

United States District Court,  
S.D. California.

**ABBOTT LABORATORIES, an Illinois corporation,**  
Plaintiff.

v.  
**SYNTRON BIORESEARCH INC., a California corporation,**  
Defendant.

**And related cross-claim,**  
And related cross-claims.

No. 98-CV-2359 H(POR)

**June 29, 2000.**

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**Amended Order (1) Denying Syntron's motion for summary judgment under 35 U.S.C. section 102; (2) Denying Syntron's motion for summary judgment under 35 U.S.C. section 112; (3) Denying Syntron's motion for summary judgment for non-infringement; and (4) Granting Abbott's motion for summary judgment for infringement.**

**HUFF, Chief J.**

On December 30, 1998, plaintiff and counter-defendant Abbott Laboratories ("Abbott"), an Illinois

Corporation, filed a complaint for patent infringement against defendant and counter-claimant Syntron Bioresearch, Inc. ("Syntron"), a California corporation. On February 22, 1999, Syntron filed their answer and counterclaims against Abbott for declaratory relief that Syntron did not infringe Abbott's patents, that Abbott's patents are invalid and that Abbott's patents are unenforceable.

On March 22, 2000, Abbott filed a motion for summary judgment against Syntron. Syntron, in turn, filed three separate summary judgment motions for non-infringement, for the invalidity of Abbott's patents pursuant to 35 U.S.C. section 102, and for the invalidity of Abbott's patents pursuant to 35 U.S.C. section 112. The Court held oral argument for all four of the motions on May 9, 2000. On May 23, 2000, the parties each submitted a summary of their oral arguments pursuant to the Court's request.

## **BACKGROUND**

### ***I. The Parties***

Abbott manufactures, researches, markets and sells healthcare products including diagnostic instruments, tests and reagents. Abbott's products also include rapid, self-performing immunoassays which are used for determining the presence of chemical substances in human body fluids. Syntron is a California corporation with its principal place of business in Carlsbad, California. Syntron also produces and sells rapid self-test diagnostic products.

### ***II. Inventions At Issue***

#### ***A. '162 and '484 Patents***

On August 5, 1997, the United States Patent and Trademark Office ("PTO") issued Patent number 5,654,162 (" '162 patent") entitled "Chemical Analysis Apparatus and Method." (Compl.Ex. A). On December 17, 1991, the PTO issued Patent number 5,073,484 (" '484 patent") entitled "Qualitative Analysis Apparatus and Method." (Compl.Ex. B). Patrick Guire and Melvin Swanson invented both patents and both assigned their patent rights to Bio-Metric Systems, now known as SunModics, Inc. Pursuant to an agreement, Abbott is now the worldwide exclusive licensee of the two mentioned patents. FN1

FN1. For the sake of clarity and convenience, the Court in this order will sometimes refer to the '162 and '484 patents collectively as "the Abbott patents" or "Abbott's patents."

Abbott contends that Syntron is violating the patents with various pregnancy and ovulation test products which they manufacture, market and sell. They specifically identify the following products:

- (1) Quick Pac II One Step Pregnancy Test (used for early detection of pregnancy)
- (2) OvuPac One Step LH Ovulation Test (used to predict ovulation time)
- (3) Quick Pac II One Step hCG Test (used for early detection and diagnosis of pregnancy)
- (4) One Step Be Sure Pregnancy Test (used for detection of pregnancy)

Abbott also alleges that other unnamed products infringe their patents.

## **B. *Technology Involved*** FN2

FN2. The description of the technology involved is taken mostly from the declaration of Edward Everett Harlow, Jr. ("Dr. Harlow") (Plaintiff's Lodgment Ex. H). Dr. Harlow is a Professor and Chair at the Department of Biological Chemistry and Molecular Pharmacology at Harvard Medical School. ( *Id.* at 1). He is also the Scientific Director at the Massachusetts General Hospital Cancer Center where he conducts cancer research. ( *Id.*). Dr. Harlow has conducted many lectures and numerous articles concerning his field of expertise.

The plaintiff's two patents relate to technology known as "Immunochemistry" or "Immunoassay" technology. (Plaintiff's Lodgment Ex. H at 3). The patents disclose "assay" methods and devices which allow detection or measurement of small amounts of chemical substances (known as analytes) in fluids such as blood or urine. ( *Id.*). A test which determines the presence of a particular analyte can be helpful in diagnosing a particular condition. For example, the presence of the pregnancy hormone known as "hCG" in a woman's urine can indicate that she is pregnant.

Immunochemistry works by utilizing the characteristics of the immune response system which protects the body from infectious organisms and other toxic substances. ( *Id.*). Specifically, immunochemistry involves the use of antibodies and antigens which are vital to the functioning of the immune response system.

When a body is invaded by infectious organisms, the immune response system manufactures antibodies to attack the invading molecules. When the infection occurs, white blood cells, or lymphocytes, secrete proteins, known as antibodies. An antibody is merely a protein which is adapted to specifically bind to a particular molecule on a particular site of the molecule known as an epitope. ( *Id.* at 4). The foreign molecule to which the antibody attaches is known as an antigen. ( *Id.*). The antibody attaches to the foreign molecule in order to facilitate the body's healing process.

