United States District Court,
S.D. Indiana, Indianapolis Division.

SYRINGE DEVELOPMENT PARTNERS LLC, MEDSAFE TECHNOLOGIES LLC,
Plaintiffs.
v.
NEW MEDICAL TECHNOLOGY INC, NMT Group PLC,
Defendants.

No. IP98-1726-C-M/S

Feb. 9, 2001.

ORDER ON SUMMARY JUDGMENT MOTIONS

McKINNEY**.**

In this case, the Plaintiffs, Syringe Development Partners L.L.C. ("Syringe Development"), and MedSafe Technologies L.L.C. ("MedSafe") (collectively "SDP"), allege that the Defendants, New Medical Technology, Inc. ("New Medical Tech.") and NMT Group, PLC (collectively "NMT"), have infringed Syringe Development's U.S. Patent No. 5,613,952 (the " '952 patent"). SDP has moved for summary judgment on infringement alleging that NMT's sole argument turns on the meaning of the words "tear" and "rupture" as used in the '952 patent. SDP averts that because the term "tear" should include a complete separation and NMT's syringe plunger has a rupturable web that separates competely, judgment as a matter of law on infringement would be proper. In addition, SDP argues that summary judgment would be proper on the issue of whether the '952 patent is valid because NMT has not met its burden to show invalidity by clear and evidence as a matter of law.

In contrast, NMT has moved for summary judgment on non-infringement of the ' 952 patent arguing that SDP limited the scope of the '952 patent during prosecution to syringe plungers that tear leaving a flap and NMT's syringe plunger tip breaks away completely, it does not tear. Moreover, NMT contends that summary judgment is proper because the retraction process of its syringe does not use one of the steps in the '952 patent process. Finally, NMT argues that there is an issue of material fact that the '952 patent is invalid because it was anticipated and obvious based on prior art not disclosed to or considered by the patent examiner.

The issues have been fully briefed and are ripe for ruling. FN1 For the reasons discussed below, the Court DENIES SDP's motion for summary judgment on infringement, GRANTS in part and DENIES in part SDP's motion for summary judgment on validity, and GRANTS NMT's motion for summary judgment on non-infringement, literally and under the doctrine of equivalents.

FN1. NMT has also moved to strike certain evidentiary materials of SDP. The motion is DENIED in part and GRANTED in part. With respect to the affidavit testimony of Pressly and Brockway, the motion is

DENIED. Experts may rely upon their experience in a field when they express an opinion. *See* Fed.R.Evid. 702. Moreover, the depth of Pressly's and Brockway's analysis of infringement in this case goes to weight rather than admissibility. With respect to the prosecution file, the motion is GRANTED. The Court will rely upon the complete prosecution history as submitted by NMT.

In addition, the Court has ruled on the various related motions of the parties as follows: Defendants' motion to strike evidence designated by Plaintiffs in support of Plaintiffs' motion for summary judgment is DENIED in part and GRANTED in part; Plaintiffs' motion to strike Defendants' "rebuttal expert" Klod Kokini is DENIED; Plaintiffs' motion to strike portions of Defendants' surreply to Plaintiffs' response to Defendants' statement of material facts is DENIED; and Plaintiffs' motion to strike certain portions of the expert reports submitted by Defendants is DENIED as moot.

I. *BACKGROUND*

A. SOUTHERN DISTRICT OF INDIANA LOCAL RULE 56.1

Before turning to a recitation of the facts in this case, the Court must address NMT's request that the Court either disregard or strike SDP's statement of material fact in support of its motion for summary judgment on liability. NMT states that SDP's statement is inappropriate because SDP either: (1) made more than one factual proposition within each numbered paragraph; (2) made an argument or legal conclusion in its numbered paragraphs rather than stating a fact; (3) made statements that mix facts with argument or legal conclusions; or (4) made statements unsubstantiated by specific citation to record evidence. NMT relies upon Southern District of Indiana Local Rule 56.1 ("L.R.56.1") to make its request. A brief review of L.R. 56.1 is necessary.

Pursuant to L.R. 56.1, the moving party is required to submit a Statement of Material Fact that complies with L.R. 56.1(f). L.R. 56 .1(a)(1). Similarly, the non-moving party is required to provide a Response to Statement of Material Facts that complies with the same section. *See* L.R. 56.1(b)(1). In addition, any facts that the non-moving party wishes to add to the Statement of Material Fact must be filed as a separate Statement of Additional Material Fact, that must also comply with L.R. 56.1(f). *See* L.R. 56.1(b)(1). Section (f) provides in pertinent part:

(f) *Requirements for Factual Statements and Responses Thereto*.

(1) *Format and Numbering*. The Statement of Material Facts shall consist of numbered sentences. The Response to Statement of Material Facts must be numbered to correspond with the sentence numbers of the Statement of Material Facts, preferably with each respective factual statement repeated therein. Any Statement of Additional Material Facts must consist of numbered sentences and start with the next number after the last numbered sentence in the Statement of Material Facts....

(2) *Format of Factual Assertions*. Each material fact set forth in a Statement of Material Facts, Response to Statement of Material Facts, Statement of Additional Material Facts *must consist of concise, numbered sentences with the contents of each sentence limited as far as practicable to a single factual proposition. Each stated material fact shall be substantiated by specific citation to record evidence....*

(3) *Format of Objections to Asserted Material Facts or Cited Evidence*. Objections to material facts and/or cited evidence shall (to the extent practicable) set forth the grounds for the objection in a concise, single

sentence, with citation to appropriate authorities.

L.R. 56.1(f)(1)-(3). Finally, the rule also provides that

In determining the motion for summary judgment, the Court will assume that the facts as claimed and supported by admissible evidence by the moving party are admitted to exist without controversy, except to the extent that such facts are specifically controverted or objected to in compliance with L.R. 56.1(f). The Court will also assume for purposes of deciding the motion that any facts asserted by an opposing party are true to the extent they are supported b the depositions, discovery responses, affidavits or other admissible evidence.

L.R. 56.1(g) (emphasis added). "The Court may, in the interests of justice or for good cause, excuse failure to comply strictly with the terms" of L.R. 56.1. *See* L.R. 56.1(k). *Cf.* Bradley v. Work, 154 F.3d 704, 708 (7th Cir.1998) (finding that the district court in that case "was within its discretion to insist on compliance with [L.R.] 56.1").

In this case, NMT complains that SDP failed to provide a statement of facts that was set out in numbered sentences limited as far as practical to a single factual proposition. In addition, NMT argues that SDP did not cite to relevant, admissible evidence to support its factual statements. NMT asks the Court to strike or disregard SDP's factual statements because of these deficiencies.

The Court agrees with NMT that SDP's statement of material facts is deficient because it does not limit each numbered sentence or paragraph to a single, factual proposition and because it does not cite to relevant evidence for each proposition. By failing to do this, SDP has made it difficult for the Court to assess which factual proposition are in dispute. However, the Court finds that SDP has not erred so egregiously in setting forth the facts in the case that either NMT or the Court cannot accurately determine whether the factual averments are supported by the evidence that SDP cites. The majority of numbered paragraphs that contain more than a single factual proposition contain citations directly after a fact before going on to the next one and providing another citation for that next fact. For those paragraphs, in the interests of justice, the Court will use those statements of fact as appropriate. In those paragraphs that do not contain such citation, the Court will rely upon NMT's responses or NMT's statement of facts in support of its motion for summary judgment for guidance on the correct factual proposition because SDP's averments lack evidentiary support as required by L.R. 56.1. The Court will not search for evidence to support SDP's factual propositions.

Furthermore, in this case the factual averments of each party are actually made twice: once in making its own motion for summary judgment; and once in response to a motion for summary judgment. As a result, the Court should have no difficulty in determining which facts the parties dispute and whether those facts are material to the issues in the case.

B. FACTUAL BACKGROUND

1. Syringe Development & The '952 Patent

Turning now to the facts, plaintiff Syringe Development is a limited liability company that designs and develops safety syringes. Pressly Decl. para. 6. Syringe Development owns the '952 patent. Id. Plaintiff MedSafe is the exclusive licensee of the '952 patent. Id. The patent lists William Pressly ("Pressly"), Charles Vaughn ("Vaughn"), G. Samual Brockway ("Brockway") and Thomas Ellis ("Ellis") (collectively the "inventors" or the "applicants") as the inventors of the apparatus and the process set forth in the patent. Pls.'

Exh. 1, U.S. Patent No. 5,613,952 to Pressly, Sr., et al., at 1 (" '952 Patent").

The '952 patent claims priority under 35 U.S.C. s. 120 through a series of related patent applications to application Serial No. 07/813,115 (the " '115 application"), which was filed on December 23, 1991. Id. *See also* Defs.' Exh. 2, File Wrapper, U .S.App. No. 07/813,115, Dec. 23, 1991 (" '115 App."). The '115 application contained twelve apparatus claims and one process claim. Defs.' Exh. 2, '115 App., at 20-23. It specifically refers to U.S. Patent No. 4,973,316 to Dysarz (the "Dysarz patent"), U.S. Patent No. 4,921,486 to DeChellis, *et al*. (the "DeChellis patent"), and U.S. Patent No. 2,460,039 to Scherer, *et al*. (the "Scherer patent") as relevant prior art. Id. at 6-7.

In an office action on the '115 application dated March 11, 1992, the Patent and Trademark Office (the "PTO") examiner allowed claims 1 through 12, but rejected claim 13, the process claim. Id . at 33-35. The examiner stated that the process described in claim 13 was anticipated by U.S. Patent No. 5,019,044 to Tsao ("Tsao '044"), U.S. Patent No. 5,053,010 to McGary (the "McGary patent"), and U.S. Patent No. 5,064,419 to Gaarde (the "Gaarde patent"). Id. at 33, 35. Claim 13 read:

13. A process for retracting a needle at the completion of subcontaneous [sic] injection with a hypodermic syringe, comprising the steps of:

forcing a plunger of said syringe downwardly to force a needle support deformable base downwardly and sever sacrificial supports;

forcing an end portion of said needle to penetrate a base portion of the syringe and plunger; and

propelling said needle into the hollow of said plunger.

Id. at 23.

In response to the examiner's action, the applicants amended claim 13 to read, in pertinent part:

13. (Amended) A process for retracting a needle at the completion of subcontaneous [sic] injection with a hypodermic syringe comprising the steps of:

* * *

forcing an end portion of said needle to [penetrate] *rupture* a base portion of the [syringe and] plunger; and....

Id. at 41. Thus, the only modification the applicants made was the substitution of the word "rupture" for the word "penetrate." Id. The applicants also submitted two new apparatus claims, claim 14 and 15. Claim 14 stated in pertinent part:

14. A syringe comprising:

* * *

whereby a fluid is moved from within the barrel [of the syringe] through the needle as the plunger moves

through the barrel to the deformable base, and when the rupturable boot contacts the deformable base, continued movement of the plunger moves the deformable base toward the first end, the rear end of the needle thereby rupturing the boot and loosing [sic] contact with the deformable base to allow the energy storing means to eject the needle into the interior of the plunger.

Id. at 42. The applicants explained the difference between the revised claim 13 and the new claim 14, in part, by distinguishing the Gaarde patent and the McGary patent as follows:

[I]t does not appear that any part of the integrity of the piston taught by Gaarde is broken or ruptured. As rupture requires breaking through an element, Applicant's [sic] claim 13, as presently claimed, is distinguishable over the teachings of Gaarde by Applicant's [sic] specific feature of rupturing the base portion of the plunger.

* * *

Clearly, McGary, et al. [sic] does not disclose an end portion of a needle breaking or rupturing the base portion of the syringe or plunger as Applicant's presently claimed subject matter requires.... [T]he reference of McGary, et al. [sic] utilizes a cutting tip that penetrates through a plunger sealing member and a needle retaining member in order to allow a compressed spring to force a needle into the hollow of the plunger.

Id. at 46-47.

On November 9, 1992, the patent examiner rejected claims 13 and 14 as being anticipated by U.S. Patent No. 4,838,869 to Allard (the "Allard patent") and U.S. Patent No. 5,114,410 to Batlle (the "Batlle patent"). Id. at 51-54. The examiner stated in pertinent part:

Claim 13 is rejected under 35 U.S.C. s. 102(b) as being anticipated by Allard.

Note Figure 5 which discloses a rupturable diaphragm 21.

Claim 14 is rejected under 35 U.S.C. s. 102 (a or e) as being anticipated by Batlle.

Element 7 of Batlle is the structural and functional equivalent of applicants [sic] "rupturable boot."

Id. at 52. The Batlle patent discloses a syringe having a piston or plunger with a discoid button that is pressure-fitted into a ring-shaped groove within the end of the piston or plunger. Defs.' Exh. 6, U.S. Patent No. 5,114,410, to Jaime Caralt Batlle, May 19, 1992, col. 3, *ll*. 37-40 ("Batlle Patent"). The discoid button is dislodged when enough pressure is exerted against it by the needle head. Id. col. 6, *ll*. 3-20.

The applicants cancelled claims 13 and 14 of the '115 application and filed a continuation application, application Serial No. 08/000,007 (the " '007 continuation application"), on January 4, 1993. Defs.' Exh. 2, '115 App., at 56-57; Defs.' Exh. 7, File Wrapper, Application Serial No. 08/000,007, at 2 (the " '007 App."). The '007 continuation application contained claims 13 and 14 in the same form as in the '115 application. *Compare* Defs.' Exh. 2, '115 App., at 23 *with* Defs.' Exh. 7, '007 App., at 22, 39-40.

In an office action dated October 26, 1993, the examiner rejected claims 13 and 14 pursuant to 35 U.S.C. s. 103, which forms the basis for obviousness objections, "as being unpatentable over Batlle in view of [U.S.

Patent No. 4,994,034 to Botich *et al*. (the "Botich patent")]...." Defs.' Exh. 7, '007 App., at 57-59. The Botich patent describes a syringe that has a plunger with a frangible end; the frangible end disassociates from the syringe plunger. Defs.' Exh. 8, U.S. Patent No. 4,994,034 to Botich *et al .,* col. 5, *ll*. 6-20; id. col. 7, *ll*. 19-39; id. col. 12, *l*. 65 to col. 13, *l*. 14; id. col. 14, *ll*. 1-4 ("Botich Patent"). Once the frangible end of the plunger disassociates from the plunger, a coiled spring ejects the syringe needle into a hollow of the plunger. Id. at col. 5, *ll*. 14-20; id. col. 13, *ll*. 1-6; id. col. 14, *ll*. 12-15.

On January 31, 1994, the inventors amended the specification of the '007 continuation application by inserting the words "tear and" before the word "penetrate." Defs.' Exh. 7, '007 App., at 60-62. The amendment read:

As deformable base 11 moves forward, enlarged needle head 13 begins to protrude from base 11 and come into contact with web 79 of rupturable boot 43 on plunger 7. Continued force causes further translation of base 11 and enlarged needle head 13 to *tear* and penetrate web 79 of rupturable boot 43 ... (page 12, lines 21 through 25) (emphasis added)[.]

Id. The change was explained, in part, as follows:

By the above amendment, the specification has been amended to more particularly describe rupturing as used herein. As clearly illustrated in figures 2 and 19 through 23, a portion of the rupturable boot 43 is torn or ruptured in order for the needle to penetrate the rupturable boot 43. According to *Webster's Dictionary,* the verb rupture (or rupturing) means "to party by violence: break, burst". [sic] The meaning of rupture as used herein and supported by the specification and the drawings clearly illustrates that the rupturable boot 43 is torn to be parted for the needle to penetrate. This rupturing or tearing differs significantly from the closing device and the end of the piston in Battle [sic] wherein the discoid button 14 is merely dislodged from its pressure-fitted position within the ring-shaped groove 15. There is clearly no rupturing as taught by applicant [sic] in the process of Battle. [sic] As such, no combination of Battle [sic] with Botich et al [sic] or WIPO 90/06146 renders applicant's [sic] process obvious.

Id. at 61-62. The applicants also distinguished the invention in Batlle, stating in pertinent part:

Battle [sic] teaches a disposable syringe utilizing as its closing device on the end of the piston (plunger) a discoid button 14 with its edge pressure-fitted into a ring-shaped groove 15 made around the mouth of the piston's cavity. During operation of the needle of Batlle, the button 14 is forced completely out of the groove 15 and forced back up into the piston.

Id. at 60-61.

But, the examiner again rejected claims 13 and 14 as being unpatentable over Batlle in view of Botich or WIPO. *Id*. at 65-67. The examiner stated, in pertinent part:

Claims 13 and 14 are rejected under 35 U.S.C. s. 103 as being unpatentable over Batlle in view of Botich et al [sic] or WIPO.

It is considered obvious and well within the skill of the art to provide the retractable needle syringe of Batlle with a hollow plunger of sufficient length to fully contain the retracted needle as taught by Botich et al [sic] or WIPO if so needed or desired.

In view of applicant's [sic] cited definition of rupture which includes "to break", [sic] it is the Examiner's position that the dislodging in Batlle is equivalent to a breaking and therefore readable on the claims. If the claims were amended to recite that the boot is "torn" or is caused to "tear" such language would render the claims allowable over the cited prior art.

Id. at 66.

In an amendment dated September 9, 1993, the applicants amended the pertinent portions of claim 13 and 14 to read:

13. (Thrice Amended) A process for retracting a needle at the completion of subcontaneous [sic] injection with a hypodermic syringe, comprising the steps of:

* * *

forcing an end portion of said needle to [rupture] *cause* a base portion of the plunger *to tear;* and

* * *

14. (Amended) A syringe comprising:

* * *

whereby a fluid is moved from within the barrel through the needle as the plunger moves through the barrel to the deformable base, and when the rupturable boot contacts the deformable base, continued movement of the plunger moves the deformable base toward the first end, the rear end of the needle thereby [rupturing] *causing* the boot *to tear* and loosing [sic] contact with the deformable base to allow the energy storage means to eject the needle into the interior of the plunger.

Id. at 69-71. To support these amendments, the applicants stated in pertinent part:

The Examiner states that it is considered obvious and well within the skill of the art to provide the retractable needle syringe of Batlle with a hollow plunger of sufficient length to fully contain the retractable needle as taught by Botich et al [sic] or the WIPO reference is so needed. In view of applicant's cited definition of "rupture", [sic] the examiner suggests to amend the claims to recite that the boot is "torn" or is caused to "tear" as such suggested language would render the claims allowable over the cited art. Such amendments have been submitted by this Amendment B.

Id. at 71. The examiner allowed claims 13 and 14 with these amendments. *Id*. at 72-73.

The inventors abandoned the '007 continuation application in view of a file wrapper continuation application, Serial No. 08/359,001 (the " '001 application"), filed on December 17, 1994. *Id*. at 75, 95. The '001 application contained claims 13 and 14; in addition, it added two new process claims, claims 15 and 16. *Id*. at 78-79. The new claims included clauses reading: "forcing an end portion of said needle to penetrate a base portion of said plunger,...." *Id*. at 79. The examiner rejected the new claims stating:

Claims 15 and 16 are rejected under 35 U.S.C. s. 102 (a or e) as being anticipated by Batlle.

The broad recitation and meaning of "penetrate" and "rupture" is considered to be fully met by the breaking action disclosed by Batlle.

Id. at 81-82. The inventors did not respond to the examiner's rejection, but allowed the '001 application to become abandoned for failure to prosecute on October 17, 1995. *Id*. at 85-86.

The inventors had not given up, however, because they filed a continuation-in-part application, Serial No. 08/481,093 (the " '093 application"), on June 7, 1995. Defs.' Exh. 9, File Wrapper, Application Serial No. 08/481,093, June 7, 1995, at 1 (the " '093 App."). The '093 application reads that it is a continuation-in-part of the '001 application, which is a continuation of the ' 115 application. *Id*. at 4. During prosecution of the '093 application, the inventors filed and Information Disclosure Statement ("IDS") on June 7, 1995 citing the Batlle patent. *Id*. at 69. However, at no time during prosecution of the '093 application, or any of its related applications, did the inventors or the examiner cite as a prior art reference U.S. Patent No. 5,084,018 to Tsao ("Tsao '018"). *See* id.; Defs.' Exh. 2, '115 App.; Defs.' Exh. 7, '007 App.; id ., '001 App. The '952 patent matured from the '093 application.

The '952 patent describes a hypodermic syringe apparatus that has a mechanism for retracting the needle of the syringe into the plunger of the device. '952 Patent, col. 2, *ll*. 1-49. The '952 patent also describes a process by which the needle of a syringe is retracted. Id. col. 15, *ll*. 22-31. Purportedly, the invention is designed to reduce the likelihood that a healthcare professional would sustain an unintentional puncture or prick from a used hypodermic syringe. Id. col. 1, *ll*. 13-21. The '952 patent describes several objectives: 1) minimize the likelihood of accidental puncture; 2) isolate the used needle to render it harmless and prevent its reuse; 3) provide a syringe with those features that is operable with only one hand; 4) seal the needle within the body of the syringe to prevent leakage of residual fluids; and 5) provide a simple device capable of manufacture in high volumes. Id. col. 1, *ll*. 50-67.

Apparently, the patented invention achieves these objectives by using a syringe plunger with a rupturable web on the end to deform a base holding the needle until the base completely releases the needle, the needle tears through the rupturable web and a spring forces the needle into a hollow in the syringe plunger. Id. col. 2, *ll*. 1-49; id. col. 2, *ll*. 50-67 to col. 3, *ll*. 1-13. The key is using continuous pressure on the syringe plunger to shift the original alignment of the needle until enough force is applied to free the needle from its deformable base. Id. col. 2, *ll*. 5-39. The needle head tears the rupturable web. Id. col. 2, *ll*. 30-32. Once that is accomplished, a spring forces the needle into the plunger's hollow center. Id. col. 2, *ll*. 34-39. Additional details about the patented apparatus and process will be discussed in more detail below.

SDP proffers the declarations of three witnesses on the infringement issue: Pressly's; Brockway's; and Dr. Richard Schapery's ("Schapery's"). *See* Pressly Decl. para. 1; Brockway Decl. para. 1; Schapery Decl. para. 1. SDP's first declarant, Pressly, is Vice President of MedSafe and President of Syringe Development. Pressly Decl. para. 6. He is one of the co-inventors on SDP's original application, Serial No. No. 813,115 (the " '115 application"). Id. Pressly has a B.S. in Electrical Engineering and has worked for a variety of companies as an engineer for thirty years. Id. para. 2.

SDP's second declarant, Brockway, is Vice President of Research and Development for MedSafe and holds an interest in Syringe Development. Brockway Decl. para. 3. Brockway also serves as a member of Syringe Development's Management Board. Id. Brockway is a co-inventor of the '952 patented device and process.

Id. para. 4. He is a plastics engineering with a B.S. in Civil Engineering, an M.S. in Engineering Mechanics and a Ph.D. in Applied Mechanics. Id. para. 2. Brockway has worked as a research scientist or research engineer for several companies since 1972 and is a professional engineer in the State of Georgia. Id.

