United States District Court,
M.D. Florida, Orlando Division.

ABP PATENT HOLDING, LLC,
Plaintiff.
v.
CONVERGENT LABEL TECHNOLOGY, INC., and MOORE NORTH AMERICA, INC,
Defendants.

No. 6:00CV1087-ORL-22JGG

Jan. 25, 2002.

Owner of patents for pharmacy form sued competitor for infringement. Parties cross-moved for summary judgment. On objections to the report and recommendation of James G. Glazebrook, United States Magistrate Judge, the District Court, Conway, J., held that: (1) representations made by plaintiff during patent prosecution effectively limited scope of claims so as to require that form's main label be connected to at least one auxiliary label, and (2) patents were not infringed by accused forms on which main label was not connected to any auxiliary labels, regardless of whether accused forms' auxiliary labels were connected to each other.

Plaintiff's motion denied; defendant's motion granted in part and denied in part.

6,036,231. Cited.

Stephen D. Milbrath, Herbert L. Allen, Brian R. Gilchrist, Allen, Dyer, Doppelt, Milbrath & Gilchrist, P.A., Orlando, FL, for ABP Patent Holding, LLC, a Florida Limited Liability Company, plaintiffs.

R. Steven Ruta, Victor L. Chapman, Barrett, Chapman & Ruta, P.A., Orlando, FL, John M. Kilroy, Jr., Shughart Thomson & Kilroy, Gardiner B. Davis, Teresa A. Woody, Richard P. Stitt, Kansas City, MO, Mark E. Brown, Shughart Thomson & Kilroy, P.C., Overland Park, KS, Jeffry H. Nelson, Robert A. Molan, Sheri L. Gordon, Nixon & Vanderhye, P.C., Arlington, VA, James H. Beusse, Beusse, Brownlee, Bowdoin & Wolter, P.A., Orlando, FL, for Convergent Label Technology, Inc., a Florida corporation, Moore North America, Inc., a Delaware corporation, defendants.

ORDER

CONWAY**, District Judge.**

This cause comes before the Court on the following motions: Defendants' Joint Motion to Construe U.S. Patent No. 5,642,906 (Doc. 80); Plaintiff's Motion for *Markman* Hearing (Doc. 83); Defendants' Joint Motion to Construe U.S. Patent No. 5,855,395 (Doc. 86); Plaintiff's Motion for Summary Judgment (Doc.

106); Defendants' Motion for Summary Judgment of Non-Infringement (Doc. 119); Defendants' Motion for Summary Judgment of Invalidity for Prior Art (Doc. 111); and Defendants' Motion for Summary Judgment of Patent Invalidity Under 35 U.S.C. s. 102(f) and s. 112 (Doc. 116).

I. BACKGROUND

Plaintiff, ABP Patent Holdings LLP ("ABP"), is the assignee of three patents, U.S. Patent No. 5,642,906 ("the '906 Patent"), U.S. Patent No. 5,855,395 ("the '395 Patent"), and U.S. Patent No. 6,036,231 ("the '231 Patent"). ABP filed this action alleging that Defendants, Convergent Label Technology, Inc. ("Convergent") and Moore North America, Inc. ("Moore"), infringed the aforementioned patents. FN1 The parties filed the instant motions asking the Court to construe certain claims in each patent. On October 17, 2001 and October 24, 2001, Magistrate Judge James Glazebrook held a *Markman* hearing on the instant motions. At the hearing, the parties agreed that the '231 patent does not require interpretation by the Court.

FN1. ABP and Moore have since reached a settlement and entered into a consent judgment. See Doc. 214. As a result of that judgment, Moore is no longer a party to this action. The Court will, therefore, only address the issues as they pertain to Convergent.

ABP's patents concern an efficient method of labeling prescription drug vials. The patents disclose pharmacy forms having labels upon which prescription information may be printed. The labels can then be simultaneously removed by a pharmacist, separated from each other if necessary, and then simultaneously applied to a prescription bottle. Additionally, ABP's pharmacy forms have a backing sheet to which the labels adhere. The labels are connected to each other by perforations that allow the labels to be readily separated from each other before being applied to the prescription bottle.

Convergent supplies pharmacy label forms to various pharmacies, in competition with ABP. ABP's Complaint alleges that Convergent has infringed or induced infringement of certain claims in the '906 and '395 patents. Convergent contends that during the prosecution of the patents, ABP limited the scope of its claims. Convergent therefore asks that the Court construe Claim 1 of the '906 patent and Claim 17 of the '395 patent to require that the main label of ABP's form be connected to the auxiliary labels on the form. FN2 ABP argues that the disputed claims merely require that *any* two labels on the form be connected.

FN2. ABP's Complaint asserts a claim for infringement of Claim 19 of the '395 Patent. However, Claim 19 is dependent on Claim 18, which is dependent on independent Claim 17. Therefore, the parties ask the Court to construe Claim 17.

After conducting a *Markman* hearing and reviewing the parties' memoranda and supporting evidence, Judge Glazebrook issued a Report and Recommendation ("R & R") in which he determined that both Claim 1 of the '906 patent and Claim 17 of the '395 patent should be construed to require that the main and auxiliary labels of ABP's form be connected. ABP filed objections to the R & R; those objections are now ripe for review.

Additionally, the parties have filed cross-motions for summary judgment which are also ripe for review.

II. MOTIONS TO CONSTRUE PATENTS

A. Standard of Review

After a magistrate judge issues a report and recommendation, the district judge must make a *de novo* determination of the findings and/or recommendations to which any party objects. 28 U.S.C. s. 636(b)(1). After reviewing the R & R, objections, and response thereto, the district judge "may accept, reject, or modify, in whole or in part," the findings or recommendations made by the magistrate. Id.

B. DISCUSSION

ABP raises essentially two objections to the R & R. First, it contends that Judge Glazebrook impermissibly added language to the disputed claims, in effect, rewriting them. Second, ABP argues that Judge Glazebrook incorrectly concluded that ABP disavowed subject matter otherwise available in the disputed claims.

[1] Before the Court undertakes an analysis of the disputed claims, it must address ABP's contention that Judge Glazebrook added language to its claims. The Court believes that Judge Glazebrook took no such steps. The motions filed by both ABP and Convergent requested that the Court construe the disputed claims. It is well settled that the task of claim construction permits and requires the Court "neither to limit nor to broaden the claims, but to define, as a matter of law, the invention that has been patented." Netword, LLC v. Centraal Corporation, 242 F.3d 1347, 1352 (Fed.Cir.2001). In the R & R, Judge Glazebrook determined that the phrase "one of the labels" should be understood to mean the "main label." He further determined that the phrase "another label" referred to the "auxiliary label." In coming to these conclusions, Judge Glazebrook did not "add" to the language of the claims. Rather, he defined those arguably ambiguous terms in a manner that he believed to be consistent with the patent specification and the prosecution history. As such, ABP's objection on the grounds that Judge Glazebrook impermissibly added language to the claims is without merit.

1. The '906 Patent

Turning now to the actual construction of the claims, the Court first addresses ABP's objections to the R & R's treatment of Claim 1 of the '906 patent.

Claim 1 reads in its entirety:

A method for use by a pharmacist in labeling a container for a prescription drug to be dispensed to a customer, comprising the steps of:

I. providing blank form for printing on at least one label to be affixed to the container, the form comprising:

(a) at least two labels releasably adhered to a backing sheet, each of said labels being provided with a printable surface upon which may be printed information relating to the prescription drug;

(b) adhesive means on the surface of each of said labels that is opposite the printable surface for affixing said labels to said container; and

(c) means for connecting said labels such that:

(1) the removal of one of the labels from the backing sheet will simultaneously remove from the backing sheet the other label to which it is connected; and

(2) the two removed labels optionally may be readily separated from each other prior to affixing any of said labels to said container;

II. printing information concerning a prescription on at least one of said labels;

III. simultaneously removing from the backing sheet at least said two labels; and

IV. affixing at least one of said two labels to said prescription drug container.

Defendants' Exhibit 2 at Tab U.S. Patent 5,642,906, MNA 000119.

ABP argues that the language of Claim 1 is not ambiguous, and must therefore, be given its plain and ordinary meaning, which is *not* limited in scope to a pharmacy form in which the main and auxiliary labels are connected. Convergent contends that both the patent specification and prosecution history of the '906 patent make it clear that the claims "are directed to a prescription pharmacy label having a main prescription label connected by tear lines to auxiliary warning labels." Doc. 81 at 9.

[2] The starting point for the Court's analysis of Claim 1 is the actual language of the claim. It is well-settled that, "as a general rule, all terms in a patent claim are to be given their plain, ordinary and accustomed meaning to one of ordinary skill in the relevant art." Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 2001 WL 1456191 at (Fed.Cir.) (quoting Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed.Cir.1999)). Ordinarily, "there is 'a heavy presumption' in favor of the ordinary meaning of claim language" Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed.Cir.2001) (quoting Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999)). However, that presumption can be overcome: "(1) where the patentee has chosen to be his own lexicographer, or (2) where a claim term deprives the claim of clarity such that there is 'no means by which the scope of the claim may be ascertained from the language used.' " *Id*. ABP argues that neither of these situations exists, and Claim 1 should, therefore, be construed only by the terms of its plain meaning.

ABP contends, and Judge Glazebrook agreed that "Claim 1 does not literally require connected main and warning labels that are simultaneously removable." Doc. 190 at 16. This Court also agrees with that statement. Claim 1 does not use the words "main" or "warning" to describe the labels on its form. ABP believes the Court's inquiry should end here. Were the Court to accept this position, any pharmacy label form in which *any two* labels were connected would infringe upon Claim 1.

Convergent argues that the literal language of Claim 1 cannot be the starting and ending point for determining its scope. The law clearly supports Convergent's position. "It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.,* the patent itself, including the claims, the specification, and, if in evidence, the prosecution history ... Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Bell Atlantic* at 1267 (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996)); *See also* Pall Corporation v. PTI Technologies, Inc., 259 F.3d 1383, 1391 ("We have repeatedly held that, in addition to the specification, the prosecution history must be considered in construing claims."). As the Federal Circuit explained:

claims are directed to the invention that is described in the specification; they do not have meaning removed

from the context from which they arose. Thus the claims are construed to state the legal scope of each patented invention, on examination of the language of the claims, the description in the specification, and the prosecution history.

Network, 242 F.3d at 1352. The prosecution history is therefore relevant to determine whether the patentee "has relinquished a potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference." Bell Atlantic, 262 F.3d at 1268.

It is to the intrinsic evidence of the '906 patent that the Court now turns its attention. The Court believes that the specification and prosecution history are relevant on two grounds: (1) first, ABP's statements in response to the examiner's concerns about the patentability of its invention amount to a disavowal of subject matter, limiting the scope of its claims; and (2) Claim 1 includes "means-plus-function" elements that require the Court to consider the scope of the invention in light of the written description of the invention as stated in the patent specification.

As a preliminary matter, ABP objects to using the specification and prosecution historyto construe Claim 1 on the basis that the statements and arguments therein were made in reference to only the *preferred embodiment* of its invention and, therefore, cannot be said to limit all the embodiments of the invention. This argument is without merit. "Although the specification need not present every embodiment or permutation of the invention and the claims are not limited to the preferred embodiment of the invention, neither do the claims enlarge what is patented beyond what the inventor has described as the invention." Network, 242 F.3d at 1352 (citing Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998)). As the following will show, the prosecution history makes it clear that ABP described its invention in such a way as to require that there be a connection between the main label and at least one of the auxiliary labels on the pharmacy form.

a. Prosecution History

[3] The R & R included a lengthy and thorough examination of the prosecution history of the ABP patents. The Court does not wish its own examination of the prosecution history to be redundant; however, the Court's *de novo* review of this matter relies heavily on the numerous representations made by ABP during the prosecution of its patents. These representations make it clear that ABP disavowed certain subject matter and limited the scope of its claims.