Immunoassays utilize the binding properties of these antibodies in order to detect or measure an analyte. ( *Id.*). Over the years, scientists developed techniques to manufacture antibodies that bind to specific molecules. ( *Id.*). Because specific antibodies bind to some molecules and not to others, the binding process allows the scientist to detect whether a particular molecule or analyte is present in a particular fluid being tested. ( *Id.*).

There are three main types of immunoassay methods. The antibody capture assay, antigen capture assay and a two-antibody sandwich assay. In the antibody capture assay, the antigen is attached to a solid support and antibody is allowed to bind to it. The bound antibody can then be measured after washing eliminates the unbound antibody. The antigen capture assay works in the same manner with the exception that the antibody is attached to a solid support and the antigen is measured after washing.

A common variation of the capture assay, known as a competition assay, can be performed in an antibody or antigen format. In the antigen capture format, a test sample with unknown sample of antigen is placed in a vessel with a known sample of "labeled" antigen. The process of labeling occurs by adding a detectable feature to an antigen or antibody in order to allow it to be detected after it has attached to the analyte. The vessel contains bound antibodies. The two antigens then compete to attach to the antibody and the test antigen prevents the labeled antigen from binding. As a result, if more test antigen remains in the vessel,

less labeled antigen will remain in the vessel. ( *Id.* at 5). The labeled antigen can then be measured to determine how much remained in the vessel and this indicates how much antigen is present in the solution. An antibody competition assay format functions in the same manner except that an unknown amount of antibody in a test sample competes with a known amount of labeled antibody. ( *Id.*).

In the two-antibody sandwich assay, one antibody is bound to a solid medium. ( *Id.*). The antigen in the test liquid is then allowed to bind to the first antibody on one epitope. ( *Id.*). Then a labeled antibody specific to the antigen is allowed to bind to the antigen on another epitope. ( *Id.*). The antigen is then analogous to a slice of meat in between two slices of bread (the two antibodies). ( *Id.*). After washing, only the labeled antibody attached to the antigen remains on the solid medium. ( *Id.*). The labeled antibody is then detected and because it is attached to the antigen, the presence and concentration of the antigen can be determined. ( *Id.* at 5-6). According to Dr. Harlow, prior to the early 1980's, these immunoassay tests could not be conducted in doctor's offices or in homes because they required laboratory equipment. (Lodgment Ex. H at 7).

### ***C. Purported Advances Created by the '162 and '484 Patents***

The inventors of the Abbott patents purportedly created a new advance in immunoassay technology by developing assays which can be conducted in a one-step process with an initially dry self-contained kit where the only ingredient needed to be added is the liquid to be analyzed. ( *Id.* at 8). According to Dr. Harlow, prior art devices required laboratory equipment, additional steps, the addition of chemicals, mixing of chemicals and washing. ( *Id.*).

Abbott contends that their patents are able to work in a one-step fashion due to the technique of allowing the test solution suspected of containing the analyte (for example, urine) to migrate along a liquid permeable "solid medium" (such as a test strip) into distinct reaction zones. ( *Id.* at 7). This flow of the liquid along the test strip into the different zones allegedly eliminates the need for washing, filtering and other steps required in the prior art immunoassay methods. ( *Id.*). Abbott further asserts that placing all of the reagents necessary for conducting the assay along one solid medium so that the tester only needs to apply the test liquid has not been used in prior art. ( *Id.*).

## **DISCUSSION**

The parties filed a total of four summary judgment motions, one by Abbott and three by Syntron. This order will first address Syntron's motion for summary judgment on the basis of invalidity of the patents under 35 U.S.C. section 102. The Court will then address Syntron's motion for summary judgment based on invalidity of the patents under 35 U.S.C. section 112. Finally, the Court will address Abbott's motion for summary judgment for infringement and Syntron's motion for summary judgment for non-infringement in the same section because both motions address almost identical issues and each party's opposition arguments are almost identical to the arguments which they offer in their respective motions for summary judgment.

### ***I. Markman Standard***

In a summary judgment motion in which construction of the patent is necessary before the motion can be decided, the Court must construe or interpret the patent, which is a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d ed 967, 976 (Fed.Cir.1995) (en banc). In ascertaining the meaning of the patent claims, the Court must consider the claims, the specification, and the prosecution history. *See Eastman Kodak Company v. Goodyear Tire & Rubber Company*, 114 F.3d 1547, 1552 (Fed.Cir.1997). A

Court may also look to expert testimony for such evidence as determining "how those skilled in the art would interpret the claims." *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (en banc)); *Aqua-Aerobic System, Inc. v. Aerators, Inc.*, 211 F.3d 1241, 1244 (Fed.Cir.2000).

## **II. *Syntron's Motion for Summary Judgment Under* 35 U.S.C. section 102**

A motion for summary judgment shall be granted where "there is no genuine issue as to any material fact and ... the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P 56(c); *British Airways Bd. v. Boeing Co.*, 585 F.2d 946, 951 (9th Cir.1978), *cert. denied*, 440 U.S. 981 (1979). The moving party bears the initial burden of showing no genuine issue of material fact. *See* *British Airways*, 585 F.2d at 951.

