United States District Court,
D. Arizona.

VENTANA MEDICAL SYSTEMS, INC,
Plaintiff.
v.
BIOGENIX LABORATORIES, INC,
Defendant.

No. CV 03-92 TUC RCC

Aug. 29, 2005.

Brian Range, Nicole W. Stafford, Wilson Sonsini Goodrich & Rosati LLP, Austin, TX, Roger J. Chin, Sarah R. Zimmerman, Wilson Sonsini Goodrich & Rosati, San Francisco, CA, Ron Eleazer Shulman, Wilson Sonsini Goodrich & Rosati, Palo Alto, CA, Craig H. Kaufman, Quarles & Brady LLP, Tucson, AZ, Jeffrey N. Danis, Ventana Medical Systems Inc., Oro Valley, AZ, for Plaintiff.

Jeffrey H. Greenberg, Leonard Felker Altfeld Greenberg & Battaile PC, Peter Bernard Goldman, Altfeld Battaile & Goldman PC, Tucson, AZ, for Defendant.

ORDER and OPINION on MOTION

RANER C. COLLINS**, District Judge.**

Pending before the Court are 1) Plaintiff's Claim Construction Brief of the U.S. Patent No. 6,352,861 ('861); and 2) Defendant's Claim Construction Brief of the '861 Patent. On February 11, 2003, Plaintiff Ventana Medical Systems, Inc. ("Ventana") brought this action against Defendant BioGenix Laboratories, Inc. ("BioGenix") alleging infringement of U.S. Patent No. 6,352,861 ('861). The issue before the Court is the interpretation of certain claim language of '861 Patent. The parties briefed their respective positions on claim construction, and the Court held a *Markman* hearing on August 11, 2005. This Memorandum Opinion presents the Court's construction of the disputed terms and phrases.

I. BACKGROUND

Ventana's patent is for an automated immunohistochemical staining device ("autostainer"), which is used for molecular analysis of tissue samples to diagnose cancer and disease. In particular, this patent involves an autostainer that has a carousel reagent support for bar coded reagent containers, a carousel slide support for bar coded slides directly under the carousel reagent support, a bar code reader to identify and locate reagents and slides, and a computer that receives information and coordinates the steps to stain the slide.

Ventana alleges infringement of independent claims 1 and 5, and dependent claims 3, 6, and 8. Both independent claims 1 and 5 recite "[a] method of dispensing reagent onto a slide." Claim 1 recites:

1. A method of dispensing reagent onto a slide, the method of comprising the steps of:

[a] providing at least one reagent container;

[b] providing at least one slide of a slide support;

[c] automatically identifying the reagent container using a computer;

[d] automatically determining whether reagent in the reagent container should be *dispensed* onto the slide; and

[e] *dispensing* the reagent in the reagent container onto the slide based on the determination of whether the reagent in the reagent container should be *dispensed* on the slide,

[f] wherein the step of automatically determining whether reagent in the reagent container should be *dispensed* on the slide includes the steps of:

[g] providing a bar code reader;

[h] reading a slide bar code placed on the slide using the bar code reader thereby acquiring slide information indicating reagent to be applied to the slide; and

[i] sending the slide information to the computer

Additionally, Claim 5 recites:

5. A method of dispensing reagents onto a slide, the method comprising the steps of:

[a] providing a plurality of reagent containers in a reagent support, each of the reagent containers having a reagent barcode;

[b] providing at least one slide on a slide support, the slide having a bar code;

[c] providing a bar code reader

[d] reading the bar codes on the reagent containers;

[e] determining reagents in the reagent containers based upon the reading of the bar codes on the reagent containers;

[f] reading the slide bar code on the at least one slide;

[g] determining a sequence of reagents to be applied on the at least one slide based upon the reading of the slide bar code on the slide; and

[h] *dispensing* the reagents in the reagent containers based upon the sequence of reagents to be applied.

After hearing and reviewing the parties' arguments, the Court finds the main dispute centers on the interpretation of "dispensing" and whether it has a narrowed meaning limited to "direct dispensing," excluding the "sip and spit" dispensing employed by the Defendant's product. The other issues before the court include the construction of the claim term "slide," and determining whether to impose a sequence limitation such that the reagent container bar code is read before the slide bar code.