SDP's third declarant, Schapery, is a professor of Aerospace Engineering and Engineering Mechanics at the University of Texas at Austin. Schapery Decl. para. 3; id. Attach. A, Richard A. Schapery, Resume, at 1 ("Schapery Resume"). In addition to teaching, Schapery has conducted research and consulted for industry and the government in the area of deformation and fracture of materials and structures. Schapery Decl. para. 4. He states that "[i]n lay terms, [his] expertise lies in understanding how materials break, fall or otherwise perform under various loads and stresses." Id.

2. ***NMT & The NMT Safety Syringe***

Defendant NMT Group is a Scottish company that developed, manufactures and sells the NMT Safety Syringe. Targell Decl. para. 4; Def.'s Statement of Facts, para. 75. FN2 Defendant New Medical Tech. is a subsidiary of NMT Group that markets and sells the NMT Safety Syringe in the United States. Targell Decl. para. 4.

FN2. NMT cited the declaration of John Targell ("Targell") at paragraphs 4 and 8 for all of the propositions in this sentence. The Court finds that all of the factual averments in the statement are unsupported by Targell's declaration alone. However, the Court will take them as true because SDP does not dispute them for purposes of this motion. *See* Pls.' Resp. to Defs.' Statement of Mat'l Facts, para. 75 ("Pls.' Resp.").

NMT offers a description of the NMT Safety Syringe by its expert, John Targell ("Targell"). Targell Decl. para.para. 2, 4, 9-20 & Attach. A-K. Targell is Research and Development Director for NMT Group. Id. para. 2. He is responsible for new product development and design. *See* id. Prior to working at NMT Group, Targell researched and designed medical devices for various companies. *See* id. para. 3.

Targell states in his declaration that the NMT Safety Syringe has a plunger assembly and a barrel assembly. Id. para. 9. The plunger assembly includes the plunger, the plunger seal, which fits over the end of the plunger, and the bursting disc. *See* id. para. 10. The bursting disc is comprised of a cone or central nose connected by a thin annular portion to the outer portion of the disc. *See* id. para. 11. The outer portion of the bursting disc is secured to the plunger. *See* id. All portions of the bursting disc are made of Styron 678E, a brittle plastic. *See* id.

The barrel assembly of the NMT Safety Syringe includes a crown, an o-ring or hub seal, and a needle hub. *See* id. para. 12. A spring is located around the needle or cannula of the device. *See* id. The spring is compressed and is held in place by the end cap at one end and, apparently, the top of the needle passageway at the other. *See* id. The parties dispute whether the end cap is secured to the end of the barrel. *Compare* id. ("The end cap is secured to the barrel.") *with* Pls.' Resp. to Defs.' Statement of Mat'l Facts para. 87 ("Inspection of the syringe [Plaintiff's Exh. 15] shows that the end cap is molded into the needle hub and held in place in the front of the barrel by the deformable base.") ("Pls.' Resp."). However, it is clear that the end cap is at the end of the barrel and a liquid tight seal is formed in some manner such that liquid in the barrel must exit through the needle. *See* Targell Decl. para. 9, Exh. B, NMT Safety Syringe Sample; *see also* id. para. 8 ("The medication in the barrel is ejected through the hollow needle (cannula) into the patient.").

Targell states that the NMT Safety Syringe works much like a traditional syringe; however, its special features prevent the reuse of syringes in drug abuse settings and prevent accidental skin penetration by the used needle. Id. para.para. 8, 5. A description of the special features as Targell describes them follows. "[T]he [syringe] plunger with the bursting disc on the end approaches the end of the barrel of the syringe as the medication is expelled through the needle." Id. para. 14. The forward edge of the bursting disc on the plunger comes into contact with the crown of the barrel and begins to push the crown forward. *See* id. Continued forward movement of the plunger and the bursting disc pushes the crown of the barrel, the needle, and the o-ring forward until the bottom portion of the needle hub contacts the internal sleeve portion of the end cap. *See* id. para. 15. When the plunger is moved even further, the cone portion of the bursting disc is pushed against the top portion of the needle hub and the outer rim of the bursting disc pushes on the crown; the crown pushes the o-ring forward on the needle hub. *See* id. Further forward movement of the plunger forces the crown to push the o-ring off the needle hub and onto the internal sleeve portion of the end cap. *See* id. para. 16. Continued pressure on the cone of the bursting disc causes the thin annular portion of the bursting disc to separate completely from the outer portion of the bursting disc. *See* id. para. 17. The separation of the cone section allows the spring to fire the used needle and the cone into the hollow of the plunger. *See* id. The parties dispute whether the needle retraction process in the NMT Safety Syringe begins while injection of medication is taking place, or after the injection is completed. *Compare* id. para. 20(h) & (i) *with* Schapery Decl. para. 11.

These are the majority of facts with which SDP and NMT make their arguments. The Court shall set out additional facts provided by the parties in their arguments as necessary.

3. ***Summary of the Arguments***

On February 8, 2000, SDP and NMT filed cross-motions for summary judgment on the issues of infringement and validity of the '952 patent. SDP contends that there is no genuine issue of material fact on infringement because NMT's sole argument is based on the meaning of the claim language, which is an issue of law. Pls.' Br. in Supp. of Mot. for Summ. J., at 1-3 ("Pls.' Br. on Summ. J.") . FN3 SDP also avers that NMT's syringe literally infringes claims 26, 30, 33, and 38 through 40, as a matter of law. Id. at 18-19. Moreover, SDP asserts that NMT's defense of invalidity for obviousness and anticipation must fail because NMT has not shown by clear and convincing evidence that the patent examiner made a mistake when issuing the patent. Pls.' Reply Br. in Supp. of Mot. for Summ. J., at 8-12 ("Pls.' Reply").

FN3. The Court notes that the Plaintiffs' brief contained two page ones and two page twos. The Court endeavored to encompass all relevant page numbers in its discussion of the background.

In response, NMT asserts that the '952 patent is anticipated by Tsao '018. Defs.' Mem. in Opp'n to Pls.' Mot. for Summ. J., at 2 ("Defs.' Mem. in Opp'n"). In addition, the combination of Tsao '018 and the Gaarde patent make the ' 952 patent invention obvious. Id. at 2. NMT also avers that under the proper claim construction, giving full weight to the prosecution history of the '952 patent, its syringe does not infringe the asserted claims as a matter of law. NMT argues that its syringe does not have a rupturable web, a deformable base or a web that tears. Id. at 3. Additionally, NMT avers that its syringe does not infringe claim 26 because the bursting disc of its syringe never contacts the o-ring holding the needle in place. Id. at 38. Similarly, NMT contends that its syringe does not infringe claim 30 because the needle retraction process for its syringe begins before the injection is complete, which is contrary to the teaching in the '952 patent. Id. at 38-41. Finally, NMT argues that prosecution history estoppel should bar SDP from arguing

that the NMT Safety Syringe infringes the '952 patent under the doctrine of equivalents. Defs.' Reply in Supp. of Defs.' Mot. for Summ. J., at 13-18 ("Defs.' Reply").

Having reviewed the facts as set forth by the parties and their arguments, the Court will now turn to the standards that govern its decision.

II. *STANDARDS*

A. SUMMARY JUDGMENT

Summary judgment is granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FedR.Civ.P. 56(c). *See also* CAE Screenplates v. Heinrich Fiedler GMBH, 224 F.3d 1308, 1316 (Fed.Cir.2000). An issue is genuine only if the evidence is such that a reasonable jury could return a verdict for the opposing party. *See* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A disputed fact is material only if it might affect the outcome of the suit in light of the substantive law. *See id*.

The moving party has the initial burden to show the absence of genuine issues of material fact. *See* Wollin v. Gondert, 192 F.3d 616, 620 (7th Cir.1999); Schroeder v. Barth, 969 F.2d 421, 423 (7th Cir.1992). This burden does not entail producing evidence to negate claims on which the opposing party has the burden of proof. *See* Green v. Whiteco Indus., Inc., 17 F.3d 199, 201 & n. 3 (7th Cir.1994). The party opposing a summary judgment motion bears an affirmative burden of presenting evidence that a disputed issue of material fact exists. *See* Wollin, 192 F.3d at 621; Gonzalez v. Ingersoll Milling Mach. Co., 133 F.3d 1025, 1031 (7th Cir.1998); Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986); Scherer v. Rockwell Int'l Corp., 975 F.2d 356, 360 (7th Cir.1992). The opposing party must "go beyond the pleadings" and set forth specific facts to show that a genuine issue exists. *See* Wollin, 192 F.3d at 621; Stop-N-Go of Madison, Inc. v. Uno-Ven Co., 184 F.3d 672, 677 (7th Cir.1999); Hong v. Children's Mem. Hosp., 993 F.2d 1257, 1261 (7th Cir.1993), *cert. denied,* 511 U.S. 1005 (1994). This burden cannot be met with conclusory statements or speculation, *see* Cliff v. Board of Sch. Comm'rs, 42 F.3d 403, 408 (7th Cir.1994) (citing McDonnell v. Cournia, 990 F.2d 963, 969 (7th Cir.1993)); *accord* Chapple v. National Starch & Chem. Co., 178 F .3d 501, 504 (7th Cir.1999); Weihaupt v. American Med. Ass'n, 874 F.2d 419, 428 (7th Cir.1989), but only with appropriate citations to relevant admissible evidence. *See* Local Rule 56.1; Brasic v. Heinemann's Inc., Bakeries, 121 F.3d 281, 286 (7th Cir.1997); Foreman v. Richmond Police Dept., 104 F.3d 950, 957 (7th Cir.1997); Waldridge v. American Hoechst Corp., 24 F.3d 918, 923-24 (7th Cir.1994). Evidence sufficient to support every essential element of the claims on which the opposing party bears the burden of proof must be cited. *See* Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

In considering a summary judgment motion, a court must draw all reasonable inferences in the light most favorable to the opposing party. *See* Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 988 (Fed.Cir.1999); Wollin, 192 F.3d at 621; Thomas & Betts Corp. v. Panduit Corp., 138 F.3d 277, 291 (7th Cir.1998); Spraying Sys. Co. v. Delavan, Inc., 975 F.2d 387, 392 (7th Cir.1992). If a reasonable fact finder could find for the opposing party, then summary judgment is inappropriate. Stop-N-Go, 184 F .3d at 677; Shields Enters., Inc. v. First Chicago Corp., 975 F.2d 1290, 1294 (7th Cir.1992). When the standard embraced in Rule 56(c) is met, summary judgment is mandatory. Celotex Corp., 477 U.S. at 322-23; Thomas & Betts, 138 F.3d at 291; Shields Enters., 975 F.2d at 1294.

B. PATENT INFRINGEMENT

Reviewing whether a device infringes a patent is a two step process. *See* CAE Screenplates, 224 F.3d at 1316; K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1362 (Fed.Cir.1999). First, a court must interpret the disputed claims, "from a study of all relevant patent documents," to determine their scope and meaning. K-2 Corp., 191 F.3d at 1362. *See also* Dolly, Inc. v. Spalding & Evenflo Cos., Inc., 16 F.3d 394, 397 (Fed.Cir.1994). Second, a court must determine if the accused device, system or process comes within the scope of the properly construed claims, either literally or by a substantial equivalent. *See* K-2 Corp., 191 F.3d at 1362; Dolly, 16 F.3d at 397; SmithKline Diagnostics v. Helena Labs. Corp., 859 F.2d 878, 889 (Fed.Cir.1988). "Infringement of process inventions is subject to the 'all-elements rule' whereby each of the claimed steps of a patented process must be performed in an infringing process, literally or by equivalent of that step, with due attention to the role of each step in the context of the patented invention." Canton Bio-Medical, Inc. v. Integrated Liner Tech., Inc., 216 F.3d 1367, 1369 (Fed.Cir.2000).

When construing patent claims, a court must determine the meaning of the language used before it can ascertain the scope of the claims the plaintiff alleges are being infringed. *See Markman I,* 52 F.3d at 979. In doing so, the court's interpretive focus is not the subjective intent of the parties employing a certain term, but the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean. *See id*. at 986. When the court undertakes its duty to construe the claims, it first must look to the intrinsic evidence: the asserted and unasserted claims, the specification, and the prosecution history. *See* Desper Prods. Inc. v. QSound Labs, Inc., 157 F.3d 1325, 1333 (Fed.Cir.1998) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581 (Fed.Cir.1996)); *Markman I,* 52 F.3d at 979. Most of the time, such evidence will provide sufficient information for construing the claims. *See* Vitronics, 90 F.3d at 1583.

The patent claims should " 'particularly point out and distinctly clai[m] the subject matter which the applicant regards as his invention.' " *Markman II,* 517 U.S. at 373 (citing 35 U.S.C. s. 112). During claim construction, the appropriate starting point for the court's inquiry is always the words of both the asserted and unasserted claims. *See* Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed.Cir.1999); Comark Comms., Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998); Vitronics, 90 F.3d at 1582; *see also* Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998). It is the claims, not the written description, that define the scope of the patent and accordingly, the patentee's rights. *See* Laitram Corp. v. NEC Corp ., 163 F.3d 1342, 1347 (Fed.Cir.1998); *Markman I,* 52 F.3d at 970-71. As the Federal Circuit has recently noted, "[c]ommon words, unless the context suggest otherwise, should be interpreted according to their ordinary meaning." Desper Prods., 157 F.3d at 1336 (citing York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed.Cir.1996)). *See also* Renishaw, 158 F.3d at 1249. Further, when there are several common meanings for a term, "the patent disclosure serves to point away from the improper meanings and toward the proper meaning." Renishaw, 158 F.3d at 1250. *Accord* Desper Prods., 157 F.3d at 1336 (stating that the context of the claims can be found in the specification and drawings).

A claim term will not be given a common dictionary meaning, however, if such a reading would be nonsensical in light of the patent disclosure, or specification. *See* Renishaw, 158 F.3d at 1250. Accordingly, the correct claim construction is also the one that "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Id*. That description, or specification, serves an important purpose. In it, the patentee must provide a written description of the invention that would allow a person of ordinary skill in the art to make and use the invention. *See Markman I,* 52 F.3d at 979. The applicable statute requires that "[t]he 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 ... to make and use the same...." 35 U.S.C. s. para. 112, para. 1. Therefore, to discover the correct meaning of a disputed claim term, the court must refer to the specification's description of the invention.

In addition, a patentee may be his or her own lexicographer and use terms in a manner different from their ordinary meaning. *See* Vitronics, 90 F.3d at 1582. If the patentee chooses to do that, he or she must clearly state the special definition in the specification or file history of the patent. *See id*. The specification then serves as a dictionary when it defines terms, either expressly or by implication, that are used in the claims. *See id*. Therefore, it is also important to review the specification to discern whether the patentee has used a term in a way that is inconsistent with its ordinary meaning. *See id*. However, the specification should be used to clarify unclear claim terms, not to "trump the clear meaning of a claim term." Comark, 156 F.3d at 1187 (citing E.I. du Pont de Nemours & Co. v. Phillips Petroleum, 849 F.2d 1430, 1433 (Fed.Cir.1988)).

Claims must be read in light of the specification. *See Markman I,* 52 F.3d at 979. However, limitations from the specification may not be read into the claims. FN4 *See* Comark, 156 F.3d at 1186; *see also* Laitram, 163 F.3d at 1347. In particular, the court should not limit the invention to the specific examples or preferred embodiment found in the specification. *See* Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed.Cir.1986); *see also* Comark, 156 F.3d at 1186. Therefore, the "repetition in the written description of a preferred aspect of a claim invention does not limit the scope of an invention that is described in the claims in different and broader terms." Laitram, 163 F.3d at 1348. *See also* Electro Med. Sys. v. Cooper Life Scis., Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994).

FN4. An exception to this rule applies when the claim is written in a means- or step-plus-function format under 35 U.S.C. s. 112, para. 6; however, the parties do not dispute any means-plus-function claim terms here.

Interpreting the meaning of a claim term "is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." Laitram, 163 F.3d at 1348 (quoting Intervet Am., Inc. v. Kee-Vet Lab., Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989)). An extraneous limitation is a limitation added "wholly apart from any need to interpret what the patentee meant by particular words and phrases in the claim." Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 950 (Fed.Cir.1993). *See also* Renishaw, 158 F.3d at 1249. Although there is a fine line between reading a claim in light of the specification and reading a limitation from the specification into the claim, the court must look cautiously to the specification for assistance in defining unclear terms. *See* Comark, 156 F.3d at 1186-87.

The third source of intrinsic evidence is the patent's prosecution history. *See Desper Prods.,* 156 F.3d at 1336-37; Vitronics, 90 F.3d at 1582. "Prosecution history is an important source of intrinsic evidence in interpreting claims because it is a contemporaneous exchange between the applicant and the examiner." Desper Prods., 157 F.3d at 1336-37. In a patent's prosecution history the court will find a complete record of the proceedings before the PTO leading to issuance of the patent. *See* Vitronics, 90 F.3d at 1582. The prosecution history contains both express representations made by the patentee concerning the scope of the patent, as well as interpretations of claim terms that were disclaimed during the prosecution. *See* id. at 1582-83; *see also* Southwall Tech Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.), *cert. denied,* 516 U.S. 987 (1995). Although the prosecution history is useful for understanding claim language, it "cannot enlarge, diminish, or vary the limitations in the claims." *Markman I,* 52 F.3d at 979 (quotations omitted).

In some cases, it may be necessary for the court to consult extrinsic evidence to aid it in construing the claim language. *See* Pitney Bowes, 182 F.3d at 1308; Vitronics, 90 F.3d at 1584. Extrinsic evidence is any evidence outside of the patent and prosecution history, "including expert and inventor testimony, dictionaries, and learned treatises." *Markman I,* 52 F.3d at 980. *See also* Pitney Bowes, 182 F.3d at 1308. It may be used to assist the court's understanding of the patent, or the field of technology. *See Markman I,* 52 F.3d at 980-81. However, "courts [should] not *rely* on extrinsic evidence in claim construction to contradict the meaning of claims discernible from thoughtful examination of the claims, the written description, and the prosecution history-the intrinsic evidence." Pitney Bowes, 182 F.3d at 1308 (citing Vitronics, 90 F.3d at 1583). Judges are not usually "conversant in the particular technical art involved," or capable of reading the patent specification and claims as one skilled in the art might. *See Markman I,* 52 F.3d at 986; *see also* Pitney Bowes, 182 F.3d at 1308-09. Therefore, "consultation of extrinsic evidence is particularly appropriate to ensure that [the court's] understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art." Pitney Bowes, 182 F.3d at 1309. When the court relies on extrinsic evidence to assist with claim construction, and the claim is susceptible to both a broader and a narrower meaning, the narrower meaning should be chosen if it is supported by the intrinsic evidence. *See* Digital Biometrics v. Identix, 149 F.3d 1335, 1344 (Fed.Cir.1998). It is entirely proper for the court to accept and admit extrinsic evidence, such as an expert's testimony, to educate itself, but then base its construction solely on the intrinsic evidence. *See Mantech,* 152 F.3d at 1373.

Further, the Federal Circuit has taken special note of the use by courts of a specific type of extrinsic evidence: dictionaries. In its *Vitronics* opinion, the court explained that although technical treatises and dictionaries are extrinsic evidence, judges are free to consult these resources at any time in order to get a better understanding of the underlying technologies. 90 F.3d at 1584 n. 6. The *Vitronics* court stated that judges may rely on dictionaries when construing claim terms as long as the dictionary definition does not contradict the definition found in, or ascertained by, a reading of the patent. *Id.*

Ordinarily, to prove infringement of a patent, the plaintiff must show by a preponderance of the evidence that every limitation of the claim asserted to be infringed has been found in an accused device or process, either literally or by an equivalent. *See* Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 796 (Fed.Cir.1990); Pennwalt v. Durand-Wayland, Inc., 833 F.2d 931, 935 (Fed.Cir.1987), *cert. denied,* 485 U.S. 961 (1988) & 485 U.S. 1009 (1988). With a method or process patent, however, the focus is on whether all of the claimed steps of the process or method are performed, either as claimed or by an equivalent step. EMI Group North Am., Inc. v. Intel Corp., 157 F.3d 887, 896 (Fed.Cir.1998), *cert. denied,* 526 U.S. 1112 (1999); Williams Gold Ref. Co. v. Semi-Alloys Inc., 434 F.Supp. 453, 454 (W.D.N.Y.1977) ("[I]t is the series of steps comprising the process that is central and only a replication of every step ... constitutes infringement."). This is because a method or process patent is only infringed when the alleged infringer practices or performs the claimed method or process. *See* Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 775 (Fed.Cir.1993); Giese v. Pierce Chem. Co., 29 F.Supp.2d 33, 36 (D.Mass.1998).

Absent a finding of literal infringement, a court could find that an accused device infringes by applying the judicially-created equitable doctrine of equivalents. *See* CAE Screenplates, 224 F.3d at 1318; Becton Dickinson, 922 F.2d at 797; ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1581 (Fed.Cir.1988); Pennwalt, 833 F.2d at 934. Under this doctrine, an accused device may still infringe a claim "if each and every limitation of the claim is literally or equivalently present." CAE Screenplates, 224 F.3d at 1318-19. "A claim limitation is 'equivalently present' in an accused device if there are only 'insubstantial differences' between the limitation and corresponding aspects of the device." Id. at 1319 (quoting Hilton Davis Chem.

Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1517-18 (Fed.Cir.1995), *rev'd on other grounds,* 520 U.S. 14 (1997)). Generally, infringement by equivalents is an issue of fact. *See id*. But, a district court may grant partial or complete summary judgment where the evidence is such that no reasonable jury could determine two elements to be equivalent. *Id*.

Infringement by equivalents is limited, however, by the doctrine of prosecution history estoppel. *Id*. "[A] patent owner can be estopped from relying upon the doctrine of equivalents when the patent applicant relinquishes coverage of subject matter during the prosecution of the patent, either by amendment or argument." *Id*. (citing Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373, 1376-77 (Fed.Cir.1999)). The purpose of this doctrine is "to protect the notice function of claims, 'measured from the vantage point of what a competitor was reasonably entitled to conclude.' " *Id*. (quoting Hoganas v. Dresser Indus. Inc., 9 F.3d 948, 952 (Fed.Cir.1993)). In other words, viewing the claims in light of the prosecution history as a whole, what would a competitor reasonably conclude was the metes and bounds of the patent grant? *See id*. Whether or not prosecution history estoppel should apply is a question of law. *See id*.

C. VALIDITY

By statute, a patent is presumed to be valid. 35 U.S.C. s. 282. The party challenging a patent's validity must prove invalidity by clear and convincing evidence. *See* Apple Computer Inc. v. Articulate Sys., Inc., 234 F.3d 14, 26 (Fed.Cir.2000); Oney v. Ratliff, 182 F.3d 893, 895 (Fed.Cir.1999) (citing Finnigan Corp. v. International Trade Comm'n, 180 F.3d 1354 (Fed.Cir.1999)); American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed.Cir.1984). In the present procedural posture, "[s]ummary judgment is inappropriate if a trier of fact applying the clear and convincing standard could find for either party." Oney, 182 F.3d at 895.