The '906 patent relates back to the original application filed when ABP first sought to patent its invention ("the '415 Application"). That application was filed with the PTO on September 16, 1993. ABP ultimately abandoned that application after the examiner rejected all claims for anticipation and obviousness, pursuant to 35 U.S.C. s.s. 103 and 112. In rejecting the claims, the examiner found that ABP's pharmacy form was obvious and anticipated in view of prior art forms disclosed in the Browning and Garrison Patents (U.S. Patent 5,147,699 and U.S. Patent 5,328,208, respectively).

After ABP abandoned the '415 Application, it filed the '906 Application as a continuation of the '415 Application. In its Patentability Brief, ABP addressed several of the grounds for rejection of the '415 Application. In describing its invention, ABP stated:

Applicants' forms may be advantageously used in any business situation *requiring* an adhesive main label and the *optional* use of one or more adhesive auxiliary labels to be applied with the main label ...

Prior to applicants' invention, the custom printing of the main prescription label and associated warning labels was done on forms that required entirely separate operations by the pharmacist dispensing the prescription to remove each of the labels from the printed form and then separately affix the main drug container label and any associated warning label(s).

According to the invention of this application, a blank business form is provided having, *inter alia,* an adhesive main label, *e.g.* a drug container prescription label, and one or more smaller adhesive auxiliary labels, *e.g.* warning labels. The form permits the user to *simultaneously* apply the main label and at least one auxiliary label from the backing sheet, readily separate any unused (*i.e.* not printed upon) auxiliary label(s) from the printed main label, and *simultaneously* apply the main label and any printed upon auxiliary label(s) to a receptive surface, *e.g.,* a prescription drug container.

Defendant's Ex. 2 at Tab '906 Patent Prosecution History, MNA 000176-77 (emphasis in original).

In responding to the examiner's determination that the '415 Application failed to sufficiently distinguish ABP's invention from the prior art of the Browning patent, ABP stated:

Second, a form according to applicant's invention *requires that at least one of the auxiliary labels ... separate from the form when the main label ... is removed from the form*. The Browning *et al*. form perforations are such that the price tags ... are not removed from the form sheet with the central portion ... or with each other.

Defendant's Ex. 2 at Tab '906 Patent Prosecution History, MNA 000178 (emphasis added).

It is clear to the Court that ABP intended to distinguish its invention from prior art on the basis that at least one of the auxiliary labels had to separate from the form when the main label was removed. Yet, ABP now urges the Court not to limit the scope of its claims on the basis of that distinction. However, it has been repeatedly stated that when a patentee relies on a limitation in its arguments to the PTO in order to distinguish prior art, it cannot later argue that the scope of its claims has not been limited. *See* Hollister Inc. v. E.R. Squibb & Sons Inc., 902 F.2d 44, 14 U.S.P.Q.2d 2069, 2070 (Fed.Cir.1990); Beloit Corp. v. J.M. Voith, GmbH, 626 F.Supp. 991, 1007 (E.D.Va.1986) ("Material representations made to the PTO (with or without amendment) to define and explain the claimed invention for the purpose of distinguishing it from the prior art limit the proper interpretation of the claim language.").

Indeed the Federal Circuit has confirmed:

Even when the ordinary meaning of the claim is clear, it is well-established that "[t]he prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution" ... "[B]y distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is *by implication* surrendering such protection."

Pall, 259 F.3d 1383, 1392 (Fed.Cir.2001) (quoting Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995); Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed.Cir.1997)) (emphasis added).

That Court's statement is particularly instructive in the instant case. In its objections to the R & R, ABP asserts that Judge Glazebrook "did not purport to find any surrender of subject matter based upon the

alteration of a claim to 'escape an examiner rejection.' " Doc. 196 at 3. It is clear from the above-quoted language, however, that such surrender can be found by implication when an applicant distinguishes its invention over the prior art. In stating that its invention "requires that at least one of the auxiliary labels ... separate from the form when the main label ... is removed from the form," and distinguishing the prior art on the basis that those forms did not require simultaneous removal, ABP, by implication, surrendered protection for any pharmacy form in which one of the auxiliary labels did not separate from the form when the main label was removed.

ABP maintains that its remarks to the PTO, as quoted in the R & R, were "taken out of their proper context and given a distorted meaning." Doc. 196 at 6. The Court disagrees. The context of ABP's statements is clear; in the face of the rejection of the '415 Application, and in an effort to obtain a patent on the invention disclosed in the '906 Application, ABP distinguished the prior art on the basis that it did not teach simultaneous removal and application of the main and auxiliary labels.Though this was not the only distinction made between the prior art and ABP's form, it was a significant one. So significant, in fact, that it now prevents the Court from interpreting Claim 1 in the same broad terms in which it is written.

ABP also argues that its representations to the PTO were made prior to the existence of Claim 60, which is now Claim 1. However, in the same response in which it first asserted Claim 60, ABP continued to distinguish its invention based on the simultaneous removal of the main and auxiliary labels. In a section entitled, "A. The References," ABP distinguished its form from the Cavender form (U.S. Patent 3,993,814), which disclosed a label form having a large address label (L') and many smaller price labels (L). The price labels on that form are connected to each other by perforations, but are severed from the larger label. In distinguishing that form, ABP stated:

Similarly, the price tag sublabels of Cavender's label L are completely separated from label L [sic. L'] and its sublabels by the recipient before use, so there can be no simultaneous removal as between any of these labels and any labels comprising L'.

Defendants' Ex. 2, at Tab '906 Patent Prosecution History, MNA 000290.

ABP explains that, in making this statement, ABP's counsel "was simply pointing out that Cavender did not teach simultaneous removal of any of the labels disclosed in the Cavender patent, whereas simultaneous removal is a novel feature of the application." Doc. 196 at 11. The Court finds it hard to accept this explanation. First, it bears repeating that Cavender's price labels (L) were attached to each other by perforation. It appears obvious that, because of the perforations, the removal of one of the price labels would result in the removal of the other price labels. Secondly, in stating that, "there can be no simultaneous removal as between any of these labels *and* any labels comprising L'," ABP's use of the conjunctive "and" shows that it intended to highlight that the Cavender form did not allow simultaneous removal of the main label *and* the sublabels. For the Court to interpret that sentence in any other way, it would have to ignore the rules regarding proper use of the English language. The Court declines to resort to such a bold action in order to spare ABP the consequences of its own statements.

Later, in addressing the differences between its invention and the Browning patent, ABP stated that "all of the observations made as to Cavender also apply to this Browning reference. There is no teaching of applicants' invention as defined in the new claims." Defendant's Ex. 2 at Tab '906 Patent Prosecution History, MNA 000290. ABP later stated, "the new claims distinguish over all of the references." Id., MNA 000291.

By again distinguishing its invention based on connecting main and auxiliary labels, and further stating that the new claims distinguished over the references, ABP limited the scope of the new claims, just as it had earlier limited the scope of the previous claims.

b. Means-Plus-Function

[4] Even if ABP's representations in the patentability brief do not limit the scope of the claims, the Court believes that they are limited by the patent specification. Claim 1 includes a "means-plus-function" element. The presence of such an element in a claim requires the Court to interpret the claim in accordance with 35 U.S.C. s. 112(6), which states:

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

Claim 1 reads in relevant part:

A method for use by a pharmacist in labeling a container for a prescription drug to be dispensed to a customer, comprising the steps of:

I. providing blank form for printing on at least one label to be affixed to the container, the form comprising:

...

(c) *means* for connecting said labels such that:

(1) the removal of one of the labels from the backing sheet will simultaneously remove from the backing sheet the other label to which it is connected; and

(2) the two removed labels optionally may be readily separated from each other prior to affixing any of said labels to said container.

Defendants' Ex. 2 at Tab U.S. Patent 5,642,906, MNA 000119.

ABP admits that there are means-plus-function claims in the '906 patent, but states that the parties have no dispute about their meaning. See Doc. 196 at 15. Indeed, Convergent acknowledges that "the 'connecting means' limitation is limited to a score line or perforated tear line between the connected labels, and to equivalents of a score or perforated tear line." Doc. 100 at 12. Though the parties agree as to the *structure* of ABP's forms, that is not the Court's sole inquiry. When a claim includes means-plus-function elements, the Court must also identify the *claimed function* of that structure. Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1536 (Fed.Cir.1991).

Claim 1 makes it clear that the function of the pharmacy form is to allow the removal of pharmacy labels so that the removal of one label from the backing sheet will simultaneously remove another label, and so that the two labels can be readily separated from each other before being affixed to the prescription bottle.

Having identified the function of the invention, the Court can now construe the means-plus-function claim, which "derive[s][its] scope from the structure disclosed in the written description." Ballard Medical Products v. Allegiance Healthcare Corp., 268 F.3d 1352, 1360 (Fed.Cir.2001).

The written description a form with "a peelable vial label having a pressure sensitive adhesive *connected to* removable strips of computer selected warning labels also having a pressure sensitive adhesive." Defendants' Ex. 2 at Tab U.S. Patent 5,642,906, MNA 000117 (emphasis added). This description only discloses the preferred embodiment of the label form, however s. 112(6) clearly states that the "claim shall be construed to cover the corresponding structure, material, or acts described in the *specification* and equivalents thereof." 35 U.S.C. s. 112(6) (emphasis added). Therefore, the Court does not have to construe the claim in light of every possible embodiment.

The description of the form in the specification informs the Court's analysis, as do ABP's representations to the PTO. In the patentability brief, ABP made the following argument:

In the Final Rejection in the parent case, the Examiner stated:

It has been held that a recitation with respect to the manner in which a claimed blank is intended to be employed does not differentiate the claimed blank from a prior art blank form satisfying the claimed *structural* limitations.

Exhibit A at page 3, No. 4, 2nd para. (emphasis added). This characterization of applicants' form seems to be off the mark.

Functionally, applicants' forms *result* in at least one auxiliary label simultaneously separating from the backing sheet with the main label *and* in that auxiliary label optionally being readily separated from the main label if desired by the user. These features are not manners of use, but *necessary functional characteristics requiring* structure(s) permitting this result. These functional requirements of applicants' new forms cannot be ignored in assessing patentability under the guise of "manner of use." *See, e.g.,* Hollister Inc. v. E.R. Squibb & Sons Inc., 14 U.S.P.Q.2d 2069, 2070 (Fed.Cir.1990) (functional limitations in claims cannot be ignored-to do so "flies in the face of the 'all elements' rule of claim construction").

Neither the Browning *et al*. form nor the Garrison form expressly taught in these references results in the *simultaneous* removal and *optional* subsequent separations features of applicants' forms. The Examiner in the Final rejection stated that Garrison's

die cuts are an equivalent structure known in the art to the tear lines and since these two paper separators were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute a die cut for a tear line.

Exhibit A at page 5, No. 6, 3rd para. . The die cuts separating Garrison's main label and adjoining auxiliary label, and each of the auxiliary labels from each other, *preclude* a Garrison form from meeting applicants' claims. That is, *because* die cuts are used by Garrison, the Garrison-form user cannot simultaneously remove one or more auxiliary labels with the main label-the main label is completely separated from *all* auxiliary labels. Also, the option of *subsequently* separating any simultaneously-removed auxiliary label from the mail label after removal from the backing sheet obviously does not exist with a Garrison-type form: since there is nothing linking the two labels in the first place, there can be no *optional* subsequent separation of

the labels.

Defendant's Ex. 2 at Tab '906 Patent Prosecution History, MNA 000179-80.

