation of the stylet. Id. at col. 1, ll. 41-42.

The prior art devices were prepared for use by plugging the end of the cannula with bone wax. Id. at col. 1, ll. 43-44. The bone wax extended into the first 2 mm. to 5 mm. of the distal tip of the cannula to contain the seeds and to prevent body fluids from entering the cannula before deployment of the seeds. Id. at col. 1, ll. 44-47. The bone-wax plugged cannula was then loaded with radioactive seeds held apart by short non-radioactive spacers that positioned the seeds in the body to achieve an even distribution to treat the suspected cancer in vivo. Id. at col. 1, ll. 47-51.

The complications involved in the prior art stemmed from the use of bone wax or other materials to plug the cannula prior to loading the radioactive seeds. Id. at col. 2, ll. 2-4. Bone wax could not be applied in a manner that assured a consistent positioning of the first seed, and the amount of bone wax varied from needle to needle. Id. at col. 2, ll. 5-9. Bone wax was

also sticky and could cause the first few seeds deployed to stick to the end of the cannula as it was being withdrawn, thus displacing them from their intended position in the treated tissue. Id. at col. 2, ll. 9-14. Further, if the seeds and spacers had to be removed after the initial loading to change the pattern of seeds and spacers in a given needle, the bone wax prevented the unloading of seeds that came in contact with the wax. Thus, the needle could not be reused in the procedure. Id. at col. 2, ll. 16-20.

The pre-loaded needle assembly that is disclosed by the '760 patent comprises a needle that is pre-plugged and pre-loaded with radioactive seeds on the order of a physician. Id. at col. 2, ll. 23-26. Once assembled, the needle is sterilized and shipped to the facility where the brachytherapy treatment will take place. The invention addresses the problem of having to load the brachytherapy needles in the operating room prior to the procedure, which, as noted above, was time-consuming and risked exposing the physician or physicist to radiation. Id. at col. 2, ll. 25-26. Additionally, the needle assembly of the '760 Patent uses an end plug that exactly locates the first seed a repeatable and known distance from the distal end of the cannula, thus improving the accuracy of placing the radioactive seeds in the body, which is important to the efficacy of the cancer treatment. Id. at col. 2, ll. 27-31.

Discussion

I. The Impact of the Certificate of Correction

Initially, the Court must determine whether additional wording added to the '760 Patent by the certificate of correction issued on November 25, 2003, should be considered in this infringement action, which was filed prior thereto. Defendant asserts that the certificate of correction should have no impact on this case because, under 35 U.S.C. § 254, a certificate of correction has no effect on causes of action instituted prior to the issuance of the certificate. Defendant maintains that the patent in suit must stand or fall without the correcting language, citing E.I. Du Pont De Nemours & Co. v. MacDermid Printing Solutions, LLC, 525 F.3d 1353, 1362 (Fed. Cir. 2008), Novo Indus., L.P. v. Micro Molds Corp., 350 F.3d 1348, 1356 (Fed. Cir. 2003), and Southwest Software, Inc. v. Harlequin, Inc., 226 F.3d 1280, 1295-96 (Fed. Cir. 2000).

Plaintiffs respond that Defendant has ignored the basic distinction between the commencement of a lawsuit and the accrual of a cause of action for infringement, citing STMicroelectronics, Inc. v. Motorola, Inc., 327 F. Supp. 2d 687, 700 (E.D. Tex. 2004) (holding that under Southwest Software the relevant inquiry is the date the cause of action arose, not when suit was filed). Plaintiffs concede that the certificate of correction cannot be applied to causes of action accruing prior to its issuance but

argue that, as to all causes of action accruing after November 25, 2003, the certificate of correction is to be treated as part of the original patent, citing Southwest Software, 226 F.3d at 1295. Because each act of infringement gives rise to a separate cause of action, see E.I. Du Pont De Nemours, 525 F.3d at 1362, Plaintiffs assert that they may rely on the certificate of correction for all acts of infringement occurring after November 25, 2003, which are encompassed in their First Amended Complaint. See LG Elecs., Inc. v. Quanta Computer Inc., 566 F. Supp. 2d 910, 912 (W.D. Wisc. 2008) (holding that the certificate of correction would not be effective for purposes of enforcement unless the plaintiff filed a new lawsuit or amended its complaint).⁶

The Patent Act, 35 U.S.C. § 254, provides:

Whenever a mistake in a patent, incurred through the fault of the Patent and Trademark Office, is clearly disclosed by the records of the Office, the Director may issue a certificate of correction stating the fact and nature of such mistake, under seal, without charge, to be recorded in the records of patents. A printed copy thereof shall be attached to each printed copy of the patent, and such certificate shall be considered as part of the original patent. Every such

⁶ In LG Electronics, the court denied the patentee's motion for leave to supplement its complaint to add claims for infringement after the Patent and Trademark Office ("PTO") issued a certificate of correction, because of the patentee's undue delay in seeking leave to supplement - the motion having been filed just three days before the dispositive motion deadline - and unfair prejudice to the defendant, including the need for new expert reports and new claims construction briefs. 566 F. Supp. 2d at 912-13.

patent, together with such certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

(Emphasis added).

It is undisputed that, at the time the original complaint was filed, the certificate of correction had not been issued. Three months after suit was filed, the Patent and Trademark Office ("PTO") issued the certificate of correction on November 25, 2003, to insert the phrase "frictionally held" in Claim 1, Column 5, Line 46, following "including a." Thus, Claim 1 of the '760 Patent (col. 5, ll. 43-51) now reads:

1. For implanting therapeutic elements, a needle assembly comprising a cannula having a wall and a sharpened distal end, a line of elements in the cannula extending rearward from the distal end, yieldable means, including a frictionally held⁷ plug, for positioning an element more proximate the distal end a predetermined distance from the distal end, and a stylet reciprocable in the cannula and having a distal end engaging an end of the line of elements more remote from the distal end of the cannula.

The prosecution history reveals that this correction was the result of a telephone interview between the patent examiner and the applicants' attorney regarding Claim 1, wherein the applicants gave their permission to this amendment to avoid a

⁷ Emphasis added by the Court to denote the language that was added by the certificate of correction issued November 25, 2003.

conflict with prior art. A notice of allowability was then mailed on January 24, 2003, including the examiner's amendment, inserting the phrase "frictionally held." ('760 Patent, Prosecution History, Ex. C, W0420, W0492-W0494.)⁸ Unfortunately, however, due to a printing error at the PTO, the issued patent did not include this language.

The certificate of correction was first referenced in this litigation as part of the Corrected First Amended Complaint,⁹ which attached the certificate of correction to the '760 Patent and which was filed as an exhibit to the complaint.

The statute itself provides that a certificate of correction will have prospective effect only "for causes thereafter arising." 35 U.S.C. § 254. Accordingly, in Southwest Software, the Federal Circuit held that a "certificate of correction is only effective for causes of action arising after it was issued." 226 F.3d at 1294 (emphasis added). In that case, because the cause of action arose before the certificate of correction issued, the certificate of correction was not given effect. Id. This holding was reiterated in Novo Industries, 350 F.3d at 1356,

⁸ Hereinafter, the Prosecution History will simply be referred to by the Bates numbered pages.

⁹ Defendant opposed the motion to amend the complaint to reference the certificate of correction. In granting leave to amend, Judge Droney did not reach the merits of this argument.

wherein the court noted that sections 254 and 255¹⁰ “deal only with the authority of the PTO to make prospectively effective corrections, and the PTO was given no authority to correct the claims retroactively.” Thus, the court held that for causes of action arising before the certificate became effective, “the patent must be considered without the benefit of the certificate of correction.” Id. Likewise, in STMicroelectronics, 327 F. Supp. 2d at 700, the court emphasized that the relevant inquiry for considering a certificate of correction is the date the cause of action arose rather than the date the suit was filed. Most recently, in E.I. Du Pont De Nemours, 525 F.3d at 1362, the court found a certificate of correction was effective only as to prospective infringement occurring after the issuance of the certificate.

Based on the holdings of Southwest Software, Novo Industries, STMicroelectronics, and E.I. Du Pont De Nemours, the Court finds that the critical date for purposes of determining whether the certificate of correction applies is the date the cause of action arose, i.e., the date the infringing conduct occurred, and not the date the complaint was filed. See also

¹⁰ Section 255 applies to a certificate of correction issued to correct an applicant’s mistake, as opposed to a mistake by the PTO. Like section 254, section 255 provides in relevant part that “[s]uch patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.” 35 U.S.C. § 255.

Rohm Co. v. Nichia Corp., No. Civ. A. 00-6379, 2003 WL 22844207, at *2 (E.D. Pa. Nov. 26, 2003) (holding that a certificate of correction is only effective as to causes of action arising after it was issued).¹¹ In the instant case, unlike Southwest Software, Plaintiffs are suing for acts of infringement taking place both before and after the certificate of correction issued. Plaintiffs filed a Corrected First Amended Complaint that included the certificate of correction and encompassed acts of infringement arising after the certificate of correction had issued.¹² As to all acts of infringement occurring after

¹¹ Because the court in Rohm found that the only valid certificate of correction was issued eleven months after the complaint was filed and was thus ineffective, the court never addressed when the causes of action arose. 2003 WL 22844207, at *2.

¹² Despite Defendant's arguments to the contrary, the propriety of the Court's granting leave to amend is not at issue. Technically, Plaintiffs' motion should have been entitled a motion to supplement under Rule 15(d), Fed. R. Civ. P., rather than a motion for leave to amend, since it sought to include causes of action accruing since the filing of the original complaint. See Cabrera v City of Huntington Park, 159 F.3d 374, 382 (9th Cir. 1998); Matsushita Elec. Indus. Co. v. CMC Magnetics Corp., No. C 06-04538, 2007 WL 127997, at *2 (N.D. Cal. Jan. 12, 2007). The Court notes that there is substantial authority for allowing supplemental pleadings where the new infringement claims relate to the same technology or to new patents containing similar claims as those in the original patent. See, e.g., Abbott Labs. v. Inverness Med. Tech., No. Civ. A. 98-10674, 2002 WL 1906533, at *2 (D. Mass. Aug. 19, 2002) (allowing the patentee to file a supplemental complaint to assert an infringement claim for a patent that issued after the original complaint was filed where the newly issued patent contained similar claims to the original patent and, therefore, adding the claims of the new patent would promote efficiency and judicial economy); Proctor & Gamble Co. v. McNeil-PPC, Inc., No. 98-361, 1998 WL 1745118, at *

November 25, 2003, and, thus, as to all causes of action arising after November 25, 2003, the Court holds that the '760 Patent must be read to include the certificate of correction.¹³

II. Claim Construction Analysis

A. General Principles of Claim Construction

An infringement analysis involves two steps. The first step requires the court to determine, as a matter of law, the meaning and scope of the patent claims alleged to have been infringed.

Markman, 52 F.3d at 979. The second step requires the fact

2-3 (D. Del. Dec. 7, 1998) (granting patentee's motion for leave to supplement its complaint to add infringement claims for a new patent that issued after the lawsuit was filed); Beery v. Hitachi Home Elec. (Am.), Inc., 157 F.R.D. 481, 483-84 (C.D. Cal. 1994) (allowing the patentee to amend his lawsuit to include a reexamination certificate issued by the PTO after the original complaint was filed since the defendants had actual knowledge that the plaintiff was asserting infringement of claims newly added or amended during reexamination); Micron Tech., Inc. v. Rambus Inc., 409 F. Supp. 2d 552, 558-60 (D. Del. 2006) (permitting patentee to add new infringement claims for additional patents drawn to the same technology as the previously asserted patents and to amend the list of accused products and to reflect allegedly new infringing sales); see also Monoplastics, Inc. v. Caldor, Inc., 264 F. Supp. 57, 65 (D. Conn. 1966) (granting leave to amend to add a second count for infringement of the design patent in addition to the utility patent), aff'd, 378 F.2d 20 (2d Cir. 1967); Kahn v. General Motors Corp., 865 F. Supp. 210, 215 (S.D.N.Y. 1994) (allowing plaintiff to supplement his complaint to allege continuing infringements); but see Rohm Co., 2003 WL 22844207, at *2 (denying plaintiff's motion for leave to amend so that the certificate of correction would be effective for the current action).

¹³ The World Wide Plaintiffs' counsel represented at the Markman hearing that all of the acts of infringement of Claim 1 arose after November 25, 2003. Therefore, the Court will only construe Claim 1 as amended by the certificate of correction.

finder to compare the properly construed claim to the accused device in order to determine whether all of the claim limitations are present in the accused device, either literally or by a substantial equivalent. Markman, 52 F.3d at 976-9.

At this stage of the proceedings, this Court is concerned only with the first step, the construction of the disputed patent claims, which is a matter of law exclusively for the Court. See Markman, 52 F.3d at 970.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc) (quoting Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)), cert. denied, 546 U.S. 1170 (2006). Courts construe claims to resolve disputes about claim terms and to assign fixed, unambiguous, legally operative meaning to the claim, so that a patentee's right to exclude is clearly defined. Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1367 (Fed. Cir. 2004). However, claims are to be construed without the objective of capturing or excluding the accused device. NeoMagic Corp. v. Trident Microsystems, Inc., 287 F.3d 1062, 1074 (Fed. Cir. 2002).

The words of a claim "are generally given their ordinary and customary meaning." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "[T]he ordinary and customary

meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” Phillips, 415 F.3d at 1313. Where such meaning is “readily apparent even to lay judges, . . . claim construction . . . involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful.” Id. at 1314 (citations omitted). In many cases, however, the meaning of a term is not “readily apparent” and “determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art.” Id. The inquiry into how a person of ordinary skill in the art would understand a claim term is based on the common understandings that inventors are generally skilled in the field of their invention and that patents are addressed to and intended to be read by others who are skilled in the art in question. Id.

The person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim at issue, but also in the context of the entire patent, including the specification and prosecution history. Id. (citing Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005)). “This last tenet derives from the fact that claims do not stand alone but rather ‘are part of a fully integrated written

instrument consisting principally of a specification that concludes with the claims.’” ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368, 1374 (Fed. Cir. 2009) (quoting Phillips, 415 F.3d at 1315). “The close kinship between the written description and the claims is enforced by the statutory requirement that the specification describe the claimed invention in ‘full, clear, concise, and exact terms.’” Phillips, 415 F.3d at 1316 (quoting 35 U.S.C. § 112).

Thus, it is well-settled that, in interpreting an asserted claim, the court should first consider the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification, and, if in evidence, the prosecution history. Vitronics, 90 F.3d at 1582. The rationale for relying on the intrinsic evidence is that this evidence is a matter of public record, a record on which the public is entitled to rely. Id. at 1583.

The court examines the intrinsic evidence seriatim. Liquid Dynamics Corp., 355 F.3d at 1367. First, the court must first consider the words of the claims themselves to define the scope of the patented invention. Bell Commc’ns Research, Inc. v. Vitalink Commc’ns Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use a term in a manner other than its ordinary

meaning. However, in such a case, the special definition must be clearly stated in the specification or prosecution history.

Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir.), cert. denied, 519 U.S. 911 (1996); Markman, 52 F.3d at 980.

Second, the court must review the specification, which contains a written description of the invention that must be clear and complete to enable one of ordinary skill in the art to make and use the invention. Markman, 52 F.3d at 979. The specification is "always highly relevant to the claim construction analysis" and is "the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582. The Federal Circuit has cautioned, however, that because the claims define the invention, limitations from the specification should not be read into those claims. Rather, a claim should be read in light of the specification. Comark Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed. Cir. 1998). Third, the court looks to the patent's prosecution history, if in evidence, which is also a matter of public record. Id. The prosecution history consists of the complete record of the proceedings before the PTO, including the prior art cited during the patent examination and the applicant's acquiescence with regard to the prior art, which indicates what the claims do not cover. Phillips, 415 F.3d at 1317; Liquid Dynamics Corp., 355 F.3d at

1367. However, since the prosecution history represents ongoing negotiations between the inventor and the PTO rather than the final product of the negotiation process, it often lacks the clarity of the specification and may be less useful in the claims construction process. Phillips, 415 F.3d at 1317; United Techs. Corp. v. PerkinElmer, Inc., 537 F. Supp. 2d 392, 398 (D. Conn. 2008).

In most cases, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term, and in such cases, it is improper to rely on extrinsic evidence. Only if there is some genuine ambiguity in the claim after consideration of all the intrinsic evidence may the court consider extrinsic evidence. Vitronics, 90 F.3d at 1583.