An accusation of anticipation is based on the requirement that an invention be novel or new. "The novelty requirement lies at the heart of the patent system." I DONALD S. CHISUM, CHISUM ON PATENTS s. 3.01 (Rel. No. 71, Sept. 1999) (hereinafter "CHISUM ON PATENTS"). The defense of anticipation "requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee." Hoover Group, Inc. v. Custom Metalcraft, Inc., 66 F.3d 299, 302 (Fed.Cir.1995). *See also* MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed.Cir.2000); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1349 (Fed.Cir.1998); Hupp v. Siroflex of Am., Inc., 122 F.3d 1456, 1461 (Fed.Cir.1997). A challenger cannot prove anticipation "by combining more than one reference to show the elements of the claimed invention." CHISUM ON PATENTS s. 3.02. Thus, a prior patent or device must contain all of the elements and limitations in the disputed patent as arranged in the patented device. *See* C.R. Bard, 157 F.3d at 1349; Hoover Group, 66 F.3d at 303. But, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." MEHL/Biophile Int'l, 192 F.3d at 1365. Anticipation is a question of fact, but may be decided on summary judgment if there is no genuine issue of material fact. Oney, 182 F.3d at 895.

Novelty also is related to the nonobvious requirement. If the invention is novel, then "further inquiry must be made into whether it is new enough" to be patented. CHISUM ON PATENTS s. 3.01 "A claimed invention is unpatentable if the differences between it 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 having ordinary skill in the art.' " Robotic Vision Sys., Inc. v.. View Engineering, 189 F.3d 1370, 1376 (Fed.Cir.1999) (quoting 35 U.S.C. s. 103(a)). *See also* Graham v. John Deere Co., 383 U.S. 1, 13-14 (1966); Ruiz v. A.B. Chance Co., 234 F.3d 654, 662 (Fed .Cir.2000); WMS Gaming, Inc. v. International Game Tech., 184 F.3d 1339, 1355

(Fed.Cir.1999). Determination of whether or not an invention is obvious is a legal conclusion. Ruiz, 234 F.3d at 662; WMS Gaming, 184 F.3d at 1355. However, the underlying inquiries are factual. Ruiz, 234 F.3d at 662; WMS Gaming, 184 F.3d at 1355. The factual inquiries for obviousness are 1) the scope and content of the prior art, 2) the level of ordinary skill in the field of the invention, 3) the differences between the claimed invention and the prior art, and 4) any objective evidence of non-obviousness, such as long-felt need, commercial success, the failure of others, or evidence of copying. *See Ruiz,* 234 F.3d at 662 63; WMS Gaming, 184 F.3d at 1355; C.R. Bard, 157 F.3d at 1351. As discussed above, the party asserting invalidity based on obviousness carries the burden of proof; however, that burden "is more easily carried when the references on which the assertion is based were not directly considered by the examiner during prosecution." WMS Gaming, 184 F.3d at 1355 (citing Applied Mat'ls, Inc. v. Advanced Semiconductor Mat'ls Am., Inc., 98 F.3d 1563, 1569 (Fed.Cir.1998) ("The presentation at trial of additional evidence that was not before the PTO does not change the presumption of validity or the standard of proof, although the burden may be more or less easily carried because of the additional evidence.")). *Accord* American Hoist & Derrick, 725 F.2d at 1360.

When a challenger asserts an obviousness defense or counterclaim based on two or more prior art references, there must be some suggestion or motivation to combine them. WMS Gaming, 184 F.3d at 1355. "The suggestion to combine may be found in explicit or implicit teachings within the references themselves, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved." *Id*.

III. *DISCUSSION*

A. CLAIM INTERPRETATION

The parties in this case dispute three terms in the relevant claims: the word "tear," the phrase "rupturable web," and the phrase "deformable base." However, interpretation of the word "tear" receives the greatest amount of attention. The Court will address the other two disputed terms first.

1. *Rupturable Web*

SDP argues that the term "rupturable web" means "a thin sheet of material, such as is located on the end of a plunger for a syringe, that can be more readily broken or burst open in order to separate that portion from the rest of the plunger." Pls.' Br. in Supp. of Summ. J. on Defs.' Liability for Patent Infringement, at 17 ("Pls.' Br. in Supp. of Summ. J."). It is important, SDP argues, that the definition for rupturable web "include the notion that one portion of the web must be weaker in order to effectuate the tearing required." Pls.' Reply in Supp. of Summ. J., at 21 ("Pls.' Reply"). SDP uses dictionary definitions of web and rupture as well as expert averment to support its construction.

In contrast, NMT argues that the term "rupturable web" means "a thin portion of a boot which covers the open end of the plunger and tears to allow the needle to pass." Defs.' Br. in Opp'n, at 15. This definition, NMT argues, is the only definition clearly supported by the intrinsic evidence. Moreover, NMT avers that SDP's definition overreaches the bounds of the claim terms by incorporating the word "break," a term distinguished by SDP during patent prosecution. *Id*. at 16-17. After reviewing the claim terms in light of the specification and the prosecution history, the Court finds that the term "rupturable web" means a material of a certain thickness that will tear or puncture when an out-of-plane force is applied against it. Starting with the claim language, the phrase "rupturable web" is used in two of the claims at issue. Specifically, claim 26 of the '952 patent reads:

A syringe comprising:

a barrel having a first end and an opposite second end;

a plunger having a forward end and movable within said barrel from said second end of the barrel towards said first end, the plunger having a hollow interior communicating with said forward end;

a deformable base within said barrel intermediate said [sic] first and second end;

a hollow needle having a pointed front, said needle extending through said first end of said barrel and a rear end received within and supported by said deformable base;

energy storage means positioned in said barrel between said first end said deformable base and in engagement with said needle; and

a *rupturable web* on said forward end of the plunger;

wherein a fluid can move from within said barrel through said needle as said plunger moves through said barrel to said deformable base, and when said *rupturable web* contacts said deformable base, continued movement of said plunger moves said deformable base toward said first end, said rear end of said needle thereby tearing said *web* wherein said rear end loses contact with said deformable base to allow said energy storage means to eject said needle into said interior of said plunger.

'952 Patent, col. 14, *ll*. 49-67, to col. 15, *ll*. 1-7 (emphasis added). Similarly, claim 38 of the '952 patent reads:

A syringe apparatus comprising:

a barrel;

a plunger movable within said barrel;

a needle assembly attached to an end of said barrel and defining a passageway therethrough;

a deformable base positioned within said barrel adjacent said [sic] needle assembly and defining a passage therethrough;

energy storage means within said passageway;

a hollow needle passing through said passageway;

an enlarged head on said needle engaged within said passage of deformable base; and

a *rupturable web* on an end of said plunger for moving a fluid within said barrel through the hollow of said needle when said plunger is moved through said barrel toward said needle assembly;

whereby when said plunger moves through said barrel toward said needle assembly, a fluid can be moved

from said barrel through the hollow of said needle, and continued movement of said plunger moves said deformable base downwardly until such time as sufficient force is imparted to said *rupturable web* by said enlarged heard of said needle to tear said *rupturable web,* said deformable base then releasing said needle with said enlarged head due to force applied thereto by said energy storage means to project said needle with said enlarged head into the interior of said plunger.

Id. col. 16, *ll*. 16-45 (emphasis added). The purpose for the rupturable web in both of these claims is the same: it forms a seal on the end of the hollow syringe plunger during medication draw-up and injection, it moves the deformable base toward the outlet end of the syringe assembly and it tears when the enlarged needle head exerts enough force against it.

The '952 patent specification confirms that these functions are performed by the rupturable web. The patent teaches:

The plunger has a thin, rupturable web on an end thereof which is part of a boot covering the end of the plunger, the boot, including the web, being liquid impermeable for forcing liquid from the barrel upon movement of the plunger. Upon completion of an injection, the boot-covered plunger contacts the deformable base, and upon application of force at the plunger, moves such base downward. Continued application of force causes the flexible supports to flex and move over the needle assembly, permitting the deformable base to move the enlarged head of the needle downward until further movement of the enlarged head is blocked by the needle assembly. With the enlarged needle head blocked by the needle assembly, continued force at the plunger causes the deformable base to move around the enlarged needle head. As the deformable base moves around the needle assembly, the enlarged needle head begins to protrude from the deformable base and come into contact with the web on the boot of the plunger. Continued force causes the enlarged needle head *to tear* the web of the boot, positioning the enlarged needle head just inside the hollow portion of the plunger. The *torn portion of the web* creates a flap just inside the hollow plunger. As the plunger moves the deformable base still further, the enlarged needle head looses [sic] contact with the deformable base, which triggers a release of energy from the energy storage means in the passageway, projecting the needle with its enlarged needle head into the hollow portion of the plunger.

Id. col. 2, *ll*. 12-34 (emphasis added).

Similarly, in the alternative embodiment,

[a]s the deformable base moves forward, the enlarged needle head begins to protrude from the deformable base and come into contact with a *thin rupturable web* on the boot of the plunger. Continued force causes the enlarged needle head *to penetrate* the web of the boot, positioning the enlarged needle head just inside a hollow portion of the plunger.

Id. col. 2, *ll*. 66-67, to col. 3, *ll*. 1-5 (emphasis added). Moreover, the detailed description of the rupturable web reads:

Plunger 7 has a hollow 41 therein and has a boot 43 covering an end thereof which is *fluid impermeable* for forced movement of a fluid in barrel 5 during ordinary injection. A portion of boot 43 is illustrated as *having been torn* by the needle head in FIG. 2, with boot web 79 laying over in the front of plunger 7.

Id. col. 5, *ll*. 39-44 (emphasis added). In addition,

To aid in the *rupturing process of the web, tear* groove 26 and *tear* groove 28, shown in figure 9B, are provided. The *thickness of web* 79 and the *tear* grooves are selected to withstand normal operating pressures within syringe 1, as shown in FIG. 1, but to allow relative ease in the *puncturing of web* 79 by enlarged needle head 13, shown in FIG. 6. The preferred material for boot 43 is an elastomer.

Id. col. 7, *ll*. 3-10 (emphasis added).

It is clear from these passages and the claims themselves that the rupturable web is a material of a certain thickness that will tear or puncture when an out-of-plane force is applied against it. SDP avers that the specification uses the terms "rupture" and "tear" interchangeably, therefore the definition for "rupture" should be used to define "rupturable web." SDP argues that the dictionary definition of the word rupture is break or burst, therefore, the rupturable web is a material that may be broken or burst when an out-of-plane force is exerted against it. However, the specification only uses the word "rupture" once to describe what happens to the "rupturable web" when the enlarged needle head comes in contact with it: "Plunger 107 has a hollow 141 therein and is terminated by a boot 143 having a rupturable web 179, the boot being fluid impermeable for movement of a fluid in the barrel during ordinary injection. Web 179 of boot 143 is illustrated as having been ruptured in FIG. 30." Id. col. 10, *ll*. 45-49. Although the word "rupture" may be used interchangeably with the word "tear" in the specification, this single reference to "rupturing" cannot overcome the repeated references to the "tearing" of the web in the claims and the remainder of the specification. In addition, although the dictionary definition of "rupture" may be helpful, the claims and the specification clearly connote that the rupturable web is torn or punctured rather than broken or burst.

Moreover, a definition for "rupturable web" that references "tear" instead of "break" or "burst" is more consistent with the prosecution history of the ' 952 patent. During prosecution of the patent's predecessor applications, the'007 continuation application filed January 4, 1993 and the '001 application filed December 16, 1994, the patent examiner rejected claims similar to the ' 952 patent's claim 30 and claim 26. Defs.' Exh. 7, File Wrapper, App. No. 08/000,007, Jan. 4, 1993, at 58, 66 ("App. No. '007"); id., File Wrapper, Continuation App. No. 08/359,001, Dec. 16, 1994, at 82 ("App. No. '001"). Those claims used the words "rupture" and "penetrate" to describe the action of the enlarged needle head pushing through the rupturable web, when those words meant "to break." *See* id.

Specifically, the claims at issue read in pertinent part:

13. (Amended) A process for retracting a needle at the completion of subcontaneous [sic] injection with a hypodermic syringe, comprising the steps of:

forcing a plunger of said syringe downwardly to force a needle support deformable base downwardly and sever sacrificial supports;

forcing an end portion of said needle to [penetrate] *rupture* a base portion of the [syringe and] plunger; and

propelling said needle into the hollow of said plunger.

* * *

14. A syringe comprising:

* * *

a rupturable boot on the forward end of the plunger;

whereby a fluid is moved from within the barrel through the needle as the plunger moves through the barrel to the deformable base, and when the rupturable boot contacts the deformable base, continued movement of the plunger moves the deformable base toward the first end, the rear end of the needle thereby rupturing the boot and loosing [sic] contact with the deformable base to allow the energy storage means to eject the needle into the interior of the plunger.

Defs.' Exh. 7, App. No. '007, at 39-40.

The patent examiner rejected both claims citing 35 U.S.C. s. 103, which forms the basis for obviousness rejections. Id. at 58. The examiner stated:

Claims 13 and 14 are rejected under 35 U.S.C. s. 103 as being unpatentable over Batlle in view of Botich et al or WIPO 90/06146.

It is considered obvious and well within the skill of the art to provide the retractable needle syringe of Batlle with a hollow plunger of sufficient length to fully contain the retracted needle as taught by Botich et al or WIPO if so needed or desired.

Id. In response, SDP distinguished its claims explaining:

... Batlle teaches a disposable syringe utilizing as its closing device on the end of the piston (plunger) a discoid button 14 with its edge pressure-fitted into a ring-shaped groove 15 made around the mouth of the piston's cavity. During operation of the needle of Batlle, the button 14 is forced completely out of the groove 15 and forced back up into the piston.

The pertinent portion of Applicant's [sic] independent claim 13 claims "forcing an end portion of said needle to *rupture* a base portion of the plunger" (emphasis added). A pertinent part of the specification as amended herein states as follows:

As deformable base 11 moves forward, enlarged needle head 13 begins to protrude from base 11 and come into contact with web 79 of rupturable boot 43 on plunger 7. Continued force causes further translation of base 11 and enlarged needle head 13 to *tear* and penetrate web 79 of rupturable boot 43 ... (page 12, lines 21 through 25) (emphasis added)[.]

By the above amendment, the specification has been amended to more particularly describe rupturing as used herein. As clearly illustrated in figure 2 and 19 through 23, a portion of the rupturable boot 43 is torn or ruptured in order for the needle to penetrate the rupturable boot 43. According to *Webster's Dictionary,* the verb rupture (or rupturing) means "to part by violence: break, burst". The meaning of rupture as used herein and supported by the specification and the drawings clearly illustrates that the rupturable boot 43 is torn to be parted for the needle to penetrate. This rupturing or tearing differs significantly from the closing device and the end of the piston in Battle [sic] wherein the discoid button 14 is merely dislodged from its pressure-fitted position within the ring-shaped groove 15. There is clearly no rupturing as taught by

applicant in this process of Battle [sic]. As such, no combination of Battle [sic] with Botich et al or WIPO 90/06146 renders applicant's [sic] process obvious.

Id. at 60-62. In this passage, the inventors appear to argue that although the definition of rupture is to break or burst, their device uses a tearing action rather than a dislodging as taught by Batlle. But, even in light of the explanation here, the examiner again rejected the claims:

In view of applicant's [sic] cited definition of rupture which includes "to break", [sic] it is the Examiner's position that the dislodging in Batlle is equivalent to a breaking and therefore readable on the claims. If the claims were amended to recite that the boot is "torn" or is caused to "tear" such language would render the claims allowable over the cited prior art[, Batlle in view of Botich et al or WIPO].

Id. at 66. Accordingly, the inventors amended the claims to read:

13. (Thrice Amended) A process for retracting a needle at the completion of subcontaneous [sic] injection with a hypodermic syringe, comprising the steps of:

forcing a plunger of said syringe downwardly to force a needle support deformable base downwardly and sever sacrificial supports;

forcing an end portion of said needle to [rupture] *cause* a base portion of the plunger *to tear;* and

propelling said needle into a hollow of said plunger such that said needle is contained entirely within said plunger.

14. (Amended) A syringe comprising:

* * *

a rupturable boot on the forward end of the plunger;

whereby a fluid is moved from within the barrel through the needle as the plunger moves through the barrel to the deformable base, and when the rupturable boot contacts the deformable base, continued movement of the plunger moves the deformable base toward the first end, the rear end of the needle thereby [rupturing] *causing* the boot *to tear* and loosing [sic] contact with the deformable base to allow the energy storing means to eject the needle into the interior of the plunger.

Id. at 69-70. Further, the inventors stated, "In view of applicant's [sic] cited definition of "rupture", the examiner suggests to amend the claims to recite that the boot is "torn" or is caused to "tear" as such suggested language would render the claims allowable over the cited art. Such amendments have been submitted by this Amendment B." Id. at 71. The examiner allowed the claims so amended. Id. at 72.

But, the inventors did not stop there; they continued the '007 application and added additional claims in the '001 application. Defs.' Exh. 7, App. No. '001, at 75, 78-79. The new claims read:

15. (New) A process for retracting a needle at the completion of substaneous [sic] injection with a hypodermic syringe, comprising the steps of:

forcing a plunger of said syringe downwardly to force a needle support deformable base downwardly and sever sacrificial supports;

forcing an end portion of said needle to penetrate a base portion of said plunger; and

propelling said needle into a hollow of said plunger.

16. (New) The process according to claim 15 wherein said end portion of said needle penetrates said base portion of the plunger by rupturing.

Id. at 78-79.

Again, the patent examiner rejected the additional claims. He wrote: "Claims 15 and 16 are rejected under 35 U.S.C. s. 102 (a or e) as being anticipated by Batlle. The broad recitation and meaning of 'penetrate' and 'rupture' is considered to be fully met by the breaking action disclosed by Batlle." Id. at 82. The inventors abandoned this application without amendment after it filed application Serial No. 08/481,093 (the " '093 application"), a continuation-in-part application of the '001 application; the '093 application later matured into the '952 patent. Id. at 85; Defs.' Exh. 9, File Wrapper, App. No. 08/481,093, Patent No. 5,613, 952, June 7, 1995, at 4 (" '093 App ."). The Court notes that all of the claims in the '952 patent state that the rupturable web or the end of the syringe plunger tears or is torn rather than ruptures or breaks. *See* '952 Patent, col. 13, *ll*. 15-18; id. col. 15, *ll*. 3-5; id. col. 15, *ll*. 29-30; id. col. 16, *ll*. 37-41.

It is clear to the Court that the patent examiner understood there to be a difference between the word "rupture," meaning "to break," and the word "tear." Where the Batlle patented device made obvious and anticipated a breaking action, according to the patent examiner Batlle did not make obvious or anticipate a tearing action. Moreover, in distinguishing their device from that in Batlle, the inventors describe the action as a tearing, and quoting from the patent specification, stated:

The pertinent portion of Applicant's [sic] independent claim 13 claims "forcing an end portion of said needle to *rupture* a base portion of the plunger" (emphasis added). A pertinent part of the specification as amended herein states as follows:

As deformable base 11 moves forward, enlarged needle head 13 begins to protrude from base 11 and come into contact with web 79 of rupturable boot 43 on plunger 7. Continued force causes further translation of base 11 and enlarged needle head 13 to *tear* and penetrate web 79 of rupturable boot 43 ... (page 12, lines 21 through 25) (emphasis added)[.]

By the above amendment, the specification has been amended to more particularly describe rupturing as used herein. As clearly illustrated in figures 2 and 19 through 23, a portion of the rupturable boot 43 is torn or ruptured in order for the needle to penetrate the rupturable boot 43. According to *Webster's Dictionary,* the verb rupture (or rupturing) means "to part by violence: break, burst". The meaning of rupture as used herein and supported by the specification and the drawings clearly illustrates that the rupturable boot 43 is torn to be parted for the needle to penetrate. This rupturing or tearing differs significantly from the closing device and the end of the piston in Battle [sic] wherein the discoid button 14 is merely dislodged from its pressure-fitted position within the ring-shaped groove 15. There is clearly no rupturing as taught by applicant in the process of Battle [sic]. As such, no combination of Battle [sic] with Botich et al or WIPO

90/06146 renders applicant's [sic] process obvious.

Defs.' Exh. 7, App. No. '007, at 61-62. In describing the changes to the specification, the inventors seem to equate rupture, with its "break; burst" definition, with tear. But, they also appear to distinguish Batlle by stating that "a portion of the rupturable boot 43 is torn or ruptured in order for the needle to penetrate the rupturable boot 43." Id. at 61. This would be different from the Batlle invention where the entire "boot" is dislodged. *See* id. at 62. Apparently, the patent examiner found this latter part of the inventors' reasoning persuasive because he allowed claims that referenced either "torn" or caused to "tear." Clearly, however, the patent examiner did not accept the inventors' definition of rupture that included "to break" because the examiner found "to break" equivalent to the dislodging taught by the Batlle invention.

As a result of these findings, a definition for "rupturable web" that includes the phrase "to break" would be inconsistent with the patent examiner's rejection of a definition of rupture that included that phrase. In light of the claims, the specification and the prosecution history, the Court finds that the phrase "rupturable web" means a material of a certain thickness that will tear or puncture when an out-of-plane force is applied against it.

2. *Deformable Base*

The parties apparently substantially agree upon the meaning of the phrase "deformable base;" their major point of disagreement centers around whether the *entire* needle head is housed, matingly engaged or locked by the deformable base. *Compare* Pls.' Reply, at 19-20 *with* Defs.' Mem. in Opp'n, at 17. SDP argues that the claims and the specification only require that the deformable base house, matingly engage or lock " *at least a portion* of the needle head." Pls.' Reply, at 20 (emphasis added by Plaintiffs). In addition, SDP argues that the deformable base does not necessarily need to be made from an elastomer. Id. at 19-20.

In contrast, rather summarily, NMT avers that the deformable base "houses, matingly engages, and locks the entire head of the needle." Defs.' Br. in Opp'n, at 17. In support of its construction NMT cites the '952 patent at column 2, lines 5-10, column 5, lines 23-30, column 6, lines 7-32, column 7, lines 40 and 44, column 10, lines 30-37 and 76, column 11, line 51, and column 12, line 32. Id. Further, NMT asserts that the deformable base must be made of an elastomer. Id.

The Court primarily agrees with SDP's construction and finds that the phrase "deformable base" means a portion of a syringe that is made of a material that can move down around a needle head when pressure is applied against it, that substantially houses, matingly engages or locks a portion of a syringe needle head, and that forms a liquid-tight seal between the needle and the syringe barrel.

As it must, the Court starts with the claim language:

26. A syringe comprising:

* * *

a deformable base within said barrel intermediate said [sic] first and second end;

* * *

wherein a fluid can move from within said barrel through said needle as said plunger moves through said barrel to said deformable base, and when said rupturable web contacts said deformable base, continued movement of said plunger moves said deformable base toward said first end, said rear end of said needle thereby tearing said web wherein said rear end loses contact with said deformable base....

* * *

30. A process for retracting a needle ... comprising the steps of:

forcing a plunger of a syringe downwardly within said syringe to force a deformable base engaging a head of said needle downwardly around said head....