For a patent to be valid, it must be novel under 35 U.S.C. section 102. *See* *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964). Under section 102, a patent cannot issue "if the invention was patented or described in a printed publication in this or a foreign country ... more than one year prior to the date of the application for patent." *See* *Lemelson v. Synergistics Research Corp.*, 669 F.Supp. 642, 649 (S.D.N.Y.1987). A patented invention is anticipated if it discloses "each and every element" of past patent claims. *See* *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444 (Fed.Cir.1984), *cert. denied*, 468 U.S. 1228, 105 S.Ct 32, 82 L.Ed.2d 923 (1984). Because an issued patent is presumed to be valid, the burden of proving that a patent is anticipated falls on the party challenging the patent. *See id.* "Further, the facts establishing anticipation ... must be proven by clear and convincing evidence." *Id.* (citing *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, slip op. at 23-24 (Fed.Cir.1984)).

### **A. *Validity of* the '484 Patent *Under* section 102**

Syntron argues that Claims 22, 23 and 26 of Abbott's '484 patent are anticipated by Claim 1 of United States Patent number 4,168,146 (hereinafter "Grubb patent"). The text of Claim 1 of the Grubb patent is as follows:

In a method of immunochemical quantification, the improvement which comprises wetting a diagnostic test strip consisting essentially of a porous, capillarity-possessing carrier material having antibodies covalently bound to it, which an aqueous sample containing the antigen to be quantified, allowing the capillary migration to take place, and then assaying the antigen-containing area of said diagnostic test strip by wetting it with antibodies in an aqueous vehicle, said antibodies being bound to a water-soluble fluorescent color indicating compound or to an enzyme that catalyzes a color-developing reaction.

The text of Claim 22 of the '484 patent is as follows:

- (a) providing a non-diffusively immobilized reactant in each of one or more reaction zones spaced successively along a flow path defined by a liquid permeable medium, wherein said reactant is the other member of said binding pair and is capable of binding with the analyte to form a predetermined product;
- (b) flowing said solution along the medium and sequentially through the reaction zone(s);
- (c) detecting the presence of analyte, said reactant or said predetermined product in the reaction zone(s), wherein the number of zones in which detection occurs is related to the p[re]sence of analyte in the solution.

An evaluation of the two claims reveals that not all elements of Claim 22 of the '484 Patent are anticipated by the Grubb patent. Although both Claims discuss the flow of the analyte along the medium or test strip, the method of reacting the analyte in order to detect it is different. Claim 1 specifies a detection method

wherein the "diagnostic strip" is placed in a sample with the analyte and the analyte, if present, migrates along the strip. However, Claim 1 involves a separate detection step in which the strip is then placed in "an aqueous vehicle" with labeled antibodies. While in this vehicle, a reaction occurs in which the labeled antibodies attach to any analyte present on the strip.

In Claim 22, the detection method is open-ended and can occur without the separate labeling step required in Claim 1. In Claim 22, the analyte flows along the solid medium and then passes through one or more reaction zones. These reaction zones contain "immobilized reactant" to which the analyte binds as the urine passes. Once bound, the analyte can then be detected. If the labeled antibodies are placed on the medium so that the analyte solution contacts with the labeled antibodies prior to contact with the reaction zones, all of the reactions necessary to conduct the assay occur on the medium. The assay would not require the removal of the strip from the analyte solution and the subsequent placement of the strip into the labeled antibody solution. Moreover, the possibility of multiple reaction zones in Claim 22 allows for more precise quantification of the analyte on the test strip without added equipment.

Contrary to Syntron's contentions, at least one element present in Claim 22 of the '484 patent is not present in the prior art of Claim 1 in the Grubb patent. The features which distinguish Claim 22 of the '484 patent from Claim 1 are also the features which distinguish Claims 23 and 26 of the '484 patent from Claim 1.

## **B. *Validity of the '162 Patent Under* section 102**

Syntron argues that the '162 patent is anticipated by an article written by Cristina Glad and Anders O. Grubb and United States patent number 4,517,288 (hereinafter "Geigel patent").

### **1. *Glad Article As Prior Art***

Syntron argues that an article written by Glad and Grubb anticipates Claims 1, and 5 to 8 of the '162 patent. See Cristina Glad and Anders O. Grubb, *Immunocapillarymigration-A New Method for Immunochemical Quantitation*, Analytical Biochemistry 85, 180-87 (1978) (hereinafter "Glad article"). Claim 1 of the '162 patent states the following:

A device generating a signal indicative of the presence of an analyte in a liquid solution suspected of containing said analyte, said device comprising:

- (a) a liquid permeable solid medium comprising a solution contact portion and one or more spaced reactive zones separated from said contact portion;
- (b) a solution suspected of containing said analyte and having traversed said medium, including said reactive zone(s);
- (c) a reactant non-diffusively bound to said medium only at said reactive zone(s), said reactant being specific for and bound to said analyte or a reaction product comprising said analyte and a chemical moiety; and
- (d) a labeled antibody specific for and bound to said analyte or said reaction product in said reactive zone(s); wherein said device provides a detectable signal in said reactive zone(s) as an indication of the presence or absence of said analyte in said solution.

(Abbott's Lodgments, Ex. BB, at 25). Claims 5 to 8 are dependent on Claim 1.

