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,	:	No. 3:03cv01382(WIG)
vs.	:	
ANAZAOHEALTH CORP., f/k/a GENESIS PHARMACY SERVICES, INC., d/b/a CUSTOM CARE PHARMACY,	:	
Defendant-Counterclaimant.	:	

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RULING ON MOTIONS FOR SUMMARY JUDGMENT

Pending before the Court are the parties' cross-motions for summary judgment [Doc. ## 434 & 447].[1] Plaintiffs, World Wide Medical Technologies, LLC, Gary Lamoureux, Advanced Care Medical, Inc., Advanced Care Pharmacy, Inc., and Advanced Care Pharmacy LLC (hereinafter "the World Wide Plaintiffs" or "Plaintiffs") have moved pursuant to Rule 56, Fed. R. Civ. P., for summary judgment on the issue of Defendant AnazaoHealth Corporation's (hereinafter "AnazaoHealth" or "Defendant") infringement of Claims 1-3, 9-10, and 16-17 of United States Patent No. 6,554,760 ("the '760 Patent"), issued on April 29, 2003, for a "Pre-Loaded Needle Assembly." Although the World Wide Plaintiffs also allege infringement of

[1] The docket sheet also shows Doc. # 440 as a pending Motion for Summary Judgment filed by Plaintiffs. This motion is the redacted, unsealed version of Doc. # 447.

Claims 18 and 21 in their Complaint, as amended,[2] they do not seek summary judgment as to those two claims nor do they seek summary judgment as to the other counts of their Complaint. Defendant AnazaoHealth, however, has cross-moved for summary judgment under Rule 56, Fed. R. Civ. P., on all counts of Plaintiffs' Complaint: Count I - Patent Infringement; Count II - Reasonable Royalty Under Provisional Rights; Count III - False Designation of Origin/False Advertising; Count IV - Breach of Contract; Count V - Unfair Competition; and Count VI - Unfair Trade Practices. Defendant has also moved for summary judgment as to the first count of its Counterclaim,[3] which seeks a Declaratory Judgment of Non-Infringement and Invalidity.

Summary Judgment Standard

"Summary judgment is as available in patent cases as in other areas of litigation." *Cont'l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1265 (Fed. Cir. 1991). Summary judgment is appropriate when, drawing all justifiable inferences in favor of the non-moving party, the pleadings, discovery and disclosure materials on file, and any affidavits, demonstrate that there exists no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 104 (2d Cir. 2010), *cert. denied,* 131 S. Ct. 1606 (2011); *Wellman, Inc. v. Eastman Chem. Co.,* 642 F.3d 1355, 1360 (Fed. Cir. 2011), *cert. denied*, 132 S. Ct. 1541 (2012). The Court's function is not to resolve disputed

[2] The operative complaint is the Corrected First Amended Complaint dated October 21, 2005 [Doc. # 76].

[3] The operative counterclaim is AnazaoHealth's First Amended Counterclaim with Jury Demand [Doc. # 86], which was incorporated by reference in its Amended Answer, Affirmative Defenses, Counterclaim and Jury Demand dated November 16, 2007 [Doc. # 192].

factual issues but rather to determine if there exists a genuine issue for trial. *Anderson,* 477 U.S. at 249. The substantive law governing the case identifies those facts that are material. *Id.* at 248. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Id.* A dispute regarding a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* Thus, in ruling on a motion for summary judgment, the Court must view the evidence presented "through the prism of the substantive evidentiary burden." *Id.* at 255.

"[W]here the moving party has the burden of proof on a claim or defense raised in a summary judgment motion, it must show that the undisputed facts establish every element of the claim or defense." *Meyers v. Brooks Shoe Inc.*, 912 F.2d 1459, 1462 (Fed. Cir. 1990), *overruled on other grounds by A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992). In other words, the moving party must demonstrate that it is entitled to judgment as a matter of law. *See Saab Cars USA, Inc. v. United States*, 434 F.3d 1359, 1368 (Fed. Cir. 2006); 11 James Wm. Moore, et al., *Moore's Federal Practice* § 56.13[1] (3d ed. 2010). If, on the other hand, the moving party does not bear the ultimate burden of proof on the issue that is the subject of the summary judgment motion, the movant nonetheless bears the initial burden of coming forward with sufficient evidence to demonstrate that there are no material issues of fact that would preclude summary judgment, and that it is entitled to judgment as a matter of law. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.,* 200 F.3d 795, 806 (Fed. Cir. 1999). "[T]he moving party may meet its initial burden on the motion either by providing evidence that negates an essential element of the opposing party's case, or by showing that the evidence on file (such as pleadings, depositions, and admissions) establishes no material issue of fact and that the opposer will not be

able to prove an essential element of its case." *Id.* at 807. If the movant meets this initial burden, the burden then shifts to the opposing party to show that the movant did not establish that it is entitled to judgment on the undisputed facts or on the movant's version of the facts, or that there are material issues of fact that require resolution at trial. *Id.*

When cross-motions are presented to the Court, the same standard is applied as in the case of individual motions for summary judgment. *Morales v. Quintel Entm't, Inc.*, 249 F.3d 115, 121 (2d Cir. 2001). "[E]ach party's motion must be examined on its own merits, and in each case all reasonable inferences must be drawn against the party whose motion is under consideration." *Id.*; *see also Make the Road by Walking, Inc. v. Turner*, 378 F.3d 133, 142 (2d Cir. 2004); *Scholastic, Inc. v. Harris*, 259 F.3d 73, 81 (2d Cir. 2001). "[N]either side is barred from asserting that there are issues of fact, sufficient to prevent the entry of judgment, as a matter of law, against it. When faced with cross-motions for summary judgment, a district court is not required to grant judgment as a matter of law for one side or the other." *Heublein, Inc. v. United States*, 996 F.2d 1455, 1461 (2d Cir. 1993); *see also Otis Elevator Co. v. Factory Mut. Ins. Co.*, 353 F. Supp. 2d 274, 279 (D. Conn. 2005). Rather, summary judgment should not be granted "unless one of the moving parties is entitled to judgment as a matter of law upon facts that are not genuinely disputed." *Heyman v. Commerce & Indus. Ins. Co.*, 524 F.2d 1317, 1320 (2d Cir. 1975); *see also Green Party of Conn. v. Garfield*, 590 F. Supp. 2d 288, 299-300 (D. Conn. 2008).

Discussion

The Court presumes familiarity with the background of this case, which is set forth at

length in the Court's Claim Construction Ruling dated November 5, 2009 [Doc. # 426],[4] and which will be repeated herein only as necessary.

I. Defendant's Counterclaim for a Declaration of Invalidity

The Court begins with Defendant's Motion for Summary Judgment as to Count One of its Counterclaim, which seeks a declaration that the patent in suit is invalid. Should the Court find in favor of Defendant on this count, there would be no need for any further consideration of Plaintiffs' allegations of patent infringement as to any claims found invalid by the Court. *See* 35 U.S.C. § 282; *Marrin v. Griffin*, 599 F.3d 1290, 1295 (Fed. Cir. 2010) (holding that there can be no infringement of claims deemed invalid).

Pursuant to 35 U.S.C. § 282, an issued patent, and each claim of the patent, is entitled to a presumption of validity that can be overcome only by facts established by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, — U.S. —, 131 S. Ct. 2238, 2242 (2011); *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004). A plaintiff in an infringement action starts with a *prima facie* or presumptive advantage on the issue of validity, and the "burden of establishing invalidity . . . rest[s] on the party asserting such invalidity." 35 U.S.C. § 282; *Microsoft Corp.*, 131 S. Ct. at 2243; *Tie Tech, Inc. v. Kinedyne Corp.*, 296 F.3d 778, 783 (9th Cir. 2002). Accordingly, a party seeking to invalidate a patent on summary judgment must submit such clear and convincing evidence of invalidity that no reasonable juror could find otherwise. *Univ. of Rochester*, 358 F.3d at 920. To invalidate an entire patent, each and every claim of the patent must be invalid. Additionally, at the summary judgment stage, all

[4] This Ruling was amended by the Court's Ruling on the World Wide Plaintiffs' Motion for Reconsideration dated January 22, 2010.

justifiable inferences from the facts must be drawn in favor of the non-moving party. *Schumer v. Lab. Computer Sys., Inc.,* 308 F.3d 1304, 1315 (Fed. Cir. 2002).

Among the statutory defenses to a claim of infringement are invalidity of the patent under § 102(a)[5] as anticipated; under 102(b) if the invention was in public use or on sale more than one year prior to the application; under § 103 as obvious; and under § 112 based upon the patent's failure to meet the statutory disclosure requirements. *See* 35 U.S.C. § 282(2) and (3). Here, Defendant asserts that (a) the Patentees' alleged disclosure of the invention in 2000 renders the Patent invalid under § 102(b); (b) Claims 1-3, 9-10, and 16-17 are invalid as anticipated under § 102(a); (c) Claims 1-3, 9-10, and 16-17 are invalid as obvious under § 103; (d) the asserted claims are invalid for want of enablement; (e) the asserted claims are invalid under § 112 because of their failure to disclose the best mode of the invention; and (f) the provisional patent application failed to disclose the best mode of the invention.

A. Whether the alleged disclosure of the invention in 2000 renders the '760 Patent invalid under § 102(b)?

The Court begins its analysis of Defendant's claims of invalidity with § 102(b), since this argument requires a brief discussion of the history of the '760 Patent and provides a background for some of the later arguments.

Defendant asserts that the asserted claims of the '760 Patent are invalid under § 102(b) because there can be no factual dispute that the "invention was . . . in public use or on sale in this country more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Defendant's arguments presents two issues: (1) whether the '760 Patent is

[5] Unless otherwise indicated, all statutory references in the text of this Ruling are to Title 35, United States Code.

entitled to priority based on the filing date of the provisional application or the filing date of the non-provisional application; and (2) whether the invention was in public use or on sale more than one year prior to that date? To resolve these questions, a brief discussion of the history of the development of the '760 Patent is warranted.

1. The Development of the '760 Patent

The '760 Patent, issued on April 29, 2003, to Plaintiffs Gary Lamoureux and Richard Terwilliger, is entitled a "Pre-Loaded Needle Assembly," used in the field of brachytherapy, in which radioactive elements are implanted in the body for the treatment of cancer (Pl.'s Compl. at ¶ 7). The invention of the '760 Patent is described in the Summary of the Invention section as a "needle assembly . . . compris[ing] 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" ('760 Patent, col. 2, ll. 23-26). "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" (*id.*, col. 2, ll. 27-30). "The positioning means for the first seed may take a variety of forms, all of them yieldable, to permit the seed to be pushed past the distal end in the implantation" (*id.*, col. 2, ll. 31-33). The Summary of the Invention then describes a variety of yieldable means that could be used including a biocompatable end plug made from a variety of materials, a plug held in place by a mechanical detail, and a plug held by modifying the diameter of the plug through various means (*id.*, col. 2, ll. 34-60). The non-provisional application, Appl. No. 09/983,463, for the '760 Patent was filed on October 24, 2001. The '760 Patent further provides that it relates to a provisional patent application Ser. No. 60/242,414, filed October 25, 2000 (*id.,* col. 1, ll. 3-4).

According to Mr. Terwilliger and Mr. Lamoureux, the invention that ultimately became the '760 Patent was first conceived by them in July 2000, following discussions with doctors and after looking at products on the market at a trade show held by the American Association of Physicists in Medicine ("AAPM")[6] (Terwilliger Dep. 28-29, Jan. 18, 2008, Lamoureux Dep. 107-08, Aug. 14, 2008, Lamoureux Testimony 54, 61-63, Apr. 26, 2006),[7] although Mr. Lamoureux testified that he had previously experimented with a pre-plugged needle as early as 1998 (Lamoureux Dep. 101-06, Aug. 14, 2008). At the time of the AAPM show, World Wide Medical Corporation ("World Wide"), for which Mr. Lamoureux and Mr. Terwilliger worked,[8] was selling only non-plugged needles, which the doctor would later plug with bone wax at the hospital and then load with seeds or strands of radioactive elements (Lamoureux Testimony 61-62, Apr. 26, 2006). At the AAPM trade show, a physician commended Mr. Lamoureux and Mr. Terwilliger on the outstanding job they were doing and suggested that they should try to find a way to eliminate the need for plugging of the needles (Lamoureux Dep. 107, Aug. 14, 2008).[9] Mr. Terwilliger described this comment as what sparked their initial experimentation with various plugging materials (Terwilliger Dep. 30, Jan. 18, 2008).