* * *

38. A syringe apparatus comprising:

a deformable base positioned within said barrel adjacent needle [sic] assembly and defining a passage therethrough;

energy storing means within said passageway;

a hollow needle passing through said passageway;

an enlarged head on said needle engaged within said passage of said deformable base; ...

* * *

... continued movement of said plunger moves said deformable base downwardly until such time as sufficient force is imparted to said rupturable web by said enlarged needle head of said needle to tear said rupturable web, said deformable base then releasing said needle....

* * *

40. The apparatus according to claim 38 wherein said deformable base is cylindrical.

'952 Patent, col. 12, *ll*. 59-67 to col. 16, *ll*. 1-49. FN5

FN5. Other claims of the '952 patent that are not disputed by the parties also refer to a deformable base. Those references are recited here as additional context for construction of this claim term. The relevant claims state in part:
1. A syringe apparatus comprising:

a deformable base positioned within said barrel adjacent said [sic] needle assembly and defining a passage

therethrough;

an enlarged head on said needle engaged within said passage of said deformable base; ...

... continued movement of said plunger flexes said supports and moves said deformable base downwardly until such time as sufficient force is imparted to said rupturable web by said enlarged head of said needle to tear said rupturable web, said deformable base then releasing said needle with said enlarged head due to force applied thereto....
2. The apparatus according to claim 1 wherein said enlarged head is generally matingly engaged by said deformable base.

'952 Patent, col.12, *ll*. 59-67 to col. 13, *ll*. 1-24.
A review of these claims, and other claims in the patent that reference a deformable base, reveals that the deformable base must house, matingly engage or support one end of a syringe needle. *See* id. col. 12, *ll*. 65-67; col. 13, *ll*. 3-5; col. 13, *ll*. 22-24; col. 14, *ll*. 55-60; col. 15, *ll*. 8-10; col. 15, *ll*. 16-21; col. 15, *ll*. 25-27; col. 15, *ll*. 32-40; col. 16, *ll*. 22-25; col. 16, *ll*. 27-29. The claims themselves provide no limitation that the entire head of the needle must be contained within the deformable base. Moreover, the claims reveal that the deformable base must move down around the needle and/or needle head as pressure is applied to the deformable base until the needle or needle head is free of the deformable base. *See* col. 13, *ll*. 12-18 ("continued movement of said plunger flexes said supports [on the deformable base] and moves said deformable base downwardly until such time a sufficient force is imparted to said rupturable web by said enlarged head of said needle to tear said rupturable web, said deformable base then releasing said needle with said enlarged head"); col. 15, *ll*. 2-6 ("continued movement of said plunger moves said deformable base toward said first end [of the syringe barrel], said rear end of said needle thereby tearing said web wherein said rear end loses contact with said deformable base"); col. 15, *ll*. 25-27 ("forcing a plunger of a syringe downwardly within said syringe to force a deformable base engaging a head of said needle downwardly around said head"); col. 16, *ll*. 27-42 ("continued movement of said plunger moves said deformable base downwardly ... said deformable base then releasing said needle").

Apparently, both parties agree that it is implied by the description of the apparatus and the process in the '952 patent that the deformable base must also provide a liquid-tight seal between the needle and the syringe barrel. *See* Defs.' Mem. in Opp'n, at 17; Pls.' Reply, at 20. This is a logical conclusion based on the function of the deformable base to house, matingly engage or support the needle head through which medication will be injected. The apparatus claims of the '952 patent that reference a deformable base state that the fluid from the barrel flows through the hollow needle. Id. col. 13, *ll*. 11-12; id. col 14, *ll*. 66-67; id. col 16, *ll*. 36-37. For that to happen in the apparatus described in those claims, the deformable base must create a seal between the barrel and the needle. Otherwise, medication would get trapped between the barrel and the needle assembly rather than get injected into the patient.

The specification supports such a purpose for the deformable base. The specification reads in pertinent part:

Positioned between the passageway within the needle assembly and a shelf on an internal wall of the syringe barrel is a deformable base, with internal flexible supports. The deformable base forms a liquid tight seal with the barrel, at the needle end of the barrel. The deformable base houses an enlarged head of the

needle which enlarged head is in contact with energy storage means within the passageway in the needle assembly.

Id. col. 2, *ll*. 5-12. Further:

Upon completion of an injection, the boot-covered plunger contacts the deformable base, and upon application of force at the plunger, moves such base downward. Continued application of force causes the flexible supports to flex and move over the needle assembly, permitting the deformable base to move the enlarged head of the needle downward until further movement of the enlarged head is blocked by the needle assembly, continued force at the plunger causes the deformable base to move around the enlarged needle head.

Id. col. 2, *ll*. 16-27. In addition, "[a]s the plunger moves the deformable base still further, the enlarged needle head looses [sic] contact with the deformable base...." Id. col. 2, *ll*. 34-36. Clearly these passages teach that the deformable base houses an enlarged head of a needle and, upon application of force, is moved downwardly around the enlarged head until the needle is completely free of the deformable base. Moreover, the specification also teaches that the deformable base forms a liquid-tight seal at the needle end of the barrel. Id. col. 2, *ll*. 8-9.

Similarly, the description of the '952 patent's alternative embodiment reveals the purpose of the deformable base. The specification reads:

In an alternative embodiment ... the deformable base is positioned between sacrificial supports in the needle assembly and an internal wedged end of the barrel. Upon completion of injection, the boot contacts the deformable base, and upon application of force at the plunger, moves the base downward, initially breaking the liquid tight seal between the base and the barrel. Continued application of force causes the sacrificial supports within the needle assembly to sever, permitting the deformable base to move the enlarged head of the needle downward until further movement of the enlarged head is blocked by the passageway in the needle assembly. With the enlarged needle head blocked by the passageway, continued force at the plunger causes the deformable base to move around the enlarged needle head. As the deformable base moves forward, the enlarged needle head begins to protrude from the deformable base and come into contact with a thin, rupturable web on the boot of the plunger. Continued force causes the enlarged needle had to penetrate the web of the boot, positioning the enlarged needle head just inside a hollow portion of the plunger. As the plunger moves the deformable base still further, the enlarged needle head looses [sic] contact with the deformable base....

Id. col. 2, *ll*. 51-67 to col. 3, *ll*. 1-7.

Therefore, the deformable base must house or matingly engage the head of a needle, must be capable of moving down around the needle head when pressure is applied against it until the needle is completely free, and, at least initially, it must provide a liquid-tight seal at the needle end of the syringe barrel.

The specification also reveals more about the inventors' intended position for the needle head within the deformable base. The description reads:

... By appropriately positioning the enlarged needle head 13 within deformable base 11 for a substantially mating engagement, the geometries of top 14 and area 15 of enlarged head 13 can be substantially mated

and locked within deformable base 11 so that a liquid tight seal between needle head 13 and deformable base 11 is created at top 14 of enlarged head 13. As seen if FIG. 1, all of enlarged head 13 but a portion of the bottom portion is contained within the deformable base.

* * *

... Deformable base 11 is designed to substantially matingly engage enlarged head 13. As seen in FIG. 4 base wedge 6 is provided, below where top 14 of enlarged head 13 can fit, for proper positioning of the needle in the deformable base. Further, cylindrical barrel seals 8 are provided to create proper sealing action between base 11 and barrel 5. The diameter and width of the barrel seals 8 can be made to create an optimum seal, while minimizing static and dynamic friction between base 11 and barrel 5. Also illustrated in FIG. 4 are supports 31, preferably formed as opposing, semicircular cantilevered beams projecting from the upper body 12 of base 11. Each support 31 has an inward engaging flange 32 for engaging a lower portion of enlarged head 13 and an end of the needle assembly, as shown in FIG. 1. needle head seal 10 is further illustrated in FIG. 4 and is where top 14 of enlarged head 13 can fit. The diameter and width of needle head seal 10 is designed to provide optimum sealing with top 14, while minimizing static and dynamic friction between enlarged head 13 and base 11.

Id. col. 5, *ll*. 23-31; id. col. 6, *ll*. 7-25. In this description, only a portion of the needle head is enclosed within the deformable base. The bottom portion remains free of the base until pressure is applied to force the deformable base downwardly. Moreover, the description uses the word "substantially" to describe the mating engagement of the deformable base and the needle head, which implies a majority, but not all of the needle head is contained within the deformable base.

Similarly, the alternative embodiment description reads:

Needle 103 has an enlarged head 113 mounted within deformable base 111. Enlarged head 113 has a wedge portion 115 and a circular flange portion 117. By appropriately positioning the enlarged head 113 within deformable base 111, the geometries of the flange portion and wedge portion of enlarged head 113 substantially lock such enlarged head portion within the deformable base, while also creating a liquid tight seal between needle head 113 and deformable base 111.

Id. col. 10, *ll*. 30-38. Again, this description uses the word "substantially" to describe the position of the needle head relative to the deformable base. This implies a portion of the needle is not "locked" by the base.

In a description of yet another embodiment, the position of the needle head within the deformable base is also discussed:

... This embodiment ... includes a cylindrical deformable base 163 having a central passage therethrough which matingly engages a cylindrical enlarged needle head 165.... Enlarged needle head 165 includes two cylindrical sections of different diameters with the larger section being held entirely within base 163 prior to initiation of needle retraction and the lower cylindrical section extending partially into the needle assembly and having a contacting portion 175 on an end thereof for contacting spring 173. Base 163 is biased in position by spring 173 against shelf 177 and by friction from barrel 171 prior to initiation of needle retraction.

Id. col. 12, *ll*. 20-38. This description clearly contemplates that the lower portion of the needle head is not

engaged within the deformable base, but "extend[s] partially into the needle assembly." Id. col. 12, *ll*. 33-34.

In summary, although these descriptions reveal that the deformable base houses or matingly engages a substantial portion of the needle head, it is clear the inventors contemplated that a portion of the needle head would not be housed, matingly engaged or locked into the deformable base. The specification supports the broader construction revealed in the claims themselves that the deformable base must house, matingly engage or lock a portion of the needle head, but not all of the needle head. Moreover, the description also supports the inference that the deformable base is intended to create a liquid-tight seal between the needle and the barrel.

Finally, NMT argues that the deformable base must be made of an elastomer. The Court finds that although at least one description of the preferred embodiments states that a preferred material for the deformable base is an elastomer, *see* id. col. 6, *ll*. 28-29 ("A preferred material for base 11 is an elastomer."), there is no requirement that the deformable base *must* be an elastomer as NMT suggests. The '952 patent claims describe how the deformable base must function when other parts of the syringe put force or pressure upon it. As long as a part that houses, matingly engages, or locks the needle head can move down the needle head when pressure from the plunger is applied against it, any material that allows for such movement could be used for that part. The inventors merely suggest that an elastomer would be preferred over other materials; it is not part of the claims.

In the context of the '952 patent, the Court finds that the phrase "deformable base" means a portion of a syringe that is made of a material that can move down around a needle head when pressure is applied against it, that substantially houses, matingly engages or locks a portion of a syringe needle head, and that forms a liquid-tight seal between the needle and the syringe barrel.

3. *Tear*

The parties vigorously dispute the meaning of the word "tear" in the context of the '952 patent. SDP avers that "tear" means "the application of force to a material ... in order to cause a division or separation between portions of the material[; t]he result of tearing usually, but not always, leaves ragged edges on the portions of material that have been torn." Pls.' Br. in Supp. of Summ. J., at 17. *See also* Pls.' Reply at 17. Apparently, SDP believes that there is an ambiguity about the meaning of "tear" in the '952 patent that is created by the claim language, the specification and the prosecution history. Pls.' Reply at 12, 16. Therefore, SDP suggests that using expert testimony and the dictionary to define "tear" is appropriate and necessary. Pls.' Reply, at 16-17. SDP asserts that the WEBSTER'S DICTIONARY definition of tear would conform with and reconcile the ambiguity in the intrinsic evidence. Id. at 17. Thus, its proposed definition for tear, excluding its references to the device itself, is directly from WEBSTER'S DICTIONARY. The definition SDP proposes states in full:

Claims 26, 30, 33 and 38-40 of the '952 Patent use the terms "tear" or "tearing." You are instructed that these terms refer to the application of force to a material, such as the base of a needle plunger, in order to cause a division or separation between portions of the material. Tear implies a forcible, somewhat crude, pulling or wrenching away. The result of tearing usually ... leaves ragged or irregular edges on the portions of material that have been torn.

Id.

In contrast, NMT contends that the proper definition for "tear" within the context of the '952 patent is "tearing a portion of the rupturable web or boot thereby forming a flap (a portion of the web or boot still attached to the remainder of the boot or web), but do[es] not include the complete separation of a button or breakable piece from the end of the plunger." Defs.' Br. in Opp'n, at 6-7. NMT avers that its definition is the only proper one when the word "tear" is defined with reference to the prosecution history. Id . at 7. According to NMT, the prosecution history reveals that a definition of "tear" that includes "to break" would be obvious in light of prior art in U.S. Patent No. 5,114,410 to Batlle (the "Batlle patent") and U.S. Patent No. 4,994,034 to Botich *et al*. (the "Botich patent"). Id. at 9. The patent examiner had rejected the use of the word "rupture" in the '952 patent's predecessor applications because SDP had defined "rupture" as "to break." Accordingly, SDP changed "rupture" to "tear" in the patent to describe what happens to the rupturable web when it is contacted by the needle head with enough force. *See* id. In addition, NMT argues, SDP sought to distinguish the prior art during prosecution by explaining that "a portion" of the rupturable web is torn or ruptured during operation of its invention, but the discoid button at the end of the plunger in Batlle is completely dislodged. Id. at 10 (citing Defs.' Exh. 7, App. No. '007, at 61, 66). Therefore, according to NMT, the definition of "tear" should include reference to leaving a portion of material behind. Further, NMT argues that the Court should construe the word "tear" without resort to extrinsic evidence, such as a dictionary or expert testimony, because the plain meaning of "tear" and the '952 patent prosecution history provide sufficient intrinsic evidence of the proper construction for the term. Id. at 11-13.

The Court finds merit in both parties' arguments. The Court will start with the plain meaning of the claim language. "Tear" is used in the disputed independent claims as follows:

26. A syringe comprising:

* * *

a rupturable web on said forward end of the plunger;

wherein a fluid can move from within said barrel through said needle as said plunger moves through said barrel to said deformable base, and when said rupturable web contacts said deformable base, continued movement of said plunger moves said deformable base toward said first end, said rear end of said needle thereby *tearing* said web....

* * *

30. A process for retracting a needle upon completion of subcutaneous injection with a hypodermic syringe comprising the steps of:

* * *

forcing an end portion of said head *to tear* a base portion of said plunger;....

* * *

38. A syringe apparatus comprising:

* * *

a rupturable web on an end of said plunger ...;

whereby when said plunger moves through said barrel toward said needle assembly, a fluid can be moved from said barrel through the hollow of said needle, and continued movement of said plunger moves said deformable base downwardly until such time as sufficient force is imparted to said rupturable web by said enlarged head of said needle *to tear* said rupturable web....

'952 Patent, col. 14, *ll*. 65-67 to col. 15, *l*. 5 (emphasis added); id. col. 15, *ll*. 22-30 (emphasis added); id. col. 16, *ll*. 30-41 (emphasis added). FN6 The plain meaning of "tear" in the claim language is "to separate a material into portions by force to create an opening therein."

FN6. The word "tear" also is used in independent claim 1:
1. A syringe apparatus comprising:

a rupturable web on an end of said plunger....;

whereby when said plunger moves through said barrel toward said needle assembly, a fluid can be moved from said barrel through the hollow of said needle, and continued movement of said plunger flexes said supports and moves said deformable base downwardly until such time as sufficient force is imparted to said rupturable web by said enlarged head of said needle *to tear* said rupturable web....

'952 Patent, col. 12, *l*. 59 to col. 13, *ll*. 6-17 (emphasis added).
The specification supports such a definition; however, the specification also seems to convey that a portion of material remains attached to the boot, or that there is not a complete separation of the web from the boot. The first reference to "tear" or "torn" in the specification teaches: "Continued force [of the plunger against the deformable base] causes the enlarged needle head to tear the web of the boot, positioning the enlarged needle head just inside a hollow portion of the plunger. The torn portion of the web creates a flap just inside the hollow plunger." Id. col. 2, *ll*. 30-34. This passage conveys that when sufficient force is applied to the web, a portion of it separates from another portion, leaving part of the web attached to the boot, thereby creating an opening in the web to allow the needle head to protrude through it and into the hollow of the plunger. Clearly, this part of the specification implies that only a portion of the web is separated, not the entire web.

Similarly, the next references to the tearing of the web read:

A portion of boot 43 is illustrated as having been torn by the needle head in FIG. 2, with boot web 79 laying over in the front of plunger 7.

* * *

... Continued force causes further translation of base 11 and needle head 13 to tear web 79 of boot 43, positioning enlarged needle head 13 just inside hollow 41 of plunger 7....

Id. col. 5, *ll*. 42-44; id. col. 9, *ll*. 24-27. Again, these descriptions imply that a portion of the web material remains attached to the original portion of the material after the tearing or separating has occurred. In other words, only a portion is separated, not the whole.

The specification also uses the words "penetrate" and "puncturing" to describe the "tearing" process of the web. The specification reads: "Continued force causes the enlarged needle head to penetrate the web of the boot, positioning the enlarged needle head just inside a hollow portion of the plunger." Id. col. 3, *ll*. 2-5. Further:

To aid in the rupturing process of the web, tear groove 26 and tear groove 28, shown in figure 9B, are provided. The thickness of web 79 and the tear grooves are selected to withstand normal operating pressures within syringe 1, as shown in FIG. 1, but to allow relative ease in the puncturing of web 79 by enlarged needle head 13, shown in FIG. 6.

Id. col. 7, *ll*. 3-10. Similarly to the other passages describing the action of the needle head being forced against the rupturable web, these passages connote the parting or the separation of a material to allow something to pass through an opening created in it, but not the complete separation of the material from its points of attachment. In other words, penetrate and puncturing connote a "breaking through" or a "breach" of the web, but not a breaking apart completely.

Moreover, it is clear that "tear" should replace "penetrate," and "tearing" should replace "puncturing" in these passages without changing the scope of the claims. For that to hold true, the definition of "tear" should convey a separating of portions to create an opening, but not a breaking apart completely, to remain consistent with the use of the word "tear" and its apparent synonyms in the '952 patent. Therefore, the specification apparently teaches that "tear" means "to separate a material into portions by force to create an opening therein, without a complete breaking away."

A definition of "tear" that excludes a complete "breaking away" is consistent with the prosecution history. As presented above at length, during prosecution of the '952 patent's predecessor applications, the inventors struggled to find a word to describe the action of the needle head through the rupturable web that was not rendered obvious by the prior art. *See generally* Defs.' Exh. 7, App. No. '007; id. App. No. '001. Initially, the applicants used the word "rupture" to describe the action of the needle against the rupturable web, which the patent examiner rejected stating: "Claim 13 is rejected under 35 U.S.C. s. 102 (a or e) as being anticipated by Batlle." Id., App. No. '007, at 43. In response, the applicants offered the definition of "rupture" to the patent examiner along with an explanation of how the action in their device differed from the action described by the Batlle patent. Defs.' Exh. 7, App. No. '007, at 60-62. The applicants used a definition of "rupture" from WEBSTER'S DICTIONARY: "to part by violence: break, burst." Id. at 61. The patent examiner rejected the use of the word "rupture" with this definition because he found "to break" equivalent to the dislodging taught in the Batlle patent. *See* id. at 66. However, the patent examiner would accept the word "torn" or caused to "tear." *See* id.

The applicants subsequently amended their claims to read "torn" and caused to "tear;" however, they introduced new claims using the word "penetrate" and the phrase "penetrates said base portion of the

plunger by rupturing." Id. at 69-71; id. App. No. '001, at 79. The patent examiner allowed the amended claims that used "torn" and caused to "tear," but rejected the new claims using "penetrate." Id. App. No. '001, at 81-82. The examiner stated: "The broad recitation and meaning of "penetrate" and "rupture" is considered to be fully met by the breaking action disclosed by Batlle." Id. at 82. Clearly, the examiner would disallow any claims that purported to use a definition of what happened to the rupturable web that included "to break."

A brief review of the cited prior art, particularly the Batlle patent, might be helpful. The Batlle patent describes a syringe with a retractable needle. Batlle Patent, Abstract. Its only independent claim describes an opening on the end of a piston without further describing the type of opening or whether it is covered. Id. col. 5, *ll*. 15-16. The only dependent claim describes a specific part that covers the opening in the end of the piston, "a discoidal button," that is fit into a groove on the inside of the hollow plunger. Id. col. 6, *ll*. 5-20. The "discoidal button is dislodged" from the groove when the needle is released into the barrel by the action of the end of the plunger against the part holding the needle, which in turn releases a spring that pushes the needle into the hollow of the plunger. *See* id. col. 6, *ll*. 16-20; id. col. 5, *ll*. 4-21. The force of the needle head, powered by the spring, dislodges the "discoidal button." *See* id. col. 5, *ll*. 11-13; id. col. 6, *ll*. 16-19. It is this dislodgment that the patent examiner found equivalent to a breaking and therefore readable on the claims of the '952 patent when "rupture" meant "to break."

The patent examiner found the use of a word that connoted "to break" objectionable because the prior art would render such an action obvious; therefore, the definition of "tear" must convey something other than a breaking away as suggested by the dislodging in Batlle. *See* Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."). The applicants themselves tried to convey a difference in the very same passage in which they defined "rupture" to mean "break." They argued:

... During operation of the needle in Batlle, the button 14 is forced completely out of the groove 15 and forced back up into the piston.

The pertinent portion of Applicant's [sic] independent claim 13 claims "forcing an end portion of said needle to *rupture* a base portion of the plunger" (emphasis added). A pertinent part of the specification is amended herein states as follows:

As deformable base 11 moves forward, enlarged needle head 13 begins to protrude from base 11 and come into contact with web 79 of rupturable boot 43 on plunger 7. Continued force causes further translation of base 11 and enlarged needle head 13 to *tear* and penetrate web 79 of rupturable boot 43 ... [.]

... As clearly illustrated in figures 2 and 19 through 23, a portion of the rupturable boot 43 is torn or ruptured in order for the needle to penetrate the rupturable boot 43.

Defs.' Exh. 7, App. No. '007, at 61 (emphasis in original). From this part of the inventors' argument, the difference between "dislodging" and "rupturing" seems to be the difference between "breaking away" and "tearing a portion." The inventors themselves argue that "a portion" of the rupturable web is torn such that the needle can penetrate it. *Id*. In other words, "tear" is the separation of a portion of a material from another portion such that an opening is created to allow the needle head to pass through it; but, it is not the complete breaking away of a part because that would be akin to the dislodging in Batlle and therefore obvious in light of the prior art.

In the analysis, although the Court agrees in large part with SDP's proffered definition for "tear," the definition must include the notion that a "breaking through" or a "breach" is acceptable, however, a "breaking away" is unacceptable. This is necessary in light of the prosecution history that indicates the patent examiner specifically found anything that conveyed "to break" the rupturable web readable on the claims of the '952 patent. In addition, such a limitation is necessary, in part, because the specification indicates that a portion of the web breaks away not the entire web. The court will construe claims terms, whenever feasible, to sustain their validity. *See* Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1383 (Fed.Cirl.1999); *see also* Southwall Tech., 54 F.3d at 1576.