II. THE LEGAL PRINCIPLES OF CLAIM CONSTRUCTION

As a matter of law, the exclusive duty before the court is the construction of disputed claim language of the patents. Markman v. Westview Instruments, Inc. 52 F.3d 967, 970 (Fed.Cir.1995). To resolve disputed claims, "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." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

The claims themselves define the limits of the patented invention and the right to exclude, while the specification and relevant prosecution history serve to understand the language in the claims. Markman, 52 F.3d at 980. The specification, or written description of the invention, acts like a dictionary by explaining the invention and defining terms used in the claims. Markman, 52 F.3d at 979. The claims "must be read in view of the specification ." *Id*. The specification is "the single best guide to the meaning of a disputed term." Vitronics Corp., 90 F.3d at 1582. The prosecution history, if in evidence, is also a significant tool in claim construction because it contains a complete record of the proceedings before the Patent and Trademark Office, including cited prior art not covered in the claims and statements by the patentee disclaiming certain interpretations. Vitronics, 90 F.3d at 1582.

Claim construction analysis begins with the patent claims. *Id*. There is a heavy presumption that claim terms carry their ordinary meaning as understood by one of ordinary skill in the art. *CSS* Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002); *see* Vitronics, 90 F.3d at 1582. This presumption can be rebutted in four ways. *CSS* Fitness, Inc., 288 F.3d at 1366-67. First, a claim term may be narrowed from its ordinary meaning if the patentee "acted as a lexicographer" and clearly disclosed a special definition for the disputed claim term in the specification or file history. Id. at 1366. Second, the ordinary meaning of a term is rebutted "if the patentee distinguished the term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." Id. at 1367. Third, the claim term does not carry its ordinary meaning if it " 'deprive[s] the claim of authority' as to require [the court to] resort to the other intrinsic evidence for a definite meaning." *Id*. (quoting Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985 (Fed.Cir.1999)). Fourth, according to statutory authority, if the claim is a step- or means-plus-function claim, it will only cover the corresponding step or means disclosed in the specification and equivalents thereto. *CSS Fitness, Inc*., at 1367.

If the disputed claim term continues to be ambiguous after examining the intrinsic evidence, only then may the court use extrinsic evidence, which includes expert and inventor testimony, dictionaries, and treatises. Vitronics, 90 F.3d at 1583. Additionally, the court's use of extrinsic evidence must be used "for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Id*. at 981.

III. DISCUSSION

A. "Dispensing" Means "Direct Dispensing."

Ventana stresses the heavy presumption that claim terms carry their ordinary and customary meaning and defines "dispensing" as "applying the agent." In claim elements 1[e] and 5[h], the step is "dispensing the reagent in the reagent container onto the slide ..." BioGenix counter-argues that the figures and specification characterize the claimed invention to limit "dispensing" to "direct dispensing," in which the reagent bottle/container is also the reagent dispenser (rather than having some intermediate transport mechanism to "sip and spit").

The ordinary meaning of the claim term may be narrowed by the specification. *CSS* Fitness, Inc., 288 F.3d at 1366-67; *see also* Telefex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed.Cir.2002) (The ordinary and customary meaning of a claim term may be narrowed by "characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope."). On the other hand, the court must avoid impermissibly adding limitations from the specification. Comark Communications v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998). The court must look at how the specification characterizes the claimed invention: does the specification "refer [ ] to a limitation only as part of less than all possible embodiments" or does the specification in its entirety "suggest [ ] that the very character of the invention requires the limitation be a part of every embodiment"? Alloc, Inc. v. Intn'l. Trade Commission, 342 F.3d 1361, 1370 (Fed.Cir.2003).

In *Alloc,* the three asserted patents claim systems and methods of joining floors. *Id*. at 1365. None of these patents explicitly recites a "play FN1" limitation; however, "the claims recite floor system features, ... in which play is necessarily present." *Id*. at 1368. The implications of a "play" limitation in the claim language were supported by the specification, which described the invention as a system in which "play exists" and "teaches that the invention as a whole, not merely a preferred embodiment, provides for play in the positioning of floor panels." *Id*. at 1369. Additionally, all of the figures and embodiments in the specification imply "play" and do not suggest any systems without "play." *Id*. at 1370. Thus, in *Alloc,* the common specification "read as a whole leads to the inescapable conclusion that the claimed invention must include play in every embodiment." *Id*. *See* Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1348 (Fed.Cir.2004) (the common specification shared by three patents led to the "inescapable conclusion" that the claims required communication over a telephone line despite the absence of such limiting claim language); *see* SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys. Inc., 242 F.3d 1337, 1342 (Fed.Cir.2001) (the common specification shared by three patents led to the "inescapable conclusion" that the claims required coaxial lumens despite the absence of such limiting claim language).