Extrinsic evidence is that evidence which is external to the patent and file history and includes expert and inventor testimony, dictionaries, and learned treatises and articles. Markman, 52 F.3d at 980. Extrinsic evidence is generally considered to be less reliable than intrinsic evidence because it is not part of the patent and was not created at the time of the patent's prosecution for the purpose of explaining the patent's scope and meaning. Phillips, 415 F.3d at 1318. While extrinsic evidence may be used by the court to explain terminology, to aid the court in understanding the state of the art at the time of the invention, and to help the court in understanding scientific

principles, it may not be used to vary or contradict the claim language. Id. at 981. Moreover, the use of extrinsic evidence is discretionary. The court may accept evidence that it finds useful and reject other evidence as unhelpful. See Robert L. Harmon, Patents and the Federal Circuit § 6.1 at 307 (8th ed. 2007) (hereinafter "Harmon"). "Thus, although construction may be enlightened by such extrinsic evidence as is helpful, it is still based upon the patent and its prosecution history." Id.

The Federal Circuit in Phillips, 415 F.3d at 1302-04, also cautioned against reliance on the dictionary definition of disputed claim terms, which focuses on the abstract meaning of the words rather than their meaning in the context of the patent. Although the court may consult dictionaries in order to better understand the underlying technology and the commonly understood meaning of a word, the dictionary definition may not contradict any definition found in or ascertained by a reading of the patent documents. Vitronics, 90 F.3d at 1584 n.6. "In sum, . . . it is '[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention [that] will be, in the end, the correct construction.'" United Techs., 537 F. Supp. 2d at 399 (quoting Phillips, 415 F.3d at 1316) (emphasis in original).

The parties do not dispute these general tenets of claim construction. Rather, their disagreement arises from the

application of these principles to the claim terms at issue in this case.

B. The '760 Patent

The '760 Patent describes Plaintiffs' invention in 21 Claims. Claims 1, 9, 17, and 18 are independent claims. The remaining seventeen claims are dependent. The World Wide Plaintiffs have alleged infringement by AnazaoHealth of nine claims. The World Wide Plaintiffs and AnazaoHealth dispute the construction of terms in each of the claims allegedly infringed: Claims 1, 2, 3, 9, 10, 16, 17, 18, and 21. The Terwilliger Plaintiffs allege infringement of Claim 9 and seek construction only as to this claim.

The claims at issue in this case are as follows:¹⁴

1. For implanting therapeutic elements, a needle assembly comprising a cannula having a wall and a sharpened distal end, a line of elements in the cannula extending rearward from the distal end, yieldable means, including a frictionally held plug, for positioning an element more proximate the distal end a predetermined distance from the distal end, and a stylet reciprocable in the cannula and having a distal end engaging an end of the line of elements more remote from the distal end of the cannula.

2. A needle assembly as claimed in claim 1 wherein the means for positioning includes an absorbable plug.

¹⁴ Emphasis added by the Court to indicate the claim terms identified by one or more of the parties as requiring construction.

3. An assembly as claimed in claim 1 wherein the line of elements is encapsulated in a biodegradable material, the seeds being held in spaced relation by the biodegradable material.

9. For implanting a therapeutic element, a needle assembly comprising a cannula having a wall and having a sharpened distal end, a generally cylindrical end plug frictionally held in the distal end having a rearward end extending from the distal end a pre-determined distance, a line of elements in the cannula contacting the plug and extending rearward therefrom, and a stylet reciprocable in the cannula and having a distal end engaging an end of the line of elements more remote from the distal end of the cannula.

10. An assembly as claimed in claim 9 wherein the line of elements is encapsulated in a biodegradable material, the seeds being held in spaced relation by the biodegradable material.

16. An assembly as claimed in claim 9 wherein said end plug seals the distal end of the needle assembly and wherein the needle assembly is pre-loaded with said line of elements and is sterile.

17. A method of making a needle assembly for implanting radiation seeds, comprising the steps of:

- a. providing a cannula having a sharpened distal end and a generally cylindrical plug,
- b. forcing the plug into the sharpened distal end of the cannula to frictionally reside there.

18. A method of making a needle assembly for implanting therapeutic elements, comprising the steps of:

- a. providing a cannula having a wall and having a sharpened distal end and providing a generally cylindrical plug,
- b. placing the plug into the sharpened distal end of the cannula to reside there, and
- c. modifying the diameter of the plug to enhance its frictional engagement with the wall of the cannula.

21. A method as claimed in claim 18 wherein the diameter of the plug is modified by mechanical distortion.

1. Claim 1

The World Wide Plaintiffs and/or AnazaoHealth have identified six terms in Claim 1 as requiring construction: "wall," "element/elements," "yieldable means," "plug," "predetermined distance," and "frictionally held."¹⁵

a. "Wall"

AnazaoHealth has identified the term "wall" in Claim 1 (and also in Claims 9 and 18) as requiring construction because it lacks any antecedent basis in the '760 Patent. It maintains that

¹⁵ The World Wide Plaintiffs and AnazaoHealth have agreed that the term "distal end" can be construed as "the tip or point of the needle cannula." The Court will adopt this agreed upon meaning to the extent "distal end" refers to the cannula. As discussed infra, the Terwilliger Plaintiffs advance a different construction when this term is used to refer to the "distal end" of the stylet. The Court has adopted the Terwilliger Plaintiffs' proposed construction in that regard and will use that construction in both Claims 1 and 9. See Discussion at 67-68, infra.

while "having a wall" is claimed as a discrete element of the invention, presumably as a characteristic of the cannula, it is not clear from the claim or specification what this "wall" element is supposed to be - other than, perhaps, the cannula itself, which only renders the claim language even more ambiguous. AnazaoHealth argues that this ambiguity runs afoul of 35 U.S.C. § 112, ¶ 2, which mandates that claims particularly point out and distinctly claim the subject matter which the applicant regards as his invention. Because this claim is "insolubly ambiguous," AnazaoHealth argues that it is invalid as a matter of law.

The World Wide Plaintiffs respond that the claim language and the intrinsic record apprise those skilled in the art of the meaning of this term. It is common for patent drafters to expressly state a component that is inherent in a limitation of an apparatus, especially if that component is useful for describing how other aspects of the claimed invention interact with the limitation. Here, they assert, it was useful to identify the cannula wall - which is inherent in the definition of cannula¹⁶ - because, as later claimed, the plug may interact with the cannula wall.¹⁷ The World Wide Plaintiffs urge the Court

¹⁶ See Note 5, supra.

¹⁷ Claim 5 provides "wherein the wall of the distal end of the cannula is formed with an irregularity cooperating with said plug to comprise the means for positioning."

to reject AnazaoHealth's attempt to create indefiniteness by injecting an ambiguity into a claim.

Claim 1 recites "a needle assembly comprising a cannula having a wall and a sharpened distal end. . . ." (Emphasis added). The specification of the '760 Patent does not define the term "wall" but it does refer to the end plug (**32** in Fig. 2) adhering to the inside of the cannula wall. ('760 Patent col. 4, ll. 8-11.) It also refers to a bridge (**364** in Figs. 7a, 7b, and 7c) in the cannula wall between the openings that is deflected inward to frictionally engage the plug and hold the plug yieldably in place. Id. at col. 5, ll. 22-25. The Preamble also speaks of a distortion of the wall of the cannula.

As the World Wide Plaintiffs point out, a cannula, which is a tube that can be inserted into the body, inherently has a wall that defines the hollow center. For purposes of this Patent, however, at times the patentees referred to the wall of the cannula (Claims 1, 5, 6, 7, 8, 9, 12, 13, 14, 18a) and at other times to the distal and/or proximal ends of the cannula (Claims 1, 5, 9, 12, 17a, 17b, 18a, 18b). Indeed, even in Claim 1, they draw a distinction between the wall of the cannula and the sharpened distal end. To equate the term "wall" with "cannula" ignores the distinction in the claims between the different parts of the cannula. Moreover, AnazaoHealth's construction would create a redundancy in Claim 1, "a cannula having a 'cannula'."

The Court rejects this construction.

The prosecution history, which was introduced into evidence at the Markman hearing, reveals that the phrase "having a wall" was added to Claim 1 by the patentees in response to an objection by the Primary Patent Examiner that the term "wall" in Claims 5, 6, 7, 12, and 17 lacked an antecedent basis. (W0467-W0469, W0480.) When the claim term "wall" is read in the context of the rest of the Patent, which describes distortions in the cannula wall to enhance the frictional hold on the plug (e.g., an irregularity, inward hump, or tab in the wall that holds the plug), and which distortions are clearly depicted in the drawings, Figures 1 through 7c, it is clear the term "wall" is intended to have its common and ordinary meaning. There is nothing in the claims of the Patent or the specification to suggest that the inventors intended to impart a novel meaning to the term "wall." See Miken Composites, LLC v. Wilson Sporting Goods Co., 515 F.3d 1331, 1337 (Fed. Cir. 2008).

It is abundantly clear to this Court from the specification, preamble, and drawings - all of which depict a cannula as a hollow tube with walls, a sharpened distal end, and a proximal end - that a person of ordinary skill in the art would understand the term "wall" as having its ordinary and customary meaning. The Court finds that this term is not indefinite, and that no further construction is needed. See Phillips, 415 F.3d at 1313;

see also U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir.) (holding that claim construction is to resolve disputed meanings, to clarify, and when necessary to explain what is covered by a claim, but it is not an "obligatory exercise in redundancy"), cert. denied, 522 U.S. 950 (1997).

b. "Element/Elements"

The World Wide Plaintiffs and AnazaoHealth have proposed two constructions of the term "element" as used in Claim 1, which differ primarily in the breadth to be ascribed to this term. The World Wide Plaintiffs ask the Court to construe this term as meaning "anything intended for use in brachytherapy, including radioactive seeds and/or spacers." The World Wide Plaintiffs argue that "seeds," "spacers," and "radioactive seeds" were simply illustrative examples of elements that might be used in a brachytherapy procedure. Instead, they maintain that if an object, material or device used in connection with the treatment of cancer is designed to fit inside a needle and is implantable, it should be included in the definition of "element."

AnazaoHealth proposes a more narrow definition of "elements," that is limited to "radioactive seed(s), spacer(s) and/or drug(s)." AnazaoHealth asserts that the language of the specification indicates that the "therapeutic elements" contained within the needle and implanted in the body are radioactive seeds and spacers. AnazaoHealth argues that the World Wide Plaintiffs'

definition is overly broad and would encompass every aspect of brachytherapy treatment, including ultrasound probes or x-rays used to identify where the radioactive seeds were deposited or the materials used pre- and post-operatively to assist in a patient's treatment. It further submits that the term should not be construed to include "markers," which do not appear anywhere in the intrinsic evidence, and there is no indication that markers formed any part of the alleged invention. It maintains that there is no basis in the intrinsic record to conclude that the patentees had anything in mind other than radioactive seeds and spacers.

Claim 1 refers to "therapeutic elements" and "a line of elements." ('760 Patent col. 5, ll. 43, 45, 50-51.) Additionally, the term "element" appears in Claims 3, 9, 10, 11, and 16, which refer to a "line of elements," (id. at col. 5, ll. 54-55; col. 6, ll. 14-15, 17-18, 19-20, 23-24, 41), and in Claims 9 and 18, which refer to "therapeutic element(s)." Id. at col. 6, ll. 9, 51. A person of ordinary skill in the art is deemed to read a claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. Phillips, 415 F.3d at 1313. The purpose of the specification is to teach and enable those skilled in the art to make and use the invention and to provide a best mode for so doing, which is often done by example.

Id. at 1323. The specification has been described by the Federal Circuit as the “single best guide to the meaning of a disputed term [and] the primary basis for construing the claims.” Id. at 1315.

Here, the specification speaks in terms of “a line of therapeutic elements, for instance, radioactive seeds.” (’760 Patent col. 3, ll. 56-57 (emphasis added).) The specification makes clear that radioactive seeds are but one type of therapeutic element that might be implanted in a brachytherapy procedure using the patented device. Although several of the claims use the term “seeds” rather than “elements,” from which one might infer that “elements” should be limited to “seeds,” id. at col. 5, ll. 56; col. 6, ll. 21, 44, even AnazaoHealth concedes that the term “element” must encompass more than seeds and spacers and could include drugs. The Court finds no basis for including drugs yet excluding other substances or materials used in connection with the treatment of cancer and which are designed to fit inside a needle assembly for implantation into a patient. The invention itself relates to the device for implanting therapeutic elements. It is not limited to certain types of therapeutic elements. Thus, the Court rejects AnazaoHealth’s definition that limits “elements” to radioactive seeds, spacers, and drugs.

When the term “element” is read in the context of the entire

patent, the claims and specification make clear that an "element" within the needle assembly is something more than seeds and spacers and is something that is intended for implantation in the body for the purpose of treating cancer. See Phillips, 415 F.3d at 1321; Visto Corp. v. Sprogit Techs., Inc., 445 F. Supp. 2d 1104, 1112 (N.D. Cal. 2006). The World Wide Plaintiffs' definition includes the limitation "intended for use in brachytherapy." Therefore, the Court adopts the construction urged by the World Wide Plaintiffs, that being "anything intended for use in brachytherapy, including radioactive seeds and/or spacers."

c. "Yieldable Means"

The third term in Claim 1 on which the parties seek construction is "yieldable means." Claim 1 recites "a needle assembly comprising a cannula . . . , a line of elements, yieldable means, including a frictionally held plug." ('760 Patent col. 5, ll. 43-46.) The World Wide Plaintiffs construe this phrase as a "means capable of yielding, or giving way, under force." AnazaoHealth proffers a more restrictive construction, that is "a plug used to position the first seed in the needle at an exact distance from the distal tip of the needle and that is capable of holding and giving way under force."

It appears from the two proposed definitions that the parties do not have a meaningful disagreement over the

construction of the word "yieldable." The primary disagreement involves whether "yieldable mean" should be construed as a means-plus-function term under 35 U.S.C. § 112, ¶ 6.¹⁸ If section 112, ¶ 6 is found to apply, then the claim term is construed by identifying the "function" associated with the claim language, and then identifying the corresponding "structure" in the specification associated with the function. The claim is then construed as limited to that structure and its equivalents. DuPuy Spine, Inc. v. Metronic Sofamor Danek, Inc., 469 F.3d 1005, 1023 (Fed. Cir. 2006), cert. denied, - U.S. -, 128 S. Ct. 58, 169 L. Ed. 2d 243 (2007). AnazaoHealth insists that the phrase must be construed as a "means-plus-function" limitation with the "structure" limited to a plug, which could perform the stated function and which was also disclosed as the preferred embodiment for positioning the element a "predetermined distance from the distal end." ('760 Patent col. 3, l. 60 - col. 4, l. 67.)

The World Wide Plaintiffs respond that the means-plus-function analysis applies only to purely functional limitations

¹⁸ 35 U.S.C. § 112, ¶ 6 provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

that do not provide any structure for performing the recited function. Here, they maintain, sufficient structure is disclosed to perform the recited function of "positioning an element . . . a predetermined distance from the distal end." AnazaoHealth replies that the World Wide Plaintiffs have failed to explain how a "yieldable means" could encompass anything other than a plug and, to the extent that this claim is interpreted more broadly, it would be invalid in light of prior art references that disclosed various "yieldable means." (W0470, W0476-W0482.)

(i). "Means-Plus-Function"

The determination of whether a claim term is written in a means-plus-function format is a question of law for the court. Linear Tech. Corp. v. Impala Linear Corp., 379 F.3d 1311, 1318 (Fed. Cir. 2004). "Means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function." Dupuy Spine, Inc., 469 F.3d at 1023 (quoting Phillips, 415 F.3d at 1311). "If the word 'means' appears in a claim element in association with a function," there is a rebuttable presumption that section 112, paragraph 6 applies. See Callicrate v. Wadsworth Mfg., Inc., 427 F.3d 1361, 1368 (Fed. Cir. 2005); see also Greenberg v. Ethicon Endo-Surgery, Inc., 91 F.3d 1580, 1584 (Fed. Cir. 1996). This presumption may be rebutted, however, when the claim element recites a sufficiently definite structure to perform the claimed

function. See Phillips, 415 F.3d at 1311; Callicrate, 427 F.3d at 1368. The Federal Circuit has held that in determining whether sufficient structure is recited by a term used in a claim limitation, the court may inquire into whether the “term, as the name for structure, has a reasonably well understood meaning in the art.” Greenberg, 91 F.3d at 1583.