In light of the plain meaning of the claim terms, the specification and the prosecution history, the Court finds that "tear" means "to separate a material into portions by force to create an opening therein, without a complete breaking away." The Court declines SDP's invitation to import the entire WEBSTER'S DICTIONARY definition that includes descriptions of edges because such description is unnecessary.

4. ***Preamble of Claim 30***

NMT argues that the preamble of claim 30 provides a limitation that the needle retraction process described by the claim must start after completion of the injection. Defs.' Mem. in Opp'n, at 38-40. *See also* Defs.' Mem. in Supp. of Mot. for Summ. J., at 24-28 ("Defs.' Mem. for Summ. J."). Apparently, SDP does not dispute that this is the case, instead arguing that the NMT Safety Syringe's needle retraction process is started after completion of the injection. Pls.' Resp. to Defs.' Mot. for Summ. J., at 17-18. The Court will make an independent assessment of whether the preamble of claim 30 is indeed a limitation on the needle retraction process that claim 30 describes.

According to the Federal Circuit, the preamble of a claim " 'has the import that the claim as a whole suggests for it.' " Rowe v. Dror, 112 F.3d 473, 478 (Fed.Cir.1997) (quoting Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed.Cir.1995)). Furthermore, "[w]here a patentee uses the claim preamble to recite structural limitations of his claimed invention, the PTO and courts give effect to that usage." *Id*. (citing Bell Communications Research, 55 F.3d at 620; Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed.Cir.1989)). However, if a patentee "uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." *Id*. (citing Bell Communications Research, 55 F.3d at 620; Kropa v. Robie, 187 F .2d 150, 152 (C.C.P.A.1951)). A court must review the entirety of the patent in order to determine whether a preamble recitation is a structural limitation or only a statement of purpose. *See id*. The court must "determine what invention the patentee intended to define and protect." *Id*.

Turning to the patent in this case, claim 30 of the '952 patent reads:

A process for retracting a needle upon completion of subcutaneous injection with a hypodermic syringe comprising the steps of:

forcing a plunger of a syringe downwardly within said syringe to force a deformable base engaging a head of said needle downwardly around said head;

forcing an end portion of said head to tear a base portion of said plunger; and

propelling said needle into a hollow of said plunger.

'952 Patent, col. 15, *ll*. 22-31. Reviewing the patent and the file wrapper in their entirety, the Court concludes that the phrase "upon completion of subcutaneous injection with a hypodermic syringe" is a limitation on the process claimed. If this phrase is omitted, the process described could happen at any time, even before complete delivery of medication to the patient. Such an occurrence would not comport with the purpose of the claimed invention to reduce the likelihood that a healthcare professional would sustain an unintentional puncture or prick from a *used* hypodermic syringe. *See* id. col. 1, *ll*. 13-21 (emphasis added).

Moreover, the patent's written description repeatedly refers to the needle retraction process occurring after an injection into or treatment of a patient. *See* id. col. 2, *ll*. 16-17 ("Upon completion of an injection, ..."); col. 2, *ll*. 55 ("Upon completion of injection, ..."); col. 4, *ll*. 48-50 ("... a syringe may be provided for normal operation but, which upon completion of normal operation ...."); id. col. 8, *ll* . 46-56 ("For normal syringe operating forces, safety syringe 1 opertes as any conventional syringe. For use, the syringe is filled form an ampule in a normal manner, as standard procedure dictates. Once filled, the injection cycle is accomplished, again according to standard practice. At completion of the injection cycle, plunger boot 43 is just mating with base 11,.... Before the syringe is released or discarded, by the user, the needle retraction cycle should be accomplished."); id. col. 11, *ll*. 14-23 ("For normal syringe operating forces safety syringe 101 operates as any conventional syringe. For use, the syringe is filled from an ampule in a normal manner, as standard procedure dictates. Once filled, the injection cycle is accomplished, again according to standard practiced. At completion of the injection cycle, plunger 104 is just mating with base 111, as shown in FIG. 36.... Before the syringe is released, or discarded, by the user, the needle retraction cycle should be accomplished."); id. col. 12, *ll*. ("[U]pon completion of injection [the syringe] captures the utilized needle and renders such harmless within the plunger and body of the syringe."). In addition, two of the stated objects of the invention reference "after utilization" or "upon the end of an injection." Id. col. 1, *ll*. 54 & 63.

Based on this evidence in the patent, the Court finds that the phrase "upon completion of subcutaneous injection with a hypodermic syringe" is part of the invention claimed in the '962 patent. As a result of this finding, the phrase is a limitation on the process claimed.

B. PATENT INFRINGEMENT

1. ***Literal Infringement***

SDP asserts that the NMT Safety Syringe infringes claims 26, 30, 33 and 38 through 40. Correspondingly, NMT asserts that the NMT Safety Syringe does not infringe those claims. Claims 26, 30 and 38 are independent claims. The Court will address whether there is a genuine issue of material fact on infringement of these claims first, then it will turn to the dependent claims if necessary.

All of the independent claims refer to a deformable base. '952 Patent, col. 15, *ll*. 2-6; id. col. 15, *ll*. 26-27; id. col. 16, *ll*. 20-23; id. col. 16, *ll*. 34-39. The Court construed that phrase to mean "a portion of a syringe that is made of a material that can move down around a needle head when pressure is applied against it, that substantially houses, matingly engages or locks a portion of a syringe needle head, and that forms a liquid-tight seal between the needle and the syringe barrel." Part III.A.2. SDP's expert, Brockway, declares that the o-ring of the NMT Safety Syringe performs the functions of the deformable base. Brockway Decl. para. 11. NMT argues that the o-ring does not completely house the head of the needle; therefore, the o-ring cannot be a deformable base.

It is clear from the Court's construction of the phrase "deformable base" that the needle head need not be "completely" housed within that part. To the contrary, the language of the claim and the specification require that the deformable base substantially house, matingly engage or lock the needle head. The o-ring of the NMT Safety Syringe clearly substantially matingly engages or locks the needle hub within the barrel of the device. *See* Targell Decl., Exh. H1.

NMT has not provided evidence that there is a genuine issue of material fact that the NMT Safety Syringe has a deformable base. Therefore, the Court finds that this element of independent claims 26, 30 and 38 reads on the alleged infringing device.

Next, claims 26 and 38 require a rupturable web that tears or is caused to tear. '952 Patent, col. 14, *ll*. 65;; id. col. 16, *ll*. 27-41. SDP alleges that the NMT Safety Syringe has a rupturable web that tears. In his declaration, Schapery avers that the rupturable web on the NMT Safety Syringe is the thin, annular-shaped portion of the bursting disk. Schapery Decl. para. 8. That portion ruptures when enough force is supplied against it. Id. Schapery defines "to rupture" as the "process of breaking open or bursting." Id. (quoting THE AMERICAN HERITAGE DICTIONARY (2d College ed.)). Further, Schapery defines "tear:" "to divide, separate, or develop breaks or rents.... Tear implies a forcible, somewhat crude, pulling or wrenching away, usually so that ragged or irregular edges result." Id. (quoting WEBSTER'S DICTIONARY). Schapery also declares that, in his experience in the engineering community, " 'tearing' refers to rupturing a material by out of plane loading." Id. In addition, Schapery's observation of the thin annular portion of an NMT Safety Syringe bursting disc after firing showed irregular edges, which Schapery found consistent with a tearing action. Id. *See also* id., Exh. D, Photos, Bursting Disc Cone at Various Magnifications and Orientations.

In contrast, NMT argues that the bursting disc is not a rupturable web because it is not "a thin sheet of material." Defs .' Mem. in Opp'n, at 35-36. Moreover, NMT avers that even if the thin annular portion of the bursting disc is considered a rupturable web, it does not tear, it breaks such that the cone is completely separated from the rest of the bursting disc. Id. at 36-37. Targell, one of NMT's experts, concurs. Targell Decl. para.para. 9-12, 17. Targell states that the cone of the disc breaks free from the remainder of the disc. Id. para. 17. Moreover, no portion of the bursting disc creates a flap that remains connected to the bursting disc after the cone has separated. *See* id.

Finally, NMT presented evidence that "tear" is not a word associated with glass; however, glass can have ragged edges when it breaks. Defs.' Exh. 21, Fair Decl., Exh. A, Photos of Broken Glass. In addition, NMT's experts Krousgrill and Kokini testified in their declarations that the brittle material from which the bursting disc is made, breaks, it does not "tear." FN7 Pls.' Exh. 10, Att. A, Charles M. Krousgrill, Jr., Expert Witness Rep., para.para. 1(a), 1(b); id. Att. B, Klod Kokini, Expert Witnes Rep., at 4-5.

FN7. On February 18, 2000, SDP filed a motion to strike NMT's rebuttal expert Klod Kokini. SDP argues that because NMT did not name Kokini on or before December 15, 1999 as required by the Amended Case Management Plan ("Amended CMP") and because his testimony will overlap with that of Krousgrill, Kokini's testimony should be striken. Pls.' Br. on Mot. to Strike Kokini, at 3-4. Moreover, SDP argues that submission of a rebuttal report is likewise improper. Id. at 2-3. SDP argues that NMT's late tender of an expert disclosure and accompanying report that is cumulative is akin to "unfair surprise" and will waste judicial resources. Id. at 4 (citing Defs.' Mem. in Supp. of Mot. to Preclude Pls.' from Offering Any Expert Testimony on the Issue of Damages, at 3 n. 1).

In rebuttal, NMT asserts that the Amended CMP did not set deadlines for rebuttal witness disclosure,

therefore, Federal Rule of Civil Procedure 26(a)(2)(C) ("Rule 26(a)(2)(C)") applies. Defs .' Mem. in Opp'n to Pls.' Mot. to Strike Kokini, at 1, 3-5. Rule 26(a)(2)(C) states in pertinent part:
In the absence of other directions from the court or stipulation by the parties, the disclosures shall be made at least 90 days before the trial date or the date the case is to be ready for trial or, if the evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another party under paragraph (2)(B), within 30 days after the disclosure made by the other party. The parties shall supplement these disclosures when required under subdivision (e)(1).

Fed.R.Civ.P. 26(a)(2)(C). Moreover, at least one court that addressed the issue of rebuttal witness disclosure, Knapp v. State Farm Fire & Cas. Co., No. 94-2420-EEO, 1995 WL 340991, at (D.Kan. May 31, 1995), found that Rule 26 "does not restrict rebuttal testimony to expert witnesses previously designated to testify in the case in chief." Finally, NMT avers that Kokini's specialty in fracture mechanics differentiates him from Krousgrill.

The Court primarily agrees with NMT. Absent a stipulation from the Court or an agreement by the parties to the contrary, Rule 26 would govern disclosure of rebuttal experts and their reports. The Amended CMP language on the issue of expert disclosures and reports is sufficiently vague about rebuttal experts to allow for resort to Rule 26(a)(2)(C). Moreover, the Amended CMP specifically refers to Rule 26. *See* Am. Case Mgmt. Plan, at 5.

In addition, based on the letters the parties' counsel exchanged regarding rebuttal expert reports it appears unlikely to the Court that disclosure of rebuttal evidence was a surprise to SDP. Further, given the parties suggestion in the Amended CMP that the case would be ready for trial any time after June 8, 2000, *see id.,* disclosure of a rebuttal expert on January 13, 2000 gave SDP ample time to make adequate preparations for trial. This is particularly true in this case where Kokini's testimony was proffered to rebut a narrow issue.

Accordingly, Plaintiffs' motion to strike Defendants' rebuttal expert Klod Kokini is DENIED.

Finally, on June 29, 2000, SDP moved to strike certain portions of the expert reports submitted by the Defendants. SDP argued that the Court should strike opinion by Krousgrill and Kokini that were based on their experience in the engineering field if the Court struck similar statements made by Brockway. The Court declined NMT's invitation to strike the Brockway statements. Therefore, SDP's motion to strike certain portions of the expert reports submitted by the Defendants is DENIED as moot.
The Court finds that there is no genuine issue of material fact that the NMT Safety Syringe does not infringe the '952 patent's claims 26 and 38 because the NMT Safety Syringe does not have a rupturable web that tears. The Court construed the term "rupturable web" to mean "a material of certain thickness that will tear or puncture when an out-of-plane force is applied against it." Part III.A.1. In addition, the Court construed "tear," in the context of the ' 952 patent, to mean "to separate a material into portions by force to create an opening therein, without a complete breaking away." Therefore, to have a rupturable web that tears, the NMT Safety Syringe must have a material of certain thickness that will separate into portions by force such that an opening is created therein, without a complete breaking away of the portions. According to claims 26 and 38, the rupturable web must be on the forward end of the syringe plunger. '952 Patent, col. 14, *l.* 65; id.

col. 16, *l*. 27.

The NMT Safety Sryinge has a bursting disc on the forward end of its plunger. *See* Targell Decl. para. 11. The bursting disc is comprised of a central nose or cone connected by a thin annular portion to the outer portion of the disc. *See* id. The outer portion of the bursting disc is secured to the plunger. *See* id. Clearly, the entire bursting disc cannot be a "rupturable web" because it is not "a material of certain thickness that will tear or puncture when an out-of-plane force is exerted against it." Part III.A.1. The bursting disc has varying thicknesses of material, and SDP does not assert that either the cone or the outer portion of the bursting disc tear or puncture upon pressure from an out-of-plane force.

Further, although the thin annular portion of the bursting disc could be "a material of certain thickness," there is no question of material fact that the portion "tears" as the Court has construed that term. Schapery, SDP's expert, stated that the thin annular portion of the bursting disc ruptures when enough force is exerted on the cone section of the disc. Schapery Decl. para. 8. Schapery defined "rupture" to include the concept of "breaking." Id. In addition, Schapery defines "tear" to include breaking. Id. para. 11.

However, the Court construed "rupturable web" to mean "a material of certain thickness that will puncture or tear." Part III.A.1. Further, "tear" in the context of the '952 patent does not include a complete breaking away. In effect, Schapery's declaration confirms that the force of the needle head against the bursting disc in the NMT Safety Syringe breaks the bursting disc.

It is clear from the testimony provided to the Court that the cone portion of the bursting disc is broken completely away from the outer portion at the annular portion. *See* id. Decl. para. 8; Targell Decl. para.para. 16-17, Exhs. H & K. This complete breaking away is inconsistent with the teaching of the '952 patent of the tearing of a web portion, as those terms have been construed by the Court. The '952 patent teaches that tearing is a separation of a material into portions, without a complete breaking away. Therefore, the NMT Safety Syringe does not infringe the '952 patent's independent claims 26 and 38 or dependant claims 39 and 40.

Similar to claims 26 and 38, claim 30 of the '952 patent requires that the base portion of a syringe plunger tear. '952 Patent, col. 15, *ll*. 28-29. Therefore, to infringe claim 30 of the '952 patent, the NMT Safety Syringe must have a plunger end portion that tears. The Court has construed the term "tear" to mean "to separate a material into portions by force to create an opening therein, without a complete breaking away." Part III.A.3. The entire bursting disc is at the end of the NMT Safety Syringe plunger. Targell Decl. para.para. 10-11. Applying the definition of tear to the NMT Safety Syringe, the Court finds that the bursting disc at the end of the NMT Safety Syringe breaks, it does not tear as that term has been defined by the Court.

According to Targell's declaration, when force is applied to the cone of the bursting disc the cone portion breaks away from the remainder of the bursting disc at the thin annular portion. Id. para. 17. Schapery concurs that the cone breaks away from the remainder of the disk. Schapery Decl. para. 8. Arguably, the bursting disc material separates into portions by force to create an opening therein because a hole is created where the cone has broken away. However, the Court has construed the term "tear" to be limited to an incomplete separation. *See* Part III.A.3. A complete breaking away of the cone portion of the bursting disc does not comport with this limitation. As a result, there is no genuine issue of material fact that the NMT Safety Syringe does not infringe independent claim 30 or dependent claim 33 because it does not have a plunger end portion that tears.

In addition to its argument that the NMT Safety Syringe does not infringe claim 30 because it does not have an end portion that "tears," NMT argues that the needle retraction process in its syringe begins before completion of subcutaneous injection.FN8 Defs.' Mem. in Opp'n, at 38-41. Therefore, NMT claims that its syringe does not infringe claim 30 as a matter of law. For infringement of process patents, the patentee must show that the accused process practices or performs each of the claimed steps, either literally or by an equivalent. *See* EMI Group North Am., Inc. v. Intel Corp., 157 F.3d 887, 896 (Fed.Cir.1998), *cert. denied,* 526 U.S. 1112 (1999). SDP avers that Targell's testimony makes clear that the needle retraction process in the NMT Safety Syringe starts after completion of the injection; therefore, the NMT Safety Syringe practices each step of claim 30. Pls.' Resp. para. 148 (citing Targell Decl. para. 20(h)); *id.* para. 164 (citing Schapery Decl. para. 11).

FN8. In addition to its alternative argument about claim 30, NMT also presents an alternative argument about claim 26. Defs.' Mem. in Opp'n, at 38. NMT avers that in the NMT Safety Syringe the bursting disc never directly contacts the o-ring; therefore, it lacks an element of claim 26 and does not infringe. *Id.* NMT's argument is not well developed. In addition, a review of the evidence on the issue from both NMT and SDP reveals that a complete analysis of NMT's alternative argument would require the Court to construe an additional term in the '952 patent that the parties did not brief. *See* Targell Decl. para. 14 (stating that the bursting disc of the NMT Safety Syringe contacts the crown, with further force on the plunger pushing the crown, which in turn pushes the o-ring off of the needle head); Schapery Decl. para. 8 (stating that the deformable base is the crown and the o-ring in combination, an argument more appropriate for an infringement by equivalents analysis); Brockway Decl. para. 11 (stating that the deformable base is the o-ring, but describing the action of the plunger on the o-ring as through the crown). In light of the Court's resolution of the literal infringement issue in NMT's favor on its primary argument, and in light of the complications that NMT's less developed argument presents the Court, the Court declines to address NMT's secondary argument at this time.

Claim 30 states in full:

30. A process for retracting a needle upon completion of subcutaneous injection with a hypodermic syringe comprising the steps of:

forcing a plunger of a syringe downwardly within said syringe to force a deformable base engaging a head of said needle downwardly around said head;

forcing an end portion of said head to tear a base portion of said plunger; and

propelling said needle into a hollow of said plunger.

'952 Patent, col. 15, *ll.* 22-30. The Court has construed the preamble of the claim to be a limitation on the process. Part III.A .4. Therefore, the first step in the claim is "upon completion of subcutaneous injection with a hypodermic syringe." '952 Patent, col. 15, *ll.* 22-23. In other words, subsequent steps in the process occur after that step.

Targell's declaration states that the user of the NMT Safety Syringe will feel a resistance in the syringe when the bursting disc contacts the crown; the crown is part of the barrel that moves around the head of the

needle and pushes the o-ring off of the needle head. Targell Decl. para.para. 12, 14, 20(e). At this point, there is still medication in the syringe barrel to deliver to the patient. *See* id. para. 20(f). Continued movement of the plunger with the bursting disc on the end pushes the crown, the needle hub and the o-ring downwardly until the needle hub contacts the internal sleeve portion of the end cap. *See* id. para. 15, Exh. H2. Further movement of the plunger/bursting disc combination pushes the crown, which in turn pushes the oring forward on the needle hub until the o-ring is forced onto the internal sleeve portion of the end cap. *See* id. para.para. 15-16. At the same time, the cone is pressed against the needle hub. *See* id. para. 15, Exh. H3. Additional pressure on the plunger/bursting disc causes the annular portion of the bursting disc to break, thereby separating the cone portion of the bursting disc completely, and the spring fires the needle into the hollow of the syringe plunger. *See* id. para.para. 16-17. The last of the medication in the syringe barrel is expelled with the final movement of the plunger/bursting disc, at substantially the same time that the cone of the bursting disc breaks and the spring fires the needle into the syringe plunger. *See* id. para. 20(h). *See also* Targell Decl. para. 20, Exh. K, CD-ROM Demo. of NMT Safety Syringe. Specifically, Targell states: "When the plunger reaches the zero point, the last of the medication is administered and the needle retracts. The needle is retracted as the injection is completed; these events occur at substantially the same time." FN9 Id.

FN9. SDP does not dispute Targell's declaration about what happens in the NMT Safety Syringe; however, it does dispute the integrity of Targell's recitation of the NMT Safety Syringe needle retraction process. Specifically, SDP denies that the needle is retracted simultaneously with completion of the injection because Targell states: "If the user were to withdraw the needle from the patient before the retraction process, the user would not have delivered all the medication to the patient." Targell Decl. para. 20(i). However, the '952 patent specifically states that the process of the plunger shifting the deformable base happens after the injection is complete. '952 Patent, col. 15, *ll*. 22-23. It is equally clear from Targell's declaration and Exhibits H and K thereto, that the plunger of the NMT Safety Syringe begins to shift the deformable base from around the needle head before the injection is complete. Targell Decl. para.para. 15-17, 20(e-h).

Based on this testimony, it appears that the steps of the needle retraction process in the NMT Safety Syringe are a) forcing a plunger of a syringe downwardly within said syringe to force a deformable base engaging a head of said needle downwardly around said head, b) completion of subcutaneous injection simultaneously with both c) forcing an end portion of said head to break a portion of said plunger, and d) propelling said needle into a hollow of said plunger. In this order, it is apparent that the NMT Safety Syringe does not follow the steps as they are delineated by claim 30 of the '952 patent. As a result of this finding, the Court concludes that even if the Court had construed "tear" to include the breaking action of the NMT Safety Syringe's bursting disc, the NMT Safety Syringe would not literally infringe SDP's ' 952 patent claim 30.

For the foregoing reasons, the Court finds that SDP's motion for summary judgment that the NMT Safety Syringe literally infringes claims 26, 30, 33, and 38 through 40 should be DENIED. Correspondingly, NMT's motion for summary judgment that the NMT Safety Syringe does not literally infringe the '952 patent's claims 26, 30, 33 and 38 through 40 should be GRANTED.

2. *Infringement By Equivalents*

A device or process that does not infringe a patent claim literally, may still infringe a claim under the doctrine of equivalents. "A claim limitation is 'equivalently present' in an accused device [or process] if there are only 'insubstantial differences' between the limitation and corresponding aspects of the device."

CAE Screenplates Inc. v. Heinrich Fiedler GMBH & Co. KG, 224 F.3d 1308, 1319 (Fed.Cir.2000) (quoting Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1517-18 (Fed.Cir.1995), *rev'd on other grounds,* 520 U.S. 17 (1997)). Similarly to literal infringement, equivalents infringement is generally a question of fact. *See id*. However, if a reasonable jury could not find two elements equivalent, then summary judgment or partial summary judgment is proper. *Id*. (quoting Warner-Jenkinson, 520 U.S. at 39 n. 8).