The method discussed in the Glad article does not anticipate each and every element present in Claim 1. In the methods discussed in the Glad article, the medium or test strip containing an antibody is placed in a solution containing the analyte. The analyte then migrates up the strip through capillary action. (Syntron's Lodgments, Ex. 15, Glad article, at 181-82). Until this point, the procedure is identical to Claim 1 of the '162 patent. The next step, however, varies from Claim 1. The test strip, which now contains analyte attached to the antibody already on the test strip, is then "incubat[ed]" in a solution containing labeled antibodies. ( *Id.* at 182). The excess antibodies are then "washed off the strip under running tap water." ( *Id.*). Consequently, the reaction allowing for the detection of the analyte occurs only after the test strip is placed in a solution containing the labeled antibody.

Unlike the Glad device, Claim 1 discloses a device in which the reaction occurs on the test strip because the reactants necessary to signal the presence of the analyte are present on the test strip. The test strip contains a labeled antibody which attaches to the analyte and another antibody immobilized in the reaction zone. (Abbott's Lodgments, BB, at 25) ("a labeled antibody specific for and bound to the analyte ... in said reactive zone(s)"). The immobilized antibody in turn, binds the analyte to the reaction zone and causes the labeled antibody-analyte compound to concentrate in the reaction zone in order to facilitate detection. ( *Id.*) ("a reactant non-diffusively bound to said medium only at said reactive zone(s), said reactant being specific to the analyte"). This is done without the required additional step of incubating the test strip in a labeled antibody solution as discussed in the Glad article. Consequently, not every element present in Claim 1 is anticipated by the Glad article.

Furthermore, in the checklist of prior art considered by Patent Examiner which appears in the prosecution history of the '162 patent, the Examiner noted that he considered the Glad article. (Abbott's Lodgments, Ex. FF at 504). This tends to indicate that the Examiner considered the Glad article and found that it did not preclude the issuance of the '162 patent. *See American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1359 (Fed.Cir.1985) (the person challenging the patent has the "added burden of overcoming the deference that is due to a qualified government agency presumed to have done its job"). Consequently, Syntron has failed to satisfy its burden of establishing the invalidity of the '162 patent.

## **2. Geigel Patent as Prior Art**

Syntron argues that Claims 1, 7 and 8 are anticipated by the Geigel patent. However, the elements present in the Geigel patent differ from those present in the Claims of the '162 patent. As discussed *supra*, the reactants and reactions necessary to produce a detectable signal indicating the presence of an analyte are placed on the test strip in Claim 1. The Geigel patent, like the Glad article, does not disclose an all-inclusive approach.

Rather, the Geigel patent requires added steps. The Geigel procedure is similar to Claim 1 insofar as antibody is bound to the medium which is capable of attaching to the analyte and the analyte solution is later applied to the medium. (Syntron's Lodgments, Ex. 16, col. 2, lns. 43-48). Unlike Claim 1, however, the labeled antibody is later applied to the strip instead of being already attached to the medium in the reaction zones. ( *Id.* at lns. 51-54) ("applying to said zone a labeled indicator"). Furthermore, Geigel requires the application of a solution to wash away excess labeled antibody from the medium prior to detection. ( *Id.* at lns. 55-59) ("applying to ... said zone a stream of solvent in quantity sufficient to ... separat[e] unbound labeled indicated from said zone"). These steps are not required by Claim 1.

As with the Glad article, the Patent Examiner's checklist of prior art indicates that the Examiner considered the Geigel patent. (Abbott's Lodgments, Ex. FF at 504). This tends to indicate that the Examiner considered the Geigel patent and found that it did not preclude the issuance of the '162 patent. *See American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1359 (Fed.Cir.1985). Consequently, Syntron has failed to satisfy its burden of establishing the invalidity of the '162 patent.

### ***C. Conclusion***

Abbott has presented evidence refuting Syntron's allegations that Claims 22, 23 and 26 of the '484 patent and Claims 1 and 5 through 8 of the '162 patent are invalid because they are anticipated by prior art. Syntron has failed to satisfy its burden of showing the invalidity of Abbott's patents with clear and convincing evidence. Consequently, Syntron's motion for summary judgment under 35 U.S.C. section 102 is DENIED.

### ***III. Syntron's Motion for Summary Judgment Under 35 U.S.C. section 112***

Syntron also submitted a summary judgment motion for failure to satisfy the "written description" and "enablement" requirements of 35 U.S.C. section 112. Section 112 reads as follows:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

These requirements are separate and distinct and both must be satisfied for a patent to be valid. *See California v. Lilly*, 119 F.3d 1559, 1567-69 (Fed.Cir.1997).

Because a patent is presumed to be valid, the burden of establishing the invalidity of a patent falls on the party challenging the patent. *See Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1573 (Fed.Cir.1985). Furthermore, the party asserting an invalidity defense must show invalidity under a clear and convincing evidence standard. *See id.* (applying clear and convincing evidence standard to claim that patent failed under written description requirement).

#### ***A. "Written Description" Requirement***

To satisfy the "written description" requirement of section 112, the specification must "convey with reasonable clarity to those skilled in the art, that as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Makurkar*, 935 F.2d 1555, 1560 (Fed.Cir.1991). The written description requirement does not require that the applicant "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed.Cir.2000) (alterations in the original).