Having made this argument to the PTO in an effort to distinguish its invention from prior art, ABP cannot now argue that those representations should not be used to determine the scope of its claims.

Accordingly, the Court determines that the scope of Claim 1 of the '906 patent is limited to a pharmacy form having a main label connected to at least one of the auxiliary labels.

2. The '395 Patent

The parties requested that the Court also construe Claim 17 of U.S. Patent 5,855,395. Judge Glazebrook also interpreted that claim to require a main label connected to auxiliary labels. ABP objects to this construction of the '395 patent on essentially the same grounds as it objects to his construction of the '906 patent.

Claim 17 reads:

A method of forming a composite label for a container useful in dispensing drugs by a pharmacist in which the composite label includes both a main label portion with specific drug or patient information and at least one warning label portion containing warning information, and in which the main and warning label portions may be rapidly and efficiently printed and affixed to the container, the method comprising the steps of:

providing a blank form having the main label portion and plural warning label portions releasably adhered to a backing sheet, both the main label portion and the warning sheet portions having respective outer surfaces for receiving printed information thereon;

printing drug or patient specific information onto the outer surface of the main label portion in a first direction; and

printing warning information onto the outer surface of at least one of the warning label portions in a second direction which is generally lateral to the first printing direction on the main label portion.

Defendants' Ex. 2 at Tab U.S. Patent 5,855,395, MNA 000476.

Read literally, Claim 17 does not state that the main label portion and one warning label portions are connected *to each other*. However, as it did with respect to Claim 1 of the '906 patent, Convergent argues that Claim 17 should be read to require such a connection, in light of the specification and prosecution history. ABP again argues that the claim language is controlling, and should not be read to require that any of the labels on the form be connected, so long as the form has the specific label portions, patient advisory form, and enumerated printing features.

Once again, the Court, in construing Claim 17, must turn its attention to the intrinsic evidence in order to "determine whether the patentee has set forth an explicit definition of a term contrary to its ordinary meaning, has disclaimed subject matter, or has otherwise limited the scope of its claims." Day International, Inc. v. Reeves Bros., Inc., 260 F.3d 1343, 1348 (Fed.Cir.2001).

It is clear to the Court that, in its communications with the PTO during the prosecution of the '395 patent, ABP disclaimed subject matter and limited the scope of Claim 17. In an Information Disclosure Statement ("IDS") to the PTO, ABP stated that it was attaching a specimen of one of Defendant Moore's business forms. At the time, it was unclear whether the Moore form was prior art; it was later deemed not to be. Nevertheless, while it was unsure whether the Moore firm was prior art, ABP submitted the form and informed the PTO that:

Applicants' undersigned counsel has removed the main drug container label portion and reattached it to the adhesive backing, so as to permit the Examiner to see that the main container label portion is not attached to the warning labels in such a way as to permit the two to come off together, as is the case with Applicant's invention.

Defendants' Ex. 2 at Tab '395 Patent Prosecution History, MNA 000535. ABP now argues that this statement should be given no weight because the Moore form was later determined not to be prior art. However, it is ironic that ABP distinguished the Moore form on the basis that the main and auxiliary labels were not attached, but later filed this action accusing that very form of being an infringing use of its patent. Obviously, at the time of submitting the IDS, ABP believed it necessary to distinguish its form from other forms on the basis that its form's main and auxiliary labels were connected.

[5] ABP argues that the R & R mischaracterized the statement made in the IDS, and that "the statement has to be evaluated in light of the claims." Doc. 196 at 19. However, the case law makes it clear that the claims are to be read in view of the specification and prosecution history, not the other way around. *See* SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, 242 F.3d 1337 (Fed.Cir.2001); Netword, 242 F.3d at 1352.

In any event, the IDS is not the only source of proof that ABP limited the scope of its claims. In an amendment to the '395 application, ABP's counsel thanked the examiner for the courtesy of a telephone interview to discuss the patentability of ABP's forms. Of particular relevance to the Court's inquiry is the following portion of ABP's remarks:

During the interview, Examiner Han also pointed out that the CVS label relied on in para. 7 of the Office Action was the label relied upon in the co-pending reexamination, and not the CVS label which is appended as Attachment A to Applicant's earlier invention disclosure statement. With reference to the CVS label included with the reexamination, Applicant's counsel then pointed out the deficiencies of that as prior art; *it was particularly observed that the three elongated strips between the main vial label portion attached to the backing strip and the patient advisory leaflet section of the form are not attached to the main vial label in such a way that those strips are lifted from the backing strip together with the vial label*.

Defendants' Ex. 2 at Tab '395 Patent Prosecution History, MNA 000590-91 (emphasis added).

Later, in addressing the rejection of its claims including the former Claim 32 (which is now Claim 17), based on the above-mentioned CVS form ABP pointed out:

... that this form does not at all relate to the subject matter of the rejected claims for the reasons discussed in Section I above. *Of particular note, the lifting of the main (vial) label portion from the backing sheet clearly does not achieve simultaneous removal of the three elongated strips underneath the main label portion, in*

direct contrast to the recitation of the rejected claims. Further the rejected claims contain additional recitation-notably the recitation to the direction of elongation in Claim 13-which also distinguishes over the CVS label.

Defendants' Ex. 2 at Tab '395 Patent Prosecution History, MNA 000596 (emphasis added).

After ABP amended the '395 application, the PTO issued a Notice of Allowability. In the section entitled, "Reasons for Allowance," the examiner stated:

the prior art of record does not show a pharmacy form having a removable label sheet with a plurality of elongated auxiliary labels smaller than a main label which extend lateral to a first tear line that is generally vertical from the top to bottom edge of the sheet which permits *the auxiliary labels to be simultaneously removed from a backing sheet with the main label and subsequently separable from the main label* and a method of labeling which prints information on the main label in one direction and in another direction on the auxiliary labels in one printing pass *and then the simultaneously affixing the main label and used auxiliary labels with printing to the surface of a drug container*.

Defendants' Ex. 2 at Tab '395 Patent Prosecution History, MNA 000625-26. Significantly this was the only reason for allowance given by the examiner. The examiner's explanation makes it abundantly clear to the Court that the patent was allowed, at least in part, on the basis that the main and auxiliary labels could be simultaneously removed from the backing sheet and affixed to a drug container. Such simultaneous removal and application would seemingly be impossible if the labels were not connected in some way.

Accordingly, the Court believes that the prosecution history shows that the scope of Claim 17 is limited both by ABP's representations to the PTO and the examiner's explanation of her reason for allowing the claims asserted in the amendment. Consequently, the Court defines Claim 17 as requiring that the main label portion be attached to at least one of the warning label portions of the pharmacy form.

Were the Court to construe Claim 1 of the '906 Patent and Claim 17 of the '395 Patent in the manner urged by ABP, it would essentially render the public notice function of patent prosecution meaningless, and prevent competitors from relying on the representations made by the patentee during the prosecution of the patent. As the case law repeatedly states, patentees cannot narrow the scope of their inventions in order to distinguish prior art, but later broaden the scope of their inventions by using broad claim language.

Nowhere in any of its communications with the PTO did ABP attempt to depict its forms as requiring anything other than a main label connected to at least one auxiliary label. ABP never stated or implied that its invention covered: (1) a pharmacy form in which the auxiliary labels connected to each other but *not* the main label, or (2) a form in which the auxiliary labels connected to *neither* the main label *or* the other auxiliary labels. ABP argues in its objections to the R & R that both Convergent and Judge Glazebrook have taken its representations to the PTO out of context. This argument is not credible. It has been shown both in the R & R and in this analysis that ABP repeatedly distinguished its forms over prior art by pointing to the connection between the main and auxiliary labels that allows the labels to be simultaneously removed and affixed. Having distinguished its invention, at least in part, on that basis, ABP cannot now have it both ways by claiming that the distinction should not be read into all the claims.

In conclusion, the dispute between the parties boils down to what evidence should be used to construe ABP's patent claims. ABP essentially asks the Court to read Claim 1 of the '906 patent and Claim 17 of the

'395 patent in a vacuum, without regard to the representations it made in order to obtain the patents. Convergent asks the Court to read ABP's patent claims in light of the way in which ABP repeatedly described and distinguished its invention during prosecution. The case law makes it clear that the patent specification and prosecution history are both necessary and useful tools in claim construction, and must be considered in addition to the language of claims. Upon review of the evidence, the Court has determined that ABP disavowed by implication any form in which the main and auxiliary labels were not connected. Consequently, the Court defines Claim 1 of the '906 Patent and Claim 17 of the '395 Patent as requiring that the form's main label be connected to at least one of the auxiliary labels.

III. INFRINGEMENT

[6] Both ABP and Convergent have filed motions for summary judgment. ABP asks the Court to grant summary judgment in its favor on the issue of whether Convergent infringed the '906 and '395 Patents. FN3 Convergent, on the other hand, asks the Court to grant summary judgment in its favor on the issue of non-infringement.

FN3. ABP's claims with respect to the '231 Patent were only applicable to Defendant Moore. Because Moore is no longer a party to this action, and Convergent is not accused of infringing the '231 Patent, the Court need only consider whether the '906 and '395 Patents were infringed by Convergent.

A patent infringement analysis requires the Court to take two steps. Pall, 259 F.3d 1383, 1389. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *Id*. (quoting Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1476 (Fed.Cir.1998)). Viewing the facts and inferences in the most favorable light to the moving party, "summary judgment is proper only if 'no reasonable jury could return a verdict for the nonmoving party.' " Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

Usually, "[t]he court's construction of the claims ... decides the question of infringement, whether literal infringement or under the doctrine of equivalents." Network, 242 F.3d 1347, 1350. The Court has already construed ABP's claims, and determined that both Claim 1 of the '906 Patent and Claim 17 of the '395 Patent require that the main label of the pharmacy form be connected to at least one auxiliary label. The only remaining issue for the Court, therefore, is whether Convergent's label forms infringe on ABP's patents.

Convergent's accused products consist of: (1) forms having labels in which the larger main label is not connected to any of the smaller auxiliary labels, but at least two of the auxiliary labels are connected ("the Group II labels"); and (2) forms in which no labels are connected, *i.e*. the main label is not connected to the auxiliary label, and none of the auxiliary labels are connected to each other ("the Group III labels"). *See* Joint Final Pretrial Statement, Doc. 169 at 56.

In order for a patentee to establish infringement, "every limitation set forth in a patent claim must be found in an accused product of process exactly or by a substantial equivalent ... [consequently] the failure to meet a single limitation is sufficient to negate infringement of the claim." Laitram, 939 F.2d 1533, 1535. It is clear from the way in which the parties have described the Group II and III forms that none of Convergent's forms consist of a main label connected to any of the auxiliary labels. Because such a connection is a claim limitation as construed by the Court, ABP has failed to establish that Convergent's labels have infringed

every element of the disputed claims. Consequently, no reasonable jury could find that Convergent infringed either the '906 or '395 Patents, and summary judgment is due to be granted in its favor.

IV. INVALIDITY

In addition to filing a motion for summary judgment of non-infringement, Convergent also filed two separate motions for invalidity of ABP's patents. Because Convergent raised the issue of invalidity as an affirmative defense to ABP's claims, rather than as a counterclaim, the Court declines to address the merits of these motions. *See* Brunswick Corp. v. United States, 34 Fed.Cl. 532, 557 (Fed.Cl.1995); Cardinal Chem. v. Morton Int'l, Inc., 508 U.S. 83, 93-94, 113 S.Ct. 1967, 1974, 124 L.Ed.2d 1 (1993) ("An unnecessary ruling on an affirmative defense is not the same as the necessary resolution of a counterclaim for a declaratory judgment ... [t]o hold a patent valid if it is not infringed is to decide a hypothetical case.").