The next industry show was held by the American Society of Therapeutic Radiation

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[6] Unless otherwise indicated, the facts set forth herein are undisputed.

[7] *See also* Third Supp. Resp. to Def.'s First Set of Interrog. to Pl. Terwilliger No. 3.

[8] Mr. Terwilliger first worked as an engineering consultant for World Wide in June 2000. He became employed as World Wide's Manager of Marketing & Product Development in August 2000, and later as Vice President Technical Director.

[9] Mr. Lamoureux also testified that this physician specifically mentioned that they should find a plugging material other than bone wax (Lamoureux Testimony 63, Apr. 26, 2006).

Oncologists ("ASTRO") from October 20 to 25, 2000, which Mr. Lamoureux described as their "main meeting" every year (Lamoureux Testimony at 73, Apr. 26, 2006). Just before the ASTRO show, Mr. Lamoureux and Mr. Terwillliger rushed to have their patent attorney prepare a provisional patent application for a pre-plugged needle. They did so because they thought they needed patent protection for their invention before showing it to the public. The provisional patent application was filed on October 25, 2000, the last day of the ASTRO show (Lamoureux Testimony at 73-74, Apr. 26, 2006; Terwilliger Aff. ¶¶ 12-17).

The provisional application was for a "Pre-Plugged Needle," described in two pages and three drawings. The provisional application provided, *inter alia*, "[t]he inventive needle defines a method where the needle may be delivered to the user preplugged and sterile thus reducing preparation time as well as personal exposure to the radioactive 'seed' sources. It is also an improvement to the prior art that the inventive needle clearly locates the first seed source a repeatable and know (sic) distance from the distal end of the cannula thus improving the accuracy of placing the radioactive 'seed' sources in the body" (Provisional Patent App. at 6-7). The provisional application further provided that the needle included a biocompatible and absorbable end plug equal in diameter to the internal diameter of the needle cannula (*id.* at 7). The plug was held in place "by a mechanical detail proximal to the distal end of the cannula" (*id.*). It then described how the mechanical detail was formed. The application then stated "[i]n each instance the 'web' of 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 in place" (*id.*). The improvements claimed for this inventive needle included a pre-plugged needle using a biocompatible absorbable plug at the distal end; a needle with a mechanical detail

at the distal end to capture and hold the plug in place until deployment; a method of sealing the distal end without the use of bone wax; and a needle that provides a consistent pre-determined positioning of the plug in the needle (*id.*).

According to Mr. Lamoureux and Mr. Terwilliger, there were no commercial embodiments of the invention disclosed at the ASTRO 2000 show. Only rudimentary prototypes were shown in confidential meetings with radioactive seed companies as potential development partners (Terwilliger Aff. ¶¶ 11, 15-17).[10] Mr. Lamoureux described these as "working models, not very good . . . a work-in-process" (Lamoureux Testimony at 75, Apr. 26, 2006). Mr. Terwilliger testified that they waited until they received telephone confirmation from their patent attorney that the provisional patent application had been filed with the U.S. Patent and Trademark Office ("PTO") before they began talking to people at the trade show about the pre-plugged, pre-loaded needle (Terwilliger Aff. ¶¶ 15-16, 18). After receiving this confirmation, they put up a banner, "Introducing Readi-Load," which was the working name for their pre-plugged, pre-loaded needle assembly in development at the time, but they did not offer these needles for sale and had not even established any pricing or terms of sale (Terwilliger Aff. ¶¶ 19, 21). They did talk to some interested parties about the pre-plugged needle assembly concept and

[10] Mr. Terwilliger contradicted this statement in his testimony in January 2008. He testified that they did, in fact, show to the public the Readi-Load needle at the ASTRO trade show and that this was a commercial embodiment of the Patent (Terwilliger Dep. 87, Jan. 18, 2008). He also testified that they had shown this product to Amersham prior to the show under a non-disclosure agreement (Terwilliger Dep. 87-88, Jan. 18, 2008). In response to an interrogatory, Mr. Lamoureux had also indicated that the Seed-Lock™ and Readi-Load™ needle assemblies were offered for sale at the 2000 ASTRO trade show (Fifth Supp. Resp. to Def.'s First Sset of Interrog. to Pl. Lamoureux No. 3, Dec. 7, 2007). This response, however, is contradicted by his testimony cited above and an earlier response to this interrogatory. *See* Discussion at 11, *infra*.

met with representatives of Med Tec, a radioactive seed company, about a potential co-development project, on a confidential basis (Terwilliger Aff. ¶ 20).

Thereafter, they continued to experiment with different materials, techniques, and modifications to develop a product that functioned properly and consistently and could be manufactured to meet tolerances required for the commercial manufacture and sale of a pre-plugged, pre-loaded needle brachytherapy kit as a medical device (Terwilliger Aff. ¶ 22). Early designs of the invention were referred to by the designations "Readi-Load," which was a pre-loaded and pre-plugged needle assembly, and "Seed-Lock," which was a pre-plugged needle that would be provided to hospitals for on-site loading.[11] According to Plaintiffs, the earliest date the Seed-Lock™, Pre-Plugged Needles (originally marketed under the name Readi-Lock) were offered for sale was March 27, 2001 (Pls.' Supp. Resp. to Def.'s First Interrog. No. 3). Mr. Lamoureux testified that the "launch" of the Readi-Load system, in the broad sense, was at the next ASTRO show in 2001 (Lamoureux De. 731, Aug. 14, 2008), and that the first sales took place in November 2001 (Pls.' Supp. Resp. to Def.'s First Interrog. to World Wide No. 3).[12]

In February 2001, World Wide had begun working with Sequel Specialty Products to assist in testing and plugging the pre-plugged needles (Terwilliger Dep. 37-38, Jan. 18, 2008). Sequel produced the first pre-plugged needle for commercial use, although there were some problems with the use of catgut for the plug (Lamoureux Dep. 412, Sept. 28, 2009). This led to

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[11] The Seed-Lock needle was simply an EZ Load needle that World Wide Plaintiffs had pre-plugged.

[12] These responses were different than their earlier responses that Seed-Lock™ and Readi-Load™ needles were first offered for sale at the ASTRO 2000 trade show and that the first sale of the Readi-Load™ needles was at the ASTRO show (Pls.' 5th Supp. Resp. to Def.'s 1st Interrog. to Lamoureux No. 3).

the development of a second generation product, Seed-Lock II, which used a synthetic material for the plug, which they found to be far superior (Terwilliger Dep. 53-54, Jan. 18, 2008).

In early to mid-2001, pre-plugged Seed-Lock™ needles were supplied to Med-Tec, a radiation seed manufacturing company, for inclusion in the Readi-Load™ program. AnazaoHealth, a national specialty pharmacy that provides pharmacy services to physicians and hospitals, began working with Med-Tec to supply pre-loaded needles using Med-Tec's radiation seeds. However, the relationship between World Wide and Med-Tec did not work out and World Wide withdrew from the relationship in July 2001. Thereafter, World Wide began having conversations with AnazaoHealth about the possibility of a business relationship.

In early September 2001, World Wide and AnazaoHealth signed a Letter of Intent for the commercialization and delivery of pre-packaged and sterile needles with brachytherapy sources included therein. World Wide agreed to provide AnazaoHealth with Patent Pending Readi-Load pre-plugged needles, which AnazaoHealth would load with radioactive seeds and spacers and deliver to customers. Thereafter, World Wide shipped to AnazaoHealth Seed-Lock II pre-plugged needles, as well as its non-plugged needles called EZ Load, which were used by AnazaoHealth to fill brachytherapy prescriptions. This relationship ended in September 2002.

On October 24, 2001, less than one year after the filing of its provisional patent application, Mr. Lamoureux and Mr. Terwilliger filed a non-provisional patent application, Appl. No. 09/983,463. This non-provisional patent application claimed priority for their invention from the date of the provisional application. Eventually, the '760 Patent issued on April 29, 2003.

According to Mr. Terwilliger, the Seed-Lock II product that was on the market at the time

the non-provisional patent application was filed did not contain all of the features later developed and incorporated into the product to address manufacturing and performance tolerances. These included reaming the inside of the needle cannula to remove burrs, applying an interior lubrious coating to the needle cannula to allow more consistent push out force and to allow the plug to eject more smoothly, and an additional heel bevel distortion to help with the frictional hold of the plug so that it was not ejected too easily. According to Mr. Terwilliger, these processes were conceived and remained in development after the '760 Patent was filed and were not claimed in the '760 Patent because they had not been developed at the time of filing and because they involved concepts relating to needle manufacturing rather than the distinct inventive features that comprise the invention of the '760 Patent. The precise processes and methods used by World Wide in the manufacture of its brachytherpay needles are considered trade secrets of World Wide, and none of these constituted the invention of the '760 Patent (Terwilliger Aff. ¶ ¶ 48-56).

2. Is the '760 Patent entitled to priority from the provisional application filing date?

As an initial matter, the Court must consider whether the '760 Patent is entitled to priority from the date the Provisional Patent Application No. 60,242,414 was filed on October 25, 2000, or whether its priority depends on the filing date of the non-provisional application, which was filed on October 24, 2001.

Section 119(e)(1) governs the priority date of a patent and provides in relevant part:

> An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the

> provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.

35 U.S.C. § 119(e)(1). Thus, under § 119(e)(1), four requirements must be met for a non-provisional patent application to claim priority to a provisional application filing date and, therefore, gain the benefit of that earlier date: (1) the provisional patent application must comply with the requirements of the first paragraph of § 112[13] and the non-provisional patent application must be for the same invention; (2) the non-provisional patent application must be filed within 12 months of the provisional filing date: (3) there must be an overlap in inventorship; and (4) the non-provisional patent application must include a specific reference to the provisional patent application. Defendant does not dispute that the last three requirements have been met. Rather, Defendant focuses solely on the first requirement.

Defendant maintains that the '760 Patent is not entitled to priority from the provisional application filing date as a matter of law because the provisional application did not contain a written description of the invention and the manner and process of making and using it in full,

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[13] The first paragraph of § 112 provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, 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 same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112.

clear, concise, and exact terms, as required by the first paragraph of § 112, so as to enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application (Def.'s Mem. in Supp. of Mot. for Summ. J. at 10) (citing 35 U.S.C. § 112 and *New Railhead Mfg. LLC v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002), *cert. denied,* 537 U.S. 1232 (2003)). Defendant argues that, in order to be entitled to priority under § 119(e)(1), the provisional application had to comply with the requirements of the first paragraph of § 112 in relation to the non-provisional application (*id*.) (citing *E.I. du Pont de Nemours & Co. v. MacDermid Printing Solutions, LLC*, 525 F.3d 1353, 1358 (Fed. Cir. 2008)). In other words, it cannot claim priority to the provisional application filing date because it included new matter not present in the earlier disclosures. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1259 (Fed. Cir. 2004), *cert. denied,* 543 U.S. 1050 (2005). Here, Defendant maintains, the provisional application filed October 25, 2000, was for a "pre-plugged needle" and did not disclose that the needle was pre-loaded or that the plug could be held in place by any means other than by mechanical distortion, and it did not contain the method claims.

Plaintiffs respond that identity of description between the provisional application and the patent is not required. They assert that one skilled in the art, reading the provisional application in its entirety, could readily discern the limitations of the asserted claims, citing *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558-59 (Fed. Cir. 1994).

The determination of whether the provisional application contained sufficient disclosure under the first paragraph of § 112 is a question of law. *Id.* However, the question of whether one of ordinary skill in the art could readily discern the limitations of the asserted claims is a question of fact. *Id.* Construing the facts in the light most favorable to Plaintiffs, as the Court is required

to do on summary judgment, the Court agrees with Plaintiffs that Defendant has not carried its burden of proving by clear and convincing evidence that one of ordinary skill in the art could not readily discern that the pre-plugged needle assembly of the provisional application disclosed a pre-loaded needle assembly or that the needle could be plugged by means other than mechanical distortion.