FN1. "play" is a space between a locking groove on a first panel and the locking element of a panel adjacent to the first panel; Alloc, 342 F.3d at 1367.

The case here is similar to *Alloc*. The asserted claims in the '861 patent do not explicitly recite "direct" dispensing; however, the context of the claim term "dispensing" supports the narrow construction that it means "direct dispensing." *See* Phillips v. AWH Corporation, 415 F.3d 1303, (Fed.Cir.2005) ("[T]he claims themselves provide substantial guidance as the meaning of particular claim terms ... To begin with, the context in which a term is used in the asserted claim can be highly instructive.") The claim language necessitates "direct dispensing" by stating that the reagent *in* the reagent container is dispensed *onto* the slide, meaning the reagent is dispensed directly from the reagent container. ('861 patent claim elements 1[e], 5[d], 5[h].

Additionally, like *Alloc,* the implication of a "direct dispensing" limitation is supported by the written description and the figures, which also strongly suggests that the reagent is directly dispensed onto the slide from the reagent container. Figure 1 of the '861 patent illustrates the front-right view of the autostainer used to perform the claimed method. In Figure 1, the reagent carousel supports inverted reagent containers directly above the slide carousel. The specification discloses that in Figure 1, "[t]he carousel is rotated ... to a position placing a selected reagent bottle in the reagent delivery position under the air cylinder reagent delivery actuator *over a slide to be treated with reagent*." (col. 6, lines 54-57). Figure 11 of '861 patent illustrates the top view of the slide support carousel of the autostainer and Figure 15 illustrates the cross-sectional view of the reagent receiving station.

In both figures, the reagent delivery actuator and the *inverted* reagent bottle are positioned directly above the slide. *See* col. 9, lines 24-26 ("Air cylinder reagent delivery actuator supported by support arm, contacts reagent bottle, directly over slide."). In this position, the autostainer applies pressurized air to the cylinder and a rod moves downward against a reagent container, col. 11, lines 40-43. As a result, the reagent container moves downward and emits a precise volume of a reagent liquid, which falls through a passageway onto the slide. Col. 11, lines 43-45; col. 12, lines 20-22. Thus, the specification and figures lead to the "inescapable conclusion that the reagent is directly dispensed (without any intermediate transferring device) from an inverted reagent container onto the slide. All of the relevant figures and embodiments in the specification imply "direct dispensing" and do not suggest any alternative dispensing method. Thus, the specification shows that "the invention as a whole FN2" provides for direct dispensing onto the slide. Essentially, the specification in its entirety "leads to the inescapable conclusion that the claimed invention must include [direct dispensing] in every embodiment."

FN2. Alloc, 342 F.3d at 1369

B. The clear and unmistakable prosecution disclaimer of "sip and spit" dispensing from the parent '052 application attaches to the same "direct dispensing" claim limitation in the '861 patent **.**

In the prosecution of a previous parent application (Application No. 07/924,052 ('052)), Ventana disclaimed "sip and spit" dispensing from the claim term "direct dispensing." In "sip and spit" dispensing, the reagent container and sample slide(s) are side-by-side. Some transport mechanism (i.e. micropipette or probe, essentially a straw-like structure) "sips" the reagent from the reagent container by suction and then moves over to the slide and "spits," or releases, the reagent onto the slide. Ventana's '861 patent claims are distinguishable from those in the '052 application because it only recites "dispensing." Ventana argues that the prosecution disclaimer from the parent application cannot apply to the '861 "dispensing" claims. BioGenix argues that the "sip and spit" disclaimer does apply and limits the scope of the '861 patent.