V. CONCLUSION

The Court has construed the disputed claims of the '906 and '395 Patents as requiring that ABP's label forms consist of a main label connected to at least one of the auxiliary labels on the form. Because the accused forms do not have connecting main and auxiliary labels, Convergent has not infringed ABP's Patents.

Based on the foregoing, it is **ORDERED** that:

1. The Report and Recommendation (Doc. 190) is approved and adopted.

2. Plaintiff's Objections to the Report and Recommendation (Doc. 196) are overruled.

3. Defendants' Joint Motion to Construe U.S. Patent No. 5,642,906 (Doc. 80), filed August 27, 2001, is **GRANTED.**

4. Plaintiff's Motion for *Markman* Hearing (Doc. 83), filed August 27, 2001, is **DENIED as moot**, as the hearing was held before Magistrate Judge Glazebrook on October 17, 2001 and October 24, 2001.

5. Defendants' Joint Motion to Construe U.S. Patent No. 5,855,395 (Doc. 86), filed August 27, 2001, is **GRANTED.**

6. Plaintiff's Motion for Summary Judgment (Doc. 106), filed October 5, 2001, is **DENIED.**

7. Defendants' Motion for Summary Judgment of Non-Infringement (Doc. 119), filed October 5, 2001, is **GRANTED.**

8. Defendants' Motion for Summary Judgment of Invalidity for Prior Art (Doc. 111), filed October 5, 2001, is **DENIED as moot.**

9. Defendants' Motion for Summary Judgment of Patent Invalidity Under 35 U.S.C. s. 102(f) and s. 112, filed October 5, 2001, is **DENIED as moot.**

10. All other pending motions in this case are **DENIED as moot.**

11. The Clerk shall enter a final judgment in this case, providing that the Plaintiff shall take nothing on its

claims against the Defendant, and that the Defendant shall recover its costs of action.

12. This case shall be removed from the January 2002 trial calendar.

13. The Clerk shall close this case.

REPORT AND RECOMMENDATION

GLAZEBROOK**, United States Magistrate Judge.**

This cause came on for consideration at a *Markman* hearing held on October 17, 2001 and October 24, 2001 on the following motions and memoranda: Plaintiff's Motion for Markman Hearing (Docket No. 83); Defendants' Joint Motion to Construe U.S. Patent No. 5,642,906 (Docket No. 80); Defendants' Joint Motion to Construe U.S. Patent No. 5,855,395 (Docket No. 86); Plaintiff's Memorandum in Opposition to Defendants Motion to Construe '395 Patent (Docket No. 90); and Defendants' Opposition to Plaintiff's Motion for Markman Hearing (Docket No. 100).

Having considered the parties' legal arguments, memoranda, and the submitted evidence, the Court finds that the patent specifications and prosecution histories show a clear and unequivocal disavowal of claim scope which restricts the language of Claim 1 in U.S. Patent No. B1 5,642,906, as reexamined ("the '906 Patent") and Claim 17 of the U.S. Patent No. 5,855,395 ("the '395 Patent"). FN1

FN1. ABP is asserting infringement of claim 19 in the '395 Patent. However, claim 19 is a dependent claim that incorporates all of the limitations of claim 17. Consequently, we are asked to construe certain language in claim 17 in a way that limits the scope of dependent claim 19.

I. ***THE CLAIMS CONSTRUCTION ISSUES***

Plaintiff ABP Patent Holdings LLP ("ABP") alleges that defendants Convergent Label Technology, Inc. ("Convergent") and Moore North America, Inc. ("Moore") have infringed the '906 Patent, the '395 Patent, and U.S Patent No. 6,036,231 ("the '231 Patent"). FN2ABP asserts that Convergent and Moore have sold and continue to sell pharmacy forms that fall withinthe scope of various claims of the patents in issue.

FN2. The parties agreed at oral arguments that the '231 Patent does not require interpretation. *See* Docket No. 157.

The ABP patents are directed to an efficient method of labeling prescription vials using a pharmacy form having certain unique characteristics. The ABP patents disclose a pharmacy prescription form having labels that are removed simultaneously by a pharmacist and applied together to a drug container. Defendants' Exhibit 2 (D's Exh. 2) at Tabs U.S. Pat. 5,642,906, 5,855,395, and 6,036,231. The pharmacy form has a backing sheet to which at "least two labels" adhere. Prescription information is printed on one or both of the labels as the form is fed through a software-driven printer. The labels are connected so that they are simultaneously removed together and then, at the user's option, readily separated from each other before being applied to a prescription drug container.

ABP's patents each describe the same pharmacy prescription form and method for applying main and auxiliary warning labels to a drug vial or container. The labels of the prescription form described in ABP's patents include a main prescription label that is connected by a perforated tear line to an auxiliary warning label. D's Exh. 2 at Tab U.S. Pat. 5,642,906, col. 5, ln. 57 to col. 6, ln. 3, *see also,* col. 1, lns. 59-64; col. 4, lns. 59-63; col. 5, lns. 25-27, 43-47.

Because the main and warning labels are connected by perforations or score lines, they peel off together. The pharmacist then can apply the connected labels to a drug container in one swift movement. ABP proved to the Patent Office that connected labels reduce the time spent by pharmacists in applying labels to drug containers, as compared to prescription forms having unconnected main and warning labels that are separately removed. D's Exh. 2 at Tab '906 Patent Prosecution History (MNA 000184-187, 000208-237).

Claim 1 of the '906 Patent expressly refers to "another label" and claim 17 of the '395 Patent expressly refers to a "warning label." According to ABP, connection between any two of the general auxiliary warning labels would suffice for coverage under claim 1 of '906 and claim 17 of '395. ABP argues that independent claim 1 of its '906 Patent and independent claim 17 of its '395 Patent do not expressly require connected main and auxiliary warning labels, but rather require connection between *any two labels*. ABP alleges that claim 1 and claim 17 cover the auxiliary warning labels on defendants' accused prescription pharmacy forms.

Defendants disagree. Defendants contend that ABP limited the scope of its claims so as to require connected main and warning labels. Defendants point to the arguments for patentability that ABP made to the Patent Office during prosecution of the applications that yielded the '906 and '395 Patents. The one claim construction issue in dispute is whether claim 1 of the '906 Patent and claim 17 of the '395 Patent require connected main and warning labels that are simultaneously removed from a pharmacy prescription form. This report agrees with defendants that claims 1 and 17 should be so construed.

II. *THE LAW OF PATENT CLAIM CONSTRUCTION*

Claim construction is the interpretation of the words in a patent's claims. Proper claim construction is necessary to determine whether a claim is valid, enforceable, and infringed. Following claim construction methodology approved by the United States Court of Appeals for the Federal Circuit, a district court determines the meaning and scope of the claims in order to ascertain the "acquired meaning" of claim language. *See* Federal Judicial Center,PATENT LAW AND PRACTICE (BNA 3rd Ed.2001) at 100-08.

The interpretation of the claims of a patent is a pure question of law to be resolved by the court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The standard of review for claim interpretation holdings is *de novo*. Hockerson-Halberstadt Inc. v. Avia Group International, Inc., 222 F.3d 951, 955 (Fed.Cir.2000). In a *Markman* hearing, the evidence is generally limited to: 1.) the patent, which includes the claims and a description of the patented invention, 2.) the prosecution history files of the application from which the patent issued and which is copied from the records of the Patent Office, 3.) prior art references which the Patent Office considered during the prosecution of the application, and 4.) dictionaries and other similar references that assist in defining terms in the claims. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-81 (Fed.Cir.1995), *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996); *accord,* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed.Cir.1996); Ballard Medical Products v. Allegiance Healthcare Corp., 268 F.3d 1352, 1358-59, No. 00-1393, 2001 U.S. APP. LEXIS 21591 at *9-11 (Fed.Cir. Oct. 9, 2001).

The claims of a patent define the boundaries of the patented invention, and the public is entitled to rely upon the claims to determine what does or does not constitute infringing activity. *See, e.g.,* London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed.Cir.1991). The Court interprets patent claims as a matter of law to "determine how a person of experience in the field of [the] invention would, upon reading the patent documents, understand the words used to define the invention." Toro Co. v. White Consolidated Indus., Inc., 199 F.3d 1295, 1299 (Fed.Cir.1999); Vitronics, 90 F.3d at 1582; Markman, 52 F.3d at 978-79.

Claim construction centers on the words actually used in the claims, without adding or subtracting words or rewriting claims. Words in a claim can acquire meaning from ordinary English, or from customary trade use. The Court first considers "the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." Vitronics, 90 F.3d at 1582. Claim terms are ordinarily given their ordinary and customary meaning.

But the district court must consult more than just the words in interpreting claims. *See* Federal Judicial Center, PATENT LAW AND PRACTICE (BNA 3rd Ed.2001) at 100-08. In construing patent claims, the Court looks to the claim language, the patent specification, and the patent's prosecution history. *Id.* Such intrinsic evidence constitutes the public record of the patentee's claim. Intrinsic evidence is the most important resource in determining the operative meaning of disputed claim language, and usually will resolve any ambiguity concerning that language. Vitronics, 90 F.3d at 1582-83. Indeed, "[i]n those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." 90 F.3d at 1583.

A patent applicant may act as his own lexicographer by clearly and precisely defining a special use or meaning during prosecution, or by disclaiming a portion of a word's ordinary meaning. The Court may consider the applicant's statements in the prosecution history in determining the acquired meaning of disputed claim language. *See* Federal Judicial Center, PATENT LAW AND PRACTICE (BNA 3rd Ed.2001) at 100-08. A patentee may "use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." 90 F.3d at 1582-83. Accordingly, the Court should review the patent specification and its prosecution history to determine whether the inventor has employed any terms or words in a way that is inconsistent with their plain and ordinary meaning or disavowed subject matter from the scope of his patent claims. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340-42 (Fed.Cir.2001); *accord,* John D. Watts v. XL Sys., 232 F.3d 877, 883 (Fed.Cir.2000) (even if the claim terms were clear on their face, the court "must consult the specification to determine if the patentee redefined any of those terms"); Interactive Gift Express v. Compuserve, 231 F.3d 859, 870 (Fed.Cir.2000); Vitronics, 90 F.3d at 1582.

It is also well established, that the court can look at the words of the preamble of a claim to determine the scope of the claim. The preamble may be a limitation, if it has been used by the patentee to define the structure of the claimed invention. Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed.Cir.1989); Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed.Cir.1995); Rowe v. Dror, 112 F.3d 473, 478-79 (Fed.Cir.1997); In re Paulsen, 30 F.3d 1475, 1479 (Fed.Cir.1994) ("[T]erms appearing in a preamble may be deemed limitations of a claim when they give meaning to the claim and properly define the invention.").

The prosecution history of a patent "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of

the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims." Vitronics, 90 F.3d at 1582; ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1580 (Fed.Cir.1988). In reviewing the prosecution history, the Court also examines the prior art considered by the Patent Office to assess what the claims do not cover. Vitronics, 90 F.3d at 1583; Watts v. XL Sys., Inc., 232 F.3d 877, 883 (Fed.Cir.2000); ZMI Corp., 844 F.2d at 1580-581; Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 (Fed.Cir.1985) ("[T]he prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance."); Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1384 (Fed.Cir.1999).

Ultimately, a review of the prosecution history ensures that an applicant has not defined claim terms one way in order to obtain the patent, and then defined them another way to support infringement allegations. *See* Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 1578 (Fed.Cir.1995) ("A patentee may not proffer an interpretation for the purposes of litigation that would alter the indisputable public record consisting of the claims, the specification and the prosecution history, and treat the claims as a 'nose of wax' "); Day Intl., Inc. v. Reeves Brothers, Inc., 260 F.3d 1343, 1348 (Fed.Cir.2001) (arguments made by the patentee during prosecution of the patent limit the scope of the invention).