Syntron alleges that Claims 9 through 30 of the '162 patent fail to satisfy the written description requirement of section 112 because of the use of the term "diffusively bound." Syntron argues that this term is ambiguous or otherwise incomprehensible to "persons of ordinary skill in the art." Abbott argues that the term is best understood when examined in conjunction with the word which it modifies, the word "labeled antibody," in Claim 22 of the '162 patent. Abbott contends that the term "diffusively bound" indicates that



the labeled antibody is both placed upstream from the application zone for the analyte and that the antibody is bound to the test strip or other solid medium in a manner by which it is capable of separating from the medium when the liquid analyte sample passes over it.

Syntron offers a strong argument to refute Abbott's claims that "diffusively bound" means "capable of flow along the flow path" by comparing the language of the claims prior to the suggested addition of the terms "diffusively bound" by the Patent Examiner. Syntron notes that Claim 22 in Abbott's original patent application contained the language "a labeled antibody specific for the analyte ... said antibody being capable of flow along the flow path." The language was amended upon suggestion of the Patent Examiner to read "a *diffusively bound* labeled antibody specific for the analyte ... said antibody being capable of flow along the flow path." Syntron persuasively asserts that if the term "diffusively bound" means "being capable of flow along the flow path," its introduction into the amended language would be superfluous because the original language, as well as the amended language, already included the words "capable of flow along the flow path."

However, evidence concerning the patent history of the '162 patent indicates that "diffusively bound" does not only mean "capable of flow along the flow path." To understand the full meaning of the language, one must consider the Patent Examiner's reasons for suggesting the addition of the terms "diffusively bound ." The Patent Examiner suggested the terms in order to distinguish Abbott's patent from the prior art.

The instant device claims do not clearly state where if at all, there is a labelled [sic] antibody on the device which would provide for a material distinction of the claimed devices over the [sic] used for competitive assays. If the claims are clarified so that it is clear that there is a zone with a non-diffusively FN3 [sic] bound labelled [sic] antibody provided on the device the claims would be allowable over the art.

FN3. The Examiner's notes use the term "non-diffusively," but the Examiner explains that he meant diffusively (Abbott's Lodgments, Ex. FF at 617) ("It was agreed in the course of the recent interview that reference in the pending Action to a labeled antibody being 'non-diffusively bound' was intended to use the term 'diffusively-bound' ").

(Abbott's Lodgments, Ex. FF at 605). The Examiner's request for clarification to distinguish the '162 patent from the prior art was satisfied with the use of the terms "diffusively bound." This is apparent from the notes taken by the Examiner concerning an agreement to change the language of the '162 patent. The Examiner's notes indicate the following: "Applicant to amend all methods and device claims to embodiment with diffusively bound labelled [sic] antibody. This would overcome prior art of record." ( Id. at 608).

The Examiner then noted that the introduction of the term "diffusively bound" was sufficient to defeat his prior contention that the patent language failed under section 112. In approving the amended language, the Examiner noted,

The diffusively bound antibody of the present claims is already positioned *along the flow path* at the time of use. The "order" in which analyte and diffusively bound antibody are provided is therefore clear. Applicants have provided a confirmatory amendment that should put his concern to rest.

Finally, as suggested by the Examiner, claim 56 has been amended to make clear that it relates to a device (as opposed to a kit), in which sample has already been applied and has traversed the device, e.g., at the

moment of being read or as saved for record purposes.

( Id. at 616) (emphasis in the original).

These notes indicate that one of the Examiner's primary concerns for these changes was to determine whether the device described in the '162 patent intended that the labeled antibody be separately added to the test strip or solid medium in addition to adding the analyte to the test strip or if the labeled antibody was to be already placed on the test strip by some binding process so that the addition of the analyte was the only liquid to be applied to the test strip. This concern is also apparent in the Examiner's notes concerning the rejection of some of the Claims in the original '162 patent which indicate,

[T]here is no clear recitation as to when the labelled [sic] antibody is applied to the medium.... It is not clear if the labelled [sic] antibody is on the medium (non diffusively bound?) or [if] it is applied to the medium.

( Id. at 603).

The distinction of whether the analyte was to be already attached or added to the test strip was an important feature in distinguishing the '162 patent from prior art because the main improvement offered by the '162 patent was the fact that it is a one-step device in which the user's only burden is to add the analyte sample to the device. (Abbott's Lodgments, Harlow Decl., Ex. H at 106) ("a further advance is the concept of having all of the reagents necessary for performing the assay already placed along the solid medium such that a user has only to apply the test sample at one end of the medium and have the device do the rest .... Nothing in the prior art taught such a one-step assay that can be performed outside of the laboratory with an initially dry [test strip].").

The addition of the language "diffusively bound" was one term supplied to alleviate the Examiner's concern that the '162 Patent, in order to overcome prior art, needed to clearly indicate that the labeled antibody was: (1) bound to the test strip; (2) placed upstream from the application zone; and (3) capable of removing from the test strip and flowing with the analyte along the tests strip in order to complete all reactions necessary to complete the assay. The fact that this language was inserted in response to the Examiner's concerns about distinguishing this device from prior art tends to show that Abbott's contentions concerning the terms "diffusively bound" prevail over Synttron's contentions. The fact that the Examiner suggested the use of these terms, without requiring further explanation of the terms, tends to indicate that they would be understood by one with ordinary skill in the art of immunoassay.