The Court agrees with the World Wide Plaintiffs that sufficient structure is disclosed in Claim 1, which recites “yieldable means, including a frictionally held plug,” to rebut the aforesaid presumption. See Phillips, 415 F.3d at 1311 (holding that a claim limitation stating “means disposed inside the shell for increasing its load bearing capacity comprising internal steel baffles” provided sufficient structure so as not to invoke § 112, ¶ 6); Cole v. Kimberly-Clark Corp., 102 F.3d 524, 531 (Fed. Cir. 1996) (holding that “perforation means . . . for tearing” did not require construction as a means-plus-function term because the claim described the structure for tearing - i.e., perforations - as well as its location and extent. “An element with such a detailed recitation of its structure, as opposed to its function, cannot meet the requirements of the statute.”), cert. denied, 522 U.S. 812 (1997).

Here, although Claim 1 uses the term “means” in the phrase “yieldable means,” creating a rebuttable presumption of a “means-

plus-function" limitation, the claim then specifically identifies a structure, i.e., a frictionally held plug, capable of entirely performing the function of "yielding." The Federal Circuit has held that "[m]eans-plus function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function," Phillips, 415 F.3d at 1311, which is not the case here. See also Watts v. XL Systems, Inc., 232 F.3d 877, 880-81 (Fed. Cir. 2000) (holding that the focus is whether the claim recites a sufficiently definite structure, but noting that the claim limitation need not connote a precise physical structure).

(ii). Limiting "Yieldable Means" to a "Plug"

AnazaoHealth argues that even if section 112, paragraph 6 does not apply, "yieldable means" must still be limited to a plug. The Court disagrees. By defining the "yieldable means" as limited to a plug, AnazaoHealth ignores the broader language in the specification and claims, which contemplate other means for achieving the recited function in Claim 1. The claim itself states "yieldable means, including a frictionally held plug." The Federal Circuit has repeatedly recognized that use of the term "including" is an open term, synonymous with "comprising," thereby permitting the inclusion of unnamed components. See Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp., 123 F.3d 1445, 1451 (Fed. Cir. 1997), cert. denied, 523 U.S. 1022 (1998);

Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1301 (Fed. Cir. 1999); Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1376 (Fed. Cir. 2003).

Additionally, the specification states, "The positioning means for the first seed may take one of a variety of forms, all of them yieldable to permit the seed to be pushed past the distal end in the implantation." ('760 Patent col. 2, ll. 30-33 (emphasis added).) "The needle assembly of the invention may include a biocompatible¹⁹ end plug. . . ." Id. at col. 2, ll. 34-35 (emphasis added). Thus, the specification makes clear that a plug is not the exclusive manner in which to attain the recited function in Claim 1. In fact, the '760 Patent expressly discloses an alternate embodiment where the yieldable means comprise the combination of a plug and a resilient tongue formed in the cannula wall. Id. at col. 5, ll. 1-20 & fig. 6d. Nothing in the prosecution history suggests otherwise. Moreover, AnazaoHealth's proposed definition that limits the yieldable means to a plug is redundant of the language already recited in the claim, "including a . . . plug." Id. at 5:46-48.

The Court finds that the World Wide Plaintiffs' proposed construction comports with the customary and ordinary meaning when viewed in the context of the intrinsic record. The

¹⁹ The Patent uses this spelling throughout. The correct spelling is "biocompatible."

Description of the Preferred and Other Embodiments discusses what the patentees meant by "yieldable means:"

In all embodiments, no matter by what means, the end plug is yieldably held in precise position and may be forced outward as the cannula is drawn backward on the stylet. The position of the end plug **32** in the cannula **12** is yieldable. Before yielding, the plug seals the needle and keeps the seeds from spilling out the needle or body fluids from entering the needle prematurely.

Id. at col. 4, ll. 17-21; see also id. at col. 2, ll. 31-34.

The only construction that is consistent with the claim language and the entire disclosure in the specification is one that construes the phrase as "means capable of yielding, or giving way under force."

d. "Plug"

The next disputed term in Claim 1 is "plug." Claim 1 provides in relevant part, "a needle assembly comprising a cannula, . . . a line of elements, . . . yieldable means, including a frictionally held plug, for positioning an element more proximate the distal end a predetermined distance from the distal end, . . ." ('760 Patent col. 5, ll. 43-38.) This term also appears in Claim 2, which speaks of an "absorbable plug," id. at col. 5, l. 53; Claims 5 and 7, which refers to "said plug," id. at col. 5, l. 63, col. 6, l. 4; Claim 9, which discusses both "the plug" and "a generally cylindrical end plug," id. at col. 6, ll. 12-13, 14; Claim 16, which refers to "said end

plug seals the distal end of the needle assembly," id. at col. 6, ll. 39-40; Claims 17 and 18, which refer to "a generally cylindrical plug," and "the plug," id. at col. 6, ll. 47-48, 53-55, 57; and Claim 21, which refers to "the diameter of the plug." Id. at col. 6, ll. 64-65.

The World Wide Plaintiffs define "plug" as "an object or material used to fill or seal an opening." AnazaoHealth construes this term to mean "a separate ejectable member of predetermined dimensions comprised of material other than bone wax."

AnazaoHealth argues that the breadth of the World Wide Plaintiffs' construction encompasses the prior art plugging materials denigrated by the '760 Patent and the plug claimed in the Mercereau patent that formed a basis for the examiner's rejection of the original claims of the '760 Patent. The World Wide Plaintiffs respond that AnazaoHealth's construction improperly imports limitations from the specification that unnecessarily narrow the scope of the claim and improperly seeks to define the term "plug" by what it does not mean rather than by what it does mean. The discussion of the use of bone wax in the prior art focused on problems with the manner in which it was used. They maintain that the term "plug" should not be construed based upon its composition where there is no restriction in the claim language regarding the material composing the plug.

The competing constructions offered by the parties present several issues: (1) whether the Court should construe the term "plug" to cover only embodiments that do not include bone wax in light of the disclaimers in the specification; (2) whether the World Wide Plaintiffs' construction is so broad as to encompass prior art; and (3) whether the limitations in AnazaoHealth's proposed construction are necessary to preserve the validity of the '760 Patent.

(i). Exclusion of Bone Wax

The specification discusses complications in the prior art that "stem from the use of bone wax or other materials that are used to plug the cannulas prior to the loading of the radioactive seeds." ('760 Patent col. 2, ll. 1-3 (emphasis added).) The specification then lists four drawbacks associated specifically with the use of bone wax. Id. at col. 2, ll. 4-20. Elsewhere, the specification describes the invention as including a "biocompatible end plug which may be made of a variety of materials including absorbable or non-absorbable suture materials either in a braided or monofilament configuration or molded biocompatible polymers." Id. at col. 2, ll. 35-39 (emphasis added). Repeatedly thereafter, the specification refers to a "biocompatible end plug" without further limitation as to the composition of the end plug. Id. at col. 2, ll. 53, 58. In the Description of the Preferred Embodiments section, the material of

the end plug is described as

biocompatible and biodegradable. It may be formed, for instance, of processed collagen (catgut), Nylon or various other organic substances. A preferred material is polyglactin acid (PGA) available under the trademark POLYGLACTIN 910.

Id. at col. 4, ll. 2-7. This section also recites the exact positioning of the end plug as a significant advantage over “the haphazard positioning of the more proximate end of a bone wax material as used in the needle assemblies of the prior art.” Id. at col. 4, ll. 36-38 (emphasis added). The inventors note that other variations of the invention are contemplated. Id. at col. 5, ll. 29.

The Federal Circuit has repeatedly cautioned against importing limitations from the specification into claim terms. See, e.g., Phillips, 415 F.3d at 1323-24; Callicrate, 427 F.3d at 1368; North Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1348 (Fed. Cir. 2005). At the same time, if the specification makes clear that the invention does not include a particular feature, that feature is deemed outside the claims of the patent even though the claims might otherwise be considered broad enough to encompass that particular feature. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1342 (Fed. Cir. 2001).

Based on a review of the intrinsic evidence, the Court concludes that the term “plug” should not be construed so as to

limit the composition of the plug to materials other than bone wax. Although the specification does discuss the disadvantages associated with the manner in which prior art used bone wax to plug cannulas prior to loading the radioactive seeds, the specification discloses that the end plug may be composed of any material that is suitable for brachytherapy operations. While it lists specific examples of preferred materials, it does not limit or foreclose the use of any other materials. Nothing in the intrinsic evidence to suggest that the inventors intended to exclude or disavow any particular material from the scope of the claim, if that material was suitable for use in brachytherapy and could be fashioned in such a manner as to create a plug that could be inserted into the cannula a predetermined distance from the distal end. Statements in the specification discussing the disadvantages of prior art do not necessarily require a limiting construction, particularly where the language of the claim and the presumption of claim differentiation call for the opposite conclusion. See Acumed LLC v. Stryker Corp., 483 F.3d 800, 805 (Fed. Cir.) (rejecting the alleged infringer's reliance on the discussion in the specification of the disadvantages of certain features of prior art to limit the claim of the asserted invention), cert. denied, - U.S. -, 128 S. Ct. 615, 169 L. Ed. 2d 393 (2007).

(ii). Distinguishing the Claimed Invention from the Prior Art

AnazaoHealth also cites to the prosecution history as limiting the breadth of the term to something that is a "separate ejectable member" and of "predetermined dimensions."

Clearly, statements made during prosecution may also affect the scope of a claim. Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1374 (Fed. Cir. 2008). "Specifically, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution." Id. (internal citation and quotation marks omitted). For example, a patentee might clearly characterize an invention in a particular way to try to overcome a rejection based on prior art. Id.

As AnazaoHealth points out, the prosecution history reveals that Claim 1 was rejected initially as being anticipated by prior art, the Mercereau Patent, et al. (U.S. Patent No. 6,450,937), which showed two different yieldable means. (W0470.) The patentees then revised Claim 1 of the '760 Patent to add "including a plug" after yieldable means (and later "frictionally held"). The Remarks submitted with the revision describe Mercereau as showing a lubricious coating, some of which was allowed to accumulate by surface tension in the end of the tube to form a web. This was formed by dipping the tube into a vat of coating material, where capillary action and surface tension caused a small quantity of the coating material to remain in the forward end of the tube. The quantity of lubricious material

entering the tube was "notoriously unreliable" and would extend over different distances, varying from one tube to the next. Additionally, the web was comprised of solid polymers that were not absorbable or biodegradable. (W0481.) In the second version of Mercereau, the lubricious coating was allowed to accumulate by capillary action and surface tension to form a "plug" that was "not a separate ejectable member," as described in the '760 Patent. Rather it was the solidified overflow into the distal end of the cannula by capillary action when the cannula was dipped into a vat. This embodiment of the prior art was considered even more unreliable in terms of the distance the material would extend into the cannula. Id.

The patentees asserted that an essential feature of their invention was the

yieldable means for positioning the element a pre-determined distance from the distal end includes a plug of predetermined dimensions with a rearward end that is positioned an exact length back from the extreme distal end of the beveled point. This distance is critical and does not vary from assembly to assembly. . . . Since Mercereau clearly does not include a plug which positions an element a predetermined distance from the distal end, Mercereau does not anticipate Claim 1.

(W0481-W0482 (first emphasis added, second emphasis in original).)

According to AnazaoHealth, these statements constitute a clear and unambiguous disavowal by the patentees that the plug of

their invention was anything other than one of predetermined dimensions that was separate and ejectable. The Court agrees that these statements, as well as the specification and other claims of the Patent, support AnazaoHealth's interpretation that the plug must be ejectable. However, that requirement is already included in Claim 1, which describes a "plug" as an example of a "yieldable means," i.e., "means capable of yielding, or giving way under force." Therefore, to include the limitation that the plug must be ejectable would be redundant.

The Court disagrees, however, that these statements in the prosecution history constitute a clear disavowal of a plug being anything other than of predetermined dimensions. While the remarks describe features of the claimed invention, including a plug of predetermined dimensions, which differentiate it from Mercereau, they do not expressly disavow all other embodiments of a plug for positioning an element a predetermined distance from the distal end of the cannula. See Northern Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281, 1294 (Fed. Cir. 2000) (refusing to limit scope of claim where statements in the prosecution history did not exclude the possibility of using a particular process); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1458 (Fed. Cir. 1998) (holding that statements in prosecution history distinguishing prior art could not properly be interpreted as precluding coverage for every type of external

reservoir). In fact, the specification and other claims in the '760 Patent describe methods of changing the size of the plug to enhance its frictional engagement with the wall of the cannula, which contradicts the requirement that the plug must be of predetermined dimensions. See, e.g., Claims 18-21. Rather, the critical distinction between the '760 Patent and Mercereau was the ability of the claimed invention to position an element a "predetermined distance from the distal end," not that the plug itself was of predetermined dimensions. The court declines to include the limitation that of "predetermined dimensions" in the definition of "plug."

(iii). Invalidity of Plaintiffs' Construction

Lastly, AnazaoHealth argues that Plaintiffs' attempts to construe "plug" in a manner than extends to bone wax renders the patent invalid for want of enablement under 35 U.S.C. § 112, ¶ 1, because the Patent does not enable the full scope of the invention claimed. AnazaoHealth asserts that Plaintiffs' position puts this case squarely within the holding of AK Steel Corp. v. Sollac and Ugine, 344 F.3d 1234 (Fed. Cir. 2003).

As AnazaoHealth correctly observes, when claims are amendable to more than one construction, they should be interpreted to sustain their validity if reasonably possible. See Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999). Claims, however, "can only be construed to preserve their

validity where the proposed claim construction is 'practicable,' is based on sound claim construction principles, and does not revise or ignore the explicit language of the claims." Generation II Orthotics Inc. v. Med. Tech., Inc., 263 F.3d 1356, 1365 (Fed. Cir. 2001). In Phillips, 415 F.3d at 1327, the Court acknowledged this "maxim," but noted that it had not been applied broadly nor had the Federal Circuit endorsed "a regime in which validity analysis is a regular component of claim construction." Instead, this principle has been limited to cases in which "the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous." Id. (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed. Cir.), cert. denied, 543 U.S. 925 (2004)). "In such cases, [the Federal Circuit has] looked to whether it is reasonable to infer that the PTO would not have issued an invalid patent, and that the ambiguity in the claim language should therefore be resolved in a manner that would preserve the patent's validity." Id.

The first paragraph of section 112 provides in relevant part that the specification shall describe "the manner and process of making and using [the invention], in such clear and concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use [the invention]." The enablement requirement is met when one skilled in the art could, after reading the specification,

practice the full scope of the claimed invention without undue experimentation. AK Steel, 344 F.3d at 1244. "That is not to say," however, "that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending on the predictability of the art." Id. (citing Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir.), cert. denied, 522 U.S. 963 (1997)).

In AK Steel, the Court held that the patent was invalid because the specification failed to enable the full scope of the patent claims where the patentee had made it clear that a specific type of material would not work with the invention, yet this material was encompassed within the construction of the claim. Id. at 1244. Here, however, as discussed above, unlike AK Steel, the patentees have not disavowed the use of any specific material, including bone wax, as a plugging material. Rather, they have disavowed the manner in which bone wax and other plugging materials were used or applied in the prior art. The Court does not find the Patent invalid for failure to meet the enablement requirement of section 112, paragraph 1.

The Court concludes that, in light of the specification, the words of the claims themselves, and the prosecution history, a

person of ordinary skill in the art would interpret the claim term "plug" to mean "an object or material used to fill or seal an opening," as urged by the World Wide Plaintiffs. Thus, Claim 1 would read in relevant part, "a needle assembly comprising a cannula . . ., a line of elements . . ., yieldable means, including a frictionally held object or material used to fill or seal an opening, for positioning an element more proximate the distal end a predetermined distance from the distal end. . . ."

e. "Predetermined Distance"

The fifth term requiring construction in Claim 1 is "predetermined distance." Claim 1 recites a "yieldable means, including a plug, frictionally held, for positioning an element more proximate the distal end a predetermined distance from the distal end." ('760 Patent col. 5, ll. 46-48.) This phrase is also used in Claim 9, which refers to "a generally cylindrical end plug frictionally held in the distal end having a rearward end extending from the distal end a pre-determined distance." Id. at col. 6, ll. 12-14. The World Wide Plaintiffs maintain that this phrase should be construed to mean "a measurement that is specified or determined beforehand." AnazaoHealth defines it as "a degree of measurement of an exact length back from the extreme distal end of the needle tip."