Infringement by equivalents is limited by the doctrine of prosecution history estoppel. *See id*. Under the doctrine of prosecution history estoppel, a patent owner may not rely on an equivalents argument if the patent applicant relinquished coverage of subject matter during prosecution of the patent, either by amendment or argument. *See id*. The primary purpose of the doctrine is to protect the notice function of claims " 'measured from the vantage point of what a competitor was reasonably entitled to conclude.' " *Id*. (quoting Hoganas v. Dresser Indus., Inc., 9 F.3d 948, 952 (Fed.Cir.1993)). Application of prosecution history estoppel is a question of law. *See id*.

In the case at bar, NMT argues that prosecution history estoppel should preclude SDP from arguing that the breaking of the bursting disc of the NMT Safety Syringe is equivalent to the tearing of the rupturable web or base of the plunger in the '952 patent. Defs.' Mem. on Summ. J., at 22-24. In contrast, SDP, summarily asserts that the NMT Safety Syringe infringes claims 26, 30, 33, and 38 through 40 under the doctrine of equivalents because every claim element has a literal or substantial equivalent. Pls.' Reply, at 21 (citing Brockway Supp. Decl. para.para. 20-31). In addition, SDP asserts that prosecution history estoppel should not apply because the only thing the inventors of the '952 patent gave up during prosecution is the dislodgment of a plug that is described by the Batlle patent. Id. at 21-22.

Court agrees with NMT that prosecution history estoppel should apply in this case to bar SDP from arguing that breaking the bursting disc of the NMT Safety Syringe is equivalent to tearing the rupturable web in the '952 patent. The prosecution history of the '952 patent reveals that the applicants relinquished equivalents that break the bottom of a plunger.

The '007 continuation application, an ancestor application to the '093 application that matured into the '952 patent, contained claims similar to claims 26 and 30 of the'952 patent, but used the word "rupture" to describe the action of the needle head against the rupturable web instead of the word "tear." *See* Defs.' Exh. 7, App. No. '007, at 39-40. The examiner rejected both claims stating in pertinent part:

It is considered obvious and well within the skill of the art to provide the retractable needle syringe of Batlle with a hollow plunger of sufficient length to fully contain the retracted needle as taught by Botich et al or WIPO if so needed or desired.

Id. at 58. In response, the applicants distinguished the claims, explaining in part:

... According to *Webster's Dictionary,* the verb rupture (or rupturing) means "to part by violence: break, burst". [sic] The meaning of rupture as used herein and supported by the specification and the drawings clearly illustrates that the rupturable boot 43 is torn to be parted for the needle to penetrate. This rupturing or tearing differs significantly from the closing device and the end of the piston in Battle [sic] wherein the discoid button 14 is merely dislodged from its pressure-fitted position within the righ-shaped groove 15. There is clearly no rupturing as taught by applicant in this process of Battle [sic].

Id. at 61-62. But, the examiner again rejected the claims, specifically pointing to the applicants' definition of

rupture and making clear that such a definition would make the claims unallowable over the prior art:

In view of the applicant's [sic] cited definition of "rupture", [sic] which includes "to break", [sic] it is the Examiner's position that the dislodging in Batlle is equivalent to a breaking and therefore readable on the claims. If the claims were amended to recite that the boot is "torn" or is caused to "tear" such language would render the claims allowable over the cited prior art [, Batlle in view of Botich et al or WIPO].

Id. at 66. The applicants acknowledged the examiner's rejection of their definition of rupture and amended the claims according to his suggestion: "In view of applicant's [sic] cited definition of "rupture", [sic] the examiner suggests to amend the claims to recite that the boot is "torn" or is caused to "tear" as such suggested language would render the claims allowable over the cited art. Such amendments have been submitted by this Amendment B." Id. at 71.

SDP argues that the definition of "tear" is not significantly different from the definition of "rupture;" therefore, the only thing the applicants gave up during prosecution of the '952 patent's predecessor applications was the dislodging of a friction-fitted piece like that described in the Batlle patent. Pls .' Reply, at 21-22. This argument ignores the patent examiner's statement that "the dislodging in Batlle is equivalent to a breaking and therefore readable on the claims" when the applicants used a word, rupture, defined as "to break." The patent examiner agreed that the applicants could distinguish their claims from the Batlle patent by using the word "tear" to describe the action of the needle head against the rupturable web. This word comports with the language that the applicants themselves used to distinguish their invention over the prior art:

... As clearly illustrated in figure 2 and 19 through 23, a portion of the rupturable boot 43 is torn or ruptured in order for the needle to penetrate the rupturable boot 43.... This rupturing or tearing differs significantly from the closing device and the end of the piston in Battle [sic] wherein the discoid button 14 is merely dislodged from its pressurefitted position within the ring-shaped groove 15.

Defs.' Exh. 7, App. No. '007, at 61-62. In this passage, the applicants convey that the action they meant to patent was the "tearing" of a portion of a web, rather than the dislodgment of an end piece. But, the patent examiner clearly would not allow the claims if the word used to describe the action of the needle head against the rupturable web or base portion of the plunger was "to break" or the equivalent of "to break."

Based on these facts, the Court finds that SDP is estopped from arguing that the NMT Safety Syringe infringes the '952 patent under the doctrine of equivalents because the NMT Safety Syringe's bursting disc breaks under pressure from the needle head, with break being the equivalent of tear. The prosecution history of the '952 patent clearly demonstrates that the applicants gave up the action "to break" the end of the syringe plunger to obtain allowance of their claims over the Batlle patent. Therefore, NMT's motion for summary judgment on infringement under the doctrine of equivalents should be GRANTED.

C. PATENT VALIDITY

In some cases, a defendant will challenge the validity of a plaintiff's patent as an affirmative defense to the plaintiff's accusation of infringement. In this case, NMT has challenged the validity of the '952 patent in a counterclaim asking for declaratory relief. In such a circumstance, it appears that the Court must address the issue of validity because the counterclaim is independent of SDP's charge of infringement. *See* Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 95 (1993) ("A party seeking a declaratory judgment of

invalidity presents a claim independent of the patentee's charge of infringement."); Hill-Rom Co. v. Kinetic Concepts, Inc., 209 F.3d 1337, 1344 (Fed.Cir.2000); Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1481 (Fed.Cir.1998); Brunswick Corp. v. United States, 34 Fed. Cl. 532, 556-57 (Fed.Cl.1995), *aff'd,* 152 F.3d 946 (Fed.Cir.1998). However, NMT has raised the issue of validity in the summary judgment context in response to SDP's motion for summary judgment that the '952 patent is valid. Despite this seemingly conflicting procedural posture, the Court will address whether NMT has supported its argument that the '952 patent is invalid with enough evidence to create an issue of material fact.

NMT argues that claims 26, 30, 33 and 38 through 40 are invalid because they were anticipated by Tsao '018 or they were made obvious by Tsao '018 in combination with the Gaarde patent. As a preliminary matter, the parties dispute whether the fact that Tsao '018 was never cited to the PTO examiner by the inventors or cited by the PTO examiner during prosecution has bearing on the question of validity. Citing Newell Window Furnishings, Inc. v. Springs Window Fashions Div., Inc., 53 U.S.P.Q.2d 1302, 1323-24 (N.D.Ill.1999), NMT asserts that SDP is not entitled to a presumption that the PTO examiner correctly allowed the '952 patent over Tsao '018 because the PTO examiner apparently never considered the Tsao '018 reference when he considered the application for the '952 patent. Defs.' Br. in Opp'n, at 29-20.

SDP counters that the disclosures in Tsao '018 were nearly identical to those in the Batlle patent that was explicitly cited and considered by the PTO examiner. Pls.' Reply, at 9. Further, SDP contends that Tsao '018 was issued by the same examiner that prosecuted and issued the '952 patent and Tsao '018 was cumulative information that it was not required to cite. Id. at 9-10. Therefore, SDP argues that the presumption that the PTO correctly viewed the subject matter of the '952 patent non-obvious applies to any asserted combination of Tsao '018 and the Gaarde patent. Id. at 9. To support its position, SDP cites the Manual of Patent Examining Procedure and case law regarding the duty to disclose when misconduct is alleged. Pls.' Br. on Summ. J., at 22-23 (citing Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1582 (Fed.Cir.1991); Halliburton Co. v. Schlumberger Techn. Corp., 925 F.2d 1435 (Fed.Cir.1991); Manual of Patent Examining Procedure s. 904.02 (Original 6th ed.1995, rev'd 1996) ("M.P.E.P.")).

On this issue, the Court finds instructive the Federal Circuit's recitation of the effect of material not considered by the PTO in American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350 (1984):

To summarize on this point, [35 U.S.C.] s. 282 creates a presumption that a patent is valid and imposes the burden of proving invalidity on the attacker. That burden is constant and never changes and is to convince the court of invalidity by clear evidence. Deference is due the Patent and Trademark Office decision to issue the patent with respect to evidence bearing on validity which it considered but no such deference is due with respect to evidence it did not consider. All evidence bearing on the validity issue, whether considered by the PTO or not, is to be taken into account by the tribunal in which validity is attacked.

Id. at 1360. In other words, evidence not considered by the PTO goes to the weight of the proffered evidence; it does not go to change the standard of proof. Therefore, the Court will consider the fact that the PTO examiner apparently did not specifically review Tsao '018 when prosecuting the '952 patent; however, the disclosures in Tsao '018 may be similar to those of Tsao ' 044 and the Batlle patent, which the examiner clearly did review when he allowed the '952 patent. More explicit findings on this issue will be made in the obviousness analysis.

Finally, NMT alleges that SDP engaged in inequitable conduct when it prosecuted the '952 patent and its ancestor applications. Specifically, NMT avers that the '952 patent applicants mislead the PTO examiner

about the scope of the claims in Gaarde. In addition, NMT asserts that the applicant's failure to cite Tsao '018, Tsao '044 and the '007 application to the examiner also amounts to inequitable conduct. NMT argues that there is at least an issue of fact on both the materiality and intent prongs of the inequitable conduct analysis to preclude summary judgment.

The Court will address each of NMT's invalidity arguments in turn.

1. ***Anticipation***

As described in more detail above, a challenge to a patent's validity based on anticipation requires that "a prior art reference [ ] disclose every limitation of the claimed invention, either explicitly or inherently." MEHL/Biophile Int'l, 192 F.3d at 1365. *See also* Hoover Group, 66 F.3d at 302. NMT alleges that Tsao '018 anticipates claims 30 and 38 through 40.

Tsao '018 teaches a method for retracting the needle of a syringe after completion of an injection. Pls.' Exh. 6E, U.S. Patent No. 5,084,018, to Chien-Hua Tsao, Jan. 28, 1992, col. 1, *ll* . 11-15 ("Tsao '018 Patent"). Tsao '018 discloses a safety syringe having a barrel, a needle, a spring and a hollow plunger. Id. Abstract. The syringe barrel has a needle cannula that is fixed to a locking tip, which is secured to a base, called a sliding base. Id. col. 1, *ll*. 61-66. The Tsao '018 patented device also has a hollow plunger. Id. col. 2, *ll*. 13-14. A stopper is around the end of the plunger, which acts as a seal with the barrel. Id. col. 2, *ll*. 16-19. The Tsao '018 safety syringe plunger has a cork element within its open end. Id. col. 2, *ll*. 23-24. When the plunger is depressed, the stopper on its end displaces the sliding base. Id. col. 2, *ll*. 40-43. Further pressure on the plunger moves the sliding base forward off the locking tip (or needle head) and the needle head pushes the cork out of its place at the open end of the plunger. Id. col. 2, *ll*. 43-51. "After completion of the injection, as soon as the needle cannula (30) is pulled out of the patient's body, the needle cannula (30) and the locking tip (34) do not have any support, and hence they are brought into the internal space of the plunger (50) through the open end (54) formed by the displaced cork (56)." Id . col. 2, *ll*. 55-61.

Specifically, Tsao '018 claims:

1. A safety syringe comprising:

a) a hollow barrel having an open back end and a front end, the front end being provided with a needle extender and a plurality of ventilation holes;

b) a locking tip disposed within the barrel and positioned adjacent the needle extender, and a needle cannula secured to the locking tip and extending outwardly through the needle extender;

c) a plunger having a front end, the plunger being slidably received in the barrel through the open back end and positioned in close contact with an inner wall of the barrel, the plunger including an opening at the front end communicating with an interior space therein, and a sealing element temporarily sealing the opening;

d) a sliding base having a hole therethrough, the locking tip being disposed within the hole, and a flange positioned at a bottom portion of the hole for securing the locking tip therein;

e) a limiting flange on the inner wall of the barrel and disposed in engagement with the sliding base to prevent the sliding base from moving away from the front end of the barrel; and

f) wherein when the plunger is axially slid towards the front end of the barrel, the front end of the plunger and sealing element engage the sliding base and locking tip to displace the sliding base and locking tip in opposite directions and also displace the sealing element, so that continued movement of the plunger towards the front end of the barrel causes the needle cannula, locking tip and sealing element to be disposed within the interior space of the plunger.

Id. col. 4, *ll*. 8-40.

NMT first compares Tsao '018 to claim 30 of the '952 patent. NMT states:

Claim 30 is a process claim for retracting a needle comprising the steps of (a) "forcing a plunger of a syringe downwardly within said syringe to force a deformable base engaging a head of said needle downwardly around said head;" (b) "forcing an end portion of said head to tear a base portion of said plunger; and" (c) "propelling said needle into a hollow of said plunger."

Defs.' Mem. in Opp'n, at 23. NMT argues that Tsao '018 teaches the same process, including the tearing of a base portion of the plunger.

The Court agrees that NMT has shown a material issue of fact on whether Tsao ' 018 teaches parts (a) and (c) of claim 30. However, the Court has construed "tear" within the context of the '952 patent to mean "to separate a material into portions by force to create an opening therein, without a complete breaking away." Part III.A.3. Tsao '018 teaches a "displacement" of the sealing member from the end of the plunger. Tsao '018 Patent, col. 4, *ll*. 35-36. Further, the specification recites that the cork or sealing member is "push [ed] ... out of the open end of the plunger." Id. col. 2, *ll*. 50-51. Although the language of the claim in Tsao '018 that describes the end of the plunger as a "sealing member" might suggest a material of certain thickness that will tear, the language of the claims and the specification make clear that the "sealing member is "displaced" or "pushed ... out." "Displacement" or "pushing" a piece out of the open end of the plunger is different than separating a material into portions at the end of the plunger by force such that an opening is created in the material, without a complete breaking away. "Displacement" or being "pushed out" is more akin to a complete breaking away, which the Court has excluded from the definition of "tear" in the '952 patent.

Because Tsao '018 teaches a displacement of the end of the plunger rather than the tearing described by the '952 patent's claim 30, the Court finds that NMT has not raised a genuine issue of material fact that Tsao '018 anticipates claim 30 of the '952 patent.

Next, NMT compares Tsao '018 to claim 38, an independent claim, of the '952 patent. Claim 38 reads:

A syringe apparatus comprising:

(a) a barrel;

(b) a plunger movable within said barrel;

(c) a needle assembly attached to an end of said barrel and defining a passageway therethrough;

(d) a deformable base positioned within said barrel adjacent said needle assembly and defining a passage therethrough;

(e) energy storage means within said passageway;

(f) an enlarged needle head on said needle engaged within said passage of said deformable base; and

(g) a rupturable web on an end of said plunger for moving a fluid within said barrel though the hollow of said needle when said plunger is moved through said barrel toward said needle assembly;

(h) whereby when said plunger moves through said barrel toward said needle assembly, a fluid can be moved from said barrel though the hollow of said needle, and continued movement of said plunger moves said deformable base downwardly until such time as sufficient force is imparted to said rupturable web by said enlarged head of said needle to tear said rupturable web, said deformable base then releasing said needle with said enlarged head due to force applied thereto by said energy storage means to project said needle with said enlarged head into the interior of said plunger.

'952 Patent, col. 16, *ll*. 15-45 (letters added). NMT asserts that Tsao ' 018 clearly discloses a syringe apparatus that has: (a) a barrel; (b) a plunger movable within said barrel; and (c) a needle assembly with a hollow needle. Tsao '018 Patent, col. 4, *ll*. 8-20. Moreover, Tsao '018 discloses a sliding base, which performs the same function as the deformable base in the '952 patent's claim 38 because it matingly engages the head of the needle or the "locking tip" and it moves off the head of the needle when force is exerted against it. Id. col. 4, *ll*. 23-34. Tsao '018 also discloses a spring or "elastic element" for urging the needle head away from the end of the barrel and toward the plunger. Id. col. 4, *ll*. 41-44. In addition, NMT asserts that the cork element or the "sealing element" of Tsao '018 is a rupturable web as described by claim 38 because it is located at the end of a plunger and is more readily burst in order to separate it from the rest of the plunger. Defs.' Mem. in Opp'n, at 24. Furthermore, the needle head tears the cork element because it applies a force to the cork element to separate that element from the rest of the plunger. *See* id. at 24-25.

Although the Court agrees that elements (a) through (f) of the '952 patent' s claim 38 can be read on Tsao '018, the Court is not convinced that the cork element is a rupturable web that tears upon the force of the needle head against it. The Court construed rupturable web in the '952 patent to mean "a material of certain thickness that will tear or puncture when an out-of-plane force is applied against it." Part III.A.1. Although the cork element of Tsao ' 018 is referred to in the claims as a "sealing element" and could be construed as "a material of certain thickness," the claim of Tsao '018 teaches that the sealing element or cork is "displace[d]" rather than torn or punctured. Tsao ' 018 Patent, col. 4, *ll*. 35-36. The Court construed "tear" in the '952 patent to mean "to separate a material into portions by force to create an opening therein, without a complete breaking away." Part III.A.3. The displacement of the entire sealing element in Tsao '018 suggests a complete breaking away. This is not the same as "tearing" a material as taught by the ' 952 patent and construed by the Court.

Although the Court finds that many of the elements in Tsao '018 read on claim 38 of the '952 patent, Tsao '018 does not disclose a rupturable web that tears. Therefore, NMT has failed to provide evidence of a material issue of fact that Tsao '018 anticipates claim 38 of the '952 patent.

Finally, in a footnote, NMT asserts that "[e]very element of [c]laims 39 and 40 (which depend from [c]laim 38) are found in Tsao '018. Claim 39 requires that the needle head be cylindrical. Claim 40 requires that the

deformable base b[e] cylindrical. Both are shown as cylindrical in Tsao '018. [Tsao '018 Patent,] Fig. 1." Defs.' Mem. in Opp'n, at 25 n. 16. The Court agrees with NMT that the additional requirements of claims 39 and 40 of the '952 patent are taught by Tsao '018. However, both claim 39 and claim 40 still require that Tsao '018 disclose the elements of the '952 patent's claim 38. '952 Patent, col. 16, *ll*. 42-45 ("39. The apparatus according to claim 38.... 40. The apparatus according to claim 38...."). The Court has determined that NMT has not shown by clear and convincing evidence that Tsao '018 discloses a rupturable web that tears as required by claim 38 of the '952 patent. Because this element is required in claims 39 and 40, the Court finds that there is no genuine issue of material fact that Tsao '018 anticipates claims 39 and 40 of the '952 patent. Therefore, SDP's motion for summary judgment on the issue of anticipation should be GRANTED.

2. ***Obviousness***

As discussed above, obviousness is a legal conclusion that is based on four underlying factual inquiries. Ruiz, 234 F.3d at 662; WMS Gaming, 184 F.3d at 1355. The factual inquiries for obviousness are: 1) the scope and content of the prior art; 2) the level of ordinary skill in the field of the invention; 3) the differences between the claimed invention and the prior art; and 4) any objective evidence of nonobviousness, such as long-felt need, commercial success, the failure of others, or evidence of copying. *See Ruiz,* 234 F.3d at 662 63; WMS Gaming, 184 F.3d at 1355; C.R. Bard, 157 F.3d at 1351. When a party bases its non-obviousness argument on two or more prior art references, there must be some suggestion or motivation to combine them. WMS Gaming, 184 F.3d at 1355. "The suggestion to combine may be found in explicit or implicit teachings within the references themselves, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved." *Id*.

In the case at bar, NMT argues that there is a genuine issue of material fact on whether Tsao '018 in combination with the Gaarde patent makes obvious the ' 952 patent invention in claims 26, 30, and 38. Similarly to Tsao '018, which contains only a few claims, the Gaarde patent contains one independent claim and six dependent claims. The relevant claims of the Gaarde patent read as follows:

1. A disposable hypodermic syringe with a needle which can be retracted and held inside the syringe, comprising:

a hollow syringe barrel with two ends, containing a piston with an attached piston rod inserted in one end, said piston rod extending out of said end and a spring retainer attached to said syringe barrel at the other end;

a needle having a point at one end and a heat attached to the other, said point extending out of said spring retainer;

a liquid chamber within said syringe barrel which has a yielding end wall opposite said piston, with an opening in said yielding end wall that is smaller then [sic] said needle head;

a spring within said spring retainer for maintaining pressure between said needle head and said opening in yielding wall, wherein the spring force is sufficient to maintain a liquid tight seal between said needle head and said opening of said yielding end wall; and

a cavity in said piston opposite said opening in said yielding end wall which receives said needle when the

piston is pushed sufficiently forward to allow the head of the needle to pass through the opening in said yielding end wall.

* * *

5. A disposable hypodermic syringe according to claim 1, wherein piston packing is attache to said piston for sealing said liquid chamber and for covering said piston cavity.

6. A disposable hypodermic syringe according to claim 5, wherein said piston packing contains a membrane to cover said piston cavity.

Gaarde Patent, col. 3, *ll*. 37-45 to col. 4, *ll*. 1-46.

The parties agree, for purposes of summary judgment, that the Gaarde patent discloses "an embodiment where the packing 8' is designed in a special way, viz. with a thin membrane 15 surrounding the tapered end of the piston [of a syringe] 14 and thus completely seals [sic] off the opening to the cavity [of the piston] 9." Id . col. 3, *ll*. 16-19. Furthermore, "[w]hen the piston 14 bottoms by usage of the hypodermic syringe shown in FIG. 3, the head 3'of the needle will rest against the face [or upper rim of a cylindrical collar around a spring] 13 and can thereby puncture or destroy the membrane 15 so that the needle 1 is displaced into the cavity 9 in the piston...." Id. col. 3, *ll*. 28-32.

In addition, the parties agree, for purposes of summary judgment, that the packing and membrane taught by the Gaarde patent fits over the open end of the plunger. *See* id. Fig. 3; id. col. 3, *ll*. 18-20. They also agree that a membrane is a type of web. Defs.' Exh. 16, Pressly Dep., at 51; Defs.' Exh. 22, Ellis Dep., at 139. Further, in the Gaarde patent, when the plunger or piston is depressed, the head of the needle punctures or destroys the membrane so that the needle can be displaced into the cavity of the plunger. Gaarde Patent, col. 3, *ll*. 29-33; Pls.' Resp., para. 55. Finally, the Gaarde patent teaches that it is advantageous to reduce the total number of parts used in syringes to control production and assembly costs, "particularly in connection with a syringe for single use." Id. col. 1, *ll*. 37-42; id. col. 1, *ll*. 64-67 to col. 2, *ll*. 1-4.