The prosecution history and the patent specification, in addition to the claims themselves, must be considered when construing claims. Biovail Corp. Int'l v. Andrx Pharm., Inc., 239 F.3d 1297, 1301 (Fed.Cir.2001) ("[W]e review both the specification and the applicable prosecution history to determine whether the patentee defined claim terminology in a manner inconsistent with its ordinary meaning."); Hockerson-Halberstadt, 222 F.3d at 955 ("The court, therefore, must examine a patent's specification and prosecution history to determine whether the patentee has given the term an unconventional meaning."); Southwall, 54 F.3d at 1576 ("Arguments and amendments made during the prosecution of a patent application and other aspects of the prosecution history, as well as the specification and other claims, must be examined to determine the meaning of terms in the claims.").

The prosecution history and patent specification are to be applied to narrow the scope of a claim where the patentee argued a narrow claim construction to obtain allowance of the claim by the Patent Office. The United States Court of Appeals for the Federal Circuit recently stated:

Even where the ordinary meaning of the claim is clear, it is well-established that "[t]he prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Thus, this court has endorsed narrowing the interpretation of the claim to be consistent with a narrow claim scope urged by the applicant during the prosecution of the patent. This narrowing claim interpretation will be adopted if the accused infringer can demonstrate that the patentee "defined" the claim as "excluding" a broader interpretation "with reasonable clarity and deliberateness."

Pall Corp. v. PTI Technologies, Inc., 259 F.3d 1383, 1392-93 (Fed.Cir. Aug.7, 2001). The public notice function of patents prohibits a patentee from expressly stating during prosecution that the claims do not cover a particular device, and then later suing for infringement by that same device. Allowing such a suit would be unfair to the manufacturer of the accused device who was entitled to rely on the surrender of claimed subject matter made in the prosecution history and contained in the file wrapper.

Each argument for patentability asserted by a patentee during prosecution of an application may give rise to an independent basis on which to construe, e.g., narrow, an express claim limitation. Southwall, 54 F.3d at

1583. In *Southwall,* the Federal Circuit rejected a patentee's argument that multiple arguments for patentability could not be applied individually to limit a construction of a claim element. During prosecution, Southwall argued that its inventive method had two steps that differed from the prior art. During litigation, Southwall argued that it surrendered during prosecution only the combination of two steps that it had said distinguished its method. The Federal Circuit rejected Southwall's argument, stating:

Accordingly, we may examine Southwall's prosecution argument distinguishing its "sputter-deposited" metal oxide from Franz's separately from Southwall's other arguments distinguishing Franz. When we do, we conclude the separate arguments create separate estoppels.

Southwall, 54 F.3d at 1583.

Furthermore, a claim in a patent may be limited by general statements made by a patentee to the Patent Office regarding how the invention differs from the prior art. Pall Corp., 259 F.3d 1383, 1391-392 (patentee submitted an information disclosure statement that distinguished the patentee's invention from prior art); Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed.Cir.1997); Ballard Medical Products, 268 F.3d at 1359-61; *see also,* Signtech USA, Ltd. v. Vutek, Inc., 174 F.3d 1352, 1357 (Fed.Cir.1999). In *Signtech,* the Federal Circuit held that a patentee had made general statements disavowing subject matter from its invention and thereby had limited the scope of even those claims that were not directly the subject of the statements. The patentee in *Signtech* stated that "certain prior art was 'incapable' of achieving the desired results of the invention." In view of this general statement, the claims were construed to avoid covering products that were incapable of performing those desired results.

General statements disavowing subject matter from the claims of a patent may be made at any time during prosecution of the application. Ballard Medical Products, 268 F.3d at 1359-61 (statements made disavowing subject matter made in arguments submitted with a patentee's amendment of claims and in an inventor's declaration submitted in support of the amendment); Pall Corp., 259 F.3d at 1392-93 (information disclosure statement included statements disavowing subject matter). General statements disavowing subject matter made in connection with one set of claims of a patent application may bar a patentee from asserting that other claims in the same patent or in a related patent cover the subject matter that had been disavowed. Ballard Medical Products, 268 F.3d at 1360-61.

Where the prosecution history of the Patent Office makes clear that a disavowal of subject matter applies to certain elements of an invention, that disavowal will apply to preclude all claims reciting that element of the invention. Thus, a patent claim is to be construed to avoid disavowed subject matter, where the disavowal was made before the claim was before the Patent Office. Ballard Medical Products, 268 F.3d at 1361. To do otherwise, would allow a patentee to make statements on the public patent application record disavowing subject matter as not being part of his claimed invention and then later add claims directed to that same subject matter. Hockerson-Halberstadt, 222 F.3d at 957.

Lastly, the Federal Circuit has recognized two additional claim construction guideposts that may assist the district court. Ordinarily, the meaning assigned to a word in a patent should align with the purpose of the patented invention. Apple Computer v. Articulate Sys., 234 F.3d 14, 25 (Fed.Cir.2000); *accord,* Hockerson-Halberstadt v. Avia Group Int'l, 222 F.3d 951, 956 (Fed.Cir.2000). If possible, the Court should construe claims so as to preserve their validity. Wang Labs. v. America Online, 197 F.3d 1377, 1383 (Fed.Cir.1999).

III. ***APPLICATION AND ANALYSIS***

A. ***The ABP Patents***

The three patents in suit are U.S. Patents Nos. 5,855,395 ('395 Patent), 6,036,231 ('231 Patent), and 5,642,906 ('906 Patent). These patents issued from a common patent application. All patents disclose the same prescription pharmacy forms, and include the same drawings and textual description of the forms. The primary difference between each of the patents is in their claims. The ABP patents disclose a prescription pharmacy form that is used by pharmacists to print prescription labels. Defendants' Exhibit 2 (D's Exh. 2) at Tab U.S. Patent 5,642,906. The patents disclose four embodiments of a computer printable prescription label blank, *e.g.,* Figs. 2, 5, 6 and 8 of each patent. Each of these embodiments uses a main prescription portion attached to warning labels via tear lines which are formed by connecting perforations. Indeed, a common feature of all of the embodiments of the ABP patents is that the main label is connected by a tear line (also referred to as a perforated line) to an auxiliary warning label.

The prescription form embodiment shown in Figure 2 of ABP patents uses a main label 96 (reference numbers are shown in the figures of the patent) portion which is attached to a number of warning label portions 98, 100, 102 and 104 via respective connecting perforated tear lines 110, 112, 114 and 116. Id. at '906 Patent, col. 4, lns. 30-44. The Fig. 5 prescription form embodiment uses a main label portion 200 which is attached to a number of warning label portions 210-13 via one or more connecting perforated tear lines 240-43. Id. at '906 Patent, col. 5, lns. 15-31. The Fig. 6 embodiment uses a main label portion 302 which is attached to a number of warning label portions 310-13 via one or more connecting perforated tear lines 330-33. Id. at '906 Patent, col. 5, lns. 33-52. The Fig. 8 embodiment uses a main label 410 portion which is attached to a number of warning label portions (no ref. numbers) via connecting perforated tear lines (no ref. numbers), as shown in Fig. 6. Id. at '906 Patent, col. 5, lns. 53-57.

The main and warning labels form a "wrap-around" composite prescription label that is affixed to a drug container. Id. at '906 Patent, col. 4, lns. 40-44; col. 5, ln. 58 to col. 6, ln. 14 ("The one piece wrap-around pressure sensitive label for the drug container optionally combines the main drug container label with one or more selected warning labels."). The wrap-around labels have an adhesive coating and a backing sheet to protect the adhesive until the label is removed from the backing. Id. at '906 Patent, col. 4, lns. 1-12. The wrap-around label peels off the label sheet and is applied by a pharmacist to a drug vial or container. Id. at '906 Patent, col. 4, lns. 59-64.

The wrap-around label includes a main label (ref. no. 96 in Fig. 2 of the '906 Patent) and auxiliary warning labels (98, 100, 102 and 104). Id. at '906 Patent, col. 6, lns. 11-14. The main drug label 96 receives printed prescription information, such as the name of the prescribed drug, the dosage of the drug and the frequency at which the drug is to be taken by the patient. Id. at '906 Patent, col. 1, lns. 11-13 ("Labels ... have been applied to drug containers for a long time by the pharmaceutical industry to identify the customer, the doctor, the drug being dispensed, and the frequency of the dosage."), *see also* col. 3, lns. 6-7 ("print a conventional drug label"), col. 4, lns. 40-41 (Label "[p]ortion 96 is a wrap-around label to be applied to a drug container."). The auxiliary warning labels (98, 100, 102 and 104) receive printed drug warnings, such as the drug "MAY CAUSE DROWSINESS: .." Id. at '906 Patent, col. 4, lns. 41-44; col. 1, lns. 28-31.

The main prescription label and warning labels in the wrap-around label are connected, but also detachable from each other. Id. at '906 Patent, col. 5, lns. 43-48. Perforated tear lines 110, 112, 114, 116 and 118 separate the main label from the warning label, and separate the warning labels from each other. These tear lines allow a pharmacist to remove unwanted warning labels from the composite wrap-around label before affixing the label to the pill vial. Id. at '906 Patent, col. 4, lns. 34, and 59-64 ("Combined [label] portions 96,

98, 100, 102 and 104... can be removed as one piece from the backing 80 [of the form sheet], the unused warning label portions removed, and the remaining piece applied to the drug container.").

The labels of the prescription form are initially blank and do not include prescription information or drug warning information. The printing of prescription information, the warning labels and other printed information occurs when the prescription form sheet is run through the computer printer at the pharmacy. Id. at '906 Patent, col. 3, lns. 3-7, 39-43; col. 5, lns. 58-60. Once the pharmacist enters the prescription information into a computer, the computer prints the prescription on the main label and appropriate prescription drug warning information on the warning labels. Id.; *see also* '906 Patent, col. 4, lns. 40-44. The computer also prints a patient advisory leaflet (PAL) on the form sheet that includes detailed information regarding the prescribed drug. D's Exh. 2 at Tab U.S. Patent 56,642,906 Patent, col. 4, lns. 24-26.

Claims 1 and 4 of the '906 Patent are the independent claims of the '906 Patent, as reexamined. The other claims depend on either claim 1 or 4, and incorporate all of the limitations of the claim on which they depend. Claim 1 reads:

1. A method for use by a pharmacist in labeling a container for a prescription drug to be dispensed to a customer, comprising the steps of:

I. providing blank form for printing on at least one label to be affixed to the container, the form comprising:

(a) at least two labels releasably adhered to a backing sheet, each of said labels being provided with a printable surface upon which may be printed information relating to the prescription drug;

(b) adhesive means on the surface of each of said labels that is opposite the printable surface for affixing each of said labels to said container; and

(c) means for connecting said labels such that:

(1) the removal of one of the labels from the backing sheet will simultaneously remove from the backing sheet another label to which it is connected; and

(2) the two removed labels optionally may be readily separated from each other prior to affixing any of said labels to said container;

II. printing information concerning a prescription on at least one of said labels;

III. simultaneously removing from the backing sheet at least said two labels; and

IV. affixing at least one of said two labels to said prescription drug container.

Claim 4 of the '906 Patent is similar in many respects to claim 1, but expressly states that one of the labels is a main prescription label that identifies the patient and the prescription drug, and the other label is a prescription drug warning label. Accordingly, claim 4 makes clear that one of the recited labels is a main prescription label (because of the limitation stating "printing information identifying the customer and the prescription drug on one of said connected labels") and the other label is an auxiliary warning label (because of the limitation stating "printing information comprising a warning relating to the prescription drug on at

least the other connected labels").