The World Wide Plaintiffs maintain that an important feature

of their invention is the consistent positioning of the first seed in the needle assembly, unlike prior art which was notoriously unreliable in this regard. Thus, for the positioning to be consistent, the measurement must be determined beforehand. AnazaoHealth argues that its construction is compelled by the description of the invention and its prosecution history, which repeatedly refer to predetermined distance as being an exact distance back from the extreme distal end of the needle tip. Id. at col. 3, ll. 61-64. The Terwilliger Plaintiffs, in their response to this argument in Claim 9, assert that AnazaoHealth's definition improperly imports an exactness requirement, despite the fact that all manufacturing processes have some degree of reasonable and necessary tolerance. Additionally, they argue that the "predetermined distance" is not necessarily limited to the extreme end of the distal tip.

The specification describes the invention as "exactly locat[ing] the first seed a repeatable and known distance from the distal end of the cannula," id. at col. 2, ll. 27-29, the clear implication being that the distance was known beforehand. One of the claimed advantages of the invention is that the needles can be preloaded, which would require knowing the spacing of the seeds beforehand.

The normal definition of "predetermine" is "to determine beforehand." Webster's at 1786. Nothing in the specification

defines "predetermined" in a non-standard way. The Court agrees with the World Wide Plaintiffs that the ordinary and customary meaning of "predetermined" to one skilled in the art would be something that is specified or determined beforehand. See Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc., 246 F.3d 1336, 1350 (Fed. Cir. 2001) (holding that "predetermined distance" meant "a distance that is determined before the fourth conductive layer is disposed on the substrate and is sufficiently close to the second shielded conductive layer to provide acceptable shielding"); Koito Mfg. Co. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1150 (Fed. Cir. 2004) (construing the phrase "predetermined general direction" as requiring that the flow direction be chosen or known beforehand, or in other words, as requiring intent or foreknowledge in the fixing of the flow direction); Precor, Inc. v. Fitness Quest, Inc., No. C05-0993L, 2006 WL 2469123, at *5 (W.D. Wash. Aug. 23, 2006) (construing "predetermined distance" as "a distance determined beforehand"); Garmin Ltd. v. TomTom, Inc., No. 06-C-0062-C, 2006 WL 6005801, at *32 (W.D. Wis. Aug. 24, 2006) (defining predetermined as "specified").

The Court finds that it unnecessary to add to the construction "the distance from the distal and of the cannula," as urged by the Terwilliger Plaintiffs, or "back from the extreme distal end of the needle tip," as suggested by AnazaoHealth.

Both Claims 1 and 9 reference a "predetermined distance" from the distal end. Therefore, to add this language referring to the distance from the distal tip would be redundant.

The more difficult issue is whether the construction of "predetermined distance" should include the concept of exactness as urged by AnazaoHealth and whether including this term would inject an ambiguous term. The World Wide Plaintiffs maintain that it is not the "exact" distance that the first seed is located from the distal end of the cannula that must be determined beforehand; rather, the positioning of the first seed only needs to be precise and repeatable from assembly to assembly during the same procedure. The Terwilliger Plaintiffs raise concerns that AnazaoHealth's requirement of exactness would not permit any tolerance in the measurement of the predetermined distance, including any manufacturing tolerances.

AnazaoHealth's position finds considerable support in the specification, which repeatedly uses the words "exact," "exactly," or "precise" to describe the positioning of the plug and the first seed.

The needle assembly of the invention exactly locates the first seed repeatable and know distance from the distal end of the cannula in each needle . . . ('760 Patent col 2, ll. 26-30.)

The end plug . . . is positioned at an exact length back from the extreme distal end of the tip. . . . This distance is critical and does not vary from assembly-to-assembly. Id.

at col. 3, ll. 61-65.

It will be understood that the exact positioning of the rear end surface **32a** at the pre-established distance back from the tip. . . . The arrangement of the present disclosure enables the operator to be assured of the precise positioning of the front end of the first seed. . . . Id. at col. 4, ll. 33-41.

Thus, in the **6a**, **6b**, and **6c** embodiment, the first seed **28** is positioned precisely. . . . Id. at col. 5, ll., 12-13.

Here again, the rearward surface **332a** is the means for precise positioning of the forward end of the first seed. Id. at col. 5, ll. 26-28.

The difficulty the Court has with AnazaoHealth's proposed construction that includes the term "exact" is that "exact" is a relative term. Including it in the construction of "predetermined distance" only serves to interject ambiguity into the claim.²⁰ The Court has reviewed countless number of patent cases involving the phrase "predetermined distance," and in the vast majority of cases, no construction of this phrase was even required. See, e.g., Gemtron Corp. v. Saint-Gobain Corp., 572 F.3d 1371, 1375 (Fed. Cir. 2009); Helena Labs. Corp. v. Alpha Scientific Corp., 274 F. App'x. 900, 903 (Fed. Cir. 2008);

²⁰ What is an "exact predetermined distance" as opposed to a "predetermined distance"? If the distance is specified beforehand, does that not define what is the "exact" distance? For example, if the physician specifies beforehand that the first seed is to placed 5 mm. from the distal end of the cannula, or 5.2 mm., or 5.225 mm., or whatever distance, does that not determine how exact the measurement must be?

Intamin Ltd. v. Magnetar Technologies, Corp., 483 F.3d 1328, 1332 (Fed. Cir. 2007). The Terwilliger Plaintiffs argue that including the word "exact" eliminates all manufacturing tolerances. The Federal Circuit, however, has held that manufacturing tolerances are "immaterial to claim construction." Senmed, Inc. v. Richard-Allan Medical Indus., Inc., 888 F.2d 815, 820 (Fed. Cir. 1989) (internal citation omitted), disapproved of on other grounds by Cardinal Chem., Co. v. Morton Int'l, Inc., 508 U.S. 83 (1993). The Court finds that one of ordinary skill in the art would construe "predetermined distance" as "a measurement that is specified or determined beforehand," and that no further "exactness" standard needs to be read into this claim term.

f. "Frictionally Held"

The last term in Claim 1 requiring construction is the phrase "frictionally held," which was added by the certificate of correction.²¹ This phrase also appears in claim 9, which refers to an "end plug frictionally held." ('760 Patent col. 6, ll. 12-13.) The World Wide Plaintiffs assert that this term should be given its ordinary and customary meaning, that is "restrained from motion by frictional force; namely, a force that opposes the relative motion of one body moving with respect to another body with which it is in contact." Relying on the dictionary definition of "frictional force," the World Wide Plaintiffs

²¹ See Discussion at 7-13, supra.

assert that when a plug is held, it is restrained from motion. This interpretation is supported by the specification, they argue, which discusses the various ways the end plug may be positioned as a friction fit pressed into the distal end, like a cork in a bottle, or alternatively, it may be treated with a solvent so it adheres to the inside wall of the cannula, or it can be put in position and the cannula heated so that it swells and is held into position, or the cannula may be distorted externally to cause it to shrink in the area of the plug and thereby to hold the plug in place. Id. at col. 4, ll. 8-16. They also cite to Figure 7c, which shows the cannula distortion and is described as “[a] bridge in the cannula wall . . . is deflected inward . . . to frictionally engage the plug and hold the plug yieldably in place until it is pressed outward by the first seed.” Id. at col. 5, ll. 22-27 (emphasis added).

The World Wide Plaintiffs assert that these are alternatives that one of ordinary skill in the art would recognize as methods for achieving a frictionally held end plug. Regardless of how a tight fit is achieved between the plug and the cannula wall - whether by heat, a distortion of the cannula wall, or treatment of the plug with a solvent - once the tight fit is achieved, the plug is then frictionally held in place.

AnazaoHealth²² relies on the same paragraph in the specification and argues that the patentees acted as their own lexicographers and expressly narrowed the scope of the phrase “frictionally held” by eliminating from the definition everything except “a friction fit pressed into the distal end of the cannula as a cork in a bottle.” Id. at col. 4, ll. 8-9. The alternatives, it contends, are what the patentees expressly disavowed as means of frictionally holding the plug in the cannula (e.g., adhesion, heat, minute distortions in the cannula, surface tension or capillary action). Thus, AnazaoHealth argues that the phrase “frictionally held” should be construed to mean “held in place by a tight fit, as a cork in a bottle, and does not include something being held by adhesion, heat, minute distortion of the cannula, surface tension or capillary action.” AnazaoHealth also relies on the prosecution history, in which the patentees distinguish their invention from Mercereau.²³

The patentees described the overflow plug of the Mercereau invention as “not held in place by friction, but rather because it is integral with the coating 480 on the outside of the cannula.” (W0481) (emphasis added). They further distinguished Claim 9 from the cited prior art by stating that Mercereau “does

²² Because AnazaoHealth contends that this phrase should not be considered as part of Claim 1, it has addressed this phrase only in connection with Claim 9.

²³ See Discussion at 40-43, supra.

not show 'a generally cylindrical end plug frictionally held in the distal end. . . ,” and Claim 12 because Mercereau “does not show an irregularity to enhance the frictional holding of the plug.” (W 0482) (emphasis in original). Finally, they distinguish Claim 16 because the method of Mercereau consisted of filling the distal end of the cannula by dipping the end into a vat to allow lubricious material to enter, rather than forcing the plug into the sharpened distal end of the cannula to frictionally reside there. Id. (emphasis added). Contrary to AnazaoHealth’s suggestion, nothing in the prosecution history constitutes a disclaimer by the patentees as to how the plug would be frictionally held in the distal end of the cannula. Rather, if anything, the prosecution history supports Plaintiffs’ position that “frictionally held” means more than just held in place like a cork in a bottle, but also includes being held by adhesion, heat, minute distortions fo the cannula, or other means. Accordingly, the Court rejects AnazaoHealth’s narrow construction. At the same time, the Court does not believe that it is necessary to define “frictional force,” as the World Wide Plaintiffs have done, as this term should be well-known to those of ordinary skill in the art and nothing in the Patent or the intrinsic evidence suggests a definition other than the customary and ordinary meaning. Thus, the Court construes “frictionally held” as meaning “restrained from motion by frictional force.”

2. Claim 2

Both parties have identified one phrase in dependent Claim 2 that requires construction - "absorbable plug." Claim 2 describes a needle assembly as claimed in Claim 1 wherein the means for positioning includes "an absorbable plug." ('760 Patent col. 5. ll. 52-53.) The Court has already construed the term plug. Thus, the only issue is the construction of the term "absorbable." The World Wide Plaintiffs urge the Court to construe this phrase as "which can be broken down and absorbed within the human body, but not necessarily eliminated." AnazaoHealth has defined absorbable as "where such material is taken up by the body especially by capillary, osmotic, solvent, or chemical action, but does not include material comprising solid polymers that can be carried in a volatile organic solvent."

Webster's Third New International Dictionary defines "absorbable" as "capable of being absorbed." Id. at 7. "Absorb" is defined as "to take up by various means," citing as examples by capillary, osmotic, solvent, or chemical means. Id. The Court agrees with the World Wide Plaintiffs that the term should not be limited to examples listed in one particular and general dictionary. See Phillips, 415 F.3d at 1321-22 (discussing the hazards of relying on general dictionary definitions). Perhaps a more meaningful dictionary definition is from Dorland's

Illustrated Medical Dictionary, which defines "absorb" as "to take in or assimilate, as to take up substances into or across tissues." Id. at 7 (28th ed. 1994).

The only reference in the specification to an absorbable plug is in the summary of the invention wherein it states that the biocompatible end plug may be made of a variety of materials including absorbable or non-absorbable suture materials. ('760 Patent at 2:36-37.) The Dorland's Medical Dictionary defines absorbable sutures as "a strand of material used for closing wounds which is subsequently either digested by proteolytic enzymes derived from inflammatory cells or hydrolyzed by water." Id. at 1614. American Cyanamid Co. v. U.S. Surgical Corp., 833 F. Supp. 92 (D. Conn. 1992), involved a patent for synthetic absorbable sutures. It described an absorbable suture as one which is designed to hold tissue together for only a few weeks while healing occurs and is then broken down by body moisture into components that the body can metabolize. Id. at 98.

The prosecution history references "absorbable" in distinguishing the Mercereau Patent, stating that Mercereau does not anticipate Claim 2, as amended, because the lubricious material, solid polymers in a volatile organic solvent, would not be absorbable. (W0481-W0482.) The fact that the patentees distinguished the material used by Mercereau, however, as not being absorbable does not mean that this should be incorporated

into the construction of the term "absorbable."

The Court also finds no support in the intrinsic record for including the phrase added by Plaintiffs "but not necessarily eliminated." There is nothing in the specification or prosecution history that discusses whether an absorbable plug is eliminated from the body or not. Plaintiffs cite to the deposition of Mr. Lamoureux, who testified that one of ordinary skill in the art would recognize such a restriction. The Federal Circuit has cautioned that the testimony of an inventor concerning claim construction should be given little or no weight as it is often self-serving and an after-the-fact attempt to state what should have been part of the patent application. See Roton Barrier, Inc. v. Stanley Works, 79 F.3d 1112, 1126 (Fed. Cir. 1996); North Am. Vaccine, Inc. v. Am. Cyanamid, Inc., 7 F.3d 1571, 1577 (Fed. Cir. 1993), cert. denied, 511 U.S. 1069 (1994).

Accordingly, the Court finds that one of ordinary skill in the art would understand "absorbable plug" in the context of the '760 Patent to mean "an object or material used to fill or seal an opening that is capable of being assimilated or broken down by the human body."

3. Claim 3

The World Wide Plaintiffs and/or AnazaoHealth have identified four terms in Claim 3 requiring construction, "biodegradable," "line of elements is encapsulated in a

biodegradable material," "the seeds," and "spaced relation."

a. "Biodegradable"

Both Claims 3 and 10 identify a "biodegradable material" that encapsulates a line of elements. The specification provides examples of biodegradable materials with respect to spacers and plugs, such as processed collagen (catgut), Nylon or various other organic substances. ('760 Patent col. 3, ll. 58-59 and col. 4, ll. 2-7.) The World Wide Plaintiffs suggest the following construction: "While inside the human body, the material decays over time by a specific mechanism and eventually eliminated." AnazaoHealth suggests "capable of being broken down by the action of microorganisms."

The Medical Dictionary defines "biodegradable" as "susceptible of decomposition by natural biological processes, as by the action of bacteria, plants, animals, etc." Dorland's at 198. Mirriam-Webster's Collegiate Dictionary contains a similar definition, "capable of being broken down especially into innocuous products by the action of living things (as microorganisms)." Id. at 114 (10th ed. 1996). The Court finds nothing in the Patent itself, the specification, or prosecution history that discusses the rate of breakdown or eventual elimination. Therefore, the Court will adopt AnazaoHealth's proposed construction with one slight modification since it is clear from the Patent that the goal of this device is to place

radioactive seeds in the human body for the treatment of cancer. Thus, the Court construes the term "biodegradable" as "capable of being broken down in the human body by the action of microorganisms."

b. "Line of Elements is Encapsulated in a Biodegradable Material"

AnazaoHealth asks the Court to construe "line of elements is encapsulated in a biodegradable material" in Claim 3 and urges the following construction: "the prior art method of stranding as described in the '760 Patent at col. 1, ll. 64-67, specifically, a premanufactured 'strand' of radioactive seeds that are encapsulated in a biodegradable material that spaces the radioactive seeds apart from one another." The World Wide Plaintiffs argue that the Court does not need to construe this phrase apart from its construction of the terms "biodegradable" and "line of elements." The Court agrees. The Court has already construed the terms "elements" and "biodegradable." When substituted, this phrase reads: "a line of anything intended for use in brachytherapy, including radioactive seeds and/or spacers, is encapsulated in a material capable of being broken down in the human body by the action of microorganisms." No further construction is necessary. This phrase should be readily understood by one of ordinary skill in the art.

c. "The Seeds"

AnazaoHealth also seeks construction of the term "seeds" in

Claims 3 and 10, which it contends means "radioactive sources." The World Wide Plaintiffs respond that "seeds" should be construed in the same manner as "elements."

In the Field of the Invention section of the specification, the patentees state that the "invention relates to a needle assembly for implanting therapeutic elements." ('760 Patent col. 1, ll. 7-8.) More specifically, it allows the user to load and place "radioactive 'seeds' in the body for the purpose of treating cancer." Id. at col. 1, ll. 8-11 (emphasis added). In the Background of the Invention section, the patentees refer to "radioactive sources or 'seeds'," id. at col. 1, ll. 18 (emphasis added), and describe two principal types of radioactive seeds: "free" seeds, which are individual radioactive seeds that are loaded in the cannula with small cylindrical spacers stacked in between the radioactive seeds, and pre-manufactured strands, where the radioactive seeds are encapsulated in a biodegradable material that spaces the radioactive seeds apart from one another. Id. at col. 1, ll. 61-67. The Description of the Preferred and Other Embodiments section describes Figure 1 as showing radioactive seeds as a type of therapeutic element, id. at col. 3, ll. 56-57, which alternate with spacers. In explaining the operation of the needle assembly, the description refers to depositing in the tissue the line of seeds and spacers, which leaves the seeds in the exact desired position in the body.