There is no question that the provisional application disclosed a needle assembly, although it did not use the term "assembly," as it disclosed a needle cannula, stylet, plug, and radioactive seeds held by the plug. The figures also depict a needle assembly. *See Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1322 (Fed. Cir. 2002) (holding that "[d]rawings constitute an adequate description if they describe what is claimed and convey to those of skill in the art that the patentee actually invented what is claimed"). Additionally, the drawings of the provisional application showed an encapsulated seed source within the cannula, thus suggesting that the needle was pre-loaded. *See Id.* The application also described one of the advantages to the user of this pre-plugged needle assembly as reducing preparation time and personal exposure to radioactive seed sources, also strongly suggesting to one skilled in the art that the needle was pre-loaded. Lastly, the provisional application disclosed means of plugging the needle assembly by means other than mechanical distortion. It described an end plug equal in diameter to the internal diameter of the cannula. To one skilled in the art, it would have been obvious that an end plug with the same diameter as the internal diameter of the cannula would be held in place by friction. The provisional application also provided that the end plug could be held in place by a mechanical detail near the distal end of the cannula created by a slitting process or by a hole that pierced the body of the cannula. That feature did not eliminate the plug

being frictionally held. As the '760 Patent itself explained, this mechanical irregularity enhanced the frictional holding of the end plug. Thus, the Court finds that the claims of the '760 Patent are consistent with and supported by the provisional application. Accordingly, the '760 Patent is entitled to the priority date of the provisional application, October 25, 2000.

3. Whether the invention was disclosed to the public or on sale in October 2000?

The on-sale and public-use bar of § 102(b) entitles a patent applicant to a one-year grace period to file an application for a patent after the public use of sale of the invention. 35 U.S.C. § 102(b). This date is commonly referred to as the "critical date." *In re Epstein*, 32 F.3d 1559, 1564 n.5 (Fed. Cir. 1994). Here, the critical date is October 25, 1999. Therefore, any activities by Plaintiffs or other third parties occurring after this date would not render the invention as unpatentable. *Id.* The earliest alleged disclosure or sale on which Defendant relies is the activity of Lamoureux and Terwilliger at the ASTRO show held on October 22 to 25, 2000. Even assuming that Plaintiffs did publicly disclose the invention at this show, this was after the critical date of October 25, 1999 and, therefore, would not trigger the on-sale and public-use bar of § 102(b).

B. Whether Claims 1-3, 9-10, and 16-17 are invalid as anticipated under § 102(a)?

"To meet the requirements of patentability a device must be new; that is, it must not have been previously known." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349 (Fed. Cir. 1998). An invention that does not meet the requirement of novelty is said to be "anticipated." *Id.* "Anticipation means that the claimed invention was previously known, and that all of the elements and limitations of the claim are described in a prior art reference." Lawrence M. Sung & Jeff E. Schwartz, *Patent Law Handbook* § 3.4 (2010). More specifically, under § 102(a), if a

claimed invention was "known or used by others in this country, or patented or described in a printed publication in this or a foreign country" before the date of the invention, 35 U.S.C. § 102(a), or if the claimed invention was "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date" of the patent application, 35 U.S.C. § 102(b), or if the claimed invention was described in a patent granted on an application filed before the invention, 35 U.S.C. § 102(e)(2), then the claimed invention is said to have been anticipated by the prior art and is, therefore, invalid. *See Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1334 (Fed. Cir.), *cert. denied*, 555 U.S. 1070 (2008). Section 102(a) explicitly refers to invention dates, not filing dates. Thus, under § 102(a), a document qualifies as prior art only when it is published prior to the date of the invention that is the subject of the patent at issue. Robert L. Harmon, *Patents and the Federal Circuit* § 3.4 at 118 (8th ed. 2007).

Although the statute speaks in terms of "the invention," the anticipation analysis proceeds on a claim-by-claim basis and requires a comparison of the construed claim to the prior art. *Orion IP, LLC v. Hyundai Motor Am.,* 605 F.3d 967, 974 (Fed. Cir. 2010); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001). A party asserting that a patent claim is anticipated under § 102(a) must demonstrate that each and every element of the claim at issue is disclosed, either expressly or under principles of inherency, in a single prior art device or practice. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365 (Fed. Cir. 1999).

The Federal Circuit Court of Appeals has held that "[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim*." *Finisar*, 523 F.3d at 1334-35 (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (internal quotation marks omitted)) (emphasis in original). "[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

The concept of "inherent disclosure" does not alter the requirement that all elements must be disclosed in an anticipatory reference in the same way as they are arranged or combined in the claim. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010). "[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation." *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002). "Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Cont'l Can Co. USA, Inc.,* 948 F.2d at 1269 (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)) (emphasis added); *see also Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) ("Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999))). Thus, the Federal Circuit has observed that "[c]ases involving novelty, with its strict identity requirement, are quite rare." *Trintec Indus., Inc.*, 295 F.3d at 1297.

Additionally, the prior art reference "must enable that which it is asserted to anticipate." *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1057 (Fed. Cir. 2003). "Enablement requires that 'the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation.'" *Id.* at 1057 (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002)); *see also Iovate Health Sci., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 586 F.3d 1376, 1383 (Fed. Cir. 2009). "Whether undue experimentation would have been required to make and use an invention, and thus whether a disclosure is enabling under 35 U.S.C. § 112, ¶ 1, is a question of law." *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369 (Fed. Cir. 1999).

Anticipation under § 102, however, is a question of fact, including whether or not an element is inherent in the prior art. *AstraZeneca LP v. Apotex, Inc.,* 633 F.3d 1042, 1055 (Fed. Cir. 2010); *Marrin*, 599 F.3d at 1293; *Liquid Dynamics Corp. v. Vaughan Co.,* 449 F.3d 1209 1218 (Fed. Cir.), *cert. denied*, 549 U.S. 1032 (2006). Although anticipation is a question of fact, it may still be decided on summary judgment if the record reveals no genuine dispute as to a material fact. *See Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001). "Summary judgment is appropriate if no reasonable jury could find that the patent is anticipated." *Id.*

Applying these principles to the construed claims at issue, the Court compares each of the claims of the '760 Patent to the prior art to determine whether Defendant has carried its burden of proving anticipation by clear and convincing evidence. If a reasonable jury could find that not every element of the claim was anticipated, then Defendant is not entitled to summary judgment on its affirmative defense of invalidity based upon anticipation as to that claim.

1. U.S. Patent 6,537,192 to Elliott

Defendant argues that Claims 1, 2, 9, 16, and 17 of the '760 Patent were anticipated by a U.S. Patent 6,537,192, issued to Elliott on March 25, 2003 (hereinafter "the '192 Patent" or "Elliott"), on an application filed June 5, 2000, which was prior to the alleged date of the '760 invention, July 2000, and are therefore invalid pursuant to 35 U.S.C. § 102(e)(2). *See In re Giacomini*, 612 F.3d 1380, 1385 (Fed. Cir. 2010) (holding that § 102(e) "codified the history of treating the disclosure of *a U.S. patent as prior art as of the filing date of the earliest U.S. application* to which the patent is entitled, provided the disclosure was contained in substance in the said earliest application") (internal citations and quotation marks omitted) (emphasis in original).

The Elliott Patent describes an "Automated Radioisotope Seed Loader for Implant Needles" for use in brachytherapy procedures and the like. According to Defendant, the invention disclosed by Elliott encompasses the same invention claimed in the '760 Patent, although Elliott also teaches how the process of needle loading and plugging can be automated through use of a computer and mechanical means and, thus, taken completely out of the hands of humans.

Reading on Claim 1, as construed, Defendant asserts that the Elliott Patent discloses: (1) a needle assembly for implanting brachytherapy elements; (2) comprising a cannula; (3) having a wall; (4) and a sharpened distal end; (5) a line of elements in the cannula; (6) a stylet reciprocable in the cannula; and (7) having a distal end engaging the end of the line of elements.

Plaintiffs do not take issue with Defendant's assertion that Elliott discloses a pre-plugged needle that is loaded beforehand and is sterile. They do, however, distinguish Elliott as failing to

teach a plug frictionally held within a needle cannula and positioned a pre-determined distance from the distal end of the cannula. Additionally, they distinguish the Elliott invention as not designed to deliver a pre-plugged and pre-loaded needle assembly to an operating room in sterile condition, as claimed in the '760 Patent. Rather, Elliott describes a different invention, an automated system used bedside in the operating room for loading radioactive seeds into a series of implant needles.

Defendant responds that Elliott requires the needles to be plugged with bone wax or a similar plugging material or with a pre-formed plug of a defined length, that is placed in the needle at an "absolute location," and that this placement insures that the plug is a pre-determined distance form the distal end of the cannula.

Construing the facts in the light most favorable to the non-movant, *see Wellman, Inc.,* 642 F.3d at 1360, the Court concludes that Defendant has failed to produce clear and convincing evidence of anticipation of Claim 1 of the '760 Patent by Elliott. Elliott describes an automated system for loading low dose radioisotope seeds into a multitude of implant needles. The invention is comprised of a loading station into which a replaceable cartridge, preloaded with radioisotopes and seeds, is positioned ('192 Patent, col. 7, ll. 46-49). The cartridge has one or more apertures, into which implant needles are positioned for loading ('192 Patent, col. 9, ll. 3-9). In one embodiment of Elliott, the implant needles are positioned tip first into the loading station, a predetermined arrangement of radioisotope seeds and spacers is then loaded into each needle, and a plug is then positioned in the tip of the needle ('192 Patent, col. 5, ll. 2-7). The tip is plugged with bone wax or a similar plugging material or, alternatively, the tip of the needle is crimped as it is loaded, which prevents the contents of the chamber from being pushed out during

the loading process (‘192 Patent, col. 10, ll. 33-38; col. 25, ll. 2-8). Unlike the ‘760 Patent, Elliott discloses a plugging process that generally occurs after the radioisotope seeds have been loaded into the needle, rather than use of a plug for positioning the radioisotope seeds. In a preferred embodiment of Elliott, the proper loading of the radioisotope seeds is detected and registered by a position sensor on the pushrod, the device that pushes the radioactive seeds from a cartridge into the needles (‘192 Patent, col. 5, ll. 54-58).

In contrast, an essential feature of the ‘760 Patent is a yieldable means, such as a frictionally held plug, used for exact positioning of the brachytherapy seeds and/or spacers a predetermined distance from the distal end (‘760 Patent, col. 4, ll. 36-38). “This distance is critical and does not vary from assembly to assembly.” *See Prosecution History* (W0481-W0482). Thus, in the ‘760 Patent, the plug is the positioner that establishes the exact location of the first seed a known and repeatable distance from the distal end of the cannula; it is not merely a means for plugging the needle to prevent the seeds from falling out (‘760 Patent, Abstract at 1). As the Court found with respect to the Mercereau Patent, *see Claim Construction Ruling* at 43, the critical distinction between the ‘760 Patent and the prior art of Mercereau was this ability of the claimed invention to position an element a “predetermined distance from the distal end.” Additionally, the ‘760 Patent sought to address complications involved in the prior art stemming from the use of bone wax (although the ‘760 Patent, as construed, does not preclude the use of bone wax, *see Claim Construction Ruling* at 39). Elliott, on the other hand, fails to recognize or address the limitations caused by the use of bone wax as a plugging material. To the contrary, it expressly approves of the use of bone wax but fails to describe how the needles are plugged with bone wax. Drawing all reasonable inferences in favor of Plaintiffs, as the non-moving parties,

one could assume that Elliott did not resolve the positioning problems associated with the use of bone wax that the '760 Patent sought to address to ensure exact and consistent positioning of the first element in the cannula.

Defendant argues that Elliott's use of various sized spacers for a plug ('192 Patent, col. 11, ll. 35-48) meets the predetermined distance limitation disclosed in the '760 Patent. The Court disagrees. This embodiment of Elliott provides for different combinations of various lengths of seeds, spacers, and plugs to be utilized "that have the same overall length when positioned in an implant needle of 10 mm. for seed and spacer or 12 mm. for seed, spacer and plug" ('192 Patent, col 11, ll. 40-42). This embodiment does not even require a plug and certainly did not teach the positioning of the plug a precise and repeatable distance from the distal end of the implant needle. Moreover, as Plaintiffs point out, this embodiment of Elliott consistently discusses placing the plug at the tip of the needle so that it is aligned with and flush with the end of the tip ('192 Patent, col. 13, ll. 24-36; col. 17, ll. 35-41). This is significantly different than Claim 1 of the '760 Patent that positions the plug a predetermined distance from the distal end.