There is a heavy presumption in claim construction that claim terms be interpreted in favor of their ordinary and customary meaning. CCS Fitness, 288 F.3d 1359, 1366 (Fed.Cir.2002). However, if the patentee "unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of surrender." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed.Cir.2003). The doctrine of prosecution disclaimer prohibits patentees from "recapturing through claim interpretation specific meanings disclaimed during prosecution." Id at 1323. In other words, the claim may not be interpreted in a certain way to obtain the patent and then interpreted differently to allege infringement. Southwall Technologies, Inc. v. Cardinal Ig.

Co., 54 F.3d 1570, 1576 (Fed.Cir.1995). The prosecution disclaimer serves as a public notice and protects reliance on clear statements during prosecution. Omega, 334 F.3d at 1324. But in order to balance the patentee's right to seek broad coverage with the public notice function of disclaimers, the Federal Circuit requires "clear and unmistakable" disavowal during prosecution to allow such statements to limit the scope of the claim. Id. at 1325.

In particular, a disclaimer made during the prosecution of ancestor patent applications may attach as long as the prosecution disclaimer is directed to a common claim limitation. Id. at 1333. *See* Advanced Caridovascular Sys., Inc. v. Medtronis, Inc. 265 F.3d 1294, 1305 (Fed.Cir.2001) ("The prosecution history of a related patent can be relevant if, for example, it addresses a limitation in common with the patent in suit."); Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed.Cir.1999) ("the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contains the same claim limitation."); Augustine Med., Inc. v. Gaymar Indus., Inc., 181 F.3d 1291, 1300 (Fed.Cir.1999) ("the prosecution of a parent application may limit the scope a later application using the same claim term."). Thus, narrowing interpretations and disclaimers made during the prosecution of a parent application may attach to subsequent continuation applications. Omega, 334 F.3d at 1333-34.

Here, Ventana made a clear and unmistakable disclaimer of the "sip and spit" dispensing method directed toward the claim term "direct dispensing" in the '052 parent application. With respect to the direct dispensing claim limitation, the Patent and Trademark Office rejected Claims 1-3 and 5-6 of the '052 application as being unpatentable FN3 over Watake et al. in view of Assmann et al FN4. Office Action of November 29, 1993, BGNX 2197. The '052 application was rejected because "[i]t would have been obvious to one having ordinary skill in the art to replace the reagent containers of Wakatake e al. with the primary vessels as taught by Assman et al. thereby eliminating the transfer device in order to avoid cross contamination." *Id*. In response, the patentee submitted an amendment, stating:

FN3. Claims 1-3 and 5-6 were rejected for obviousness under 35 U.S.C. s. 103:
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

FN4. Watake et al. discloses an automatic analyzer that has a reagent carousel containing reagent containers. BGNX 2197. Assman et al. discloses an automatic analyzer having a moveable primary vessel containing the reagent that is directly passed to a sample. BGNX 2197.

Even in the unlikely event that Wakatake and Assman were successfully combined into one system FN5, the resulting system would still lack the present invention's novel capability to dispense reagent "directly to a sample" as set for in Applicants' Claim 1, at line 16.Amendment dated April 29, 1994, BGNX 2213.
FN5. Neither Wakatake nor Assman teach or suggest the combination of the two references ... the two systems involve incompatible referencing and indexing systems, with Wakatake teaching variable reagent container and sample positions, while Assman depends on stationary reagent container and sample positions ...

Claim 1 of the '052 application recites:

1. A biological reaction apparatus for dispensing a selected reagent *directly to a sample,* said biological reaction apparatus having:

... drive means, engaging the reagent carousel and operatively coupled to said homing and indexing means, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone wherein said reagent supply zone is oriented so that a reagent in a container in said preselected reagent container support is *dispensable directly to a sample*.

'052 Application, BGNX 2083. Exemplary reagent carousel and reagent supply zone encompassed by Applicants' Claim 1 are shown in Figures 1, 2, 3, 15 and 16 of the application. Amendment, BGNX 2215. These figures show that the reagent carousel is positioned above the samples and the reagent containers are inverted to dispense the reagent directly to the sample. *Id*. The patentee disclaims Wakatake by stating:

In contrast, Wakatake et al teaches reagent tables positioned side-by-side with a reaction table (Wakatake et al, Figure 2). This side by side configuration precludes dispensing of the reagent "directly to the sample" or the incorporation of a "reagent delivery zone" as set for in Claim 1 of the present invention. The Wakatake side by side configuration requires an additional device, a reagent pipetting device, to transfer the reagent between tables and mediate the dispensing of reagent to the sample. The reagent pipetting device is used to suck up an aliquot of reagent from a reagent container on one of at least two reagent tables, pivot so that the pipetting tube of the device is held just above a selected reaction vessel on a separate reaction table, and dispense the aliquot of reagent to the vessel (Wakatake at Col. 4, line 42-Co. 5, line 10). Such devices are referred to in the trade as 'sip and spit' devices."