NMT argues that the packing and the membrane at the end of the plunger, as taught in the Gaarde patent, is identical to the boot with a rupturable web as claimed in the '952 patent. *See* '952 Patent, col. 14, *l*. 65; id. col. 16, *l*. 27; id. col. 2, *ll*. 16-18; id. col. 5, *ll*. 38-39. Similarly to the function of the boot and rupturable web in the '952 patent, the packing and the membrane in the Gaarde patent provide a liquid tight seal between the plunger and the barrel. *See* Gaarde Patent, col. 4, *ll*. 36-42. Moreover, the membrane of the device in the Gaarde patent is "puncture[d] or destroy[ed]" by the needle head similarly to how the rupturable web is caused to "tear" by the needle head in the '952 patent. *See* id. col. 3, *ll*. 28-37; *see also* Pls.' Resp., para. 55. In its anticipation argument, NMT already pointed out that Tsao '018 discloses a deformable base, with a passageway therethrough, which secures and locks the needle head of a syringe. Defs.' Mem. in Opp'n, at 24 (citing Tsao '018 Patent, Fig. 1; id. col. 1, *ll*. 64-66). In addition, Tsao '018 teaches the placement of an energy storage means or spring, and a hollow needle with an enlarged head. *See* id. (citing Tsao ' 018 Patent, Fig. 1; id . col. 2, *ll*. 81-12). NMT also asserts that Tsao ' 018 discloses

a syringe "whereby when said plunger moves through said barrel toward said needle assembly, a fluid can be moved from said barrel though the hollow of said needle, and continued movement of said plunger moves said deformable base downwardly until such time as sufficient force is imparted to said rupturable web by said enlarged head of said needle to tear said rupturable web, said deformable base then releasing

said needle with said enlarged head due to force applied thereto by said energy storage means to project said needle with said enlarged head into the interior of said plunger."

Id. at 25 (quoting '952 Patent, col. 16, *ll*. 31-41). NMT asserts, and Targell affirms in his declaration, that the combination of Tsao '018 and the Gaarde patent discloses each and every element of claims 26, 30 and 38 of the ' 952 patent. *See* Targell Second Decl. para. 10.

NMT avers that the combination of these two disclosures would be implicit to one skilled in the art of safety syringe development. Id. The Gaarde patent describes the embodiment with the membrane on the end of the plunger as an improvement over the open plunger design. Gaarde Patent, col. 3, *ll*. 15-18 ("FIG. 3 shows an embodiment where the packing 8' is designed in a special way."). Moreover, the Gaarde patent teaches the advantage of reducing the number of parts to reduce production and assembly costs. Id. col. 1, *ll*. 37-42. Tsao '018 includes two structures on the end of the plunger. Tsao '018 Patent, col. 2, *ll*. 13-29 (referring to a stopper element and a cork element). Reducing the number of parts in Tsao '018 by using the Gaarde patent's packing and membrane design would apply the improved embodiment of the Gaarde patented device to Tsao '018 in a way that furthers the teaching of the Gaarde patent to minimize parts for production, yet maintains the sealing function found in both patents. Defs.' Mem. in Opp'n, at 28-29. *See also* Targell Second Decl. para. 10.

NMT also argues that the combination would be obvious to one skilled in the art because the field of retractable needle safety syringes was very crowded at the time of the invention and the claim elements of the '952 patent are clearly shown in the cited references " 'used in the same way, for the same purpose as in the claimed invention.' " Defs.' Mem. in Opp'n, at 29-30 (quoting Nordberg Inc. v. Telsmith, Inc., 881 F.Supp. 1252, 1295 (E.D.Wis .1995), *aff'd,* 82 F.3d 394 (Fed.Cir.1996) (quoting In re Gorman, 933 F.2d 982, 987-88 (Fed.Cir.1991))). In other words, the nature of the problem, producing a commercially viable, retractable needle safety syringe at minimum cost, invites one with ordinary skill in the art of safety syringe development to combine the teachings in the Gaarde patent and Tsao '018.

SDP argues that the disputed facts center around two issues: whether the combination of Tsao '018 and the Gaarde patent result in the subject matter claimed; and whether a person of ordinary skill in the art would have been motivated to make that combination. Pls.' Reply, at 10. With respect to the first issue, SDP contends that the combination invention that NMT suggests lacks a rupturable web. *Id*. SDP relies upon its definition of rupturable web that requires a portion of the web be more easily broken. *Id*. In addition, SDP asserts that Figure 3 of the Gaarde patent shows that the cutting surfaces at the end of the plunger would cut the web, rather than the needle tearing through the web. *Id*. Further, SDP continues, the plunger used in Tsao '018 does not have such cutting devices; therefore, the combination NMT suggests would not work.FN10 *Id*. at 10-11.

FN10. The Court notes that SDP asserts several facts in the upcoming analysis without citation to evidence. NMT objected to this practice and replied to each of SDP's factual assertions as it would reply to a statement of facts. *See* Defs.' Surreply to Pls.' Resp., at 4-8. In turn, SDP moved to strike those pages of NMT's reply. The Court can determine from the briefs, the statements of fact and the responses thereto what is truly a factual dispute and what is argument. In addition, as the nonmovant on the validity issue, NMT enjoys a reading of the facts in the light most favorable to it. The Court has endeavored to do that in this analysis. Therefore, SDP's motion to strike is DENIED.

With respect to the second issue, SDP argues that NMT's evidence of motivation to combine the inventions in the Gaarde patent and Tsao '018 is deficient. *Id*. at 11. SDP claims that simplifying manufacture is a suspect motivation in this case because the "boot would need to have [a] weakened portion, ... which further complicates manufacture." *Id*. Further, SDP contends that a skilled person in the art would end up with an unworkable syringe because if the cork element of Tsao '018 were eliminated, the resulting plunger would not have a surface capable of moving the Tsao '018 deformable base downwardly to trigger release of the spring. *Id*. Therefore, SDP concludes, one skilled in the art would not be motivated to combine the Gaarde patented device and the Tsao '018 patented device because he or she would not be motivated to make a device that would not work. *Id*. at 11-12.

Although the parties have condensed their arguments, for purposes of clarity, the Court will make specific findings with respect to each of the factors underlying a determination of obviousness. *See* Apple Computer, Inc. v. Articulate Sys., Inc., 234 F.3d 14, 26 (Fed.Cir.2000) (suggesting that a trial court needs to make proper factual findings in accordance with the factors set forth in Graham v. John Deere Co., 383 U.S. 1, 17 (1966) to support a ruling on obviousness).

a.) The Level of Ordinary Skill in the Field of the Invention

NMT proffers Targell as an example of one of ordinary skill in the field of the invention. Targell started working in the safety syringe field in 1990. Targell Second Decl. para. 2; Targell Decl. para. 3. Prior to joining NMT Group in 1995, Targell spent fourteen years working as a research designer specializing in medical devices and ten years as a director of a consulting company designing medical devices. Targell Decl. para. 3; Targell Second Decl. para. 2.

SDP offers the inventor of Tsao '018 and Tsao '044 as one of ordinary skill in field of safety syringe development. Pls.' Br. on Summ. J., at 26-27. It states that "with two safety syringe patents to his name [he] is unquestionably one of ordinary skill in this art." *Id*. at 27.

In addition to this evidence of the level of ordinary skill in the field, the Court may presume that the patent examiner who issued the '952 patent over the prior art that was cited to him, had some expertise in both interpreting references and the level of ordinary skill in the field of safety syringes. *See* American Hoist, 725 F.2d at 1359. The patent examiner who issued the ' 952 patent was clearly concerned about whether the invention was obvious in light of the Batlle patent and the Botich patent. *See* Defs.' Exh. 7, '007 App., at 57-82. SDP argues that Tsao '018 and Batlle were similar. Pls.' Reply, at 9-10. There is no argument from the parties about the Botich patent, however, as discussed above, the Botich patent discloses a "frangible end" on the syringe plunger. Botich Patent, col. 5, *ll*. 6-20; *id*. col. 7, *ll*. 19-39; *id*. col. 12, *l*. 65 to col. 13, *l*. 14; *id*. col. 14, *ll*. 1-4. Therefore, if the examiner had specifically reviewed the Gaarde patent when he reviewed the Batlle patent and the Botich patent, with the Gaarde patent disclosing a membrane that "puncture[s] or destroy[s]," he may have had even more concern about the obviousness of the '952 patent invention.

It is clear that one of ordinary skill in the field of safety syringe development at the time of the invention would have some level of background in designing medical devices or other similar mechanical devices. In addition, a person of ordinary skill in the safety syringe field would know the advantages and disadvantages of each of the needle retraction systems that had been developed, including the Tsao '018 patented device and the Gaarde patented device. At the very least, one of ordinary skill in safety syringe design would know there were at least two ways to provide a temporarily sealed, hollow syringe plunger, with a plug or with a membrane, and there were several ways to hold the needle assembly in place during an injection. Moreover,

it is very clear that one of ordinary skill in the field of safety syringes would know the general problems to solve with a retractable needle device: 1) easy to use; 2) complete injection of the medication before needle retraction; 3) complete containment of the needle to prevent reuse; 4) lowest possible production cost because the device must be disposable, yet economic. It is possible that problems or improvements related to any of these issues might motivate one of ordinary skill to combine the benefits of existing designs to make improvements related to any or all of these elements.

b.) Objective Evidence of Non-Obviousness

NMT points to evidence that the particular field of the '952 patent at the time of the invention was competitive. Pressly, one of the co-inventors listed on the '952 patent and an SDP expert, testified during his deposition about a handwritten letter he wrote to "Charlie" dated January 29, 1992. Defs.' Exh. 16, Pressly Dep., at 38-39. Specifically, his deposition testimony states:

... We had filed the patent at that time in December of '91. We were starting to go to the next phase of the project in terms of what do we do next to try to get this thing into the market and I had been nosing around in the library looking at the Gazette and there were just an awful lot of patents.

I think [my statement that "It ain't over till the fat lady sings"] goes back to the statement I made earlier that I was surprised that there were so many and the reality that we had a very crowded art was there. So it ain't over until the fat lady sings.

Id. The letter itself reads:

Charlie:

Well, like we said last night on the telephone, "It ain't over till the fat lady sings"! [sic] I've marked the patent of interest (# 5,053,010, issued October 1, 1991) with a yellow "stick on". [sic] Some comments:

1) From the quick search I did of the Gazzett, there were in access [sic] of 40 patents issued on syringes since Sept. 1, 1991 when we did our search.... We are in a very competitive field! ...

Defs.' Exh. 20, Letter, From Bill to Charlie, Jan. 29, 1992 (ellipses in original). This evidence tends to support a conclusion that there were many people skilled in the art trying to obtain patents on safety syringes. Arguably, this evidence could weigh in favor of either non-obviousness, in light of the fact that the patent examiner allowed the '952 patent over the cited prior art, or obviousness, in light of the fact that Tsao '018 was neither cited to the '952 patent's examiner nor apparently considered by him and the fact that the Gaarde patent had been cited in the parent application to the patent, but not in the continuation-in-part application that eventually matured into the '952 patent (in other words, it was considered by the patent examiner distant in time from eventual grant of the '952 patent).

However, viewing this evidence in the light most favorable to NMT, as the non-movant, the fact that there were many designs for safety syringes, tends to show that one of an ordinary level of skill in the art might try to combine the advantages of existing systems to optimize achievement of the stated objectives in the field. For example, the '952 patent, the Gaarde patent and Tsao '018 all have nearly identical objectives. Only one of them, the Gaarde patent, mentions the specific advantages of its design over the prior art. The Gaarde patent discusses a disposable safety syringe under U.S. Patent No. 4,650,468 (the " '468 patent") that

has a retractable needle system; however, the Gaarde patent concludes: "the ['468 patent] design can work according to purpose, but it does in fact comprise at least fifteen single parts which means that the production and assembly costs of the syringe become considerable which is a disadvantage, particularly in connection with a syringe for single use." Gaarde Patent, col. 1, *ll*. 37-42. Therefore, given that one of ordinary skill in the field would know the objectives of a device, with economical production and assembly costs being one them, motivation to combine could come from a desire to incorporate the benefits of two prior art systems and, at the same time, achieve an easier to produce or lower cost end product.

SDP does not present any objective evidence of non-obviousness, instead relying upon the strength of its argument on the scope and content of the prior art.

c.) Scope and Content of the Prior Art/Differences Between the Claimed Invention and the Prior Art

1.-Presumption of Non-Obviousness over Tsao '018: Central to the parties' debate about the scope and content of the prior art is how the fact that the PTO examiner did not consider Tsao '018 when he issued the '952 patent should affect the presumption that the PTO correctly viewed the subject matter of the '952 patent non-obvious. SDP argues that the disclosure in Tsao '018 was "almost identical" to that in the Batlle patent, which was explicitly cited and considered by the examiner during prosecution of the '952 patent. Pls.' Reply, at 9. Therefore, Tsao '018 would be cumulative and unnecessary. Id. at 9-10. In addition, SDP asserts that Tsao '018 was issued by the same examiner that prosecuted the '952 patent application and all of its prior related applications. Id. at 9. These facts taken together, rebut an inference that the PTO's failure to consider Tsao '018 should overcome the presumption of nonobviousness. *See* id. at 9-10.

NMT argues that the differences between the subject matter considered by the PTO examiner and Tsao '018 is significant and not cumulative. Defs.' Mem. in Opp'n, at 30. First, NMT asserts that although the PTO did consider a patent related to Tsao '018 (Tsao '044) during prosecution of applications that led to the '952 patent, Tsao '018 involved new subject matter. Id. Tsao '018 states that it is a continuation-in-part application of Tsao '044. Tsao '018 Patent, at 1. SDP's expert admits that a continuation-in-part application "involves 'new' subject mater not before disclosed in prior related applications." Pressly Decl. para. 13.

NMT asserts that the "new" subject matter in Tsao '018 over Tsao '044 was the deformable base. Where Tsao '044 disclosed a "clamping means 20," which includes a "cylindrical front half portion with inner thread 22 ... and a rear half portion comprised of two L-shaped clamping elements 24 and 26, [and][a] hypodermic needle 30 which is fixedly connected to a holder plate 34 firmly retained by the two elastic clamping elements 24 and 26," Tsao '044 Patent, col. 2, *ll*. 52-62, Figs. 1-3, Tsao '018 disclosed a sliding base that secures the locking tip of a needle and is displaced upon pressure from the syringe plunger. Tsao '018 Patent, col. 1, *ll*. 63-65; id. col. 2, *ll*. 44-50. NMT contends that the disclosure in Tsao '018 is much more similar to the '952 patent disclosures than the disclosure in Tsao '044. Defs.' Mem. in Opp'n, at 31.

NMT also points to evidence that the applicants themselves distinguished the disclosures in Tsao '018 for a deformable base from that in Tsao '044 when they took a position about the scope of Tsao '044 when prosecuting the '952 patent's parent application, the '115 application. Id. at 32. In prosecuting the '115 application, the applicants distinguished a claim that reads similarly to claim 26 of the '952 patent by stating, in pertinent part: "Tsao's teaching of using the end of the needle to force a plug from the end of the plunger does not suggest the very different deformable base and rupturable boot of proposed claim 14 and, accordingly, does not render the new claim obvious." Defs.' Exh. 2, File Wrapper, U.S. Patent No. 5,211,629, App. Ser. No. 07/813,115, May 18, 1993, at 43 (" '115 App."). NMT asserts that SDP cannot take

a position contrary to that it took in prosecuting a parent application and now argue that the "sliding base" in Tsao '018 is not materially different from the corresponding structure in Tsao '044.

NMT also argues that the discoidal part in the syringe barrel taught in the Batlle patent, which "slidingly receive[s][and] circumferentially surround [s][the] enlarged head of [the] needle," is also materially different from the Tsao '018 disclosure, because the Batlle patent teaches that the discoidal part has flexible appendages, unlike either Tsao '018 or the '952 patent. Defs.' Mem. in Opp'n, at 33 (citing Battle Patent, col. 3, *ll*. 16-18).

Taking this evidence together, NMT avers that although other features in Tsao '018 were similar to those in Tsao '044 and to those in the Batlle patent, Tsao '018 was materially different in the context of prosecution of the '952 patent because Tsao '018 disclosed a more complete combination of relevant features. Defs.' Mem. in Opp'n, at 31-33 (citing Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 (Fed.Cir.1995) (affirming a trial court's finding that an undisclosed piece of prior art was material because it disclosed more relevant features than cited items); Semiconductor Energy Lab. Co. v. Samsung Elec. Co., 2000 WL 233253, (Fed.Cir. Mar. 2, 2000) (upholding a trial court's determination that an undisclosed piece of prior art was material, in part, because it contained a more complete combination of the elements claimed in the patent at issue than any of the cited references)).

The Court agrees with NMT that it appears likely that Tsao '018 makes a more complete disclosure of the relevant elements of the '952 patent than Tsao ' 044. In addition, NMT has pointed to facts that also suggest that the disclosure for a deformable base in Tsao '018 was more similar to the disclosure in the '952 patent than the disclosure for a similar part in the Batlle patent. It appears from a review of the Batlle patent that the disclosure for a deformable base and its function in the device in that patent is more complicated than the disclosure in either Tsao '018 or the '952 patent. *See* Batlle Patent, col. 2, *ll*. 5-26; id. col. 2, *ll*. 62-64; id. col. 3, *ll*. 7-36.

However, SDP does point out that Tsao '018 and the '952 patent had the same primary examiner. Arguably then, Tsao '018 was *defacto* before the examiner during prosecution of the '952 patent. But, if the '952 patent examiner had in fact considered Tsao '018 when reviewing the '952 patent, he would have cited that reference; he never cited Tsao '018.

At the very least, NMT has raised a material question of fact about whether Tsao '018 was cumulative or not to prosecution of the '952 patent. Taking the facts in the light most favorable to the nonmovant, NMT, the Court finds NMT's evidence is enough to overcome the presumption that the PTO considered the '952 patent non-obvious over Tsao '018 alone.

The Court notes that NMT apparently does not argue that the PTO failed to consider the Gaarde patent when it issued the '952 patent. NMT does argue that the applicants may have misrepresented the teachings of Gaarde to the PTO. Therefore, although the presumption that the PTO found the '952 patent non-obvious over the Gaarde patent still applies, the Court considers the misrepresentation as evidence that helps rebut the presumption of validity.

2.-The Prior Art & Differences Between the '952 Patent & the Prior Art-Turning now to the merits of the parties' arguments about the scope and content of Tsao '018 and the Gaarde patent, the Court is persuaded that a reasonable jury could find by clear and convincing evidence that the subject matter of the '952 patent was disclosed in Tsao '018 and the Gaarde patent.

In discussing the content of Tsao '018 for purposes of examining NMT's anticipation argument, the Court agreed with NMT that Tsao '018 clearly teaches the elements of (a) a syringe barrel, (b) a plunger movable within said barrel, (c) a needle assembly attached to an end of a syringe barrel and defining a passageway therethrough, (d) a deformable base positioned within the syringe barrel, adjacent to the needle assembly, and defining a passageway therethrough, (e) an energy storage means, and (f) an enlarged needle head on the needle within the passageway of the deformable base.FN11 The Court also agrees that the elements of Tsao '018 teach the following elements of claim 26 in the ' 952 patent:

FN11. These elements are taken from the '952 patent claim 38. ' 952 Patent, col. 16, *ll*. 15-26.

a barrel having a first end and an opposite second end;
a plunger having a forward end and movable within said barrel from said second end of the barrel towards said first end, the plunger having a hollow interior communicating with said forward end;

a deformable base within said barrel intermediate said first and second end;

a hollow needle having a pointed front, said needle extending through said first end of said barrel and a rear end received within and supported by said deformable base;

energy storage means positioned in said barrel between said first end said deformable base and in engagement with said needle;....

'952 Patent, col. 14, *ll*. 50-64. *See also* Tsao '018 Patent, col. 4, *ll*. 7-40.
Similarly, Tsao '018 teaches that the syringe is designed to retract a needle upon completion of an injection, similarly to the process described in the ' 952 patent. *See, e.g.,* id. In Tsao '018, the retraction process is accomplished by sliding the plunger

towards the front end of the barrel [of the syringe], the front end of the plunger and sealing element engage the sliding base and locking tip to displace the sliding base and locking tip [of the needle] in opposite directions and also displace sealing element, so that continued movement of the plunger towards the front end of the barrel causes the needle cannula, locking tip and sealing element to be disposed within the interior space of the plunger.

Id. col. 4, *ll*. 31-40. Clearly this passage describes a) a process for retracting a needle of a hypodermic syringe after completion of an injection, b) "forcing a plunger of a syringe downwardly within said syringe to force a deformable base engaging a head of said needle downwardly around said head [,]" c) "forcing and end portion of said head" to displace a plunger sealing element, and d) "propelling said needle into a hollow of said plunger." '952 Patent, col. 15, *ll*. 22-30 (elements of claim 30).

The sealing element discussed in Tsao '018 is broadly claimed; however, it is clear that the action disclosed by the patent claims and the specification is a "displace[ment]." *See* id. col. 3, *ll*. 19-21 ("Consequently, the locking tip [of the needle] (34) and the cork [or sealing element] (56) are displaced and fall into the interior space of the plunger (50)."); id. col. 2, *ll*. 23-26 ("The plunger (50) has a cork element (56) at its front end and seal [sic] the open end (14) of the barrel (12) to form a tightly closed space within the barrel (12)."); id. col. 2, *ll*. 49-61 ("By the upward pushing force from the plunger (50), the locking tip [of the needle] (34)

reacts and push [sic] the cork (56) out of the open end (54) of the plunger (50).... [The needle and locking tip] are brought into the internal space of the plunger (50) through the open end (54) formed by the displaced cork (56)."); id. col. 4, *ll*. 35-36 ("also displace the sealing element, so that continued movement...."). The Court is persuaded that this element of Tsao '018 is the major difference between Tsao '018 and the '952 patent's claims 26, 30 and 38.

Even if the cork or sealing element in Tsao '018 is considered a web, Tsao ' 018 teaches that the element is displaced such that it becomes "disposed within the interior space of the plunger." Id. col. 4, *ll*. 38-40. This language connotes a "breaking away;" an action that the patent examiner and the Court construed to be different from the tearing action disclosed by the '952 patent. The Court construed "tear" to mean "to separate a material into portions by force to create an opening therein, without a complete breaking away." Part III.A.3. In other words, "tear" in the context of the '952 patent means a "breaking through" or "breaching" rather than a "breaking away." Therefore, although Tsao '018 teaches many of the elements described in the ' 952 patent, it does not appear to teach a rupturable web that tears.

In addition to the structural and process elements in Tsao '018, the patent also teaches the importance of retracting the needle of a syringe "to assure the safety of medical personnel and prevent reuse of the used syringe." Id. col. 1, *ll*. 14-15. In addition, Tsao '018 teaches the importance of having close contact between the sliding base or deformable base and a plunger in a barrel to prevent residue of medicine in the syringe barrel after injection. Id. col. 1, *ll*. 29-32. Finally, another object of Tsao '018 is to provide a simple structure to permit mass production of the device at a low cost. Id. col. 1, *ll*. 33-36.