Furthermore, Dr. Harlow has stated that "diffusively bound" would be understood, by one with ordinary skill in the art of immunoassay, to mean capable of detaching from the solid medium and capable of flow along the remaining portions of the test strip. (Abbott's Lodgments, Ex. HH, at 748). The plain language of the terms supports this interpretation. The dictionary lists the term "diffusively" as the adverb of "diffusive." (Webster's New International Dictionary 631 (3d ed.1981) (unabridged). The word "diffusive" has three definitions-"having the quality of diffusing," "tending to diffuse," and "characterized by diffusion." ( Id.). Similarly, the verb diffuse possesses such meanings as "to pour out and permit or cause to spread freely (as a fluid out of a container)." ( Id.). Moreover, the examples used in the definition of "diffusive" include "a drop of dye *diffused* through water" or "gas being *diffused* through the air." ( Id.). Consequently, Synttron has failed to satisfy its burden of establishing that the use of the terms "diffusively bound" invalidates the Abbott patents.

## ***B. Enablement Requirement***

To satisfy the enablement requirement of section 112, the patent in question must "teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" ' In re Wright, 999 F.2d 1557, 1561 (Fed.Cir.1993). However, a patent is not invalid if "some experimentation is needed, for the patent document is not intended to be a production specification." Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed.Cir.1990), *cert. denied*, 498 U.S. 920 (1990). Furthermore, a specification need not disclose what is well-known in the art. *See Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d ed 1361, 1366 (Fed.Cir.1997), *cert. denied*, 522 U.S. 963 (1997).

Syntron contends that there is no instruction in the '162 patent of how to create and use a "diffusively bound" labeled antibody as discussed in the patent. Syntron argues that because this feature is supposedly novel, Abbott should be required to include such instruction. Furthermore, Syntron alleges that a "diffusively bound" antibody cannot be reproduced without "undue experimentation."

However, the '162 patent does disclose methods of applying a "diffusively bound" labeled antibody in which the antibody is bound to the solid medium, capable of detaching from the medium and capable of flowing down the test strip with the analyte. In some examples, the patent instructs that the antibody be dried onto the solid medium. (Abbott's Lodgments, Ex. BB, '162 Patent, col. 15, lns. 12-15). In another example, the patent instructs that the labeled reactant be "dissolved in a solution [and] applied to the bottom paper strip and dried." ( *Id.* at col. 14, lns. 56-63).

Furthermore, Dr. Harlow, an expert on immunoassay technology, stated that these examples sufficiently describe to one with ordinary skill in the art of immunoassay technology, the process of creating and using a "diffusively bound" labeled antibody as described in the patents. (Abbott's Lodgments, Ex. HH, Harlow Rebuttal, at 755-56).

## ***C. Conclusion***

Abbott has presented evidence refuting Syntron's allegations that the '162 patent does not satisfy the "written description" and "enablement" requirements and Syntron has failed to satisfy its burden of showing the invalidity of Abbott's patents with clear and convincing evidence. Consequently, Syntron's motion for summary judgment under 35 U.S.C. section 112 is DENIED.

## ***IV. Abbott's Motion for Summary Judgment for Infringement and Syntron's Motion for Summary Judgment for Non-Infringement***

Abbott filed a motion for summary judgment for infringement and Syntron filed a motion for summary judgment for non-infringement. Syntron's motion contains virtually the same arguments which Syntron uses to oppose Abbott's motion. Consequently, the Court will address the arguments from both parties concerning infringement and non-infringement in the same section.

### ***A. Legal Standards***

A motion for summary judgment shall be granted where "there is no genuine issue as to any material fact and ... the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P 56(c); *British Airways Bd. v. Boeing Co.*, 585 F.2d 946, 951 (9th Cir.1978), *cert. denied*, 440 U.S. 981 (1979). The moving party bears the initial burden of showing no genuine issue of material fact. *See British Airways*, 585 F.2d at 951.

In the context of patent infringement actions, determining infringement is a two-step process in which the Court must construe or interpret the patent, which is a question of law, and then the interpretation is applied to the allegedly infringing device, which is a factual determination. *See Markman v. Westview Instruments, Inc.*, 52 F.3d ed 967, 976 (Fed.Cir.1995) (en banc). "To ascertain the meaning of the claims, [a court must] consider three sources: The claims, the specification, and the prosecution history." *Eastman Kodak Company v. Goodyear Tire & Rubber Company*, 114 F.3d 1547, 1552 (Fed.Cir.1997). "Expert testimony, including evidence of how those skilled in the art would interpret the claims, may also be used." *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (enbanc)).