Id. at 2216. Thus the patentee made a "clear and unmistakable" disclaimer of the "sip and spit method" directed toward Claim 1 and Figures 1, 2, 3, 15 and 16 of '052 application.

The clear and unmistakable disclaimer of the "sip and spit" dispensing from the '052 parent application attaches to the '861 "dispensing" limitation because there is a common claim limitation to which the disclaimer is directed: "direct dispensing." The court has already construed the claim term "dispensing" in the '861 patent to mean "direct dispensing" and thus, the ' 052 application and '861 patent have the same claim limitation. The "sip and spit" disclaimer may properly attach to the '861 patent (direct) dispensing limitation.

C. The Reagent Container and Slide Bar Code Reading Steps Occur in Any Order.

Based on the "natural language of the claims" and the Examiner's Reasons for Allowance FN6, BioGenix argues that the claims should be construed to include a sequence limitation in which a bar code reader first reads the reagent bar codes, then reads the slide bar codes, the staining run begins and reagents are dispensed. Ventana counters that the claims themselves do not impose an explicit limit on the order of steps.

FN6. BioGenix cited the Examiner's Reasons for Allowance, which indicated some order:
... Wherein the apparatus provides a barcode reader for reading the bar codes on the reagent containers, determining reagents in the reagent containers based on the reading of the bar codes. *Thereafter,* the barcode reader reading the slide bar codes and determining the sequence of reagent to be applied on the slides

base[d] upon the reading of the slide bar codes. *Lastly,* dispensing reagents in the reagent containers based upon the sequence of reagents to be applied.

However, according to the current version of the Manual of Patent Examining Procedure (MPEP), the patentee's failure to respond/object to the Examiner's Reasons for Allowance is not equivalent to acquiescence:
The failure of applicant to comment on the examiner's statement of reasons for allowance should not be treated as acquiescence to the examiner's statement. Any inference or presumption are to be determined on a case-by-case basis by a court reviewing the patent, the USPTO examining the patent in a reissue application or a reexamination proceeding, the Board of Patent Appeals and Interference reviewing the patent in an interference proceeding, etc.

Thus, the court will not consider the Examiner's Reasons for Allowance as evidence of a sequence limitation.
In *Interactive Gift Express, Inc. v. CompuServe Inc.*, the Federal Circuit held that "[u]nless the steps of a method actually recite an order, the steps are not ordinarily construed to require one.FN7" 256 F.3d 1323, 1342 (Fed.Cir.2001). However, the Federal Circuit continues to state that method steps can also implicitly require performance of the steps in the order written. *Id.* In *Altiris, Inc. v. Symantec Corp.,* the Federal Circuit clarified its decision in *Interactive* and stated a two-part test for determining if the claimed steps must be performed in the written order when the claim does not explicitly recite an order. 318 F.3d 1363, 1369 (Fed.Cir.2003).

FN7. claim language that "actually reciting an order," or explicitly reciting an order, uses signal words such as "first," "second," "next," "lastly"

First, the court must look to the logic and grammar of the claim language to determine if the steps must be performed in the order written. *Id. See, e.g.,* Loral Fairchild Corp. v. Sony Electronics Corp., 181 F.3d 1313, 1321 (Fed.Cir.1999) (the claim language indicated a sequence limitation because a subsequent step required the completion of a prior step); Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc., 152 F.3d 1368, 1375-76 (Fed.Cir.1998) (the claim language indicated a sequence limitation because each subsequent step made a logical reference indicating the prior step had been completed). Second, if the claim language is not indicative of a sequence limitation, the court must look to the rest of the specification to determine whether the specification directly or implicitly requires such a limitation. Altiris, 318 F.3d at 1369. If the specification also fails to require an implicit or explicit sequence limitation, the steps in the claim will not be construed as requiring performance of the steps in the order written.