Id. at col. 4, ll. 32-33. Figures 3 and 4 show an encapsulated line of seeds **128** connected by spacing webs **131**. Id. at col. 4, ll. 45-46. In addition to Claims 3 and 10, Claim 17 references "radiation seeds." Id. at col. 6, ll. 44. Thus, the specification draws a clear distinction between seeds and spacers.

It is true, as the World Wide Plaintiffs point out, that the prosecution history indicates that they substituted "line of elements" for "line of seeds" in Claim 3 after the Examiner had objected to this Claim as anticipated by combining Mercereau and Langton (Patent No. 5,460,592) (W0470), which teaches a seed train that uses encapsulation to eliminate the need for spacers.²⁴ In explaining why their invention was not anticipated by Mercereau and Langton, however, the patentees did not rely on the distinction between "elements" and "seeds."²⁵ Instead, they relied on the distinction between their needle assembly and that of Mercereau. "[T]he needle assembly as recited in base Claim 1 distinguishes over the needle assembly of Mercereau, and hence Claim 3 is not rendered obvious by combining Mercereau and

²⁴ The Examiner stated that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to use the encapsulation with the seeds of Mercereau et al. to eliminate the need for spacers as taught by Langton et al." (W0470.)

²⁵ "Applicant admits that Langton discloses seeds spaced at pre-determined intervals in a bio-absorbable material, this construction being known in the art." (W0482.)

Langton.” (W0482.) The Court is not persuaded by Plaintiffs’ argument that the prosecution history supports a finding that the term “seeds” should be construed as “elements.”

The Court also notes that, while the patentees changed “line of seeds” to “line of elements” in Claim 3, they did not substitute “elements” for the second reference to “seeds” in Claim 3. (W0485.) Additionally, Claim 10 contains this same distinction. (W0486.)

To construe “seeds” as “elements,” as suggested by the World Wide Plaintiffs, would render the term “seeds” as encompassing “anything intended for use in brachytherapy, including radioactive seeds and/or spacers.” This does not make sense. “Seeds” are just one form of an “element.”

The Court finds that the patentees have acted as their own lexicographers and have defined “seeds” as “radioactive sources.” Additionally, it is clear from an examination of the specification that “seeds” are one form of “elements” and, thus, are intended for use in brachytherapy.” While at times this construction will import redundancy into the claims, to use the definition of “elements” would suffer from the same infirmity. Where the claim speaks of “radioactive seeds,” the term “seeds” should be construed simply as “sources intended for use in brachytherapy.”

d. “Held in Spaced Relation” or “Spaced Relation”

The last term in Claim 3 that the parties have identified as requiring construction is "held in spaced relation" or just "spaced relation." Claim 3 states "the seeds being held in spaced relation by the biodegradable material." ('760 Patent col. 5, ll. 56-57.) The World Wide Plaintiffs propose a construction of "set apart a particular distance from one another." AnazaoHealth has proposed "fixed in place with respect to other radioactive sources by the biodegradable material." The Court adopts the construction proposed by Plaintiffs.

The most critical aspect of the invention is its ability to improve the positioning of the radioactive seeds in the body upon implantation. Thus, the "spaced relation" of the seeds vis-a-vis one another - that is, the distance between the seeds - is extremely important. Had the patentees intended "spaced relation" to have no spatial relationship, they could have simply used the word separated. The dictionary defines "spacer" as "one that spaces," "a device or piece for holding two members at a given distance from each other." The Court finds that one of ordinary skill in the art would construe "held in spaced relation," as meaning that the seeds were "set apart a particular distance from one another."

4. Claim 9

Claim 9 is the only claim that the Terwilliger Plaintiffs are alleging that AnazaoHealth has infringed, and have identified

four terms as requiring construction - "distal end," "generally cylindrical end plug," "frictionally held," and "predetermined distance." In addition, the World Wide Plaintiffs have identified "generally cylindrical," "end plug," and "elements." AnazaoHealth has identified the following additional terms: "a therapeutic element," "wall," "rearward end," "line of elements," and "thereform." Claim 9, reformatted to show the various limitations set forth therein, discloses:

For implanting a therapeutic element, a needle assembly comprising a cannula having a wall and having a sharpened distal end, a generally cylindrical end plug frictionally held in the distal end having a rearward end extending from the distal end a pre-determined distance, a line of elements in the cannula contacting the plug and extending rearward thereform [sic], and a stylet reciprocable in the cannula and having a distal end engaging an end of the line of elements more remote from the distal end of the cannula.

('760 Patent col. 6, ll. 9-18) (underlining denoting the terms requiring construction).

a. "Thereform"

AnazaoHealth argues that the word "thereform" has no meaning that can be understood, which renders Claim 9 invalid as being insolubly ambiguous. The Court finds no support for this position whatsoever and concludes from its examination of the prosecution history that "thereform" was obviously a

typographical error, and a minor one at that. "Therefrom" is spelled correctly in the original application and in the amended application. (W0446, W0478, W0486.) Clearly, this spelling error was inadvertently introduced by the PTO when the '760 Patent was printed after it had been duly examined and issued.

The Court has the power to correct such errors and does so in this case to correct the spelling to "therefrom." See Novo Indus., 350 F.3d at 1354; Lemelson v. General Mills, Inc., 968 F.2d 1202, 1203 & n.3 (Fed. Cir. 1992), cert. denied, 506 U.S. 1053 (1993).

b. "A Therapeutic Element"

Claim 9 begins with the preamble, "[f]or implanting a therapeutic element." ('760 Patent col. 6, l. 9.) The Terwilliger Plaintiffs assert that this preamble simply states a purpose for the invention and need not be construed.

AnazaoHealth argues that construction is necessary because this preamble clearly limits Claim 9 to a single therapeutic element, as opposed to multiple therapeutic elements described in the preamble to Claim 1 ("[f]or implanting therapeutic elements"). Id. at col. 5, l. 43. Accordingly, AnazaoHealth proposes that this phrase be construed as "a single radioactive seed; also would include a drug."

The Court agrees with the Terwilliger Plaintiffs that no further construction of this phrase is necessary. The Court has

already construed the term "element(s)."²⁶ This phrase appears in the preamble. The courts will not construe the preamble of a claim as a limitation where the patentee "defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1288-89 (Fed. Cir. 2008); see also On Demand Mach. Corp. v. Ingram Indus., Inc., 442 F.3d 1331, 1343 (Fed. Cir. 2006) ("In considering whether a preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim."), cert. denied, 5549 U.S. 1054 (2006). In this case, the preamble simply states a purpose or intended use for the invention and, therefore, does not limit the scope of Claim 9. See IMS Tech, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1434-35 (Fed. Cir. 2000) (holding that the preamble phrase "control apparatus" did not limit the claim scope because it merely gave a name to the structurally complete invention).

Moreover, the Court rejects Defendant's construction that would limit this phrase to a single therapeutic element. The Federal Circuit has "repeatedly emphasized that an indefinite article "a" or "an" in patent parlance carries the meaning of

²⁶ See Discussion at 26-29, supra.

“one or more” in open-ended claims containing the transitional phrase “comprising,” as appears in Claim 9. See KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000); Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1342 (Fed. Cir. 2008); see generally Harmon § 6.2(d) at 334-35. “The exceptions to this rule are extremely limited: a patentee must evince a clear intent to limit ‘a’ or ‘an’ to ‘one.’” Baldwin Graphics, 512 F.3d at 1342 (original quotation marks and citations omitted). Such clear intent must be shown by the language of the claims themselves, the specification, or the prosecution history. Id. at 1343. Nothing in the claims, the specification, or the prosecution history of the ‘760 Patent shows that the patentees intended to depart from this general rule and specifically limit the scope of Claim 9 to a single therapeutic element. Thus, the Court declines to construe the preamble as limiting Claim 9 to a single therapeutic element.

c. “Wall”

The Court has previously held that the term “wall” needs no construction and has its plain and ordinary meaning as would be understood by one having ordinary skill in the art.²⁷ The Court adheres to that ruling with respect to Claim 9.

d. “Distal End”

As the Court noted, see Note 15, supra, the World Wide

²⁷ See Discussion at 22-26, supra.

Plaintiffs and AnazaoHealth agree that this term in Claim 1 could be construed as "the tip or point of the needle cannula," and the Court adopted their proposed construction. The Court adopts this construction for Claim 9 when "distal end" is used in connection with the term "cannula."

The same phrase, however, is also used in Claim 9 with respect to the "stylet" and, as the Terwilliger Plaintiffs point out, it makes no sense in this context to construe "distal end" as "the tip or point of the needle cannula." The Court finds that "distal" when used with the term "stylet" should be given its ordinary meaning, "remote from the point of view," or "the far" end, the opposite of proximal. Webster's at 658. There is no indication in the claim or specification that the patentees intended to use this term in a novel way or impart any special meaning to it. Thus, the Court will apply the ordinary meaning. See Symantec Corp., 522 F.3d at 1291-92 (holding that it is appropriate to apply the plain and ordinary meaning to claim terms when those terms are not expressly defined in the patent and there is nothing to suggest that a special meaning was intended); Miken Composites, 515 F.3d at 1337 (holding that a particular claim term, used in its ordinary sense, should take its dictionary definition).

e. "Generally Cylindrical End Plug"

All three parties have proposed constructions for this

phrase. AnazaoHealth asks the Court to construe this as

a separate ejectable member of predetermined dimensions comprised of material other than bone wax that is in the shape of a cylinder (i.e. the surface traced by a straight line moving parallel to a fixed straight line and intersecting a fixed planar closed curve), including end surfaces at a ninety (90) degree angle to the side of the plug, and placed into the distal end of the needle.

The World Wide Plaintiffs have broken the phrase into two constituent parts: "generally cylindrical" - "an object or material having the general form or properties of a cylinder" and "end plug" - "an object or material used to fill or seal an opening and positioned toward an extreme portion of the object it is filling." The Terwilliger Plaintiffs propose a construction of "a piece of material having the general form of a cylinder used to fill an opening and positioned at the distal end of the object it is filling."

Initially, the Court has construed "plug" in Claim 1 as "an object or material used to fill or seal an opening,"²⁸ and will incorporate that construction into "generally cylindrical end plug."

As for the phrase "generally cylindrical," the Court rejects Defendant's proposed construction for several reasons. It gives no effect to "generally" and improperly reads this term out of the Claim. See Innova/Pure Water, 381 F.3d at 1119 (holding

²⁸ See Discussion at 35-46, supra.

that “[w]hile not an absolute rule, all claim terms are presumed to have meaning in a claim”). In the context of claim construction, use of the adverb “generally” is to account for “some amount of deviation from exact.” See Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1311 (Fed. Cir. 2003); see also Playtex Prods., Inc. v. Procter & Gamble Co., 400 F.3d 901, 908 (Fed. Cir. 2005) (holding that “generally” is a term of approximation).

Additionally, Defendant’s proposal would exclude several of the embodiments of the invention disclosed in the specification and depicted in the drawings. For example, Figures 1 and 2 show end plugs and spacers that are described as of “cylindrical shape,” although they possess rounded ends and are clearly not perfectly cylindrical. This provides an indication of how the patentees used the term “cylindrical” in the Patent. Because the end plug resides inside the cannula, its shape is necessarily constrained by the internal bore of the needle cannula, which is circular when viewed as a cross-section. Thus, the end plug should be “generally cylindrical” to fit within the cannula, but there is nothing in the claim or specification that would require the degree of precision set forth in Defendant’s proposed construction. The Court finds that “cylindrical” was intended by the Patentees to have its ordinary meaning, that is, “having the form or properties of a cylinder.” Webster’s at 565. As used in

this Claim, it is the shape that is critical and, thus, the Court construes "cylindrical" to mean "having the form or shape of a cylinder."

Claim 9 also refers to an "end plug," as opposed to simply "a plug" as in Claim 1. The World Wide Plaintiffs maintain that in the context of Claim 9 "end plug" can be construed in the same manner as "plug" since the Claim provides that it is to held in the distal end, which has been construed as "the tip or point of the needle cannula." The Terwilliger Plaintiffs ask the Court to add a limitation to the construction of "end plug" as "a piece of material used to fill an opening and positioned at the distal end of the object it is filling." The Court finds that in the context of Claim 9, this additional language is redundant of what is already in the claim.

Accordingly, the Court construes the phrase "a generally cylindrical end plug" to mean "an object or material generally having the form or shape of a cylinder used to fill or seal an opening."

f. "Frictionally Held"

The Court adheres to its construction of this phrase in Claim 1.²⁹

g. "Rearward End"

AnazaoHealth has identified this phrase as requiring

²⁹ See Discussion at 51-54, supra.

construction. It proposes that the Court construe it as meaning "that portion of the generally cylindrical end plug, once inserted into the cannula, closest to the hub of the needle."

The World Wide Plaintiff suggest as a construction, "that portion of the plug, once positioned inside the cannula, that is closest to the proximal end of the needle." The Terwilliger Plaintiffs assert that no construction is necessary.

Claim 9 reads in relevant part, "a generally cylindrical end plug frictionally held in the distal end and having a rearward end extending from the distal end a pre-determined distance."

('760 Patent col. 6, ll. 11-13 (emphasis added).) The difficulty that the Court has with Defendant's proposal is that it introduces an undefined term, "hub." The Description of the Preferred and Other Embodiments describes Figure 2 as depicting an end plug **32** at the distal end of the cannula, which "comprises a rearward cylindrical end surface 32a which is positioned an exact length back from the extreme distal end of the tip **20a** of the beveled point **20**." Id. at col. 3, ll. 61-64. Figure 2 very clearly points to the "rearward end" of the plug **32a**. The Description further refers to "the exact positioning of the rear end surface **32a** at the pre-established distance back from the tip." Id. at col. 4, ll. 34-36. It is absolutely clear to the Court that one of ordinary skill in the art would understand from the Claim and the specification precisely what was meant by

"rearward end" and that no further construction is necessary.

h. "Predetermined Distance"

The Court has previously construed this term in Claim 1 and adheres to this construction in Claim 9.³⁰

i. "Line of Elements"

The Court construed this phrase in Claim 3 and adheres to that construction in Claim 9.³¹

j. "Elements"

Likewise, the Court adheres to its prior construction of "elements."³²

5. Claim 10

The parties seek construction of four terms in Claim 10, which is a dependent claim, "line of elements encapsulated in a biodegradable material," "biodegradable," "the seeds," and "spaced relation." The Court has previously construed all of these terms in Claim 3 and adopts those constructions of these terms in Claim 10.

6. Claim 16

Initially, AnazaoHealth and the World Wide Plaintiffs identified six terms requiring construction in Claim 16, a dependent claim. They have since agreed on the construction of

³⁰ See Discussion at 46-51, supra.

³¹ See Discussion at 59, supra.

³² See Discussion at 26-29, supra.

three of those, "distal end," discussed above; "seals" as meaning "closes the distal tip of the cannula, thereby preventing radioactive seeds from spilling out of the cannula or bodily fluids from entering the cannula prematurely;" and "sterile," as meaning "free from living germs or microorganisms." The Court adopts those constructions.

Two of the remaining terms, "line of elements" and "end plug," have already been construed by the Court. The Court adheres to those prior constructions.³³

The one remaining term requiring construction is "pre-loaded," which appears in Claim 16 in the context of "[a]n assembly as claimed in claim 9 . . . wherein the needle assembly is pre-loaded with said line of elements. . . ." ('760 Patent col. 6, ll. 40-41.) The World Wide Plaintiffs propose that this term be construed as "loaded beforehand at a facility other than the location of the procedure." AnazaoHealth argues that the term has no discernible meaning in the context of the claim and, to the extent that it can be construed as advocated by the World Wide Plaintiffs, it inappropriately claims both an apparatus and a method in a single claim, thereby rendering the claim invalid.

The intrinsic evidence contains several references to the needle assembly being pre-loaded. The title of the '760 Patent is "Pre-loaded Needle Apparatus." The Summary of the Invention

³³ See Discussion at 59, 70-71, supra.

describes one of the advantages of the Patent as being that the needle assembly may be delivered to the user already loaded and sterile, which reduces preparation time as well as personal exposure to radioactive seeds. ('760 Patent col. 2, ll. 23-26.) This is reiterated in the prosecution history, which states that a new Claim 21³⁴ was added to recite this improvement disclosed in the specification. (W0483.)