These teachings in Tsao '018 are nearly identical to those of the '952 patent. Specifically, the '952 patent discloses at least five objectives: 1) minimize the likelihood of accidental puncture; 2) isolate the used needle to render it harmless and prevent its reuse; 3) provide a syringe with those features that is operable with only one hand; 4) seal the needle within the body of the syringe to prevent leakage of residual fluids; and 5) provide a simple device capable of manufacture in high volumes. '952 Patent, col. 1, *ll*. 50-67. The only one missing from Tsao '018 is providing a syringe with the other four features that is operable with one hand. This features seems implicit, however, in the manner in which Tsao '018 works.

The Gaarde patent also teaches similar objectives to that of the ' 952 patent. The Gaarde patent discusses the importance of designing a disposable syringe for single use and retraction of the needle for containment inside the syringe. Gaarde Patent, col. 1, *ll*. 19-22. In other words, the syringe design should make retraction of the needle quick and reliable such that the syringe cannot be used again. *See* id. col. 1, *ll*. 43-46. Moreover, the Gaarde patent teaches that reducing the number of parts in the syringe will both simplify manufacture and reduce manufacturing costs. Id. col. 1, *ll*. 37-42 (discussing the disadvantages of the prior art U.S. Patent No. 4,650,468); id. col. 2, *ll*. 1-4 (discussing reduction of parts as a way to reduce costs); id. col. 2, *ll*. 7-10 (discussing the simplicity of using a standard spring to achieve the desired needle retraction). Finally, the Gaarde patent states that one of its objectives is to provide a safety syringe that is easy to use such that no directions are required to achieve its benefits. Id. col.1, *ll*. 52-55. Again, like the comparison with the objectives of Tsao '018, it seems that the only objective that the Gaarde patent is missing from those stated in the '952 patent is "usable with a single hand." However, this objective also seems implicit in the structure and design of the Gaarde patented device.

Looking at the scope and content of the Gaarde patent, it clearly teaches a retractable needle syringe structure; a structure that the parties agree on in large part. As discussed above, the parties agree that Gaarde discloses a packing and membrane structure that fits over the open end of the plunger. Id. col. 4, *ll*. 36-39;

id. Fig. 3. The parties agree that a membrane is a type of web. Defs.' Exh. 16, Pressly Dep., at 51; Defs.' Exh. 22, Ellis Dep., at 139. In addition, when the plunger or piston is depressed in the Gaarde patented device, the head of the needle "puncture[s] or destroy[s]" the membrane so that the needle can be displaced into the cavity of the plunger. Gaarde Patent, col. 3, *ll*. 29-33; Pls.' Resp., para. 55.

SDP argues that Figure 3 of the Gaarde patent shows that cutting surfaces on the end of the plunger or piston of the device would cut the membrane, or web, rather than the needle head "punctur[ing] or destroy[ing]" the membrane; therefore, there is no rupturable web that tears disclosed in the Gaarde Patent. Pls.' Reply, at 10. But, SDP admitted for purposes of summary judgment that the needle head of the Gaarde patented device would "puncture or destroy" the membrane. Pls.' Resp. para. 55. Moreover, it is clear from the claims and specification of the Gaarde patent that it discloses a part that functions similarly to the '952 patent's rupturable web.

The Gaarde patent teaches that the plunger or piston of a hypodermic syringe can be fitted with "piston packing ... for sealing [the] liquid chamber [of the syringe] and for covering [the] piston cavity .... wherein [the] piston packing contains a membrane to cover [the] piston cavity." Gaarde Patent, col. 4, *ll* .37-42. The Gaarde patent also discloses that the head of the needle will "puncture or destroy the membrane 15 so that the needle 1 is displaced up into the cavity 9 in the piston...." Id. col. 3, *ll*. 29-32.

The Court construed rupturable web to mean "a material of certain thickness that will tear or puncture when an out-of-plane force is applied against it." Part III.A.1. It is clear that the membrane described by the Gaarde patent is material of certain thickness that will puncture when an out-of-plane force is exerted against it. In addition, "tear" in the context of the '952 patent was construed to mean "to separate a material into portions by force to create an opening therein, without a complete breaking away." Part III.A.3. From the description of the Gaarde patent embodiment, it is likely that the membrane would separate into portions, without completely breaking away, when the needle head is forced against it such that an opening is created to allow the needle to pass through. In addition, the description of the Gaarde patent embodiment states that the membrane is either "puncture[d] *or* destroy [ed]," which conveys that the membrane could be structured to either separate into portions or be shattered into indistinguishable pieces. Although the concept of "destroy[ed]" is not taught by the '952 patent, the concept of "puncture[d]" is clearly taught by the '952 patent. For purposes of this analysis, it is clear that the Gaarde patent discloses a web that could tear. As a result of these findings, SDP's argument that the Gaarde patent does not disclose a rupturable web is unpersuasive.

The most obvious difference between the Gaarde patented device and that disclosed in the '952 patent is the structure holding the needle head. The Gaarde patent discloses a "yielding end wall" in the syringe barrel that contains an opening that is smaller than the needle head. Gaarde Patent, col. 4, *ll*. 4-7. A spring keeps enough pressure against the needle head to create a liquid-tight seal between the needle head and the yielding wall. Id. col. 4, *ll*. 8-13. When the syringe plunger is pushed forward onto the yielding wall with enough pressure, the needle head passes through the opening in the wall and into the hollow of the plunger on the other side of the wall. Id. col. 4, *ll*. 14-18.

Arguably, it is a stretch to find that the yielding wall discloses a deformable base as taught by the '952 patent. The Court construed the term "deformable base" in the '952 patent to mean "a portion of a syringe that is made of a material that can move down around a needle head when pressure is applied against it, that substantially houses, matingly engages or locks a portion of a syringe needle head, and that forms a liquid-tight seal between the needle and the syringe barrel." Part III.A.2. Clearly the Gaarde patent's yielding wall

is made of a material that can move down around a needle head when pressure is applied against it. However, it is questionable whether the yielding wall "substantially houses, matingly engages or locks a portion of a syringe needle head." Certainly the yielding wall and the needle head are matingly engaged, but to use the word "substantially" to describe the engagement reaches too far. In addition, the yielding wall and the needle head do form a liquid-tight seal between the needle head and the syringe barrel. But the Gaarde patent teaches that the seal is created not because of any property of the yielding wall itself; the seal is created because of the force of the spring against the head of the needle holding the needle in place. Gaarde Patent, col. 4, *ll*. 8-13.

The Court finds that a reasonable jury could conclude that NMT has proven by clear and convincing evidence that Tsao '018 in light of the Gaarde patent discloses each element of claims 26, 30 and 38 of the '952 patent. However, that does not end the inquiry. The Court must look at whether NMT has provided a reason, suggestion or motivation to combine the devices described in Tsao '018 and the Gaarde patent.

3.-Reason, Suggestion or Motivation to Combine the Prior Art-The Federal Circuit has stated that part of the *prima facie* case for obviousness is determining whether there is a reason, suggestion or motivation to make a combination of two prior art references. *See* Ecolochem, Inc. v. Southern Cal. Edison Co., 227 F.3d 1361, 1371-72 (Fed.Cir.2000); *see also* Ruiz, 234 F.3d at 665. The party challenging validity must establish such reason, suggestion or motivation by clear and convincing evidence. *See* Ecolochem, 227 F.3d at 1371-72. The Federal Circuit states that rigorous application of this requirement is "the best defense against hind-sight based [sic] obviousness analysis." Id. at 1371. *See also* Ruiz, 234 F.3d at 664-65 ("In order to prevent a hindsight-based obviousness analysis ... the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references."). A court may find such motivation or suggestion

explicitly or implicitly: 1) in the prior art references themselves; 2) in the knowledge of those of ordinary skill in the art that certain references, or disclosures in those references, are of special interest or importance in the field; or 3) from the nature of the problem to be solved, "leading inventors to look to references relating to possible solutions to that problem."

Ruiz, 234 F.3d at 664 (quoting Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1572 (Fed.Cir.1996) (internal citations omitted in original)).

NMT makes two arguments in this regard. First, NMT argues that the teachings in Tsao '018 and the Gaarde patent themselves implicitly suggest that a combination would be desirable. Defs.' Mem. in Opp'n, at 28-29. NMT avers that the Gaarde patent teaches a boot at the end of the syringe plunger, comprised of a packing material designed with a thin membrane that surrounds the end of a syringe plunger. *Id*. at 28 (citing Gaarde Patent, col. 3, *ll*. 17-20). The so called boot is advantageous because it seals the inner cavity of the plunger and forms a seal between the plunger and the interior wall of the barrel. *See id*. at 28-29. In addition, the Gaarde patent teaches that reducing the number of parts to simplify production and reduce assembly costs would be advantageous. *Id*. at 29 (citing Gaarde Patent, col. 1, *ll*. 37-42; *id*. col. 1, *ll*. 65-67 to col. 2, *ll*. 1-4). NMT suggests that one of ordinary skill in the field would look at Tsao '018 with its two piece arrangement on the plunger end (a sealing element or cork, and a stopper element), and see an advantage in using the Gaarde patent's "boot" design to simplify production and reduce assembly costs of the Tsao '018 design. Id.

SDP argues, without citation to evidence supporting its claim, that the motivation suggested by NMT to simplify production and reduce assembly costs "is suspect in view of the fact that the boot would need to have a weakened portion ... which further complicates manufacture." Pls.' Reply, at 11. In addition, SDP counters that NMT's arguments are insufficient because the combination of the two references that NMT suggests would result in an unworkable syringe that would not motivate anyone of ordinary skill in the art to make it. Id. at 11-12. SDP argues that without the cork element of Tsao ' 018, the plunger would not have a surface capable of moving the Tsao '018 deformable base down in order to trigger release of the spring. Id. (citing Tsao '018, Fig. 1).

The Court finds NMT's argument persuasive. Each of the patents the Court is considering for the obviousness discussion, including the '952 patent itself, discusses the importance of keeping the cost of the product reasonable. It follows that a person of ordinary skill in the field would look for ways to decrease the costs of manufacturing such a device. Further, it follows that reducing the number of parts in a safety syringe, as suggested by the Gaarde patent, would be one way to reduce production costs. Moreover, whether the boot would necessarily need a weakened portion, as SDP suggests, in order for the boot to "tear," and whether such a piece would complicate manufacture are facts without support in the record. Therefore, taken in the light most favorable to NMT, a single piece at the end of the plunger in place of the two in Tsao '018, could potentially simplify manufacture and reduce production costs.

In addition, SDP's argument that the design NMT suggests would not work is also a question of fact. As NMT points out, in light of Tsao '018's disclosure that "the front end of the plunger and sealing element engage the sliding base and locking tip [of the needle] to displace the sliding base and locking tip ... and also displace the sealing element," it is quite possible that SDP's assertion is wrong. Tsao '018 Patent, col. 4, *ll*. 32-36 (portion of claim 1, element (f)). Tsao '018 discloses that both the sealing element and the front end of the plunger engage the sliding base. Arguably, it is the wall of the plunger that pushes the sliding base off the needle head, not the sealing element. The figure that SDP points to also seems to suggest this is the intended function of the Tsao '018 patented device. Taken in the light most favorable to NMT, there is certainly a question of material fact on whether the teachings inherent in Tsao '018 and the Gaarde patent would make obvious the ' 952 patented invention.

NMT's second argument bolsters the argument that Tsao '018 and the Gaarde patent themselves suggest that the combination is desirable. NMT asserts that the nature of the problem to be solved, in light of the crowded field would motivate one of ordinary skill at the time of the invention to combine the cited references. Defs.' Mem. in Opp'n, at 29-30. NMT avers that " '[w]here the claim elements "are all shown in the cited references in various subcombinations, used in the same way, for the same purpose as in the claimed invention," and where the references are all from the same pertinent art or field of endeavor as the claimed invention, a strong case for obviousness is made.' " Id. at 29-30 (quoting Nordberg Inc. v. Telsmith, Inc., 881 F.Supp. 1252, 1295 (E.D.Wis .995), *aff'd,* 82 F.3d 394 (Fed.Cir.1996) (quoting In re Gorman, 933 F.2d 982, 987-88 (Fed.Cir.1991)). In this case, NMT argues, the field of retractable needle safety syringes was crowded with multiple references. *Id*. at 29. Further, the inventors were all concerned with the same, specific problem: Retracting the needle of a syringe after usage of it for purposes of safety. *See id*. Therefore, NMT asserts that one of ordinary skill in the art would be motivated to combine the references. *Id*. at 30.

The Court agrees with NMT that there were multiple references that disclosed the same or similar elements in various subcombinations to achieve the same purpose as the '952 patent. In addition, the Court takes notice of the line of case law that holds that such references, when they teach toward the combination rather

than away from it, can substantiate a claim of obviousness. *See* In re Gorman, 933 F.2d 982, 987-88 (Fed.Cir.1991); Nordberg Inc. v. Telsmith, Inc., 881 F.Supp. 1252, 1295 (E.D.Wis .995), *aff'd,* 82 F.3d 394 (Fed.Cir.1996). In this case, the other references clearly teach toward the combination; particularly with reference to reducing the number of parts to simplify production and lower manufacturing costs. This fact certainly bolsters NMT's argument that the motivation to combine Tsao '018 with the Gaarde patented device would have been obvious to one of ordinary skill in the art of safety syringe design who reviewed the plethora of patents in the field.

SDP counters that the combination that NMT suggests could not have been very important to a person of ordinary skill in the field at the time of the invention because Tsao made an improvement to his safety syringe design embodied in Tsao '044, but did not incorporate a different element on the plunger. Pls. Br. on Summ. J ., at 25-28. The difference between Tsao '044 and Tsao '018 is primarily in the deformable base and needle assembly portions of the devices. *Compare* Tsao '044 Patent, col. 4, *ll*. 55-59 *to* Tsao '018, col. 4, *ll*. 23-30. Therefore, SDP concludes, the combination of Tsao '018 and the Gaarde patent was not obvious to one skilled in the field of safety syringes at the time of the '952 invention because Tsao did not make an improvement in the cork element of his Tsao '044 device at the same time he improved the deformable base and needle assembly elements. Apparently SDP is arguing that because Tsao was not motivated to improve his design by incorporating the packing and membrane element of the Gaarde patent's design, no one else would have been motivated to make the change either.

The Court is not convinced that if Tsao himself was not motivated to make the change that NMT suggests, then no one would have been motivated to make it. The examiner who investigated the '952 patent found obvious the invention therein with its rupturable web or end that ruptures, when rupture meant "to break." *See* Defs .' Exh. 7, App. No. '007 & App. No. '001, at 39-82. He found the invention obvious in light of the Batlle patent and the Botich patent, where the Batlle patent disclosed a discoid button on the end of a plunger and the Botich patent disclosed a frangible end on the plunger. *See* Batlle Patent, col. 3, *ll*. 37-40; Botich Patent, col. 5, *ll*. 6-20; id. col. 7, *ll*. 19-39; id. col. 12, *l*. 65 to col. 13, *l*. 14; id. col. 14, *ll*. 1-4. Given that the safety syringe field was crowded with patents disclosing various elements for the plunger end and the needle assembly, NMT has raised a question about whether the patent examiner would have found obvious the '952 patented invention if he had specifically reviewed Tsao '018 and if the applicants had represented correctly the Gaarde patent disclosure of a plunger end that "puncture[s]." There appears to be little difference between a "frangible" end and a "punctur[able] or destroy[able]" end. In other words, if the patents with the dislodgable and disassociable ends made the rupturable web's breaking obvious, then the disclosure of a membrane that punctures is likely to make a rupturable web's tearing obvious.

Moreover, with the field crowded with other examples, the problems associated with a cork-like element in Tsao '018, or even with a yielding wall element in the Gaarde patent could have made the combination of the prior art's advantages obvious to one of ordinary skill in safety syringe design. This finding is supported by the consistent recitation of objectives in Tsao '018, the Gaarde patent and the '952 patent. Clearly, those of ordinary skill in the art at the time of the invention were all looking for ways to maximize the functionality of the syringe for delivering accurate dosages of medication, while solving the accidental needle puncture and reuse issues as cost effectively as possible. Therefore, it is more likely than not that one of ordinary skill in safety syringe design would look to prior art to solve the common problems.

Combining NMT's two theories for motivation or suggestion to combine, the Court finds that a reasonable jury could conclude that the prior art teachings and the crowded nature of the field would motivate one of ordinary skill in safety syringe design to combine Tsao '018 and the Gaarde patent. Taken together with the

Court's findings on the other elements of a *Graham* analysis, the Court finds that NMT has made a *prima facie* case for obviousness of claims 26, 30 and 38 under the clear and convincing standard and in light of the presumption that the '952 patent is valid. As a result, SDP's motion for summary judgment on the obviousness issue should be DENIED.

C. *Inequitable Conduct*

The defense of inequitable conduct arises from the patent applicant's duty to prosecute patent applications with candor, good faith, and honesty. *See* Semiconductor Energy, 204 F.3d at 1373 (citing Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed.Cir .1995)). " '[I]nequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.' " *Id*. (quoting Molins, 48 F.3d at 1178). The challenger to the patent's enforceability must demonstrate by clear and convincing evidence that the information was material and that the conduct was intended to deceive. *See id* . A district court faced with an inequitable conduct defense must make two threshold determinations: whether the withheld references or misrepresentations satisfy a threshold level of materiality; and whether the applicant's conduct satisfies a threshold showing of intent to deceive. *See id*. If the evidence supports an affirmative finding on each of these elements, then the "court balances materiality and intent to determine whether the equities warrant the conclusion that inequitable conduct occurred." *Id*. The question for the court is "whether the applicant's conduct is so culpable that the patent should not be enforced." *Id*.

NMT asserts that in prosecuting the '952 patent's ancestor application, the '115 application, the applicants materially misrepresented the disclosure in the Gaarde patent. Specifically, in reviewing the '115 application, the patent examiner rejected claim 13 "under 35 U.S.C. s. 102 (a or e) as being anticipated by Tsao, McGary et al. [sic] or Gaarde." Defs.' Exh. 2, '115 App., at 34-35. Claim 13 of the '115 application read:

A process for retracting a needle at the completion of subcontaneous [sic] injection with a hypodermic syringe, comprising the steps of:

forcing a plunger of said syringe downwardly to force a needle support deformable base downwardly and sever sacrificial supports;

forcing and end portion of said needle to penetrate a base portion of the syringe and plunger; and

propelling said need into the hollow of said plunger.

Id. at 23. In defending the claim, the applicants responded by stating, in pertinent part:

[I]t does not appear that any part of the integrity of the piston taught by Gaarde is broken or ruptured. As rupture requires breaking through an element, Applicant's [sic] claim 13, as presently claimed, is distinguishable over the teachings of Gaarde by Applicant's [sic] specific feature of rupturing the base portion of the plunger.

Id. at 46. NMT asserts that this statement is clearly misleading because the Gaarde patent teaches that the head of the needle "puncture[s] or destroy [s]" the membrane of the packing component that covers the base portion of the plunger. Defs.' Mem. in Opp'n, at 34 (citing Gaarde Patent, col. 3, *ll*. 29-35). Moreover, NMT argues that the applicants never cited the Gaarde patent during prosecution of any subsequent applications,

even though they repeated the citations of other previously disclosed prior art. *Id*.

In addition, NMT argues that the '952 patent applicants failed to cite the '007 application to the patent examiner as well as other relevant prior art. Id. at 34-35 (citing '952 Patent, at 1). NMT suggests that this was material because the inventors negotiated with the patent examiner over the terms "rupture" and "tear" during prosecution of the '007 application, which apparently is the primary distinguishing feature of the patent over the prior art. Other prior art that the applicants failed to cite included Tsao '044, Tsao '018 and the McGary patent. *See id*. at 35. NMT avers that these references were material because the examiner cited them. *See* Defs.' Exh. 2, ' 115 App., at 35.

Based on these facts, NMT contends that issues of fact preclude summary judgment on inequitable conduct.

SDP contends that NMT's argument does not meet the threshold requirement of showing both materiality and intent by clear and convincing evidence. Pls.' Reply, at 3. First, SDP avers that the patent examiner did review all of the sources cited by NMT, except Tsao '018, during prosecution of the '952 patent or its predecessor applications. SDP asserts that having cited the references in the original application, it did not need to recite them in subsequent, related applications. Id. at 4-5 (citing ATD Corp. v. Lydall, Inc., 159 F.3d 534, 547 (Fed.Cir.1998)).

Further, SDP argues that NMT points to no evidence that anyone at SDP knew about Tsao '018 during prosecution of the '952 patent so that it could be cited as relevant prior art. Id. at 5. SDP asserts that Tsao '018 was not discovered by SDP until NMT made it aware of the reference after this law suit was filed. Id. Therefore, SDP argues that NMT's argument for inequitable conduct fails because there is no clear and convincing evidence of intent to deceive. Id. at 5-6. In addition, SDP avers that NMT proffers no evidence that the misstatements about the Gaarde patent or the failure to cite Tsao '018 were made with the specific intent to deceive the patent examiner. Id. at 6-7. Without this evidence, SDP asserts, NMT's accusation of inequitable conduct must fail.

The Court agrees with SDP. Although the evidence NMT presents that the applicants may have misrepresented the teaching in the Gaarde patent is troubling, particularly in light of the materiality of the misrepresentation, there is little evidence from which the Court could conclude that SDP or the inventors intended to deceive the patent office. As SDP points out, a finding of deceptive intent cannot be based on mere inference of negligence or that information was misrepresented or undisclosed. *See* Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed.Cir.1996). NMT relies solely on the facts of a misrepresented patent disclosure and failure to cite relevant prior art as the basis for its inequitable conduct defense. Apparently, NMT would rely on the fact that some prior art was cited more than once to the PTO, but the Gaarde patent was not, as circumstantial evidence of an intent to deceive. This is not enough evidence to meet the clear and convincing threshold on this element. Therefore, NMT has failed to carry its burden of establishing by clear and convincing evidence that a material issue of fact exists on its allegations of inequitable conduct. For these reasons, SDP's motion for summary judgment on the inequitable conduct issue should be GRANTED.

IV. *CONCLUSION*

For the reasons discussed at length above, the Court hereby DENIES the Plaintiffs' motion for summary judgment on infringement, GRANTS the Plaintiffs' motion for summary judgment on anticipation and inequitable conduct, but DENIES the Plaintiffs' motion for summary judgment on obviousness. Furthermore,

the Court hereby GRANTS the Defendants' motion for summary judgment on noninfringement, literally and under the doctrine of equivalents.

In addition, the Court has ruled on the various related motions of the parties as follows: Defendants' motion to strike evidence designated by Plaintiffs in support of Plaintiffs' motion for summary judgment is DENIED in part and GRANTED in part; Plaintiffs' motion to strike Defendants' "rebuttal expert" Klod Kokini is DENIED; Plaintiffs' motion to strike portions of Defendants' surreply to Plaintiffs' response to Defendants' statement of material facts is DENIED; and Plaintiffs' motion to strike certain portions of the expert reports submitted by Defendants is DENIED as moot.

IT IS SO ORDERED this-day of February, 2001.