Here, the claim language does not explicitly or implicitly require a specific order of the steps regarding reading the reagent bar code and slide bar code. All of the steps in the asserted claims do not explicitly indicate an order with language such as "first," "second," "last," etc. Additionally, the logic and grammar of the claimed steps do not require that the bar code reader read the reagent container bar code before the slide bar codes. In Claim 1, the reagent container may be identified 1[c] before or after the determination of whether the reagent should be dispensed 1[d], which includes the slide bar code reading step 1[h]. In Claim 5, the bar code reader 5[c] may read the reagent container bar code 5[d] before or after reading the slide bar code 5[f].

In contrast, the logic and grammar of other claim elements in Claims 1 and 5 require a sequence limitation based on language such as "based on/upon" and logical references to completion of a prior step. The following steps in Claim 1 occur in this order: [d], [f], [g], [h], [i], [e] FN8; in Claim 5, there are two set of steps that have a sequence limitation, the sets being of any order: [d], [e] FN9 and [f], [g], [h] FN10.

FN8. [d] automatically **determining whether reagent in the reagent container should be dispensed onto the slide;** and

[f] wherein the step of automatically **determining whether reagent in the reagent container should be dispensed on the slide** includes the steps of:
[g] providing a **bar code reader;**

[h] **reading a slide bar code** placed on the slide using the bar code reader thereby **acquiring slide information** indicating reagent to be applied to the slide; and

[i] sending the **slide information** to the computer

[e] dispensing the reagent in the reagent container onto the slide **based on the determination of whether the reagent in the reagent container should be dispensed on the slide,**
FN9. [d] **reading the bar codes on the reagent containers;**

[e] determining reagents in the reagent containers **based upon the reading of the bar codes on the reagent containers;**
FN10. [f] **reading the slide bar code** on the at least one slide;

[g] **determining a sequence of reagents to be applied** on the at least one slide **based upon the reading of the slide bar code on the slide;** and

[h] dispensing the reagents in the reagent containers based upon the **sequence of reagents to be applied.**
The court then must turn to the specification to determine whether the reagent bar code must be read before the slide bar code. BioGenix cites the following in the specification as indicating a particular sequence: *At the beginning* of a slide treatment operation, the reagent carousel is rotated past the bar code reader, and the bar code on each reagent bottle is scanned. Col. 12, lines 31-39. Although the terms "At the beginning" indicate when the bar code reader reads the reagent bar code with respect to the "slide treatment operation," it does not explicitly or implicitly indicate when the bar code reader reads the reagent bar code with respect to reading the slide bar code. BioGenix does not provide sufficient evidence in the specification explicitly or implicitly requiring the reagent bar codes to be read before the slide bar codes. Thus, according to *Altiris,* the reagent bar code may be read before or after the slide bar code.

D. "Slide" Means a Plain Microscope Slide.

Ventana argues that the term "slide" in claim elements 1[b] and 5[b] should be interpreted by its plain meaning to be an ordinary microscope slide ("a thin glass plate or other material on which an object is placed for microscopic examination"). BioGenix argues that the term "slide" also means "sample container," based upon the specification which states, "The apparatus preferably has bar code readers positioned to read bar codes on the sample containers or slides and on the reagent containers," Col. 2, lines 60-62.

There is a heavy presumption in claim construction that claim terms be interpreted in favor of their ordinary and customary meaning. CCS Fitness, 288 F.3d 1359, 1366 (Fed.Cir.2002). The words of the claims are given their "ordinary and customary meaning" unless a "special definition of the term is clearly stated in the patent specification or file history." Vitronics Corp., 90 F.3d at 1582. For example, departure from the ordinary and customary meaning of slide may be necessary if "a patentee [has chosen] to be his own lexicographer and use terms in a manner other than their ordinary meaning." *Id*. However, the court must be wary of improperly reading a limitation into the claim from the specification. Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998).