The Court agrees with Defendant that Elliott inherently discloses a frictionally held plug (*see, e.g.,* '192 Patent, col. 13, ll. 24-36). However, Elliott does not disclose a plug that is used for positioning. Elliott teaches the contents of a given chamber that will be delivered into the needle, which will push back the stylet that is already in the needle. Thereafter, a plug will be inserted so that it is flush with the end of the tip of the implant needle[14] and will remain there

[14] As Plaintiffs point out, standard brachytherapy needles are pointed with a beveled opening. Thus, it is not clear how a plug would be positioned such that it would be flush with the tip of the needle.

until the contents are pushed out by the stylet into the body of the patient. Although Elliott does not specifically recite that the plug is held by friction, it inherently would include this unstated limitation. Nevertheless, Elliott did not disclose a plug used for positioning an element a predetermined distance from the distal end of the implant needle, an essential element of the '760 Patent.

As discussed above, for a claim to be anticipated, each and every element of the claim must be disclosed in the prior art reference and must be arranged as in the claim. *See Therasense, Inc.*, 593 F.3d at 1332-33. "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Found. v. Genentech, Inc.,* 927 F.2d 1565, 1576 (Fed. Cir. 1991), *overruled on other grounds by Abbott Labs. v. Sandoz, Inc.,* 566 F.3d 1282, 1293 (Fed. Cir. 2009). "For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art." Robert L. Harmon, *Patents and the Federal Circuit* § 3.2(a) at 99 (8th ed. 2007). Here, the Court finds that Defendant has not carried its burden of proving by clear and convincing evidence an identity of inventions as between Elliott and Claim 1 of the '760 Patent. Because Elliott does not include all of the elements of Claim 1, including a plug for positioning the radioactive seeds a precise and repeatable distance from the distal end of the needle, the Court holds, as a matter of law, that Claim 1 was not anticipated by Elliott. The Court, therefore, denies Defendant's motion for summary judgment on this issue.

Claim 2 of the '760 Patent, which depends from Claim 1, adds the use of an absorbable plug. For the same reasons set forth above, the Court holds that it was not anticipated by Elliott.

Claim 9 of the '760 Patent independently claims a needle assembly for implanting a therapeutic element. As opposed to the "yieldable means" of Claim 1, Claim 9 recites "a generally cylindrical end plug frictionally held in the distal end having a rearward end extending from the distal end a pre-determined distance." Again, for the reasons set forth above, the Court finds that Claim 9 was not anticipated by Elliott, including the embodiment using a pre-formed plug of 2 mm., because Elliott did not disclose a pre-plugged needle assembly where the plug is placed a predetermined distance from the distal end of the needle and is used for consistent positioning of the radioactive elements from needle to needle.

Likewise, Claim 16, which depends from Claim 9, adds to the assembly of 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." Again, for the reasons set forth above, Claim 16 was not anticipated by Elliott.

Claim 17 is a method claim that discloses the method of making a needle assembly for implanting radioactive seeds, comprising the steps of providing a cannula having a sharpened distal end or point and a generally cylindrical plug, and forcing the plug into the sharpened distal end of the cannula to frictionally reside there ('760 Patent col. 6, ll. 43-49). Unlike the previous claims discussed above, Claim 17 does not claim any "predetermined" location of the plug beyond placement in the sharpened distal end, but it does claim a generally cylindrical plug. Elliott never describes the shape of the plug. Although Elliott discloses a 2 mm. plug in one embodiment, as discussed above, it places this plug at the tip of the sharpened implant needle so that it is flush with and aligned with the end of the tip. Because of this placement, the Court infers that the plug cannot be cylindrical, a required element of Claim 17 of the '760 Patent.

Accordingly, the Court finds that, as a matter of law, Claim 17 was not anticipated by Elliott.

2. U.S. Patent No. 6,210,315 to Andrews

Defendant asserts that Claims 1, 9, and 17 of the '760 Patent are invalid under § 102(e)(2) as anticipated by U.S. Patent No. 6,210,315 issued to Andrews in 2001 ("the '315 Patent" or "Andrews") on an application filed in July 1999, which is prior art to the '760 Patent. The invention of the '315 Patent is described as a "Brachytherapy Device Including an Anti-Static Handle," which discloses a ramp surface in the handle for easier loading of the radioactive seeds and spacers into the needle; a preferred anti-static, reduced-static, or static-free handle that eliminates the previously encountered risks of static interference, static cling, and ignition spark generation; and a localized friction portion near the proximal end of the needle or distal end of the stylet, which provides a controlled and predetermined amount of friction between the needle and stylet to prevent the stylet from slipping out of the needle and reduces the risk of the unintended ejection of the radioactive seeds and spacers from the needle ('315 Patent, col. 11, ll. 34-48).

As Plaintiffs argue, Andrews fails to anticipate the '760 Patent because it does not disclose a plug frictionally held within the needle cannula at a pre-determined distance from the distal end of the cannula. Although Andrews does mention a 1 mm. wax plug in the distal end of the needle, "closely adjacent to the sharp end of the needle," which prevents the seeds from falling out ('315 Patent, col. 8, ll. 54-5), it does not disclose how the plug is positioned within the needle or how the plug is used for positioning the first radioactive seed an exact and repeatable distance from the distal end of the needle. Rather, Andrews focuses primarily on the anti-static handle and creating a certain amount of friction between the needle and stylet so that the stylet

does not slip out. The only references to a plug are use of a plug to retain the seeds and spacers in the needle "in any convenient way, for example, by a small plug of wax closing the distal end" ('315 Patent, col 5, ll. 36-38), and the 1 mm. wax plug discussed above ('315 Patent, col. 8, ll. 54-58).

The Court finds that Andrews did not anticipate Claim 1 of the '760 Patent, which, *inter alia*, includes the limitations of a yieldable means, including a frictionally held plug, for positioning an element a predetermined distance from the distal end of the cannula; Claim 9, which, *inter alia*, includes the limitation of a generally cylindrical end plug frictionally held in the distal end and having a rearward end extending a predetermined distance from the distal end; and Claim 17, which, *inter alia*, includes the limitation of a generally cylindrical plug. As discussed above, a prior art reference must expressly or inherently describe each and every limitation set forth in a patent claim. *Trintec Indus., Inc.*, 295 F.3d at 1295. "Anticipation cannot be found, as a matter of law, if any claimed element or limitation is not present in the reference." *In re Skvorecz*, 580 F.3d 1262, 1268 (Fed. Cir. 2009). Accordingly, the Court denies Defendant's motion for summary judgment as to Claims 1, 9, and 17 of the '760 Patent having been anticipated by Andrews.

3. U.S. Patent No. 5,395,319 to Hirsch

Defendant next cites as prior art the U.S. Patent No. 5,395,319 issued to Hirsch in 1995 (hereinafter "the '319 Patent" or "Hirsch") as anticipating Claims 1, 2, 9, and 16 of the '760 Patent. The invention described by the Hirsch Patent is a "Needle For Inserting An Object Into The Body." The "objects" contemplated by Hirsch include longterm medicinal preparations, identification tags such as those implanted by veterinarians in animals, a capsule containing

radioactive substances, or a metallic contrast element (‘319 Patent, col. 4, ll. 42-47). The invention includes a needle assembly with a sharpened point, but it does not disclose a plug frictionally held within the needle cannula a pre-determined distance from the distal end, which is used for consistent positioning of the first element to be implanted in the body.

While Hirsch does refer to “unequivocally fix[ing]” the object [including a capsule containing radioactive substances] inside the needle (‘319 Patent, Abstract), it does so by arranging the object between a closure toward the tip of the needle and a constriction toward the handling end. The closure is further described as closing off at least a region of the needle and is destroyed or removed by the object when it is inserted (‘319 Patent, col. 2, ll. 1-4). The closure is an ointment-like material containing a medicinal active ingredient, which remains adhering at least to regions of the object during insertion (‘319 Patent, col. 2, ll. 8-11), or an adhesive material or silicone stopper (‘319 Patent, col. 2, ll. 13-14). Hirsch teaches that, if adhesive material is used for the closure, it should have adhesive properties such that, when penetrated by the object or mandrel, the adhesive material remains adhered within the needle (‘319 Patent, col. 2, ll. 41-46). The preferred method for applying the closure material is in a “noncontact manner,” for example, by dripping it in (‘319 Patent, col. 2, ll. 47-50). Fixed positioning is achieved by means of a change in cross section at the holder end, such as by two indentations, and on the other hand, by means of a droplet or ring arranged at a distance from the needle point (‘319 Patent, col. 2, ll. 16-29; col. 6, ll. 24-27).

As discussed above, anticipation requires the presence of all claimed elements arranged as in the claim. *See Therasense*, 593 F.3d at 1332-33; *Finisar*, 523 F.3d at 1334-35. While Hirsch addresses, *inter alia*, the same objective as the ‘760 Patent, the fixed positioning of the

object that is being implanted, it achieves this through means different than the '760 Patent. Hirsch relies largely on a rear constriction to restrict the rearmost position of the element(s) in contrast to the '760 Patent that relies on the positioning of the plug in the distal end of the needle cannula to ensure a consistent placement of the first element. In fact, as Plaintiffs correctly note, there is no express disclosure in Hirsch as to how the closure is created so that the object is maintained in a fixed position from the distal end. The '760 Patent, on the other hand, consistently positions the plug a predetermined distance from the distal tip of the cannula and is not dependent upon the size of the elements being blocked or the location of any constriction in the cannula located at the proximal end.

As reflected in the "prior art" references discussed in the '760 Patent, there were a number of prior art devices that plugged the end of the cannula with bone wax to hold the radioactive seeds within the needle. But these, like Hirsch, did not include the element that the position of the closure or plug or other yieldable means was a pre-determined distance from the distal end of the needle. Thus, the Court finds, as a matter of law, that Hirsch did not anticipate Claim 1 or dependent Claim 2, which includes yieldable means, including a frictionally held plug, for positioning an element a predetermined distance from the distal tip; nor Claim 9 or dependent Claim 16, which includes a generally cylindrical end plug frictionally held in the distal tip of the needle having a rearward end extending a predetermined distance from the distal end.

4. U.S. Patent No. 4,759,345 to Mistry

Defendant next argues that U.S. Patent No. 4,759,345 to Mistry (hereinafter "the '345 Patent" or "Mistry"), issued in 1988, is prior art that anticipates Claims 1 and 9 of the '760 Patent under § 102. The Mistry Patent is entitled "Radiation Shielded Seed Loader for Hand Implanter

Hypodermic Needles Apparatus and Method." It discloses a device for loading a plurality of hand implanter needles with radioactive seeds in a manner that limits the exposure of an individual to radiation, that expedites the loading process, that allows for loading of the needles outside of the implant area and for safely transporting them to the implant area ('345 Patent, col. 2, ll. 3-30). Mistry utilizes needles with tips plugged with a tiny amount of sterile bone wax, so that approximately 2 mm. of the needle tip is plugged ('345 Patent, col. 6, ll. 37-39), although the needles are not part of the invention ('345 Patent, col. 3, ll. 58-60; col. 4, ll. 19-20). The bone wax prevents the seeds from dropping out of the needle. Up to seven needles are then loaded into an alignment disk, after which a seed loading disk is placed over the blunt ends of the needles. One seed, or a maximum of two seeds, is then loaded into each needle, followed by a plunger or obturator, which is partially inserted into each loaded needle such that at least one-half inch of travel is still left in the needle ('345 Patent, col. 6 & 7).

Review of the Mistry Patent reveals that Mistry fails to teach a plug that is positioned within the needle cannula a pre-determined distance from the distal end and that is used for positioning the first element. Thus, Mistry does not anticipate Claim 1 or 9 of the '760 Patent. As discussed above, an essential element of Claim 1 is a yieldable means for positioning an element a predetermined distance from the distal end of the needle cannula. Additionally, Claim 1 requires the distal end of the stylet to engage an end of the line of elements, whereas Mistry requires a space between the plunger or obturator, which functions as the stylet in the '760 Patent. Likewise, Claim 9 requires a generally cylindrical end plug, having a rearward end extending a predetermined distance from the distal end, and a stylet having a distal end engaging an end of the line of elements, which limitations again are not part of Mistry. Therefore, the

Court finds that Mistry did not anticipate Claims 1 and 9 of the '760 Patent since it did not disclose all of the elements of these claims.