In the '395 Patent, asserted claim 19 depends on independent claim 17 and dependent claim 18. These claims are as follows:

17. A method of forming a composite label for a container useful in dispensing drugs by a pharmacist in which the composite label includes both a main label portion with specific drug or patient information and at least one warning label portion containing warning information, and in which the main and warning label portions may be rapidly and efficiently printed and affixed to the container, the method comprising the steps of:

providing a blank form having the main label portion and plural warning label portions releasably adhered to a backing sheet, both the main label portion and the warning label portions having respective outer surfaces for receiving printed information thereon;

printing drug or patient specific information onto the outer surface of the main label portion in a first direction; and

printing warning information onto the outer surface of at least one of the warning label portions in a second direction which is generally lateral to the first printing direction on the main label portion.

18. The method recited in claim 17 further comprising the steps of: removably affixing a patient advisory form alongside the main label portion; and printing patient advisory information onto an outer surface of the patient advisory form in either the first or second printing directions.

19. The method recited in claim 18 further comprising the step of printing the main label portion, the warning label portions and the advisory patient form during one printing pass.

B. ***Claim Construction Analysis***

1. ***The Words of the Patent***

The Court begins its claim construction analysis by focusing on the words actually used in claim 1 of the '906 Patent and claim 17 of the '395 Patent, without adding or subtracting words. Claim 1 of the '906 Patent expressly refers to two labels such that the removal of one of the labels will simultaneously remove "another label." The ordinary and customary meaning of the words in claim 1 permits connected main and warning labels that are simultaneously removable. Nevertheless, ABP is correct that claim 1 does not literally require connected main and warning labels that are simultaneously removable.

Claim 17 of the '395 Patent includes the limitation that "the main and warning label portion may be rapidly and efficiently printed and affixed to the container." This limitation is a reference to a warning label connected to a main label so that a pharmacist peels off both labels simultaneously and can apply both labels to the drug container. ABP argues that the section of claim 17 regarding rapidly affixing the main and warning labels is in the preamble of the claim and, thus, is not a limitation of the claim. As noted above, the preamble of a claim is a limitation if it has been used by the patentee to define the structure of the claimed invention. In claim 17, the requirement for rapid affixing of the main and warning is a reference to the simultaneous removal of these labels, which feature is common to all embodiments shown in the ABP patents. Accordingly, the preamble of claim 17 of the '395 Patent is a limitation of the claim.

Second, the Court reviews the patent specification to determine whether ABP has employed terms in a way that is inconsistent with their plain and ordinary meaning, or whether ABP has disavowed subject matter from the scope of its patent claims. The abstracts of the reexamined '906 Patent and the '395 Patent state: "The label section is comprised of a plurality of adhesive backed labels and a backing sheet, including a main label portion and at least one smaller auxiliary label." D's Exh. 2 at Tab '906 Reexamination Certificate, U.S Patent B1 5,642,906, abstract, ln. 57; Tab U.S. Pat. 5,855,395, abstract, ln. 57.

The specifications of the '906 Patent and '395 Patent expressly provide:

However, there is no known prior art reference which provides a blank for a computer printer that contains portions for both a removable prescription drug label and a removable warning label with portions for other printed information. Such a system would reduce package costs, provide greater flexibility, and be compatible with existing computer software used by pharmacies.

Accordingly the present invention is designed to provide a multi-part blank which can be fed in a computer driven printer and when printed, will contain all of the parts needed for a complete set. Such a set contains a peelable vial label having a pressure sensitive adhesive connected to removable strips of computer selected warning labels also having a pressure sensitive adhesive.

D's Exh. 2 at Tab U.S. Pat. 5,642,906, col. 1, lns. 52-65; Tab U.S. Pat. 5,855,395, col. 1, ln. 57-col. 2, ln. 5. This description precedes any discussion of the preferred embodiment.

Furthermore, the specifications of the '906 Patent and '395 Patent provide:

As described in detail above, in carrying out a method of labeling utilizing blank forms according to the invention, the user causes the desired information to be printed on the main label and, optionally, on one or more auxiliary labels, simultaneously removes the printed main label and at least one auxiliary label from the backing sheet, separates any simultaneously removed but unused auxiliary label(s), and simultaneously applies the main label and any remaining, i.e., used, auxiliary label(s) to another surface.

D's Exh. 2 at Tab U.S. Pat. 5,642,906, col. 5, lns. 57-65; Tab U.S. Pat. 5,855,395, col. 6, ln. 6-14. Thus, the specifications of the '906 Patent and the '395 Patent show that ABP has employed terms in a way that is less broad than their plain and ordinary meaning. According to these specifications, the claims do require *connected* main and warning labels that are simultaneously removable.

2. ***The ABP Patent Prosecution History***

Next, the Court reviews the patent prosecution history to determine whether ABP has disavowed subject matter from the scope of its patent claims. The '906 Patent relates back to a first patent application (the '415 Application) filed by ABP on September 16, 1993 in the Patent Office. *See* D's Exh. 2 at Tab File History 08/121, 415 ('415 Application File). FN3 After being unable to convince the Patent Office to allow any claims during prosecution of the '415 Application, ABP abandoned that application and filed a continuation-in-part (CIP) application on July 20, 1995, that claims priority to the '415 Application. P's Exh. 4 ('906 Application and Claims). The CIP application incorporates the same description of a pharmacy prescription label that is in the '415 Application, and added descriptions of additional embodiments of an ABP prescription form. ABP did obtain Patent Office approval of claims during prosecution of the application of

the CIP application. See D's Exh. 2 at Tab '906 Patent Prosecution History. The '906 Patent issued on July 1, 1997, D's Exhibit 2 at Tab U.S. Patent 5,642,906.

FN3. Defendants' Exhibit 2 comprises portions of the prosecution histories of the ABP patents in suit, as do ABP's Exhibits 1 and 4. A complete copy of the prosecution histories of ABP's patents is in Exhibit A to Defendants' *Markman* Motion Regarding Claim Construction of the '906, '395 and '231 Patents. *See* Docket No. 82.

The '906 Patent was the subject of a reexamination proceeding in the Patent Office that commenced on July 15, 1998, during which some of the claims of the '906 Patent were amended.FN4 D's Exh. 2 at Tab '906 Reexamination File History. On July 20, 1999, the amended claims were issued by the PTO in a reexamination certificate. It is the claims of the reexamination certificate that ABP alleges to be infringed, and that are the subject of this report and recommendation.

FN4. Defendants assert that all of the claims were substantively amended during reexamination. ABP argues that, if all claims were substantively amended, then ABP can recover damages for infringement of the '906 Patent only for infringements occurring after the reexamination certificate issued on July 20, 1996. *See* 35 U.S.C. s.s. 252, 307(b); Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1346-48 (Fed.Cir.1998). Defendants sought to raise this issue in the *Markman* context, but the Court determined that the issue is better resolved in the context of summary judgment.

The '395 Patent issued on January 5, 1999 is based on a continuation application filed on June 3, 1997. D's Exh. 2, Tab U.S. Patent 5,855,395. The application for the '395 patent claims priority to the CIP application from which the '906 Patent issued and the original '415 application. D's Exh. 2 at Tab '395 Patent Prosecution History.

The '231 Patent issued on March 14, 2000 is based on a continuation application filed on December 31, 1998. D's Exh. 2 at Tab U.S. Patent 6,036,231. The application for the '231 patent claims priority to the continuation application from which issued the '395 Patent, the CIP application from which the '906 Patent issued, and the original '415 application. D's Exh. 2 at Tab '231 Patent Prosecution History. The following portions of the prosecution histories of ABP's patents are material to construction of the asserted claims of these patents:

a. '415 Application

The prosecution history of the '906 Patent, as well as the prosecution of the '415 Patent from which the '906 Patent is derived, indicates that the ABP limited its invention to include main and auxiliary labels. While ABP may not be directly bound by its arguments in prosecuting the abandoned '415 patent, the prosecution history of that patent may still be helpful in construing the '906 Patent because the '906 Patent is a continuation-in-part of the '415 patent.

During prosecution of the original '415 Application, the Patent Office rejected all claims for anticipation and obviousness (35 U.S.C. s.s. 102, 103) because the prescription pharmacy form recited in those claims was anticipated by and obvious in view of prior art forms shown in the Browning and Garrison Patents. D's Exh. 2 at Tab File History of 08/121,415 (MNA 000051-55); Tab Prior Art Patents (includes copies of Browning

and Garrison Patents). Browning shows a multi-part shipping label having a larger data label (48 in Fig. 1 of Browning) and several smaller price labels (36). D's Exh. 2 at Tab Prior Art Patents, Browning, col. 6, lns. 11-23. The smaller price labels are separated from each other by perforation lines. The Browning price labels would separate from the backing paper simultaneously. Id. at Browning, col. 6, lns. 19-22 ("The price tags 38 are then removed from the liner 16, as required, along with the data portion 48, as desired.").

Garrison discloses a pharmacy prescription form having a large main prescription label (20 in Fig. 1 of the Garrison Patent) that is adjacent to several auxiliary warning labels 22, 23 and 24. Id. at Garrison, col. 2, lns. 58-63. These and other labels, e.g., a prescription information label 26, are included on a single form sheet and are "printed at the same time on one printer." Garrison, col. 1, lns. 26-30. The prescription label and warning labels are adhesive labels mounted on a backing sheet, but they are not connected to each other. The prescription and warning labels are removed separately by a pharmacist from the form before being applied to a drug container. Id. at Garrison Patent, col, 3, lns. 13-18. ABP admitted that the Garrison Patent is prior art during prosecution of its patent. D's Exh. 2 at Tab File History of 08/121,415 (MNA 000051-67, "the Garrison disclosure, which is perhaps the most state-of-the art prior art" MNA 000065).

In response to the Patent Office Action, ABP distinguished its prescription pharmacy forms from the prescription form shown in Garrison, and the shipping and price labels shown in Browning as follows:

With applicants' [ABP's] form, a plurality of warning labels, e.g., 98, 100, 102, 104, are simultaneously removed from the form *along with* the main container label 96, requiring that the pharmacist simply separate any unused warning labels (if any) from the strip and affix the main label *and* any connected warning labels(s) to the drug container in a single operation.... This advantage of applicants' form is arrived at by judicious use of perforation lines that the Examiner agrees are not disclosed by Browning *et al* and is an element of every claim.

D's Exh. 2 at Tab File History of 08/121,415 (MNA 000051-67, see especially MNA 000065) (bolding supplied and underlining in original).

The Patent Office issued a final rejection in the '415 Patent application, from which ABP did not appeal. Rather, ABP filed the continuation in part application for the '906 Patent. In the final rejection in the '415 Application, the Patent Office stated:

The step of simultaneously removing the backing sheet from a printed vial label and a plurality of drug warning labels and separating any unused drug warning labels from the printed label means would have been an obvious matter of design choice since applicant has not disclosed that the step of simultaneously removing the backing sheet from a printed vial label and a plurality of drug warning labels and separating any unused drug warning labels from the printed label means solves any stated problem and it appears that the invention would perform equally well with the step of removing the label from the form and applying it to the medicine container and applying the warning labels to the medicine container as in Garrison in column 3, lines 14-19.

D's Exh. 2 at Tab '906 Patent Prosecution History, MNA 000189, 192-93 (Final Patent Office Action from the '415 Application). Faced with this final rejection, ABP abandoned its '415 application.

b. '906 Patent **Prosecution**

ABP is bound by the positions taken during the prosecution of the '906 Patent. The introduction of the patentability brief for the '906 Patent clearly and unequivocally states ABP's intention that its invention includes a main label and at least one auxiliary label.