BioGenix's reference to "sample containers or slides" does not indicate that sample containers and slides are the same thing, rather the "or" indicates they are different. The specification does not specifically define "slide" or indicate that slide is intended to have a new meaning. The specification supports this conclusion because it refers to a flat plate with edges. *See, e.g* . "slid surface," Col. 4, line 18; "longitudinal edge of the slide" and "distal edge of the slide," Col. 4, lines 56-57. BioGenix counters Ventana's construction by pointing to the inventor's depositions made in other litigation over the '861 patent where they equate a slide to a micro-titer plate (a slide with a well in it to hold fluid), sample container, and/or a test tube. *See* Exhibits 18 at 41 and 19 at 97. However, expert testimony, or extrinsic evidence (evidence outside of the claim, specification, and prosecution history) is relied on only when "the claim language remains genuinely ambiguous after consideration of the intrinsic evidence." Bell & Howard Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed.Cir.1997). Here, after reviewing the intrinsic evidence, it is clear that slide carries its ordinary meaning as a microscope slide and the court construes it as such.

E. The Steps in the Claims Are Not Step-Plus-Function Limitations.

BioGenix argued in their brief that the asserted claims were in step-plus-function format and subject to 35 U.S.C. s. 112, para. 6 FN11 which limits the claimed function by the corresponding step or act in the specification. During the *Markman* hearing, BioGenix did not argue this point, conceding that the argument was weak and not necessary to limit "dispensing" to the "direct dispensing" acts described in the specification.

FN11. 35 U.S.C. s. 112, para. 6:
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.

The language "steps of" in the disputed method claim elements 1[c], 1[d], 1 [e], 3[a], 5[e], 5[g], 5[h], 6[a] does not invoke 35 U.S.C. s. 112, para. 6. In the application of s. 112 para. 6 to method claims, the statutory term "steps" refers to "the generic description of elements of a process, and the term "acts" [refers] to the

implementation of such steps." O.I. Corp. v. Tekmar Co. Inc., 115 F.3d 1576, 1583 (Fed.Cir.1997). The statute applies only when the claim recites the steps plus function without reciting the acts supporting the function FN12. *Id*. The tradeoff for using functional expressions without reciting all possible acts in the claim is limiting the claim to the corresponding acts specified in the written description and equivalents thereof. *Id*.

FN12. Step-plus-function applies when:
1) the claim recites **a step** and **a function;** and

2) the claim **does not recite an act** corresponding to the step-plus-function

In addition, in *Cardiac Pacemakers,* the Federal circuit held that s. 112 para. 6 should not be applied to a clause which only recites a step in a method claim and does not use the "steps for" language. 381 F.3d 1371, 1382 (Fed.Cir.2004). The Federal Circuit Court stated, "[m]ethod claims necessarily recite the steps of the method" and the language "the method comprises the steps of" does not change the subsequent claimed steps into step-plus-function form under s. 112 para. 6. *Id*. In fact, the absence of "steps for" language creates the presumption that the claimed steps are *not* in step-plus-function form. *Id*. Furthermore, the Federal Circuit Court disregarded the lower court's concern that the claimed steps would be interpreted too broadly without the limitations of s. 112 para. 6, stating that "[a] claim limitation is always construed in light of the specification, whatever the form of the claim." *Id*. at 1381.

Given that the asserted claims do not use the "steps for" language and the claimed elements are written as steps in a method claim, or acts, rather than in purely functional terms, the court will not impose step-plus-function limitations in the asserted claims.

CONCLUSION

For the reasons stated in the court's Memorandum on this same date, the disputed claim terms of the '861 patent shall be construed as set forth in the court's Order of this same date.

IT IS HEREBY ORDERED that:

1. The term **"DISPENSING"** is construed to mean **"DIRECT DISPENSING."**

2. The prosecution disclaimer of **"SIP AND SPIT"** dispensing from the parent ' 052 application attaches to the '861 patent and further **narrows the construction of the term "DISPENSING" by excluding "SIP** AND SPIT DISPENSING" from its meaning.

3. The bar code reader may read the reagent container bar code and the slide bar code in any order.

4. The term **"SLIDE"** is construed to mean **"PLAIN MICROSCOPE SLIDE."**

5. STEP-PLUS-FUNCTION limitations **do not apply** to the asserted claims of the '861 Patent.

Dated this 23rd day of August, 2005.

D.Ariz.,2005.
Ventana Medical Systems, Inc. v. Biogenix Laboratories, Inc.