Initially, the Court rejects the World Wide Plaintiffs' proffered construction to the extent that it adds "at a facility other than the location of the procedure." First, there is nothing in the intrinsic evidence to support this limitation on the term "pre-loaded." Secondly, it introduces ambiguity by use of the undefined term, "facility." Under their construction, would the needle assembly have to be pre-loaded in a different building and not in a laboratory at the hospital or facility where the procedure was to take place? Or, does it mean that it just had to be pre-loaded in a different room? The intrinsic evidence of record does not answer these questions. The specification simply states that the needles could be delivered to the user already loaded and sterile, ('760 Patent col. 2, ll. 24-25), but there is no limitation on where the pre-loading had to take place. Therefore, the Court declines to add this

³⁴ The Examiner allowed this additional Claim 21, which was re-numbered as Claim 16 in the published '760 Patent.

limitation to the construction of the term "pre-loaded."

Instead, the Court construes the term "pre-loaded" according to its customary meaning - "loaded beforehand."

As to AnazaoHealth's argument that the patentees' introduction of the term "pre-loaded" as a claim element created an ambiguity between what is claimed in dependent Claim 16 and what is claimed in Claim 9, the independent claim on which it depends, the Court disagrees. Claim 9 expressly claims as a distinct element, "a line of elements in the cannula." Thus, AnazaoHealth argues, the World Wide Plaintiffs' interpretation of "pre-loaded" logically means that the needle assembly, already containing a line of elements, is somehow again being loaded beforehand at a facility other than the location of the procedure. As AnazaoHealth points out, it does not make sense that the needle assembly would be loaded with a line of elements twice. This simply is not a logical reading of dependent Claim 16.

As the prosecution history reveals, Claim 16 was added to "recite the improvement disclosed by the specification by which the needle assembly may be delivered to the user already loaded (pre-loaded) and sterile." (W0483.) The Court finds that when "pre-loaded" is given its ordinary and customary meaning of "loaded beforehand" or already loaded, this claim is not rendered "insolubly ambiguous," as urged by AnazaoHealth. Cf. Star

Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1371 (Fed. Cir. 2008), cert. denied, – U.S. –, 129 S. Ct. 1595, 173 L. Ed. 2d 678 (2009).

Alternatively, AnazaoHealth argues that even if a reasonable construction of the term “pre-loaded” could be determined, the Plaintiffs’ proffered construction would render the claim invalid because it combines a product claim (“the assembly as claimed in Claim 9”) with a method claim (“wherein the needle assembly is pre-loaded with said line of elements and is sterile”). The Federal Circuit has squarely held that a single claim purporting to cover both an apparatus and a method for using that apparatus is invalid as a matter of law under 35 U.S.C. § 112 ¶ 2, citing IPXL Holdings, LLC v. Amazon.com, Inc., 430 F.3d 1377, 1384 (Fed. Cir. 2005). Here, as in IPXL Holdings, AnazaoHealth asserts that it is unclear whether infringement of claim 16 would occur when someone created a needle assembly comprising a line of elements, or when the off-site facility loaded it beforehand and sterilized it. Thus, it would be invalid because, in reciting both an apparatus and the method for using the apparatus, it would not apprise a person of ordinary skill in the art of its scope. Id. at 1384. Again, the Court disagrees.

Section 112, paragraph 2, requires that the claims of a patent “particularly point[] out and distinctly claim[]the subject matter which the applicant regards as his invention.” 35

U.S.C. § 112 ¶ 2. A claim is considered indefinite if it does not reasonably apprise someone skilled in the art of its scope. IPXL, 430 F.3d at 1384. In IPXL, the Federal Circuit considered for the first time the issue of whether a single claim that covers both an apparatus and a method of using that apparatus is invalid. Id. The Court held that where a claim combines two separate statutory classes of invention, a manufacturer or seller of the apparatus would not know from the claim whether it might also be liable for contributory infringement if a buyer or user of the apparatus later performed the claimed method of using the apparatus. Id. Thus, the Court concluded that such a claim was not sufficiently precise to provide competitors with an accurate determination of the “metes and bounds” of the protection involved and, therefore, was ambiguous under section 112, paragraph 2. Id. In that case, the claim at issue clearly covered both the system and the user’s active “use” of the system.³⁵

³⁵ The claim at issue in IPXL read:

The system of claim 2 [including an input means] wherein the predicted transaction information comprises both a transaction type and transaction parameters associated with that transaction type and the user uses the input means to either change the predicted transaction information or accept the displayed transaction type and transaction parameters.

430 F.3d at 1380 (emphasis in original).

In this case, however, Claim 16 describes an apparatus - a "needle assembly," modified by the term "sterile," which is simply an adjective that further describes the apparatus. It does not describe a separate method of use. Where "[t]he clause at issue is not a separate method step, but rather is descriptive of the apparatus itself," the holding of IPXL is not implicated. Sienna LLC v. CVS Corp., No. 06 Civ. 3364, 2007 WL 13102, at *8 (S.D.N.Y. Jan. 3, 2007). As the court noted in Ricoh Co., Ltd. v. Katun Corp., 486 F. Supp. 2d 395, 420 (D.N.J. 2007), in almost all cases where this issue has been raised post-IPXL, the courts have found that the suspect claims did not cover both an apparatus and a method, but rather were apparatus claims containing functional limitations. (Citing cases).

Accordingly, the Court construes the term "pre-loaded" as "loaded beforehand."

7. Claim 17

The parties initially sought construction of five disputed claim terms in Claim 17. They have since agreed to the construction of two of these: "radiation seeds" - "radioactive sources;" and "distal end," discussed supra. Of the three remaining terms, the Court has already construed "generally cylindrical plug," and adheres to that construction for Claim 17. The two remaining terms are "into the sharpened distal end" and "to frictionally reside there."

Claim 17 is a method claim, which recites:

A method of making a needle assembly for implanting radiation seeds, comprising the steps of:

- a. providing a cannula having a sharpened distal end and a generally cylindrical plug,
- b. forcing the plug into the sharpened distal end of the cannula to frictionally reside there.

('760 Patent col. 6, ll. 43-49) (emphasis added).

a. "Into The Sharpened Distal End"

AnazaoHealth asks the Court to adopt the following construction of this phrase: "taking the separate ejectable member and putting it into the sharpened distal end by force." The World Wide Plaintiffs maintain that no construction is necessary. The Court agrees with Plaintiffs. AnazaoHealth's construction unnecessarily repeats the introductory language of this claim. It also includes a construction of the term "plug" that the Court has previously rejected.³⁶

b. "To Frictionally Reside There"

The World Wide Plaintiffs construe this phrase as "restrained from motion by frictional force for a period of time." AnazaoHealth offers the following construction: "forcing the separate ejectable member into the cannula such that it is held in place by a tight fit, as a cork in a bottle, until it is

³⁶ See Discussion at 35-46, supra.

intentionally dislodged and is not held by adhesion, heat, minute distortions of the cannula, surface tension or capillary action.”

In Claim 17, the plug is forced into the cannula “to frictionally reside there.” The Court has previously addressed the term “frictionally held,” which it construed to mean “restrained from motion by frictional force.” The only difference here is that Claim 17 speaks in terms of “reside,” rather than “held.” As Plaintiffs point out, the term “reside” connotes staying in place for a period of time. Webster’s defines “reside” as “to settle oneself or a thing in a place; be stationed; remain; stay.” Id. at 1931. Thus, there is a temporal element to “reside,” which Plaintiffs’ proffered construction has captured with the phrase “for a period of time.” Therefore, the Court adopts the construction offered by Plaintiffs, modified slightly to fit grammatically into Claim 17 - “to be restrained from motion by frictional force for a period of time.”

8. Claim 18

Claim 18, another method claim, presents eight contested terms. The parties have agreed to one, “distal end,” discussed supra. The Court has previously construed “therapeutic elements” in Claim 9, “wall” in Claim 1, and “generally cylindrical plug” in Claims 9 and 17. The Court adopts those constructions for those terms as used in Claim 18. Four terms remain.

Claim 18 recites:

A method of making a needle assembly for implanting therapeutic elements, comprising the steps of:

- a. providing a cannula having a wall and having a sharpened distal end and providing a generally cylindrical plug,
- b. placing the plug into the sharpened distal end of the cannula to reside there, and
- c. modifying the diameter of the plug to enhance its frictional engagement with the wall of the cannula.

(`760 Patent col. 6, ll. 50-59) (emphasis added).

a. "Placing The Plug Into The Sharpened Distal End"

The Court has previously construed "plug" and has held that "into the sharpened distal end" required no construction. The only term that has not been construed is "placing." The parties do not differ significantly in their interpretation of this term. AnazaoHealth suggests the construction of "taking the separate ejectable member and putting it into the sharpened distal end." The World Wide Plaintiffs suggest "to put in position." The Court finds that the ordinary and customary of the term "placing" to one skilled in the art is "putting into position." When this construction is read into Claim 18, the claim would read, "Putting an object used to fill or seal an opening into position in the sharpened distal end."

b. "To Reside There"

The Court has previously ruled on the construction of “reside” as used in Claim 17. AnazaoHealth maintains that the ordinary meaning of “to reside there” in the context of Claim 18 is “forcing the separate ejectable member into the needle so as to enhance the separate ejectable member’s frictional engagement with the needle.” AnazaoHealth’s proposed construction overlooks the distinction between Claim 17, in which the method involves “forcing” the plug into the distal end of the cannula to frictionally reside there, and Claim 18 which involves “placing” the plug into the distal end of the cannula and then modifying the diameter of the plug to enhance its frictional engagement with the wall. Moreover, AnazaoHealth’s proposed construction does not make sense in the context of Claim 18, b., which would read “placing the plug into the sharpened distal end of the cannula to force the separate ejectable member into the needle so as to enhance the separate ejectable member’s frictional engagement with the needle.” Therefore, the Court rejects AnazaoHealth’s proposed construction and adopts instead “to remain in place for a period of time.”

c. “Frictional Engagement”

Claim 18 recites a “frictional engagement” between the plug and the wall of the cannula. The World Wide Plaintiffs construe the phrase as to “restrain from motion by frictional force.” AnazaoHealth urges the following construction: “forcing the

separate ejectable member into the cannula such that it is held in place by a tight fit, as a cork in a bottle, until it is intentionally dislodged and is not held by adhesion, heat, minute distortions of the cannula, surface tension or capillary action."

Although the Court has not previously construed the phrase "frictional engagement," it has construed "frictionally held" in Claims 1 and 9. AnazaoHealth's proposed construction is essentially the same as that which it advanced for "frictionally held." For the same reasons that the Court rejected that construction, it also rejects it here.

Per the claimed method, modifying the diameter of the plug enhances the frictional engagement of the plug with the cannula wall. As the specification instructs, by enlarging the diameter of the plug, a tight fit is created between the plug and the cannula wall. ('760 Patent col. 2, ll. 58-60.) Webster's defines the term "engage" as "to come into contact or interlock with" and "engagement" as the "state of being engaged." Id. at 751. The specification describes the manners in which "holding" the end plug in place inside the cannula may be accomplished ('760 Patent col. 2, l. 52), thus suggesting that engagement means "holding."

The World Wide Plaintiffs' proposed construction, however, does not fit grammatically into the claim, which uses "engagement" as a noun not as a verb. Thus, the Court adopts

what it believes would be the ordinary and customary meaning to one skilled in the art of “frictional engagement” - that is, “the state of being restrained from motion by frictional force exerted against” the wall of the cannula.

d. “Modifying the Diameter”

The World Wide Plaintiffs also seek construction of the phrase “modifying the diameter” in Claim 18c, which uses the phrase in terms of “modifying the diameter of the plug to enhance its frictional engagement with the wall of the cannula.” (’760 Patent col. 6, ll. 58-59.) Each of the three dependent claims that follow Claim 18 recites one of these three methods of modifying the diameter. Id. at col. 6, ll. 60-65. The World Wide Plaintiffs propose a construction of “to change the form or qualities of the plug.” AnazaoHealth suggests a more specific definition, “mechanical distortion so as to alter the diameter of the plug or expanding the diameter of the plug by heating the material until it swells or exposing the plug to solvents.”

The specification states that holding the plug in place “may be accomplished” by modifying the diameter by mechanical distortion, or by expanding the diameter through heat, or by exposing the plug to solvents, id. at col. 2, ll. 53-57, and depicts in Figure 5 a plug that “may be held in place” by a solvent coating to adhesively fix the plug in place, or by heat, or by minute distortions of the cannula. Id. at col. 4, ll. 65-

67. The World Wide Plaintiffs argue that use of the term “may” indicates that the recited methods are merely illustrative examples. AnazaoHealth argues that the Court should construe the phrase in terms of the express disclaimers in the intrinsic record as to how modification of the plug is to be accomplished.

Where the specification makes clear that the invention does not cover a particular feature or embodiment, that feature or embodiment is deemed outside the reach of the patent even though the language of the claims without reference to the specification might be considered broad enough to encompass that feature in question. Harmon at § 6.3(a)(ii) at 345; Honeywell Inc. v. Victor Co. of Japan, Ltd., 298 F.3d 1317, 1325 (Fed. Cir. 2002). That disclaimer, however, must be clear. Likewise, a disavowal of the scope of a claim in the prosecution history must be clear and unequivocal. See Harmon at § 6.3(c); Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324-25 (Fed. Cir. 2003). Here, the Court finds no such clear and express disavowal. Thus, the Court declines to limit “modifying the diameter” to the three methods disclosed in the three dependent claims. At the same time, the Court finds that Plaintiffs’ proposed construction is overbroad and ignores the specific language of the Claim which speaks of modifying the diameter. The Court construes this phrase as “changing the diameter of the plug by means such as by heat, by treating the plug with a solvent, or by mechanical distortion.”

9. Claim 21

The last claim term requiring construction is found in dependent Claim 21, "mechanical distortion." The World Wide Plaintiffs construe it as "changing with the assistance of tools, fixtures, devices, or machinery." AnazaoHealth proffers a construction of "changing the diameter of the plug by physical processes or actions directed at the cannula, as opposed to biological or chemical processes or actions."

Claim 21 depends on Claim 18 and recites a method for modifying the diameter of the plug to enhance its frictional engagement with the cannula wall, specifically "[a] method as claimed in claim 18 wherein the diameter of the plug is modified by mechanical distortion." ('760 Patent col. 6, ll. 64-65.)

As AnazaoHealth points out, the patentees did not provide any definition or limitation as to the scope or meaning of "mechanical distortion" in the intrinsic record. And, as the World Wide Plaintiffs argue with respect to AnazaoHealth's proposed construction, there is nothing in the intrinsic evidence that would prevent the combination of biological and/or chemical processes with the use of tools, fixture, devices, or machinery. Although the specification does not define the term "mechanical distortion," it does make clear that the "mechanical distortion" is of the cannula. ('760 Patent col. 4, ll. 66-67.)

Webster's sets forth several definitions of "mechanical"

that are applicable here: "of, relating to, or concerned with machinery or tools," "of or relating to manual operations," "done as if by a machine," "caused by, resulting from, or relating to a process that involves a purely physical as opposed to a chemical change." Id. at 1400-01.

AnazaoHealth argues that Plaintiffs' proposed construction contravenes the ordinary definition of "mechanical" by not excluding biological or chemical processes. While Plaintiffs have not specifically excluded these processes, they have not included them, although they have introduced a vague and undefined term, "devices." Additionally, the construction need not include "changing the diameter of the plug," as requested by AnazaoHealth, since that is already set forth in Claim 21.

Accordingly, the Court finds that a person of ordinary skill in the art would understand "mechanical distortion" to mean "by physical processes directed at the cannula."

Conclusion

In conclusion, having ruled on all of the disputed terms, the Court now incorporates those constructions into the claims at issue:

1. For implanting therapeutic elements, [that is, anything intended for use in brachytherapy, including seeds and/or spacers], a needle assembly comprising a cannula having a wall and a sharpened distal end [tip or point], a line of elements [that is, anything intended for use in brachytherapy, including seeds and/or

spacers] in the cannula extending rearward from the distal end [tip or point of the needle cannula], yieldable means [that is, means capable of yielding or giving way under force], including a frictionally held plug [an object or material used to fill or seal an opening that is restrained from motion by frictional force], for positioning an element [that is, anything intended for use in brachytherapy, including seeds and/or spacers] more proximate the distal end [the tip or point of the needle cannula] a predetermined distance [a measurement that is specified or determined beforehand] from the distal end [tip or point of the needle cannula], and a stylet reciprocable in the cannula and having a distal end [that being the end remote from the point of view, the far end] engaging an end of the line of elements [that is, anything intended for use in brachytherapy, including seeds and/or spacers] more remote from the distal end [tip or point] of the cannula.