ABP filed its continuation-in-part (CIP) application for the '906 Patent before abandoning the '415 application. In filing the CIP application for the '906 Patent, ABP added claims directed to a "method of labeling a container for a drug dispensed by a pharmacist." P's Exh. 4 at 22 (claims 25 and 26). During prosecution of the application for the '906 Patent issued, ABP submitted a Patentability Brief that responded to rejections the Patent Office had made in the '415 application. D's Exh. 2 at Tab '906 Patent Prosecution History, Patentability Brief at MNA 000174-187. In its brief, ABP distinguished its prescription pharmacy form from the prior art as follows:

[p]rior to applicants' invention, the custom printing of the main prescription label and associated warning labels was done on forms that required entirely separate operations by the pharmacist dispensing the prescription to remove each of the labels from the printed form and then separately affix the main drug container label and any associated warning label(s).....

* * * * * *

According to the invention of this application, a blank business form is provided having *inter alia,* an adhesive main label, e.g., a drug container prescription label, and one or more smaller adhesive auxiliary labels, e.g., warning labels. The form permits the user to *simultaneously* remove the main label and at least one auxiliary label from the backing sheet, readily separate any unused (i.e., not printed upon) auxiliary label(s) from the printed main label, and *simultaneously* apply the main label and any printed upon auxiliary label(s) to a receptive surface, e.g., a prescription drug container.

D's Exh. 2 at Tab '906 Patent Prosecution History, Patentability Brief at 2-3 (MNA 000177). ABP's Brief further stated:

a form according to applicants' invention requires that at least one of the auxiliary labels,...separate from the form when the main label...is removed from the form.

Id. at 4 (MNA 000178) (distinguishing Browning). ABP's Brief further stated:

Functionally, applicants' forms *result* in at least one auxiliary label simultaneously separating from the backing sheet with the main label *and* in that auxiliary label optimally being readily separated from the main label if desired by the user....

* * * * * *

Neither the Browning et al form nor the Garrison form expressly taught in these references results in the *simultaneous* removal and *optional* subsequent separation features of applicants' form.

Id. at 5-6 (MNA 000179). The ABP Brief continues:

The die cuts separating Garrison's main label and adjoining auxiliary label, and each of the auxiliary labels from each other, *preclude* a Garrison form from meeting applicant's claims. That is, because die cuts are

used by Garrison, the Garrison-form user cannot simultaneously remove one or more auxiliary labels with the main label-the main label is completely separated from all auxiliary labels. Also, the option of *subsequently* separating any simultaneously-removed auxiliary label from the main label after removal from the backing sheet obviously does not exist with a Garrison-type form...

* * * * * *

In fact, it is impossible for a Garrison form to be used in a manner where removal of the main label from the backing sheet *simultaneously* removes one or more auxiliary labels.

Id. at 6-7 (MNA 000180). The ABP Brief continues:

Pharmacist Sikes conducted a time study comparing the use of ABP's prescription form having connected main and warning labels to a Garrison type form (i.e., Walgreens) which has no connections between labels.

Id. at 10 (MNA 000184). Finally, the ABP Brief states:

Mr. Sikes' studies showed that the forms of this invention worked and that there were surprising and substantial increases in efficiency when pharmacists used forms according to the invention in labeling prescription containers as opposed to using Wal-Mart and Walgreens forms, *i.e.,* Garrison-type forms.

Id. at 11-12 (MNA 000185-86) (bold emphasis supplied; underlining in original).

To overcome the statement in the Patent Office rejection that ABP had submitted no evidence that its prescription form was better than the form shown in the Garrison Patent (MNA 000192-93), ABP submitted a declaration of Richard Foote, who is named as an inventor on the patents. The Foote Declaration states as follows:

Both the Walgreens and Wal-Mart forms require that the dispensing pharmacist separately and individually remove the printed main drug container prescription label and each of the printed warning labels from the backing sheet and separately apply same to the container.....

* * * * * *

According to the invention of this application, a business form is provided having an adhesive main label, e.g., a drug container prescription label, and one or more smaller adhesive auxiliary labels, e.g., warning labels, which permits the user to *simultaneously* remove the main label and at least one auxiliary label from the backing sheet, readily separate any unused (i.e., not printed upon) auxiliary label(s) from the printed main label, and *simultaneously* apply the main label and any printed upon auxiliary label(s) to a receptive surface, *e.g.,* a prescription drug container.

* * * * * *

The results of Mr. Sikes' studies show, among other things, that the use of forms according to the invention saves pharmacists time *and* money when compared to the use of forms such as the Walgreens form ... The May 1995 study shows that the use of one form according to this invention required only 55 percent as much time to fully label a prescription container with a prescription label and two warning labels as was

required using the Walgreens form ....

D's Exh. 2 at Tab '906 Patent Prosecution History, Foote Declaration, paragraphs 6, 7, 11 at MNA 000211-12 (bold supplied; underlining in original). The Foote Declaration goes far beyond merely discussing the preferred embodiment of his invention. Id.

The Patent Office rejected the claims of the '906 Patent on October 7, 1996. *See* Docket No. 82, Exhibit A to Defendants' *Markman* Motion Regarding Claim Construction of the '906, '395 and '231 Patents, '906 Prosecution History (MNA 000264-65 and 278-282). The prior art rejections were again based on the Browning and Garrison Patents, and the Cavender Patent which shows a business form with an address label and a group of fold-under price labels. See D's Exh. 7 (which is a Fig. 2 of Cavender).

In response to the rejections of October 7, 1996, ABP filed an amendment that substituted new claims for the rejected claims. D's Exh. 2 at Tab '906 Patent Prosecution History, MNA 000284-293. The new claims included application claim 60 that subsequently became (after further amendment) claim 1 of the '906 Patent. Id. at MNA 000286-87. In the response, ABP argued that its new claims (including claim 60) were patentable over the combined address label and price labels shown in Cavender, Browning and Garrison. Id. at MNA 000289-290. ABP distinguished the Cavender address/price label by stating:

the price tag sublabels of Cavender's label L are completely separated from label L [sic. L'] and its sublabels by the recipient before use, so that there can be no simultaneous removal as to between any of the labels [i.e., the price labels-L] and any labels comprising L'.

D's Exh. 2 at Tab '906 Patent Prosecution History, Response to Office Action of October 7, 1996, MNA 000290 (bold supplied).

ABP argued that the Cavender label form is separated between the larger address label (L') and the price labels (L) before the labels are removed from the backing web-sheet. D's Exh. 2 at Tab Prior Art Patents, Cavender, col. 3, In. 64 to col. 4, In. 4. The price labels (L) are shown as a group of individual price labels connected by a perforated line. Id. at Cavender, Figs. 1 and 2, col. 4, Ins. 1-4. The adhesive labels shown in Cavender are releasably mounted on a backing web-sheet. Id. at Cavender, col. 3, Ins. 4-9 ("The web 20 is constructed of a web of supporting material 22 and a web of printable label material 23 releasably adhered by means of pressure sensitive adhesive 24 to the supporting material 22.").

Although the Cavender price labels (L) are connected to each other, ABP distinguished Canvender by stating that

Cavender does not teach any simultaneous removal of the price labels. Indeed, he specifically teaches, for example, that lines 31 and 31' are "lines of *at least* partial severing" ... "and can be completely severed as shown in Fig. 10 ..." Thus applicant's invention was not contemplated by Cavender and it cannot be determined whether any of Cavender's " *at least* partial severing" would *permit* simultaneous removal, *i.e.*, retain sufficient strength to overcome the releasable bond between the labels and the carrier.

D's Exh. 2 at Tab'906 Patent Prosecution History, Response to Office Action of October 7, 1996 (MNA 000290) (bold supplied; underlining in original).FN5

FN5. Defendants argue that Cavender *erroneously* stated that the price labels shown in Cavender are not

simultaneously removed together. Defendants contend that the Cavender price labels, in one embodiment, are separated from each other by perforated lines 33 and 33'. D's Exh. 2 at Tab Prior Art Patents, Cavender, Fig. 1; col. 3, Ins. 30-34 ("The lines 31 and 31' are shown to be lines of partial severing although the label material 23 is at least partially severed along the lines 31 and 31' and can be completely severed as shown in FIG. 10."). The perforated lines connect the price labels to each other, and ensure that all of the price labels will peel off simultaneously together. The perforated lines 31 and 31' between the price labels do have sufficient strength to overcome the releasable adhesive bond between the price labels and the "carrier," which is the backing web-sheet. Figures 1 and 4 of Cavender show the labels being peeled off while still connected to each other. Accordingly, the defendants argue that ABP's statement that "Cavender does not teach any simultaneous removal of price labels" is simply wrong, and should therefore be discounted. Defendants raise an issue of patent validity not properly before the undersigned. The undersigned examines the prosecution history relating to the Cavender Patent only to determine ABP's stated disavowment and claim limitations.

ABP made further amendments to application claim 60 in a supplemental amendment, but the prosecution history does not explain why the amendments were made. D's Exh. 2 at Tab '906 Patent Prosecution History (MNA 000295-99). Thereafter, the Patent Office approved of the application and issued a notice of allowability. D's Exh. 2 at Tab '906 Patent Prosecution History (MNA 000300). The '906 Patent issued on July 1, 1997.

ABP argues that its prosecution of the amended '906 claim 1, as stated in the recertification, does not focus on separate main and auxiliary labels and that any previously disavowed subject matter does not apply to the amended claim 1 because it was prosecuted separately and subsequent to any disavowment with regard to the previous claims. However, case law indicates that any disavowment continues to apply to further prosecution. *See* Ballard Medical Products, 268 F.3d at 1360. The Federal Circuit held the inventor to his disavowment with regard to a subsequent claim within the same patent even though he was prosecuting a separate, yet directly-related, patent. Similarly, ABP is bound not only by a disavowal of subject matter as to prior claims within the same patent, but also as to disavowals concerning a directly-related patent.

The prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertainingthe degree of lawful conduct, such as designing around the claimed invention. Hockerson-Halberstadt, 222 F.2d 951, 957 (Fed.Cir.2000) (citing Vitronics, 90 F.3d at 1583); Lemelson v. General Mills, Inc., 968 F.2d 1202, 1208 (Fed.Cir.1992). If a competitor of ABP were to read the prosecution history of the '906 Patent-particularly the '906 patentability brief and portions of the '415 prosecution history-that competitor would reasonably believe that ABP had limited its invention to require a main label connected to at least one auxiliary label. Having prosecuted the patent as one requiring a main label connected to at least one auxiliary label, ABP cannot then broaden its patent to include any two labels which can be simultaneously removed.

c. '395 Patent **Prosecution History**

The '395 prosecution history includes similar documentation indicating that the invention is to include a main label and at least one auxiliary label. Most significantly, ABP submitted to the PTO one of defendant Moore's labels in an attempt to distinguish its label from prior art. See D's Exh. 2 at Tab '395 Patent Prosecution History (MNA 000534-39) (June 5, 1998). ABP asked the PTO to specifically note how

defendant's label did not allow for the simultaneous removal of a main label and at least one auxiliary label from a backing sheet. ABP is bound by this distinction it made to the PTO in prosecuting the '395 Patent. Furthermore, it is illogical to contend that a product which is used as an example of prior art for the purpose of distinguishing a patent can later infringe the patent.