5. The AAPM Task Force Article

Defendant next contends that Claims 1-3, 9-10, and 16-17 of the '760 Patent are invalid as anticipated under § 102(b) by an article published in the October 1999 issue of *Medical Physics*, entitled "Permanent Prostate Seed Implant Brachytherapy: Report of the American Association of Physicists in Medicine Task Group No. 64" (hereinafter "AAPM Article").

Section 102(b) provides in relevant part that a person shall not be entitled to a patent if "the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." Under § 102(b), whether a document qualifies as a printed publication is a question of law based upon whether the publication was disseminated or otherwise made accessible to persons interested and ordinarily skilled in the subject matter to which the publication relates more than one year prior to the filing date of the patent application. *Orion IP, LLC,* 605 F.3d at 976; *Iovate Health Sci., Inc.,* 586 F.3d at 1380; *In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981). In addition to qualifying as a printed publication, the prior art reference must expressly or inherently disclose each and every claim limitation and must enable one of ordinary skill in the art to make the invention without undue experimentation. *Iovate Health Sci., Inc.*, 586 F.3d at 1380.

Plaintiffs do not dispute that the AAPM Article is a printed publication within the meaning of § 102(b) and that it was published more than one year prior to the '760 Patent application. They do, however, contend that the AAPM Article does not disclose every limitation of the claims at issue, most notably its failure to teach a plug frictionally held in a

needle cannula that is positioned a pre-determined distance from the distal end of the needle. On the contrary, they assert that the AAPM Article identified a plugging technique no different from the prior art techniques described in the '760 Patent.

The AAPM Article presented a review of then-current techniques in prostate seed implant brachytherapy treatments, including using a pre-loaded needle technique at the time of treatment in the operating room, although the Article noted that this technique required a longer time for preparation (AAPM Article at 2061). The Article described sterilized needles with sharp beveled points and blunt stylets, slightly shorter than the needles, into which radioactive seeds and spacers were loaded according to a treatment plan. *Id.* The needles and stylets typically had centimeter markings to help visually determine the depth of needle insertion and the length of the needle that was filled with seeds and spacers. *Id.* Each needle tip was plugged with a piece of surgical bone wax or rectal suppository. *Id.* The Article stated that the length of the wax (approximately 5 mm.) should be accounted for when the seeds were deposited into the prostate. *Id.* The loaded needles were then placed in a sterilized needle box, ready for implantation. *Id.* The AAPM Article noted problems expelling bone wax when Rapid Strands of seeds, enclosed in an absorbable suture material, were used. *Id.* Instead, the Article recommended the use of a suppository, such as Anusol-HC. *Id.* The suppositories were then heated, a needle was dipped into the molten suppository to a depth at least covering the needle bevel, approximately 5 mm., and the needle was removed and allowed to cool. "Upon removing the needle vertically, capillarity and gravity equalize to form a liquid column 7-9 mm. long that solidifies in 3-10 min." *Id.* at 2062. Once the needles had cooled, lengths of Rapid Strand were cut and inserted in the needles, followed by the stylets. *Id.* The needles were then inserted into the patient, where

they were allowed to remain for 2 to 3 minutes for the suppository to melt sufficiently around the perimeter so that the strands could be expelled. *Id.*

The Court agrees with Plaintiffs that the AAPM Article did not anticipate Claims 1-3, 9-10, and 16-17 of the '760 Patent based upon its failure to teach all of the elements in these claims, including a plug of pre-determined dimensions, frictionally held within the needle cannula, which is positioned a pre-determined distance from the distal end of the needle. The focus of the '760 invention was its ability to locate the first seed an exact, repeatable, and known distance from the end of the needle cannula ('760 Patent, col. 2, ll. 27-31), which was something that had not been achieved by the prior art devices described in the '760 Patent. Indeed, the pre-loaded needles and plugging techniques described in the AAPM Article are virtually the same as the known prior art described in the Background section of the '760 Patent ('760 Patent, col. 1, ll. 36-60). The prosecution history of the '760 Patent, for example, distinguished U.S. Patent No. 6,450,937 issued to Mercereau, *et al.*, based on the unreliability of the size of the plug in Mercereau, which was not a separate ejectable member, but a solidified overflow into the distal end of the cannula created by capillary action when the needle was dipped into a vat, similar to the needles plugged with a molten suppository, as described in the AAPM Article . (Def.'s Ex. Q at 94). Accordingly, the Court finds as a matter of law that the identified claims of the '760 Patent were not anticipated by the AAPM Article.

6. C.R. Bard's FastFill Needle

Defendant next argues that the C.R. Bard FastFill Needle anticipates Claims 1, 3, 9, and 10 of the '760 Patent because the deposition testimony of the C.R. Bard representative and exhibits thereto establish unequivocally that the FastFill Needle was developed and commercially

sold and delivered by C.R. Bard not later than February 2000, which is before the claimed date of invention of the '760 Patent, July 2000. *See* 35 U.S.C. § 102(a) (providing that a person shall not be entitled to a patent if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent").[15]

Based upon the uncontradicted testimony of C.R. Bard's designated 30(b)(6) witness, Mr. Michael Krachon, and the documents produced at his deposition, it is clear that the FastFill Needle, which was marketed and produced commercially no later than February 2000 (Krachon Dep. 27-28), disclosed most of the limitations of Claims 1, 3, 9, and 10 of the '760 Patent. It included a needle assembly with a cannula, a wall, a sharpened distal end, and a removable stylet (Krachon Dep. 41-44, 69). It had a bone wax tip insert that was frictionally held in the cannula (Krachon Dep. 45, 71). The part of the bone wax that extended inside the cannula was cylindrical. The part that was in the tip of the needle was contoured to the outside of the needle, "almost like a pyramid or a coned off or shaved off version of the cone" (Krachon Dep. 65). The bone wax plug would give way under force and would remain in the prostate once expelled (Krachon Dep. 63, 75). According to Mr. Krachon, the needle had 1 cm. markings to show the distance from the tip, and the stylet had .5 cm. markings to show how far the stylet was protruding from the rear hub of the needle (Krachon Dep. 48-49). When the stylet was inserted into the needle to the point that it reached the bone wax plug, one could "in a general sense" tell

[15] Contrary to the arguments presented by Plaintiffs, Defendant is not relying on § 102(b), which requires the invention to have been patented or described in a printed publication or to have been in public use or on sale in this country, more than one year prior to the date of the application for patent. *See* Def.'s Reply Mem. in Support of Mot. for Summ. J. at 17 n.14.

the amount of bone wax in the distal end of the needle by virtue of the markings on the stylet (Krachon Dep. 54-55). Mr. Krachon further testified that the amount of bone wax in the cannula was the same from needle to needle, plus or minus a manufacturing tolerance, and that the placement of the bone wax insert tip was repeatable from needle to needle (Krachon Dep. 55-56).

In response, Plaintiffs point to the fact that there is no discussion in any of the Bard advertisements or publications on the FastFill Needle as to how the bone wax is loaded or how much is used or precisely how it was to be positioned. Moreover, they cite to the fact that the Bard witness was not testifying based on his personal knowledge, as he was not even employed by Bard at the relevant time period, and his testimony as to the exact positioning of the bone wax plug has not been corroborated by any documentary evidence. *See Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1369 (Fed. Cir. 1999) (noting that the law disfavors invalidating patents on the basis of mere testimonial evidence absent other evidence corroborating that testimony).

Defendant distinguishes *Finnigan* and other cases requiring corroboration on the ground that C.R. Bard's witness was not an interested party and, thus, outside corroboration of his testimony was not required. *See Thomson, S.A. v. Quixote Corp.*, 166 F.3d 1172, 1176 (Fed. Cir. 1999).

The Court need not reach the corroboration issue, since even if Mr. Krachon's testimony were corroborated, the Court finds genuine issues of material fact as to whether the C.R. Bard bone wax end plug positioned the first seed a known, exact, and repeatable distance from the distal end of the cannula. That factual issue, however, does not end the anticipation analysis, for the Court finds that at least one other limitation of the claims at issue was not anticipated by the FastFill Needle.

The evidence is undisputed that the FastFill Needles were not preloaded with radioactive seeds and spacers and, thus, failed to include a line of elements, an essential element of Claims 1, 3, 9, and 10. The FastFill Needles were sterilized and shipped to the customer for loading (Krachon Dep. 34, 61-62). Prior to October 2001, Bard never shipped any FastFill Needles that were loaded with seeds, spacers, or any other type of element (Krachon Dep. 93-94).

Defendant relies on the principal of inherency to get around this undisputed fact. "[T]he principal of inherency can by implication work to complete the anticipation analysis" (Def.'s Mem. in Support of Mot. for Summ. J. at 23). The only purpose for the FastFill Needle was the delivery of radioactive elements, and, therefore, Defendant argues that the FastFill Needle inherently disclosed the loading of the needle with therapeutic elements.

Plaintiffs, however, maintain that Defendant has failed to provide any evidence that such "inherent" features are the natural, invariable and, thus, the only result of the known FastFill Needle structure" (Pls.' Mem. in Opp'n to Mot. for Summ. J. at 41). They cite *Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999), for the proposition that "the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency."

"[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation. . . ." *Transclean Corp.,* 290 F.3d at 1373. "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."

Cont'l Can Co. U.S.A., 948 F.2d at 1269. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* (quoting *In re Oelrich*, 666 F.2d at 581); *see also Trintec Indus., Inc.*, 295 F.3d at 1295 ("Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art.") (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir.1999)).

Despite Defendant's vigorous arguments to the contrary, the Court holds that the doctrine of anticipation by inherency does not apply here to add the element of preloaded seeds and spacers to the C.R. Bard FastFill Needle, when these were not part of the Bard invention but were supplied at a later point in time by the customer. These are not missing descriptive material that was necessarily present. These are simply not present. Defendant has not cited any case in which inherency was used to supply an element missing entirely from the prior art that was supplied by a third party, and the Court has found no such case. As discussed above, unless the prior art disclosed all of the limitations claimed, it cannot anticipate under § 102. *See Net MoneyIN, Inc.,* 545 F.3d at 1371. The evidence is not clear and convincing that the Bard FastFill Needle inherently anticipated Claims 1, 3, 9, and 10 of the '760 Patent. Accordingly, the Court denies Defendant's motion for summary judgment in this respect.

Thus, in conclusion, the Court denies Defendant's motion for summary judgment seeking a declaration as to the invalidity of Claims 1-3, 9-10, and 16-17 the '760 Patent under § 102 as anticipated.

C. Whether Claims 1-3, 9-10, and 16-17 of the claimed invention of the '760 Patent would have been obvious at the time the invention was made so as to render it invalid under § 103(a)?

Defendant next challenges the validity of the claimed invention of the '760 Patent pursuant to § 103(a), which "forbids the issuance of a patent where 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting 35 U.S.C. § 103); *see also In re Huai-Hung Kao*, 639 F.3d 1057, 1065 (Fed. Cir. 2011). Section 103(a) focuses on the "subject matter to be patented" and whether "the subject matter as a whole" would have been obvious in light of prior art. Thus, unlike the defense of anticipation, obviousness focuses on an entire claim and not each claim element. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987).

The question of obviousness is viewed from the standpoint of a hypothetical "person having ordinary skill in the art" "at the time the invention was made." 35 U.S.C. § 103(a). Here, Defendant maintains that a person having ordinary skill in the art is someone who has knowledge of brachytherapy needles and loading, and Plaintiffs do not contend otherwise. Thus, the Court must step back in time to the moment just prior to the invention of the '760 Patent and consider the scope and content of the prior art from the viewpoint of this hypothetical person who has knowledge of brachytherapy needles and loading, but who does not know about the '760 invention. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Whether an invention would have been obvious at the time it was made is a question of law. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1366 (Fed. Cir. 2011). "[A] district court can properly grant summary judgment when the factual inquiries into obviousness present

no genuine issue of material fact." *Id.* (internal citations and quotation marks omitted). Those underlying factual inquiries include: "(1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the prior art and the claimed invention as perceived before the time of invention; and (4) the extent of any objective indicia of non-obviousness." *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1338 (Fed. Cir. 2010). "If a person of ordinary skill, before the time of invention and without knowledge of that invention, would have found the invention merely an easily predictable and achievable variation or combination of the prior art, then the invention likely would have been obvious." *Id.* The Federal Circuit has cautioned that "[c]lose adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one 'to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.'" *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) (involving a large orange plastic trash bag covered with black lines and facial features such that, when filled with trash or leaves, it resembles a jack-o-latern) (*quoting W.L. Gore & Assocs., Inv. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)).