2. A needle assembly as claimed in claim 1 wherein the means for positioning includes an absorbable plug [that is, an object or material used to fill or seal an opening that is capable of being assimilated or broken down by the human body].

3. An assembly as claimed in claim 1 wherein the line of elements is encapsulated in a biodegradable material [that is, a line of anything intended for use in brachytherapy, including radioactive seeds and/or spacers, which are encapsulated in a material capable of being broken down in the human body by the action of microorganisms], the seeds [or radioactive sources] being held in spaced relation [that is, set apart a particular distance from one another] by the biodegradable material [that is material capable of being broken down by the action of microorganisms].

9. For implanting a therapeutic element [that is, anything intended for use in

brachytherapy, including seeds and/or spacers], a needle assembly comprising a cannula having a wall and having a sharpened distal end [tip or point], a generally cylindrical end plug frictionally held [an object or material having the form or shape of a cylinder used to fill or seal an opening that is restrained from motion by frictional force] in the distal end [the tip or point of the needle cannula] having a rearward end extending from the distal end [the tip or point of the needle cannula] a pre-determined distance [a measurement that is specified or determined beforehand], a line of elements [a line of anything intended for use in brachytherapy, including radioactive seeds and/or spacers] in the cannula contacting the plug and extending rearward therefrom, and a stylet reciprocable in the cannula and having a distal end [that being the end remote from the point of view, the far end] engaging an end of the line of elements [that is, a line of anything intended for use in brachytherapy, including radioactive seeds and/or spacers] more remote from the distal end [tip or point] of the cannula.

10. An assembly as claimed in claim 9 wherein the line of elements is encapsulated in a biodegradable material [that is, a line of anything intended for use in brachytherapy, including radioactive seeds and/or spacers, which are encapsulated in a material capable of being broken down in the human body by the action of microorganisms], the seeds [or radioactive sources] being held in spaced relation [that is, set apart a particular distance from one another] by the biodegradable material [material capable of being broken down by the action of microorganisms].

16. An assembly as claimed in claim 9 wherein said end plug [an object or material used to fill or seal an opening] seals the distal end of the needle assembly [that is, closes the tip or point of the needle cannula, thereby preventing radioactive seeds

from spilling out of the cannula or bodily fluids from entering the cannula prematurely] and wherein the needle assembly is pre-loaded [that is, loaded beforehand] with said line of elements [that is, a line of anything intended for use in brachytherapy, including radioactive seeds and/or spacers] and is sterile [free from living germs or microorganisms].

17. A method of making a needle assembly for implanting radiation seeds [radioactive sources], comprising the steps of:

- a. providing a cannula having a sharpened distal end [tip or point] and a generally cylindrical plug [that is, an object or material having the form or shape of a cylinder used to fill or seal an opening],
- b. forcing the plug into the sharpened distal end [tip or point] of the cannula to frictionally reside there [to be restrained from motion by frictional force for a period of time].

18. A method of making a needle assembly for implanting therapeutic elements [that is, anything intended for use in brachytherapy, including seeds and/or spacers], comprising the steps of:

- a. providing a cannula having a wall and having a sharpened distal end [tip or point] and providing a generally cylindrical plug [that is, an object or material having the form or shape of a cylinder used to fill or seal an opening],
- b. placing the plug into the sharpened distal end [that is, putting an object used to fill or seal an opening into position in the

sharpened tip or point] of the cannula to reside there [to remain in place for a period of time], and

- c. modifying the diameter of the plug [that is, changing the diameter of the plug by means such as by heat, by treating the plug with a solvent, or by mechanical distortion] to enhance its frictional engagement with [that is, its state of being restrained from motion by frictional force exerted against] the wall of the cannula.

21. A method as claimed in claim 18 wherein the diameter of the plug is modified by mechanical distortion [that is, by physical processes directed at the cannula].

The parties having consented to proceed before this Magistrate Judge for all purposes, this ruling is not a recommended ruling. See 28 U.S.C. § 636(c)(1); Roell v. Withrow, 538 U.S. 580, 585 (2003).

SO ORDERED, this 5th day of November, 2009, at Bridgeport, Connecticut.

/s/ William I. Garfinkel
WILLIAM I. GARFINKEL
United States Magistrate Judge

ATTACHMENT "A"



US006554760B2

(12) **United States Patent**
Lamoureux et al.

(10) **Patent No.:** **US 6,554,760 B2**
(45) **Date of Patent:** **Apr. 29, 2003**

(54) **PRE-LOADED NEEDLE ASSEMBLY**

(76) Inventors: **Gary A. Lamoureux**, 373 Old Sherman Hill Rd., Woodbury, CT (US) 06790;
Richard A. Terwilliger, 604 Old Field Rd., Southbury, CT (US) 06488

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/983,463**

(22) Filed: **Oct. 24, 2001**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 60/242,414, filed on Oct. 25, 2000.

(51) **Int. Cl.**⁷ **A61N 5/10**

(52) **U.S. Cl.** **600/7**

(58) **Field of Search** 600/1-8; 604/264-266, 604/57, 60

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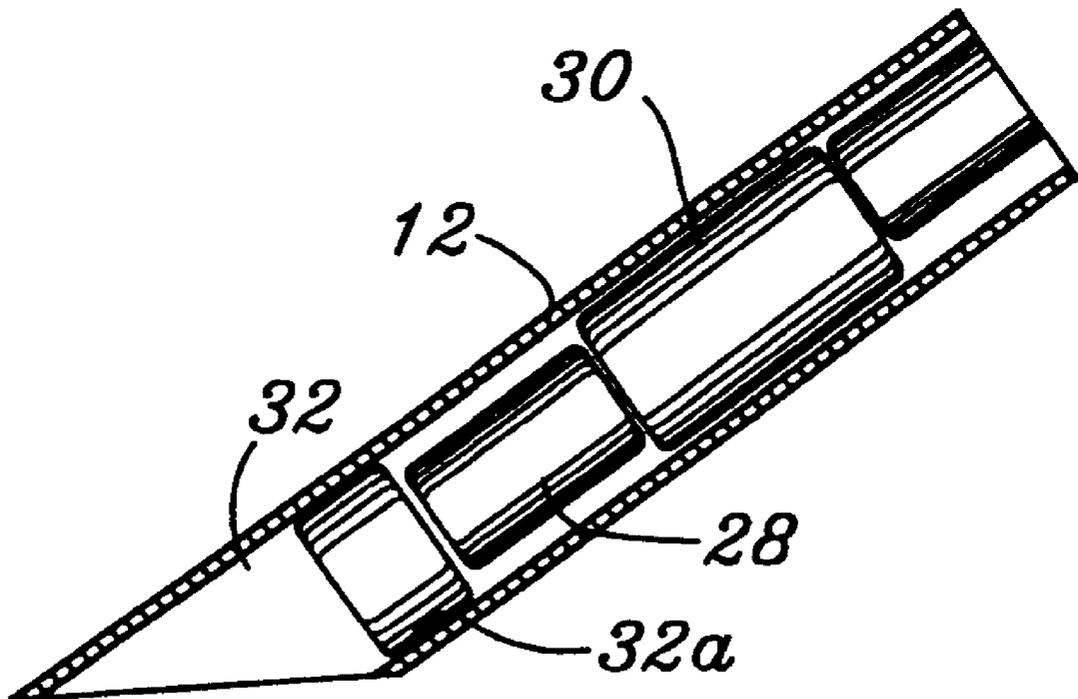
Primary Examiner—Samuel G. Gilbert

(74) *Attorney, Agent, or Firm*—William C. Crutcher

(57) **ABSTRACT**

For implanting a therapeutic element, this needle assembly includes a cannula having a sharpened distal end, a line of elements in the cannula extending rearward from the distal end. A yieldable positioner including an absorbable plug positions the element more proximate the distal end a predetermined distance from the distal end. The positioner may be in various forms including an end plug, a tab in the cannula. The needle assembly may also be pre-loaded with the line of elements and be sterile and a distortion of the wall of the cannula. A stylet is reciprocable in the cannula and engages the end of the line of elements more remote from the distal end of the cannula.

21 Claims, 2 Drawing Sheets



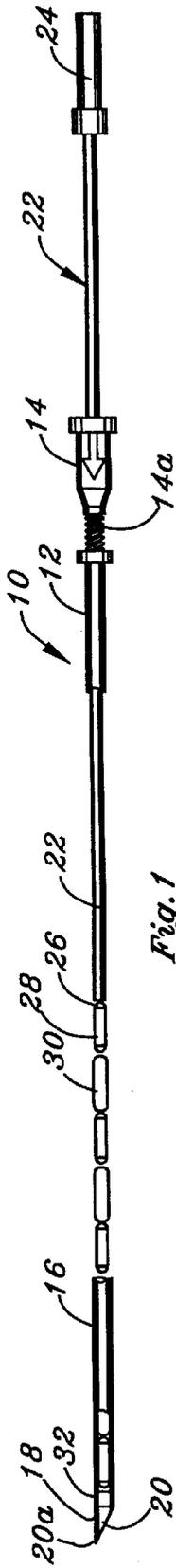


Fig. 1

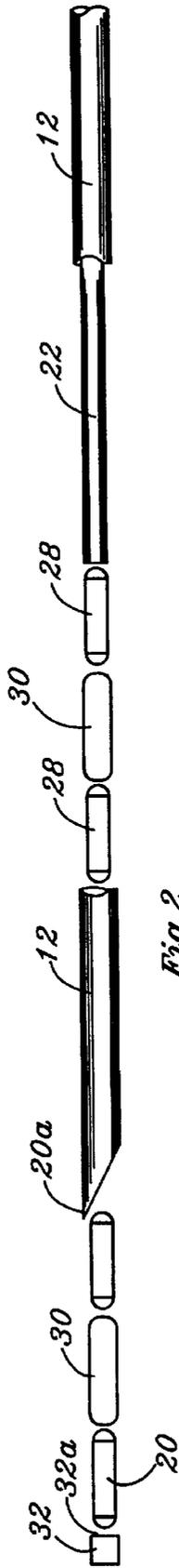


Fig. 2

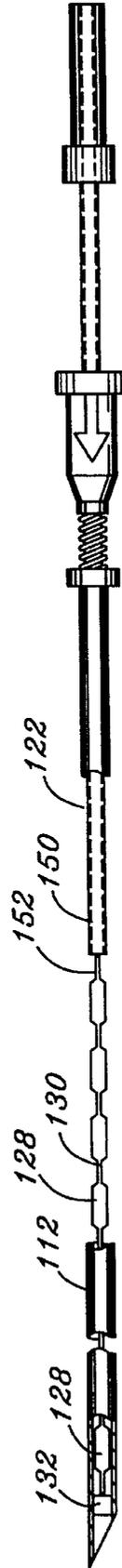


Fig. 3

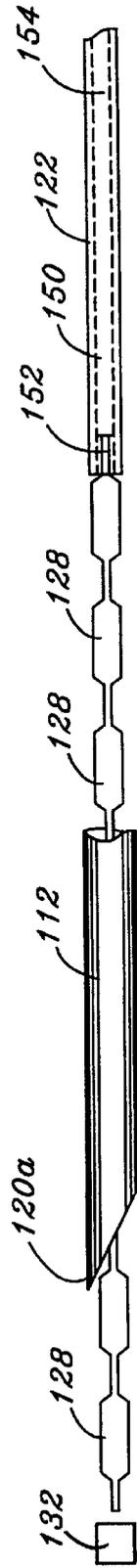


Fig. 4

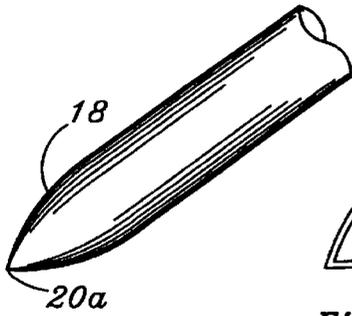


Fig. 5a

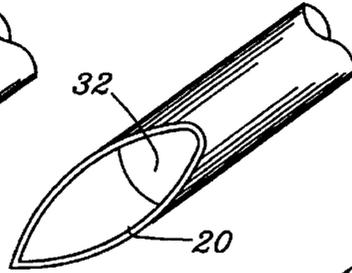


Fig. 5b

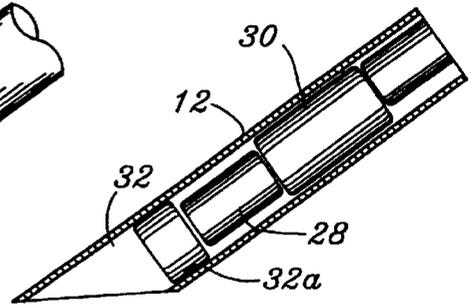


Fig. 5c

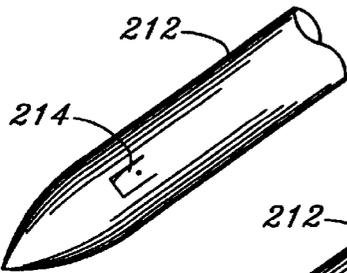


Fig. 6a

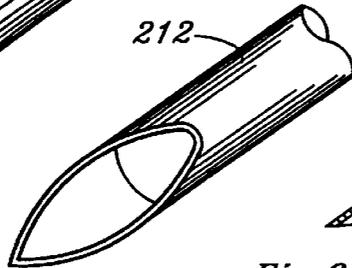


Fig. 6b

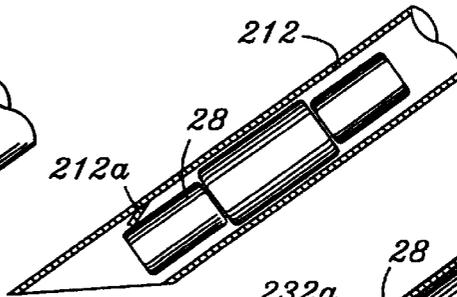


Fig. 6c

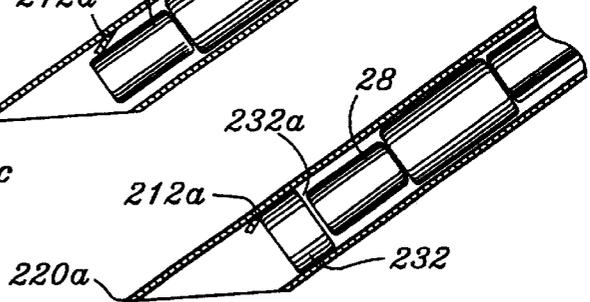


Fig. 6d

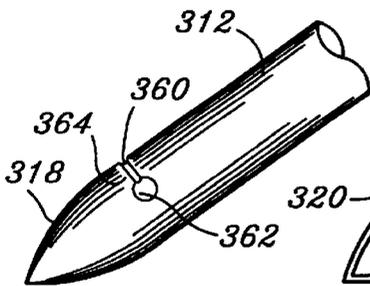


Fig. 7a

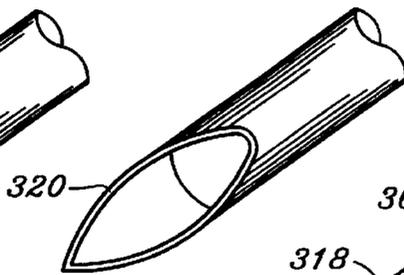


Fig. 7b

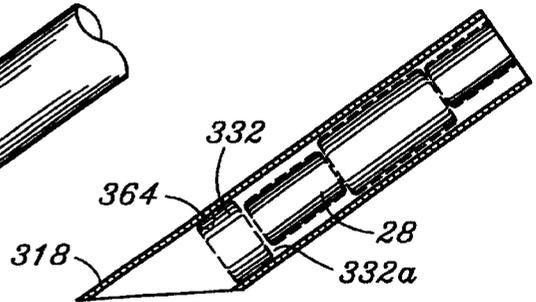


Fig. 7c

PRE-LOADED NEEDLE ASSEMBLY

This application is related to Provisional patent application Ser. No. 60/242,414 filed Oct. 25, 2000.