ABP filed its continuation application for the '395 Patent before the '906 Patent issued. In connection with the application, ABP filed a preliminary amendment that added several new claims including application claim 32 for a "method of forming a composite label for a container useful in dispensing drugs ..." D's Exh. 2 at Tab '395 Patent Prosecution History (MNA 000526). Application claim 32, after amendments, became claim 17 of the '395 Patent. Application claim 32 (and patent claim 17) include the limitation that "the main and warning label portion may be rapidly and efficiently printed and affixed to the container." It is this limitation that requires interpretation.

Early in prosecution of the application for the '395 Patent, ABP filed an Information Disclosure Statement (IDS) which cited a Moore prescription pharmacy form ("Moore Script Business Form"), that is similar in structure to a Walgreens prescription form included with the Sikes time study and the prescription form shown in the prior art Garrison Patent. D's Exh. 2 at Tab '395 Patent Prosecution History (MNA 000534-39) (June 5, 1998). In its IDS, ABP stated that the Moore Script Business Form has a "main drug container label portion [that] is not attached to the warning labels in such as way as to permit the two to come off together, as is the case with Applicants' invention." Id. at MNA 000535. The Moore Script Business Form is one of the forms that ABP now accuses of infringement of the '395 Patent. ABP's statement distinguishing its patented form from the Moore Script Business Form was made about its invention in general, and was not directed to any particular claim of the application of the '395 Patent.

The Patent Office rejected the claims of the application for the '395 Patent. D's Exh. 2 at Tab '395 Patent Prosecution History (MNA 000564-572). The Patent Office rejected application claim 32 (claim 17 of the '395 Patent) in view of a prior art CVS prescription label (which is not the same as the Moore Script Business Form), a prescription drug label shown in the Haines Patent, and the prescription form shown in the Garrison Patent. Id. at MNA 000567, 569, 570-72.

In response to the rejection, ABP amended application claim 32 to require "plural" warning label portions to be included with a main label portion on a blank form, and that at "least one warning label portion" and the main label portion be "rapidly and efficiently ... affixed to the container." D's Exh. 2 at Tab '395 Patent Prosecution History, Amendment at MNA 000575-531, especially 000587. In addition, ABP argued with respect to application claim 32 (patent claim 17) that in the CVS form "the lifting of the main (vial) label portion from the backing sheet clearly does not achieve simultaneous removal of the three elongated strips underneath the main label portion, in direct contrast to the recitation of the rejected claims." D's Exh. 2 at Tab '395 Patent Prosecution History, Amendment at MNA 000596. Accordingly, ABP specifically distinguished claim 17 of the '395 Patent because the prior art CVS form did not disclose main and warning labels that are simultaneously removed so that they may be rapidly affixed to a drug container. The Patent Office approved the application, in view of the claim amendments and arguments made by ABP. D's Exh. 2 at Tab '395 Patent Prosecution History, MNA 000624. The '395 Patent issued on January 5, 1999.

d. Disavowal in Prosecution

ABP clearly disavowed from its patent claims prescription pharmacy forms in which a main label is not connected to an auxiliary warning label such that the main and warning label are simultaneously removed.

The statements by ABP regarding simultaneous removal of main and warning labels is a reference to the connection between those labels. The patents describe a perforated tear line connecting the main and warning label as the means by which the labels are removed simultaneously. D's Exh. 2 at Tab U.S. Patent 5,642,906, Col. 4, Ins. 59-64. In prosecution, ABP distinguished forms without connected main and warning labels as not providing for simultaneous removal of labels. ABP disavowed this subject matter in the prosecution of the '415 application, and in the applications for the '906 and '395 Patents.

The disavowals were clear and explicit. ABP stated that its invention is "a business form [ ] having an adhesive main label, e.g., a drug container prescription label, and one or more smaller adhesive auxiliary labels, e.g., warning labels, which permits the user to *simultaneously* remove the main label and at least one auxiliary label from the backing sheet." D's Exh. 2 at Tab '906 Patent Prosecution History, Foote Declaration, MNA 000210 (emphasis in original). The disavowals were equally clear and explicit as to what ABP's invention is not: "the Garrison-form user cannot simultaneously remove one or more auxiliary labels with the main label-the main label is completely separated from all auxiliary labels." Id. at MNA 000180. Indeed, ABP stated to the Patent Office that a Moore prescription form (which is now accused of infringement) is distinct from the form that ABP was seeking to patent because the Moore form did not have the main prescription label attached to a warning label. Id. at MNA 000535.

The general statements made by ABP disavowing subject matter relate to limitations of claims of the '906 Patent and claim 17 of the '395 Patent. Claim 1 of the '906 Patent includes a limitation that "the removal of one of the labels from the backing sheet will simultaneously remove from the backing sheet another label to which it is connected." This limitation of claim 1 (as well as limitations in all other claims) is the subject of ABP's disavowal of forms that lack a main label connected to an auxiliary warning label such that these two labels are removed simultaneously. This limitation of claim 1 must be construed to make plain that the two labels recited in claim 1 are a main and auxiliary label as ABP argued during prosecution of the claims of the '906 Patent.

ABP submitted to the Patent Office Dr. Sikes' time study that demonstrates a time savings in applying connected main and auxiliary warning labels to a drug container, as compared to separately peeling and applying individually main and warning labels. D's Exh. 2 at Tab '906 Patent Prosecution History, Foote Declaration, MNA 000209-12. A form containing a main label separated from two connected warning labels, does not permit the *simultaneous* removal and labeling of a prescription bottle. Clearly, the meaning given to claim 1 of the '906 Patent should align with the purpose of the patented invention. Unlike a connected main label and at least one warning label, the connection of two warning labels, without more, hardly solves any problem facing pharmacists. Indeed, the non-connection of the main label and a warning label defeats the very purpose of the '906 Patent and, refutes the stated advantage of the '906 Patent over the prior art.

Further, ABP argued the patentability of claim 17 by stating that the prior art did not disclose main and warning labels that are removed simultaneously. D's Exh. 2 at Tab '395 Patent Prosecution History, MNA 000595-96. Accordingly, claim 17 of the '395 Patent does have limitations that should be construed as requiring connected main and warning labels.

In view of the disavowal of subject matter made by ABP during prosecution of its patents, claim 1 of the '906 Patent and claim 17 of the '395 Patent should be construed to require a main label connected to an auxiliary warning label. Limitation (c)(1) of claim 1 of the reexamined '906 Patent reads:

(c) means for connecting said labels such that:

(1) the removal of one of the labels from the backing sheet will simultaneously remove from the backing sheet another label to which it is connected;

The term "one of the labels" has acquired the meaning "main label." The term "another label" has acquired the meaning "auxiliary label." Similarly, in claim 17 of the '395 patent, the phrase "the main and warning label portions may be rapidly and efficiently printed and affixed to the container" has acquired the meaning that the main and warning labels are releasably connected.

ABP contends that the above construction of claims 1 and 17 impermissibly adds words to a claim. ABP is mistaken. The public is entitled to rely on the patents and their prosecution history to determine the scope of the claims. The interpretation of the acquired meaning of terms in this manner is the essence of claim construction.

ABP argues that claim 1 of the '906 Patent (claim 60 in the application) had not been added to the application when it made many of the arguments that its form had connected main and auxiliary labels. However, ABP made many general statements that its invention has connected main and warning labels. These statements were not limited to any particular claims, and address the connection between labels, a limitation of claim 1. Moreover, when claim 60 was added to the application, ABP made no statement that the claim was directed to connected warning labels, rather than connected main and warning labels. Accordingly, the prosecution history of the '906 Patent makes clear that ABP disavowed the subject matter of unconnected main and warning in general, and not with respect to only certain claims.

ABP argues that the construction given to claim 1 is inconsistent with the other claims of the '906 Patent. Interpreting claim 1 to require a main prescription and prescription drug label and a smaller auxiliary prescription drug label does not render the claim inconsistent with any other claim, as is argued by ABP. In particular, dependent claims 2 and 3 do not suggest that "[c]laim 1 encompasses a form in which neither of the connected labels contains information identifying either the customer or the prescription drug," as ABP contends. Claims 2 and 3 depend on and incorporate all of the limitations of claim 1. Claims 2 states that prescription form blank includes a label to receive "information identifying at least the customer and the prescription drug." The label may or may not be the main prescription label, because the labels that identify the patient and the drug disclosed in the '906 Patent are both the main prescription label and the separate recordation labels. D's Exh. 2 at Tab U.S. Patent 5,642,906, Fig. 4; col. 4, Ins. 49-53. It is not inconsistent with claim 2 to construe claim 1 as requiring a main label to receive printed prescription and prescription drug label, and a smaller auxiliary label that receives prescription drug information.

Claim 3 depends on claim 2 and further states that "one of said two connected labels is adapted to receive printed information identifying at least the customer and the prescription drug." The "one of said two connected labels" is the same label that in claim 1 is to receive information "concerning a prescription." Claim 3 makes clear that the "one of said two connected labels" is the main prescription label which receives prescription information, including the identity of the customer and prescription drug. Claim 3 is consistent with a construction of claim 1 that requires the "one of said two connected labels" to be a main prescription and drug label.

Independent claim 4 is also consistent with claim 1 as construed here. If possible, the Court should construe claims so as to preserve their validity. Both of these independent claims are directed to the same pharmacy

prescription forms shown in the '906 Patent. The claims are similar in scope. Claim 1 states that one of the labels receives printing that relates to the prescription and prescription drug. Similarly, claim 4 states that one of the labels receives printing "identifying the customer and the prescription drug." It is entirely consistent with claim 4 to interpret claim 1 as requiring a main prescription label.

Independent claims 1 and 4 of the '906 patent include a means-plus-function limitation for a "connecting means." Defendants and ABP are in agreement as to the interpretation of the "connecting means" limitation of claims 1 and 4. In view of its means-plus-format, the connecting means is limited to a score line or perforated tear line between the connected labels, and to equivalents of a score or perforated tear line.

IV. ***CONCLUSION***

The Court agrees with the defendants' argument as to proper claim construction. The Court construes claim 1 of the '906 Patent and claim 17 of the '395 Patent as requiring a main label connected to an auxiliary warning label. In limitation (c)(1) of claim 1 of the reexamined '906 Patent, the term "one of the labels" has acquired the meaning "main label." The term "another label" has acquired the meaning "auxiliary label." Similarly, in claim 17 of the '395 patent, the phrase "the main and warning label portions may be rapidly and efficiently printed and affixed to the container" means main and warning labels that are releasably connected.

It is therefore **RECOMMENDED** that **DEFENDANTS' MOTION TO CONSTRUE** U.S. PATENT NO. 5,642,906 (Docket No. 80) filed August 27, 2001 be **GRANTED IN PART AND DENIED IN PART** pursuant to this report and recommendation. It is

FURTHER RECOMMENDED that **ABP PATENT HOLDINGS' MOTION FOR *MARKMAN* HEARING (Docket No. 83)** filed August 27, 2001 be **GRANTED IN PART AND DENIED IN PART** pursuant to this report and recommendation. It is

FURTHER RECOMMENDED that DEFENDANTS' MOTION TO CONSTRUE U.S. PATENT NO. 5,855,395 (Docket No. 86) filed August 27, 2001 be **GRANTED IN PART AND DENIED IN PART** pursuant to this report and recommendation.

Failure to file written objections to the proposed findings and recommendations in this report pursuant to 28 U.S.C. s. 636(b)(1) and Local Rule 6.02 within ten days of the date of its filing shall bar an aggrieved party from a *de novo* determination by the district court of issues covered in the report, and shall bar an aggrieved party from attacking the factual findings on appeal. Any party filing an objection to this report an recommendation shall file and serve a copy of the *Markman* hearing transcript with the objections unless the transcript has already been filed. Any motion to extend time to file and serve objections to this report and recommendation will likely be denied due to the proximity to trial.

Dec. 11, 2001.