In *Graham v. John Deere Co.,* 383 U.S. 1 (1966), the Supreme Court set forth the underlying factual inquiries that must be addressed. "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, *etc*., might

be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy." *Graham*, 383 U.S. at 17-18; *see also Ball Aerosol & Speciality Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 991 (Fed. Cir. 2009).

In *KSR International Co.,* 550 U.S. at 407, the Supreme Court reaffirmed its adherence to the *Graham* factors, but provided additional guidance to courts in ruling on the § 103 obviousness claims. The Court rejected the Federal Circuit's rigid application of what is commonly referred to as the "teaching, suggestion, or motivation" test, or "TSM test," under which a patent claim is only proved obvious if "some motivation or suggestion to combine the prior art teaching can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art." *Id.* (internal citations and quotation marks omitted).[16] Instead, the Court advocated a flexible, common sense approach. *Id.* at 421. The Court stated that a court's analysis should be specific. "There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). The Court stated that

> [o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents, the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

Id. at 418. In making this determination, "neither the particular motivation nor the avowed

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[16] Put another way, the "TSM" test asks whether a person having ordinary skill in the art would have found some teaching, suggestion, or motivation to combine or modify the prior art. *See Comaper Corp. v. Antec, Inc.*, 596 F.3d 1343, 1352 (Fed. Cir. 2010).

purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *Id.* at 419. Thus, a court should not look only to the problem the patentee was trying to solve. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Nor, should a court assume that a person of ordinary skill in the art would only look to those elements of prior art designed to solve the same problem. "[F]amiliar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* Nor should a court conclude that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.* at 421. "[T]he fact that a combination was obvious to try might show that it was obvious under § 103." *Id.*; *see also Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). Lastly, the Court cautioned against a court falling prey to hindsight bias and *ex post* reasoning. *KSR Int'l Co.*, 550 U.S. at 421.

As for the secondary considerations of non-obviousness discussed in *Graham*, the Federal Circuit has held that, although they are not always dispositive, if they exist, it is error not to consider them. *In re Huai-Hung Kao*, 639 F.3d at 1065. However, in order for these factors to be accorded substantial weight, there must be a nexus between the evidence and the merits of the claimed invention. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 1531 (2011). Additionally, where the secondary consideration results from something other than what is claimed and novel in the claim - for example, if the commercial success of the invention is due to an element in the prior art - there is no nexus between that

secondary consideration and the claimed invention. *See, e.g., Tokai Corp.,* 632 F.3d at 1369; *Ormco Corp. v. Align Tech., Inc.,* 463 F.3d 1299, 1312 (Fed. Cir. 2006).

As with the question of whether the patent claims were invalid based upon anticipation under § 102, the question of whether a patent is invalid based upon obviousness under § 103 begins with the same presumption of statutory validity. That is, a patent is, by statute, presumed valid upon issuance, 35 U.S.C. § 282, and included within that presumption of validity is a presumption of non-obviousness. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 714 (Fed. Cir. 1984). Thus, the party challenging a patent bears the burden of proving the factual elements of invalidity by clear and convincing evidence. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986).

The determination of obviousness must be based on the totality of the evidence. *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000). "In particular, each prior art reference must be evaluated as an entirety, and all of the prior art must be evaluated as a whole. The test for obviousness is what the combined teachings of the reference would have suggested to one of ordinary skill in the art." *Id.; see also Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1567, 1574 (Fed. Cir. 1983). Although the standard of proof does not depart from that of clear and convincing evidence, the Federal Circuit has held that a party challenging validity shoulders an enhanced burden if the invalidity argument relies on the same prior art considered during examination by the U.S. Patent and Trademark Office ("PTO"). *Tokai*, 632 F.3d at 1367. "When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job."

PowerOasis, Inc. v. T–Mobile USA, Inc., 522 F.3d 1299, 1304 (Fed. Cir. 2008) (internal citations and quotation marks omitted). With respect to invalidity arguments based on evidence that the PTO did not consider, however, an added burden of deference to the PTO is not required. *Tokai*, 632 F.3d at 1367.

Applying these principles, the Court turns to the merits of Defendant's counterclaim of patent invalidity under § 103(a) based upon the obviousness of the claims of the '760 Patent.

1. Ths Scope of the Prior Art

As Defendant points out, neither the process of implanting radioactive elements into the body for the purpose of radiation therapy nor utilizing a preloaded needle assembly to do so were developments brought about by the '760 Patent. The Background section of the '760 Patent establishes that needle assemblies of the prior art disclosed a needle assembly with a cannula ('760 Patent, col. 1, l. 36), a sharpened distal tip (*id.* at l. 37), a stylet (*id.*), a line of seeds and spacers (*id.* at ll. 53-54, 62-67), and a bone wax plug that extends 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 ll. 43-51). The Background section also describes the operation of the brachytherapy needles, as established in the prior art (*id.* at ll. 55-60). 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, which deposits the radioactive seeds and spacers into the body (*id.*). Indeed, Mr. Lamoureux testified that the prior art worked essentially the same way as the '760 invention (Lamoureux Dep. 429-30, Aug. 12, 2008). The Background section further describes the two principal types of radioactive seeds, free seeds that are loaded into the cannula with spacers and pre-manufactured strands of seeds that are encapsulated in a

biodegradable material (*id.* at ll. 61-67). As to these elements of the invention, there can be no doubt that they were established in the prior art.

Defendant cites to Andrews ('315 Patent) and its discussion of the background of the invention as confirming the existence of each of these elements in the prior art and the general operation of brachytherapy needles. Defendant also points to the variety of plugging materials disclosed by prior art, including, *inter alia,* biocompatible and bioabsorbable wax in U.S. Patent No. 6,454,696 issued to Kindlein on September 24, 2002; and a silicone stopper, adhesive stopper, and a viscous material containing a medicinal active ingredient in the '319 Patent to Hirsch. Defendant asserts that, by the time of the '760 Patent, those skilled in the art had also determined that there was a need to keep the stylet in the needle cannula to prevent the untimely ejection of radioactive elements. For example, Mistry used a spacer key to hold the loaded needles in place and to prevent the plungers from pushing the seeds through the bone wax plug ('345 Patent, col. 2, ll. 48-51). Andrews taught a "localized friction portion," such as a deformation in the wall of the needle cannula, to provide a controlled and predetermined amount of friction between the needle and stylet to prevent the stylet from slipping out ('315 Patent, col. 6, ll. 35-43).

Defendant further cites to the Bard FastFill Needle as evidence that pre-plugged needles were already known in the art prior to the '760 invention. Finally, Defendant asserts that the concept of providing pre-loaded, sterilized implant needles was known in the prior art as evidenced by Mistry, which disclosed a shielded seed loader device that was used to transport radioactive seeds from a loading area to the implant area or even farther ('345 Patent, col. 2, ll. 16-20); and by Taylor, which disclosed a system of providing brachytherapy needles, loaded in

advance in accordance with a treatment plan (U.S. Patent 6,530,875 Patent to Taylor, Abstract).

In terms of secondary considerations, Defendant maintains that Plaintiffs have not produced evidence of any relevant secondary considerations. There is no evidence in the record of a long-felt, unresolved need, and Plaintiffs have affirmatively disclaimed relying on commercial success. Thus, citing *KSR*, 550 U.S. at 427, Defendant contends that summary judgment is appropriate because the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors.

However, as Plaintiffs correctly point out, the obviousness inquiry does not focus on each element of a claim, but on the claim in its entirety, and requires a showing that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of a prior art reference or combine the teachings of more than one reference to accomplish the claimed invention. *See SIBIA Neurosciences, Inc.*, 225 F.3d at 1356. Plaintiffs further respond that Defendant, who at all times bears the burden of proving obviousness, has not carried its burden of proving by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the '760 invention. Citing *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1336 (Fed. Cir. 2006), Plaintiffs fault the approach taken by Defendant of merely identifying each claimed element in the prior art in an attempt to establish unpatentability of the combined subject matter as a whole. Plaintiffs emphasize that the claimed invention itself cannot be used as a blueprint for concluding what one of ordinary skill in the art would have known or believed. Additionally, they argue that Defendant failed to identify any specific combinations as support for its obviousness argument.

Lastly, they cite to secondary considerations of non-obviousness that Defendant totally ignored, including consumers' need for a pre-plugged, pre-loaded brachytherapy needle to reduce preparation time and exposure to radiation seeds. Plaintiffs also point to evidence of praise of their invention and others copying their invention, specifically Defendant. At a minimum, Plaintiffs assert that genuine issues of material fact exist, which preclude the grant of summary judgment in Defendant's favor.

2. The Differences Between the Prior Art and Claimed Invention

a. Claims 1 and 9

As to Claims 1 and 9 of the '760 Patent, Defendant argues that the problem facing the Patentees was the need to provide a positioning means for the elements loaded in the needle assembly. Defendant maintains that the alleged invention of the pre-plugged, pre-loaded needle centered "was nothing more than a combination of existing prior art elements to produce a predictable, common sense result" (Def.'s Mem. in Supp. of Mot. for Summ. J. at 44).

Claims 1 and 9 recite a needle assembly, for implanting therapeutic elements, a cannula having a wall and a sharpened distal end, a line of elements extending rearward from the distal end of the cannula, yieldable means, including a plug, a stylet reciprocable in the cannula and having a distal end engaging an end of the line of elements. All of these claim elements were disclosed in prior art. *See, e.g.,* Background of the '760 Patent, col. 1 & 2; '315 Patent to Andrews, Figure 1;[17] the C.R. Bard FastFill Needle.[18] But, under § 103, the claim must be considered in its entirety. Claim 1 also teaches a "yieldable means" that locates the first element

[17] *See* Discussion at 27-28, *supra*.

[18] *See* Discussion at 34-38, *supra*.

a known and repeatable distance from the tip of the cannula, which is distinct from any one prior art invention. As opposed to the "yieldable means" of Claim 1, Claim 9 recites a "generally cylindrical end plug frictionally held in the distal end having a rearward end extending from the distal end a pre-determined distance." Thus, the issue is whether prior to the '760 invention, based on the combined teachings of the prior art, evaluated as a whole, it would have been obvious to one of ordinary skill in the art to create and use an end plug for positioning the first element a predetermined and repeatable distance from the distal end. As discussed at length above, the Court found that these limitations of Claims 1 and 9 were not anticipated by any one of the prior art references cited by Defendant. But that holding does not resolve the issue of obviousness.

The need for a yieldable means was certainly inherent in the prior art, since the very purpose of any brachytherapy needle was to deposit radioactive seeds in the patient, and to do this plugging material had to yield to allow the seeds to be discharged from the needle assembly.

The need for careful positioning of the first radioactive seed in a brachytherapy needle was also appreciated in the prior art. The Bard FastFill Needle, for example, was preplugged and had centimeter markings on the needle cannula and half-centimeter markings on the stylet.[19] Bard's representative, Mr. Krachon, testified that the amount of bone wax in the needle was the same and was repeatable, subject to manufacturing tolerances (Krachon Dep. 54-55). U.S. Patent No. 6,450,938 to Miller disclosed a distal retention tab used to support and retain the seeds that allowed the first seed to always be in a known location within the passageway of the cannula, unlike prior art devices that employed bone wax with the inexactness that accompanied its use

[19] *See* Discussion at 34-38, *supra*.

('938 Patent, col. 6, ll. 45-59).[20] The '938 Patent provided, "[o]f course, the depth of the wax plug determines the location of the first seed. The present invention solves this problem [of the uncertainty as to the depth of the bone wax and thus the location of the first seed] because the location of the first seed is always known and can be easily determined by examining the outer surface of the cannula to determine the location of the retention tab" (*id.* at ll. 62-67). One feature of the '938 Patent revealed in trials of the invention was the "precise and reproducible placement of the first seed within the cannula wall" (*id.* at col. 7, ll. 66-67). Although the '938 Patent did not use a plug, it used a flexible tab. The AAPM Article also directed that the length of the plug should be accounted for (AAPM Article at 2061-62). Taylor observed that "[c]are should be taken to ensure consistent needle to needle plug size, so that the seeds may be precisely placed at the treatment site" ('875 Patent, col. 11, ll. 26-28). Even Plaintiffs' expert witness, Peter Sanchez, testified that he was "quite consistent in plugging the tip of the needle" with bone wax, although he noted that, depending on the individual involved, there could be variations in waxing the needles (Sanchez Dep. 25, 152-53).