## **B. Syntron's Arguments**

In support of their motion for summary judgment, Abbott points to Claim 22 of the '162 patent as being infringed by the Syntron products. The language of Claim 22 of the '162 is as follows:

A device for detecting the presence of an analyte in a carrier liquid suspected of containing said analyte, which device comprises a liquid permeable solid medium which defines a path for fluid flow capable of supporting capillary flow, along which are:

- i) a site for application of the carrier liquid,
- ii) a diffusively bound labeled antibody specific for the analyte or a chemical moiety which is itself the reaction product of the analyte with another chemical moiety, said antibody being capable of flow along the flow path, and
- iii) one or more zones spaced along said flow path, each zone having a predetermined amount of a reactant bound to it which is specific for either the analyte or a chemical moiety which is itself the reaction product of the analyte with another chemical moiety;

wherein said device can be used by contacting a carrier liquid with said application site in such a manner that permits said liquid to pass along the flow path by capillary flow such that analyte or reaction product of the analyte with another chemical moiety becomes bound to both the labeled antibody and the reactant bound to the solid medium; and

wherein the labeled antibody, with the reactant bound to the solid medium, sandwiches the analyte or a chemical moiety which is itself the reaction product of the analyte with another chemical moiety.

(Abbott's Lodgments, Ex. BB, col. 17, ln. 16 to col. 18, ln. 9).

In response to Abbott's claim of infringement, Syntron, in addition to filing an opposition to Abbott's motion, filed their own summary judgment motion for non-infringement. Syntron offers six main arguments to support their allegations of non-infringement.

### **1. Abbott's Patents Disclose Quantitative and Not Qualitative Assays**

Syntron first argues that its products do not infringe Abbott's patents because its products are qualitative, meaning that Syntron's products measure whether an analyte is simply present in a test liquid, instead of quantitative, meaning that Abbott's patents cover devices which examine the quantity of analyte present in a

particular liquid sample.

Syntron does present evidence indicating that the patents disclose quantitative assays. For example, the '162 patent is introduced as an "invention in the field of quantitative chemical analysis." (Abbott's Lodgments, Ex. BB, col. 1, lns. 10-11). Despite these claims, portions of the '162 patent language also include references which imply a qualitative assay. (Abbott's Lodgments, Ex. BB, col. 17, ln. 16) (Claim 22 of the '162 patent describes a device "for detecting the presence of an analyte"). Moreover, the Patent Examiner suggested that the title for the '162 patent be changed to remove the term "Quantitative" because the "claims are drawn to qualitative rather than 'quantitative' analysis." (Abbott's Lodgments, Ex. FF at 535).

The title of the '484 patent, "Quantitative Analysis Apparatus and Method," also tends to indicate that it is a quantitative assay. (Abbott's Lodgments, Ex. AA at 2). However, the quantitative functions of the inventions do not take away from possible dual uses as a qualitative and quantitative test. As noted by Harlow, any test which examines the quantity of substance must necessarily indicate the presence of the substance when measuring the quantity. (Abbott's Lodgments, Ex. HH at 4-10). Moreover, a qualitative test necessarily must incorporate elements of a quantitative test because some threshold quantity of analyte must be present in the test sample in order to react and indicate the presence of the analyte. Consequently, Syntron's devices may possess all of the elements of the Abbott patents and infringe those patents even if Syntron's intent was to make a purely qualitative test.

## ***2. Syntron Alleges That Its Products Do Not Have the Same Reactant in Each Reaction Zone***

Syntron contends that each example in the '484 patent discusses a device in which the reaction zones on the device all contain the exact same reactant capable of reacting with the analyte. From these examples, Syntron concludes that its products do not infringe Abbott's patents because its products allegedly do not have the same reactant in each of its reaction zones.

Syntron alleges that it has three reaction zones—a "labeling" zone in which the analyte reacts to bind to the labeled antibody, a "test" zone which contains an antibody capable of binding to the analyte to allow detection of the analyte and a "control" zone which contains a reactant that does not react with the analyte. (P. & A. for Syntron's Mtn. for Summ. J. for Non-Infringement at 13-14) (hereinafter "Syntron's Non-Infringement Mtn."). Whether Syntron's labeling zone is a reaction zone is immaterial because the existence of a labeled antibody on a solid medium is an element of the '162 patent regardless of whether it is defined as a reaction zone or not. However, a discussion of whether the control zone is a reaction zone is necessary to determine whether Syntron's devices infringe Claim 22.

Abbott contends that the "control" zone is not a "reaction zone" as defined in Claim 22. There is evidence in the plain language of the patent which supports Abbott's contentions. The language of Claim 22 discusses "one or more [reaction] zones spaced along said flow path, each zone having a predetermined amount of reactant ... specific for the analyte." ( Id.). Syntron seems to argue that any zone in which a chemical reaction occurs on the solid medium is a reaction zone under the patent. However, the Claim 22 language indicates that a reaction zone is an area in which detection of the analyte occurs. This is apparent by the fact that the reaction zone contains "reactant bound" to the medium which is "specific for the analyte." The reactant needs to be bound to the medium so that the analyte, after being bound to the labeled antibody, will bind to the reaction zone and become concentrated in the reaction zone for the purpose of allowing detection of the presence of the analyte. Syntron's control zone does not have a reactant which is "specific for the analyte" so it does not serve this function.

If Syntron's contention that any area where a reaction takes place is a reaction zone were true, then the area in which the labeled antibody attaches to the analyte would be a reaction zone. The language of Claim 22 indicates otherwise. In Claim 22, a portion of the claim language discusses the inclusion of a "diffusively bound labeled antibody specific for the analyte" along the "liquid permeable solid medium." (Abbott's Lodgments, Ex. BB, col. 17, ln. 16 to col. 18, ln. 9). This area is analogous to Syntron's labeling zone. The fact that the definition of the labeled antibody is separate from the definition of the reaction zones provides evidence that the area with the labeled antibody is not a reaction zone as defined under Claim 22. If the labeled antibody were intended to be a reaction zone as defined by Claim 22, the patent description could have specified that this portion where the labeling takes place is a reaction zone. However, the patent does not so specify and the discussion of the labeled antibody appears prior to the definition of the reaction zone indicating that the two are distinct.