FIELD OF THE INVENTION

This invention relates to a needle assembly for implanting therapeutic elements. More specifically, this invention relates to such an assembly which allows the user to load and place radioactive "seeds" in the body for the purpose of treating cancer.

BACKGROUND OF THE INVENTION

The placement of a pattern of radioactive sources in the body to treat cancer by destroying cancer cells with low dose radiation is an accepted and preferred method of treatment as an alternative to general surgery.

These radioactive sources or "seeds" are placed into the body using multiple hollow needles or needle assemblies. The needles act as holders and carriers of such seeds until the needles are inserted into predetermined areas of the body. Once the needles are positioned, the seeds are deployed from each hollow needle by a solid wire stylet to permanently reside in the body as the radioactive dose decays over the treatment time. As many as 25 or more needles are used in each procedure. Typically, a physicist must prepare the needles or cannula and load the seed sources and spacers into each cannula prior to the procedure. Bone wax has been used to close the end of the cannula. The wax is placed into the first 2-5 mm of the distal tip of the cannula to prevent the radioactive "seeds" from dislodging or falling out prior to insertion of the cannula into the body. The doctor then inserts the cannulas into the patient and deploys the seeds into the area to be treated.

Prior art needle assemblies disclose a cannula with a sharpened distal tip and an inner solid wire stylet that is used to push the radioactive seeds into the body. The proximal end of the cannula consists of a plastic or metal hub that allows the loading of the radioactive seeds into the cannula. The proximal end of the stylet is a plastic or metal handle for manipulation of the stylet.

The prior art devices are prepared for use by plugging the end of the cannula with bone wax. The bone wax extends into the first 2-5 mm of the distal tip of the cannula to contain the seeds and to prevent body fluids from entering the cannula before deployment of the seed. The bone-wax-plugged cannula is loaded with radioactive seeds held apart by short non-radioactive spacers that position the seeds in the body to achieve an even distribution of radiation to treat the suspected cancer *in vivo*.

Prior to insertion, the stylet is axially introduced into the proximal end of the cannula and rests upon the stack of seeds and spacers, which are held in place by the bone wax at the distal tip of the needle. Once the cannula is inserted into the body to the proper position, the stylet is held firm and the cannula is axially moved toward the proximal end of the stylet. This motion deposits the radioactive seeds and spacers into the body in a track or line of seeds as the cannula is pulled back.

There are two principal types of radioactive seeds. "Free" seeds are individual radioactive seeds that are loaded in the cannula with small cylindrical spacers stacked in between the radioactive seeds. The second type is a pre-manufactured "strand" of radioactive seeds that are encapsulated in a biodegradable material that spaces the radioactive seeds apart from one another.

The complications involved in the prior art stem from the use of bone wax or other materials that are used to plug the cannulas prior to the loading of the radioactive seeds.

Bone wax has many drawbacks:

1. Bone wax cannot be applied into the distal end of the cannula in a manner which assures a consistent positioning of the first seed in the cannula. The amount of wax varies needle to needle.
2. Bone wax is sticky and difficult to apply.
3. Bone wax may cause the first few seeds being deployed to stick to the end of the cannula as it is being withdrawn, displacing them from their intended position in the treated tissue (adjacent the prostate, for instance).
4. If the seeds and spacers must be removed after initial loading to change the pattern of seeds and spacers in a given needle, the bone wax prevents the unloading of the seeds in contact with the wax. This prevents the needle from being able to be reused in the procedure.

SUMMARY OF THE INVENTION

The needle assembly of the invention comprises a needle which may be delivered to the user already loaded and sterile. This reduces preparation time as well as personal exposure to the radioactive seeds.

The needle assembly of the invention exactly locates the first seed a repeatable and known distance from the distal end of the cannula in each needle used thus improving the accuracy of placing the radioactive seeds in the body.

The positioning means for the first seed may take one of a variety of forms, all of them yieldable to permit the seed to be pushed past the distal end in the implantation.

The needle assembly of the invention may include a biocompatible end plug which may be made of a variety of materials including absorbable or non-absorbable suture materials either in a braided or monofilament configuration or molded biocompatible polymers. In one embodiment of the invention, the plug may be held in place by a mechanical detail proximal to the distal end of the cannula.

This detail may be formed by parallel slits in the body of the cannula, a "U" shaped cutout in the cannula creating a "tongue" that can be displaced into the interior of the cannula, or small holes that pierce the tubular body of the cannula leaving a web between the holes. In each instance the "web" of needle material created by the hole or slitting process in the tubular body of the cannula allows for a predetermined sizing of the inner diameter of the cannula to hold the end plug or seeds in place prior to deploying them into the body.

In an alternate embodiment of the invention, holding the biocompatible end plug in place inside the cannula at the distal end of the cannula may be accomplished by modifying the diameter of the plug by mechanical distortion means or expanding the diameter of the plug by heating the material until it swells or exposing the plug to solvents.

By enlarging the diameter of the biocompatible end plug, there is created a tight fit between the plug and the cannula body at the distal tip.

The stylet of the inventive needle may be provided in a hollow tubular form. The tube used in the stylet extends through the stylet handle to create an air passageway. This hollow stylet is provided to prevent air pressure from building up inside of the cannula caused by the tight fit of the stylet and the interior diameter of the cannula. This build-up of air pressure may cause premature dislodging of the seed

source as the stylet is introduced into the cannula after loading and prior to expulsion of the seeds in the body.

In the case of encapsulated seed sources, the hollow stylet can capture the tail end of the encapsulated strand and prevent the tail end from becoming entrapped between the inner diameter of the cannula and the outer diameter of the stylet during its deployment.

In essence, for implanting a therapeutic element, the invention is a needle assembly comprising a cannula having a sharpened distal end, a line of elements in the cannula extending rearward from the distal end and yieldable means for positioning the element more proximate the distal end a predetermined distance from the distal end. The assembly also includes a stylet reciprocable in the cannula and engaging the end of the line of elements more remote from the distal end of the cannula.

BRIEF DESCRIPTION OF THE DRAWINGS

Further objects and features of the invention will be clear to those skilled in the art from a review of the following specification and drawings, all of which present a non-limiting form of the invention. In the drawings:

FIG. 1 is a side view with the cannula partly broken away of a preferred needle assembly embodying the invention.

FIG. 2 is a fragmentary enlarged view partly exploded, of the distal end of the assembly.

FIG. 3 is a side view with the cannula partly broken away showing use with an encapsulated line of seeds.

FIG. 4 is a fragmentary enlarged view, partly exploded, of the distal end of the assembly of FIG. 3.

FIGS. 5a, 5b and 5c are enlarged fragmentary top, bottom and sectional views respectively of the preferred embodiment.

FIGS. 6a, 6b and 6c are enlarged fragmentary top, bottom and sectional views respectively of a modified form of the invention.

FIG. 6d is similar to FIG. 5c but showing the combination with an end plug, and

FIGS. 7a, 7b and 7c are fragmentary top, bottom and sectional views respectively of a further modified form of the invention.

DESCRIPTION OF THE PREFERRED AND OTHER EMBODIMENTS

A preferred embodiment of needle assembly of the invention is shown in FIG. 1 and generally designated 10. It comprises a cannula 12 having a hub 14 formed with gripping surfaces 14a. The cannula has a tubular body 16 broken away in FIG. 1 to show its contents and a sharpened distal end 18 beveled off at 20 to provide a point 20a.

Reciprocally disposed in the cannula is the wire stylet 22 having an handle 24 at its proximate end. The distal end of the stylet comprises an engagement surface 26.

Also disposed within the cannula is a line of therapeutic elements, for instance, radioactive seeds 28. The seeds 28 alternate with spacers 30 of cylindrical shape and made of a biocompatible and biodegradable material such as catgut.

An end plug 32 is disposed at the distal end of the cannula. The end plug comprises a rearward cylindrical end surface 32a (FIG. 2) which is positioned at an exact length back from the extreme distal end of the tip 20a of the beveled point 20. This distance is critical and it does not vary from assembly-to-assembly.

The means by which the end plug 32 is positioned in the cannula with its end surface 32a at the pre-determined

distance back may be based on one of a variety of structures and techniques. To begin with, the material of the end plug is again biocompatible and biodegradable. It may be formed, for instance, of processed collagen (catgut), Nylon or various other organic substances. A preferred material is polyglactin acid (PGA) available under the trademark POLYGLACTIN 910.

The end plug 32 may be positioned as a friction fit pressed into the distal end of the cannula as a cork in a bottle. Alternatively, it may be treated with a solvent so that it adheres to the inside of the cannula wall. By another technique it may be put in position and the cannula heated to cause the end plug to swell and hold its position. As an additional variation, the cannula may be infinitesimally distorted externally to cause it to "shrink" in the area of the plug and thereby hold the plug in position.

In all embodiments, no matter by what means, the end plug is yieldably held in precise position and may be forced outward as the cannula is drawn backward on the stylet. Thus, the positioning of the end plug 32 in the cannula 12 is yieldable. Before yielding, the plug seals the needle and keeps the seeds from spilling out the needle or body fluids from entering the needle prematurely.

In more detail, in the operation of the needle assembly shown in FIGS. 1 and 2, as with the other embodiments to follow, the needle assembly is inserted in the tissue of the body to be treated, distal end first. When the insertion is to the desired depth, the stylet 22 is held firmly and the cannula is drawn back toward the handle 24 of the stylet causing the end plug 32 to give way from its initial position and deposit in the tissue the line of seeds and spacers. This operation leaves the seeds in the exact desired position in the body.

It will be understood that the exact positioning of the rear end surface 32a at the pre-established distance back from the tip 20a is a significant advance over the haphazard positioning of the more proximate end of a bone wax material as used in the needle assemblies of the prior art. The arrangement of the present disclosure enables the operator to be assured of the precise positioning of the front end of the first seed 28 and the succeeding spaced seeds as they are inserted.

FIGS. 3 and 4 show a similar arrangement of the plug 132—numerals augmented by 100 are used to designate corresponding parts—in the cannula 112, but instead of the line of seeds and spacers 28, 30, there is the encapsulated line of seeds 128 connected by spacing webs 131.

For the encapsulated seeds versions shown in FIGS. 3 and 4, the stylet 122 may be provided with a cylindrical recess 150 to receive the tail 152 on the proximate end of the encapsulated seeds. If desired, the cylinder recess 150 may be extended rearwardly in the form of a vent 154 which extends all the way to the end of the stylet. Such an axial vent of the stylet is also contemplated for the FIGS. 1 and 2 and other embodiments. The purpose of the vent as stated is to prevent a pressure build-up as the stylet is introduced into the cannula. Such pressure can result from the close fitting nature of the stylet in the cannula and can have the effect of a piston in a cylinder pumping inadvertent pressure on the line of seeds and spacers 28, 30 to move them prematurely.

FIGS. 5a, 5b and 5c are enlarged views of the distal end of the cannula in the FIGS. 1, 2 embodiment. FIG. 5a, a sectional view shows the plug 32 in place with the seeds 28 and spacers 30 lined up behind it. As stated, the plug 32 may be a friction fit or may be held in place by a solvent coating to adhesively fix the plug in place, or by heat or by minute distortions of the cannula.

In the modification of FIGS. 6a, 6b and 6c, the first seed 28 is held in place by a tongue 212a which is formed from a U-shaped incision (FIG. 6) 214 wherein the legs "U" are longitudinal of the cannula 212. The cannula wall portion between the legs is bent inward of the cannula so that the distal end of the tongue engages the first seed 28 (FIG. 6c) and yieldably holds it in place. When the cannula is drawn back along the stylet, the pressure on the line of seeds will cause the tongue 212a to yield and permit the first seed 28 in the line of spacers and seeds thereafter to move past the tongue and assume their proper place in the tissue. Thus, in the 6a, 6b and 6c embodiment, the first seed 28 is positioned precisely, but rather than by the rear surface of an end plug, it is by distortion of the cannula itself, namely, the tongue 212a which engages the first seed 28.

In the FIG. 6d variation the end plug 232 is engaged by the tongue 212a and the plug, rather than the seed 28, is yieldably held in position with the rear surface 232a of the plug in the exact pre-determined position in the cannula back from the point 220a.

In the embodiment shown in FIGS. 7a, 7b and 7c, the cannula 312 is formed adjacent the distal end 318 with a pair of spaced openings 360 and 362. A bridge 364 in the cannula wall between the openings 360 and 362 is deflected inward in U-shape (FIG. 7c) to frictionally engage the plug 332 and hold the plug yieldably in place until it is pressed outward by the first seed 28. Here again, the rearward surface 332a is the means for precise positioning of the forward end of the first seed.

Other variations of the invention are contemplated. In every variation the positioning of the first seed 28 is consistently established by the surface against which it abuts. Usually the abutment surface is in the form of the rear surface of a plug, but, as in the FIG. 6c arrangement, the positioning of the lead end of the first seed 28 may be a mechanical yieldable portion of the cannula itself.

Further variations in the invention are possible. Thus, while the invention has been shown but in a few forms, it is not so limited but is of a scope defined by the following claim language which may be broadened by an extension of the right to exclude others from making, using or selling the invention as is appropriate under the doctrine of equivalents.

What is claimed is:

1. For implanting therapeutic elements, a needle assembly comprising a cannula having a wall and a sharpened distal end, a line of elements in the cannula extending rearward from the distal end, yieldable means, including a plug, for positioning an element more proximate the distal end a predetermined distance from the distal end, and a stylet reciprocable in the cannula and having a distal end engaging an end of the line of elements more remote from the distal end of the cannula.

2. A needle assembly as claimed in claim 1 wherein the means for positioning includes an absorbable plug.

3. An assembly as claimed in claim 1 wherein the line of elements is encapsulated in a biodegradable material, the seeds being held in spaced relation by the biodegradable material.

4. An assembly as claimed in claim 1 wherein the line of elements has a rearward tail and the distal end of the stylet is formed with an axial recess receiving the tail.

5. An assembly as claimed in claim 1 wherein the wall of the distal end of the cannula is formed with an irregularity cooperating with said plug to comprise the means for positioning.

6. An assembly as claimed in claim 5 wherein the irregularity is an inward hump in the wall of the cannula between the slits.

7. An assembly as claimed in claim 1 wherein the wall is longitudinally slitted at peripherally spaced location and the wall is deflected inward between two adjacent slits to form an inward tab cooperating with said plug to comprise the means for positioning.

8. An assembly as claimed in claim 7 wherein the inward tab extends inward from the wall of the cannula and has a U-shaped outline.

9. For implanting a therapeutic element, a needle assembly comprising a cannula having a wall and having a sharpened distal end, a generally cylindrical end plug frictionally held in the distal end having a rearward end extending from the distal end a pre-determined distance, a line of elements in the cannula contacting the plug and extending rearward therefrom, and a stylet reciprocable in the cannula and having a distal end engaging an end of the line of elements more remote from the distal end of the cannula.

10. An assembly as claimed in claim 9 wherein the line of elements is encapsulated in a biodegradable material, the seeds being held in spaced relation by the biodegradable material.

11. An assembly as claimed in claim 9 wherein the line of elements has a rearward tail and the distal end of the stylet is formed with an axial recess receiving the tail.

12. An assembly as claimed in claim 9 wherein the wall of the distal end of the cannula is formed with an irregularity to enhance the frictional holding of the plug.

13. An assembly as claimed in claim 12 wherein the irregularity is in the form of a tab extending inward of the wall.

14. An assembly as claimed in claim 12 wherein the wall is formed with peripherally spaced openings and an inward hump is deflected inward between the openings to comprise the irregularity.

15. An assembly as claimed in claim 9 wherein the stylet is formed with an axial vent.

16. An assembly as claimed in claim 9 wherein said end plug seals the distal end of the needle assembly and wherein the needle assembly is pre-loaded with said line of elements and is sterile.

17. A method of making a needle assembly for implanting radiation seeds, comprising the steps of:

- a. providing a cannula having a sharpened distal end and a generally cylindrical plug,
- b. forcing the plug into the sharpened distal end of the cannula to frictionally reside there.

18. A method of making a needle assembly for implanting therapeutic elements, comprising the steps of:

- a. providing a cannula having a wall and having a sharpened distal end and providing a generally cylindrical plug,
- b. placing the plug into the sharpened distal end of the cannula to reside there, and
- c. modifying the diameter of the plug to enhance its frictional engagement with the wall of the cannula.

19. A method as claimed in claim 18 wherein the diameter is modified by heating.

20. A method as claimed in claim 18 wherein the diameter of the plug is modified by treating the plug with a solvent.

21. A method as claimed in claim 18 wherein the diameter of the plug is modified by mechanical distortion.