The Court concludes that it would have been obvious to a person of ordinary skill in the art to combine the teachings of the prior art to use an end plug for positioning the first element a predetermined and repeatable distance from the distal end in a pre-plugged, pre-loaded needle. This was a predictable, common sense result. Therefore, the Court finds that Claims 1 and 9 are invalid for obviousness under § 103.

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[20] Like the '760 Patent, the '938 Patent described as one of the problems associated with the use of bone wax the uncertainty over how deep the wax plug extended into the aperture of the cannula, since the amount of wax that was caught within the aperture was variable ('938 Patent, col 6, ll. 59-64).

b. Claim 2

Claim 2 of the '760 Patent adds the use of an absorbable plug. The prior art disclosed absorbable materials that were used to plug brachytherapy needles. *See* U.S. Patent No. 6,454,696 to Kindlein, col. 4, ll. 11-13. Since the plug was to be deposited into the body, along with the needle contents, it would have been obvious to one skilled in the art to use an absorbable material that could be assimilated into the body for the plug. For the same reasons discussed as to Claims 1 and 9, the Court finds that Claim 2 is invalid as obvious.

c. Claim 16

Claim 16, which is dependent on Claim 9, added an end plug sealing the distal end of the needle assemble and a preloaded, sterile needle assembly. Elliott ('192 Patent, Abstract) and Mistry ('345 Patent, Abstract) both disclosed the use of preloaded brachytherapy needles. Mr. Lamoureux testified that in July of 2000, he conceived of pre-loading of needles. "It was an obvious benefit of the product" (Lamoureux Dep. 118, Aug. 14, 2008). He discussed this with Mr. Terwilliger at that time (*id.*). He explained that by "obvious," he meant that "based on our knowledge of what would constitute a good commercial product for the company, there was a natural extension of the innovation of having a needle plugged to pre-load it and put it in a thermal formed tray and sterilize it and deliver it to the hospital ready to be used, as is done with our bone marrow trays" (*id.* at 119). Given Mr. Lamoureux's testimony that preloading the brachytherapy needles was a "natural extension" of the preplugged needles, and that the prior art already taught how the needles could be pre-loaded, the Court concludes that the invention of Claim 16 of the '760 Patent was an obvious, common sense extension of the prior art.

d. Claim 17

Claim 17 is a method claim and, as discussed above, describes a method of making a needle assembly for implanting radioactive seeds, comprising the steps of (a) providing a cannula having a sharpened distal end and a generally cylindrical end plug; and (b) forcing the plug into the sharpened distal end of the cannula to distally reside there ('760 Patent, col. 6, ll 43-49). As Defendant argues, given the need for a yieldable plug in the distal end of the cannula, it would have been obvious to one skilled in the art that one could attain this by forcing a cylindrical plug into the tip of the cannula. In fact, such an assembly was disclosed in Elliott, Hirsch, and the Bard FastFill Needle, as well as Plaintiffs' own instructions for use. The Court agrees.

e. Claims 3 & 10

Claims 3 and 10 teach the use of free seeds or pre-manufactured strands of seeds encapsulated in a biodegradable material that spaces the seeds apart from each other. The '592 Patent issued to Langston, however, taught the use of a pre-manufactured strand. Plaintiffs responded by stressing that the needle assemblies of Claims 1 and 9 made Claims 3 and 10 possible (Pl.'s Mem. at 47). However, since the Court has determined that the needle assemblies would have been obvious to one skilled in the art, Claims 3 and 10, which depend on Claims 1 and 9, would also be unpatentable for reasons of obviousness.

3. Secondary Considerations

Plaintiffs urge the Court, as part of the *Graham* analysis, to consider the secondary indicia of non-obviousness, including copying of the invention by others, praise of their invention, and long-felt need in the industry (Pls.' Mem. at 49). As Plaintiffs suggest, in any discussion of obviousness, the Court must consider evidence of secondary indicators if they are present. *See Hybritech Inc.*. 802 F.2d at 1380; *Stratoflex Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed.

Cir. 1983).[21]

To demonstrate a long-felt need for their invention, Plaintiffs cite to the statement by a doctor at the AAPM Show in July 2000 to Mr. Terwilliger to the effect that, if they really wanted to make a difference or come up with something unique and novel, they should figure out a way to make a needle that was already plugged (Terwilliger Dep. 29-30 Jan. 18, 2008). According to Terwilliger, this was the beginning of the conception for their invention (*id.*). Yet, the need for a pre-plugged needle assembly was not an "unmet" need. *See Tex. Instruments v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993). Prior art, such as the Bard FastFill Needle, had already included a pre-plugged needle. Moreover, Mr. Terwilliger himself admitted that he was "aware that there were pre-plugged needles out in the market, pre-plugged with bone wax" prior to June 2000 (Terwilliger Dep. 69 Mar. 13, 2006).

Plaintiffs also cite to the praise that their pre-plugged, pre-loaded needle received in the industry, including the comment by Robert McKenzie, Senior Vice President for Research and Development at AnazaoHealth, that appeared on an advertising brochure:

> With Readi-Load™ you pick the source brand you want to use, and provide the pre-plan, then you just show up to do the case and you have pre-loaded Seed-Lock™ needles waiting for you with independent assay and load verification. What a time saver.

(Pls.' A-5, Ex. U). The Court is not convinced that testimonials on promotional brochures constitute the type of industry praise contemplated by *Graham*, and Plaintiffs have cited no case so holding.

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[21] While commercial success of the invention is also a secondary consideration that is frequently given substantial weight where there is a nexus between the success and the merits of the invention, *see Cable Elec. Prods. v. Genmark, Inc.*, 770 F.2d 1015, 10026 (Fed. Cir. 1985), Plaintiffs in this case do not rely on this secondary consideration.

Plaintiffs also cite to evidence of copying of the invention by AnazaoHealth, which lies at the heart of their patent infringement claims. As Defendant points out, "not every competing product that falls within the scope of a patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent." Robert L. Harmon, *Patents and the Federal Circuit* § 4.6(c) at 210 (8th ed. 2007). Rather, copying involves an exact replication of the specific patented product. *Id.* AnazaoHealth's alleged infringing needle assembly used a compounded bone wax as plugging material. There is no evidence in the record that this material was ever used by Plaintiffs or that this material was capable of exactly positioning the first seed in the cannula, one of the key features of the '760 Patent. As the Federal Circuit held in *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 317 (Fed. Cir. 1985), copying by the accused infringer should be given little weight where the accused infringer's development efforts were not extensive, its product was not identical to the claimed invention, and it vigorously denied infringement.

The Court finds that the secondary considerations advanced by Plaintiffs do not outweigh the Court's determination that, based upon the teachings of the prior art when considered in its totality, Claims 1-3, 9-10, and 16-17 of the '760 Patent would have been obvious to one of ordinary skill in the art and, therefore, invalid under § 103. Accordingly, the Court grants summary judgment to Defendant on Count One of its Counterclaim for a declaration of invalidity and non-infringement of Claims 1-3, 9-10, and 16-17 of the '760 Patent, and denies Plaintiffs' motion for summary judgment as to Defendant's alleged infringement of these claims. Having found these claims invalid under § 103, the Court need not consider AnazaoHealth's additional arguments that the claims of the '760 Patent are invalid for want of enablement and due to the

Patentees' failure to disclose the best mode of their invention under § 112 ¶ 1 and based upon the Patentees' alleged inequitable conduct.

II. Plaintiffs' Complaint of Infringement of Claims 18 and 21 of the '760 Patent

In their complaint, the World Wide Plaintiffs also alleged infringement by Defendant of Claims 18 and 21 of the '760 Patent. Plaintiffs have not moved for summary judgment as to these two claims. They concede that factual issues exist that should be decided by a jury. Defendant, however, contends that there are no genuine issues of material fact and has moved for summary judgment on Plaintiffs' complaint against it for infringement of these two claims.

Claims 18 and 21 are method claims. To show infringement, Plaintiff must establish that "each step of the claimed method is performed." *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 (Fed. Cir. 2008). This Court has previously construed "modifying the diameter of the plug" limitation of independent Claim 18 as meaning "changing the diameter of the plug by means such as by heat, by treating the plug with a solvent, or by mechanical distortion." *Claim Construction Ruling* at 85-86. 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." *Id.* at 87. This Court construed "mechanical distortion" to mean that such distortion occurred by "physical processes directed at the cannula and/or the plug." *Amended Claim Construction Ruling* at 6. Defendant maintains that there is no evidence of record to support Plaintiffs' claim that Defendant modifies the diameter of its accused device to enhance the plug's frictional engagement with the wall of the cannula.

Plaintiffs, however, cite to the two sets of instructions created by Defendant, one for use

with needles supplied by C.R. Bard, an AnazaoHealth customer, and the other for use with all other needle assemblies. These instructions for plugging the needle provide that the needle, with the stylet in place, should penetrate the primary waxing block to a depth of no more than 1.0 cm., which will cause the stylet to rise out of the needle. If the stylet rises higher than the prescribed level, the stylet should be slowly depressed "to remove a small amount of wax to bring the stylet to the correct level" (Pls.' A-5, Ex. J, GEN 8262). Plaintiffs maintain that pressing the stylet against the plugging material may modify the diameter of the plug by a physical process, *i.e.*, mechanical distortion, and therefore, Defendant's method infringes on Claims 18 and 21.

Defendant responds that this step in the waxing process takes place only if and when the technician determines that there is too much bone wax in the cannula, in which event he or she should remove some by depressing the stylet. Once the needle is properly waxed, the bone wax residue is wiped off of the exterior using an alcohol wipe (*Id.* at GEN 8263). Defendant argues that there is no evidence that this step is directed to any change in the diameter of the plugging material or that the diameter of the plugging material actually changes in any measure or that this step would enhance the engagement of the plugging material to the cannula wall.

The Court agrees with Defendant. Plaintiffs bear the burden of proving infringement, either literally or under the doctrine of equivalents, by a preponderance of the evidence. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1242, 1247 (Fed. Cir.), *cert. denied*, 531 U.S. 993 (2000). Infringement is found only where all of the claimed elements and limitations are present in the accused device. *Jurgens v. McKasy*, 927 F.2d 1552, 1560 (Fed. Cir.), *cert. denied*, 502 U.S. 902 (1991). Plaintiffs' speculation that this remedial step in Defendant's waxing procedures "likely modifies" (Pls. Mem. in Opp'n to Summ. J. Mot. at 87) the diameter of the plug by a

physical process does not constitute sufficient evidence to create a genuine issue of material fact to defeat Defendant's motion for summary judgment. As the Supreme Court held in *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986), "[w]hen the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts. . . . [T]he nonmoving party must come forward with 'specific facts showing that there is a *genuine issue for trial.* '" (Internal citations omitted; original emphasis). This Plaintiffs have not done. Indeed, even their expert, Mr. Sanchez, testified that he did not know "how, if at all, AnazaoHealth modifies the diameter of the plug to enhance its frictional engagement with the wall of the cannula within the meaning of [claim element] 18-C" (Sanchez Dep. 191).

Accordingly, finding no genuine issue of material fact as to Defendants' infringement of Claims 18 and 21, the Court grants summary judgment in Defendant's favor on Plaintiffs' complaint of infringement as to these claims.

III. Count II of Plaintiffs' Complaint - Reasonable Royalty Under Provisional Rights

Count II of Plaintiffs' complaint is a claim against Defendant for a royalty for the period April 25, 2002, the date of the Published Application for the '760 Patent, and April 29, 2003, the date the '760 Patent issued. However, since the Court has found that the claims allegedly infringed were either invalid or not infringed as a matter of law, Plaintiffs are not entitled to a royalty for alleged infringing activities of Defendant during this period in question. Therefore, Defendant is entitled to summary judgment on this Count.

IV. Count III of Plaintiffs' Complaint - False Designation of Origin/False Advertising

Count III of Plaintiffs' complaint alleges a violation of the Lanham Act, 15 U.S.C. §

1125(a), by virtue of Defendant's utilization on its website of images of Plaintiffs' Seed-Lock™ and Readi-Load™ needle assemblies to advertise its own products.

Section § 43(a) of the Lanham Act provides:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which--
>
> (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1). "The statutory protection of unregistered trademarks extends to trade dress." *Fun–Damental Too, Ltd. v. Gemmy Indus. Corp.*, 111 F.3d 993, 999 (2d Cir. 1997). "The concept of trade dress encompasses the design and appearance of the product together with all the elements making up the overall image that serves to identify the product presented to the consumer." *Fun–Damental Too*, 111 F.3d at 999 (citing *Jeffrey Milstein, Inc. v. Greger, Lawlor, Roth, Inc.*, 58 F.3d 27, 31 (2d Cir. 1995)). "Trade dress 'originally included only the packaging, or "dressing," of a product,' but it has been expanded to encompass what is at issue in this case: the design or configuration of the product itself." *Wal–Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205, 209 (2000).

To recover for trade dress infringement under § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), a plaintiff must prove two elements: (1) that its trade dress is protectable because (a) it is inherently distinctive or (b) it has acquired distinctiveness by achieving a "secondary meaning"

in the marketplace; and (2) that there is a likelihood of confusion between its product and the defendant's product. *Fun-Damental Too*, 111 F.3d at 999. A plaintiff seeking to protect a product design as trade dress must establish that the claimed trade dress has acquired a secondary meaning and that it is not functional - *i.e.,* essential to the basic purpose the product is meant to serve - or generic. *Yurman Designs, Inc. v. PAJ, Inc.*, 262 F.3d 101, 115-16 (2d Cir. 2001). The Second Circuit has held that the party attempting to show that a product has acquired secondary meaning has a heavy burden, proof of which entails vigorous evidentiary requirements. *Coach Leatherware Co. v. AnnTaylor, Inc.*, 933 F.2d 162, 168 (2d Cir. 1991). When determining whether a trade dress has attained secondary meaning, courts have assessed "advertising expenditures, consumer studies, unsolicited media coverage of the product, sales success, attempts to plagiarize the [dress], and length and exclusivity of use." *Id.* at 169. "The careful weighing of evidence necessary to determining secondary meaning renders it an unlikely candidate for summary judgment." *Id.*

According to Plaintiffs, their needle assemblies and their trade dress are inherently distinctive and have acquired a secondary meaning in the eyes and minds of consumers as being uniquely identified with products of Plaintiffs. The hub of the needle assembly was distinctive in design. It had a double helix thread around the top, the round body of the hub tapered toward the distal end, and it had multiple ribs which could be sensed by the user when holding the needle. By virtue of Defendant's using pictures of its products to promote its own products and services, Plaintiffs maintain that Defendant has misrepresented the source of its products and services and has caused or is likely to cause confusion, in violation of the Lanham Act. As a result, Plaintiffs' reputation and goodwill has been damaged.

Defendant does not deny that it used pictures of Plaintiffs' products, but claims that at that time, Plaintiffs were in fact providing Defendant with those needles to fill the brachytherapy prescriptions. Alternatively, it argues that Plaintiffs cannot carry their heavy burden of proving that the trade dress of their product had acquired a secondary meaning. *See Atlantis Silverworks, Inc. v. 7th Sense, Inc.*, No. 96 civ. 4058(MBM), 1997 WL 128403, at *4 (S.D.N.Y. Mar. 20, 1997) (holding that to establish secondary meaning, a party must establish that the purchasing public associates goods designated by a particular trade dress with but a single source). The only alleged "trade dress" is the shape and look of the hub of the Seed-Lock™ needle but, according to Defendant, Plaintiffs have not produced any evidence establishing that the shape and look of the hub have acquired a secondary meaning. Defendant further argues that trade dress law does not protect a generalized type of appearance, such as the shape of a product. *Id.* at *5.

Plaintiffs respond that, at the time Defendant published these pictures, World Wide Medical Technologies had just terminated its relationship with Defendant. Defendant did not have authority to use these images of Plaintiffs' products to advertise its own products, which the text of the advertisement makes clear was exactly what it was doing. Under the pictures of Plaintiffs' products was the following: "Custom Care Pharmacy is excited to offer our Prescription Loading Needle service" (Pls.' A-5, Ex. I). Plaintiffs maintain that Defendant's use of pictures of their needles in an advertisement for Defendant's services clearly caused confusion between Plaintiffs' Seed-Lock™ and Readi-Load™ needle assemblies and Defendant's newly launched pre-plugged needle line, and allowed Defendant to benefit from Plaintiffs' established market reputation.

Plaintiffs have presented evidence that the business arrangement between Defendant and

World Wide Medical Technologies and its affiliate, Advanced Care Medical, LLC, to co-market the Seed-Lock™/Readi-Load™ pre-plugged needle assemblies had ended in September 2002 (Pls.' A-5, Ex. I). After the termination of their relationship, Defendant continued to use pictures of Plaintiffs' Seed-Lock™/Readi-Load™ pre-plugged needle assemblies to advertise its own pre-plugged services (A-5, Ex. I; Terwilliger Aff. ¶¶ 57, 60 June 2, 2010). Plaintiffs have also produced the testimony of Gary Lamoureux and Richard Terwilliger as to the distinctive appearance of Plaintiffs' brachytherapy needles (Lamoureux Dep. 897 Oct. 1, 2008, Terwilliger Aff. ¶ 60 June 2, 2010). Additionally, they have submitted the affidavit of Matthew Bouffard, Product Technology and Clinical Affairs Manager of BrachySciences, a division of Biocompatibles, Inc., the current licensor of the rights to the '760 Patent, confirming the distinctive trade dress of Plaintiffs' needles that customers associated with World Wide Medical Technologies, a source known for producing high quality products. Thus, they argue, Defendant's continued use of photographs of their needles in advertising Defendant's services created a distinct risk of customer confusion, specifically, confusion between Defendant's newly launched pre-plugged needle line and Plaintiffs' Seed-Lock™/Readi-Load™ pre-plugged needle assemblies.

They have also produced a document from Defendant, entitled "Nuclear/Brachytherapy Situation Analysis," acknowledging in October 2003 the success of World Wide Medical Technologies and Advanced Care Pharmacy "with their strand technology and their lock on the World Wide needle" (Pls.' A-5, Ex. J, GEN 7737). The memorandum further acknowledges as a "weakness" in the appearance of Defendant's product that it "is not as professional as it could be and as the competitions [sic] is (in some ways)" (*id.*). Plaintiffs assert that there is at least a

question of fact raised by the documents produced by Defendant on the issues of the value, secondary meaning, and motivation to create confusion between its products and those of Plaintiffs.

"It is well established that using a photograph of another's product to sell one's own cheaper product is unfair competition under Section 43(a)" of the Lanham Act. *Sublime Prods., Inc. v. Gerber Prods., Inc.*, 579 F. Supp. 248, 250 (S.D.N.Y. 1984) (citations omitted) (using "cheaper" to refer to dissimilar or inferior). Plaintiffs have produced sufficient evidence to create a genuine issue of material fact on the distinctiveness of their needle assemblies to survive summary judgment on the issue of protectable trade dress. *See R.F.M.A.S., Inc. v. Mimi So*, 619 F. Supp. 2d 39, 79 (S.D.N.Y. 2009). They have also produced evidence of secondary meaning, which fact-intensive determination the Second Circuit has cautioned should be avoided at the summary judgment phase. *Coach Leatherware*, 933 F.2d at 169; *see also Gross v. Bare Escentuals, Beauty, Inc.*, No. 08 Civ. 3089, 2008 WL 2332307, at *5 (S.D.N.Y. June 4, 2008). And, they have produced enough evidence of the likelihood of confusion to survive summary judgment on that step of the infringement analysis. *See R.F.M.A.S.*, 619 F. Supp. 2d at 82 ("While '[q]uestions regarding the likelihood of confusion are normally factual in nature, . . . summary judgment is appropriate if the court is satisfied that the products . . . are so dissimilar that no question of fact is presented.'")(quoting *Universal City Studios, Inc. v. Nintendo Co., Ltd.*, 746 F.2d 112, 116 (2d Cir. 1984)). Having reviewed the evidence presented by both sides, the Court concludes that there are genuine issues of material fact as to the likelihood of confusion, and summary judgment is thus inappropriate. Accordingly, the Court denies Defendant's motion for summary judgment as to Count III of Plaintiffs' complaint for violation

of the Lanham Act.

V. Count IV of Plaintiffs' Complaint - Breach of Contract

The fourth count of Plaintiffs' complaint is for breach of contract by virtue of Defendant's failure to exclusively employ Plaintiffs' Seed-Lock™ and Readi-Load™ pre-plugged needles in producing and delivering kits and assemblies to customers. Instead, Plaintiffs maintain that Defendant used pre-plugged needles of its own manufacture or from others, and failed to pay Plaintiffs the 10% marketing fee to which Plaintiffs were entitled. In support of this claim, Plaintiffs rely on the verbal understandings between the parties, actual performance, and three written agreements between the parties: (a) a Non-Disclosure Agreement dated August 30, 2001; (b) a Letter of Intent dated September 6 and 7, 2001; and (3) an Initial Agreement dated September 25, 2001, all signed by Richard Terwilliger on behalf of World Wide Medical Technologies, and Robert MacKenzie on behalf of Custom Care (AnazaoHealth). However, as Defendant correctly notes, none of these agreements required Defendant to exclusively employ the Seed-Lock™/Readi-Load™ products. In fact, the Initial Agreement expressly contemplated just the opposite. It states, "Unless customers specifically request othwise, CCP™ [AnazaoHealth] will use WWMT's™ Readi-Load™ Pre-plugged needle and spacers for the supply of pre-loaded Brachytherapy sources within needles" (A-5, Ex. I, WWMT/AC 000014 ¶ 2) (emphasis added). While the parties also entered into confidentiality agreements, there was nothing in these agreements that required Defendant to exclusively use Plaintiffs' products. Nor is there any evidence to support Plaintiffs' claim that they were entitled to a 10% marketing fee on brachytherapy kits sold by Defendant using needle assemblies manufactured by companies other than Plaintiffs. Although Mr. Lamoureux testified that it was his understanding that

Defendant would not attempt to sell brachytherapy kits other than ones that Plaintiffs did with them (Lamoureux Dep. 770-71 Aug. 15, 2008), his unilateral understanding does not establish a meeting of the minds, as required under Connecticut law for the formation of a contract. *See Thames River Recycling, Inc. v. Gallo*, 50 Conn. App. 767, 798 (1998). Accordingly, the Court finds that Defendant is entitled to summary judgment as a matter of law on the fourth count of Plaintiffs' complaint.

VI. Counts V & VI of Plaintiffs' Complaint - Unfair Competition and Unfair Trade Practices

In Counts V and VI, Plaintiffs alleged that Defendant's acts of false designation of origin, false advertising, and other acts described in the complaint constitute unfair competition under state common-law and unfair trade practices, in violation of Connecticut's Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110b. Defendant argues that because there is no genuine issue for trial with respect to any of the predicate claims, there can be no issue for trial as to these claims. That argument, however, was premised on Defendant's assumption that the Court would grant summary judgment in favor of Defendant on all of the preceding counts. That it has not done. For the same reasons that the Court finds genuine issues of material fact as to Plaintiffs' third count for violations of the Lanham Act, it also finds genuine issues of material fact as to Plaintiffs' claims of unfair trade practices and CUTPA violations. Accordingly, Defendant's motion for summary judgment is denied as to Counts V and VI.

Conclusion

For the reasons set forth above, the Court grants Defendant's Motion for Summary Judgment [Doc. # 434] as to Counts I, II, and IV of Plaintiffs' Amended Complaint and Count I of Defendant's Counterclaim. The Court denies Defendant's Motion as to Counts III, V, and VI.

The Court also denies Plaintiffs' Motion for Summary Judgment [Doc. # 447].[22]

SO ORDERED, this 24th day of September, 2012, at Bridgeport, Connecticut.

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

[22] Doc. # 440, the redacted, unsealed version of Plaintiffs' Motion for Summary Judgment should also be terminated.