Although the control zone is not a reaction zone, it does not appear on the Abbott patents. However, a patent not only "forbid[s] exact copies of an invention, but products that go to 'the heart of an invention but avoids the literal language of a claim by making a noncritical change.'" *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373, 116 S.Ct. 1384 (1996). "Thus ... a claim for a ceiling fan with three blades ... would also cover a similar fan [with] some additional feature, e.g., ... a cord or switch for turning it on or off." *Id.* at 373 n.1. Consequently, even though the control zone is an added feature not discussed in the '162 patent, the remainder of the Syntron device infringes the patent.

Even if the control zone is considered a reaction zone, the prosecution history of the '162 patent supports the notion that the reaction zones do not need to have the same reactant. In the prosecution history, the inventors discussed the possibility of having the same or different reactants in each of the reaction zones. The inventors stated that if the same reactant was present in each reaction zone, the device could be configured for "quantification or semi-quantification of a *single* analyte." (Syntron's Lodgments, Ex. 5, at 150). However, the inventors noted the possibility of having different reactants in each zone. The inventors noted that one possible purpose for having different reactants would be for the "detection of *different* analytes." (*Id.*).

### ***3. Syntron's Products Do Not Have a "Non-diffusively Bound" Reactant or a Reactant Bound in a "Predetermined Amount"***

#### ***a. Non-diffusively Bound***

Syntron argues that Claims 22, 23 and 26 of the '484 patents and Claims 1, 7, and 8 of the '162 patents require a "reactant non-diffusively bound to [a] medium." (Abbott's Lodgments, Ex. BB, col. 16, ln. 1). Syntron argues that "non-diffusively" means in such a manner that the reactant is attached to the medium with a very strong bond such as covalent bonding. Syntron bases this contention partly on the assumption that the Abbott patents disclose quantitative assays only. (Syntron's Non-Infringement Mtn. at 16). Syntron notes that "[i]n order to obtain an accurate result in a quantitative assay, it is essential that the amount of the reactant be defined and not vary during the assay." (*Id.*).

Although there are examples in the patents which utilize covalent bonding, there is no language in any of the claims which require that such a method be used. Moreover, Abbott's patents disclose quantitative and qualitative assays. Consequently, not all of the claims would require such strong covalent bonding for the assay to function properly. As explained by Dr. Harlow, " 'non-diffusively bound' simply means binding that is strong enough to permit detection at the intended site." (Opp. to Syntron's Non-Infringement Mtn. at 15).

In other words, it means that the reactant is immobilized to sufficiently allow the analyte and labeled antibody to attach to the reactant, which is in turn, attached to the medium. This then allows the labeled antibody and analyte to concentrate in a specific area in order to allow detection of the analyte in the reaction zone area.

Syntron's own description of its product clearly indicates that its products utilize an "immobilized" antibody in the "test zone" which captures the analyte and labeled antibody in order to produce a "pink-rose color band" to indicate the presence of an analyte. (Abbott's Lodgments, Ex. Q).

#### ***b. Predetermined Amount***

Syntron next argues that its products do not contain a "predetermined amount" of reactant in the reaction zones. The ordinary meaning of "predetermined" is "to determine beforehand" or "to settle in advance." Webster's New International Dictionary 1786 (3d ed 3d ed.1981) (unabridged). Syntron undoubtedly places a "predetermined" threshold amount of reactant in its reaction zone in order to insure that a minimal concentration of labeled antibody binds to the reactant in order to produce a signal detectable by the naked eye.FN4

FN4. Dr. Lee, Syntron's President, in describing the application of the antibodies to the reaction zones, states that "a sufficient amount of antibodies are deposited during manufacture so that even with varying degrees of loss ... color will still be generated in both the test and control zones." (Lee Decl. para. 15).

Syntron seems to be arguing that "predetermined amount" means a fixed and specifically measured amount. Syntron bases this contention on the assumption that the Abbott patents disclose quantitative assays and that such assays would require specifically measured amounts of reactant in the reaction zones in order to signal that the amount of analyte present is within a specified range. However, as noted *supra*, Abbott's patents do not disclose solely quantitative assays. Consequently, Syntron's reading of the terms "predetermined amount" is not supportable.

#### ***4. Syntron's Utilization of Colloidal Gold***

Syntron argues that Claims 22, 23 and 26 of the '484 patent and Claims 9 and 10 through 21 of the '162 patent require a separate detection step in order to allow visible detection of a signal indicating the presence of an analyte. Despite Syntron's allegations, the Abbott patents do not require a separate detection step for the detection of the analyte. Claim 22 of the '162 patent, for example, simply requires that the labeled antibody be placed on the medium, that the analyte contact with the labeled antibody, that the analyte-labeled antibody pair flow along the test strip and that the analyte-labeled antibody pair attach in a reaction zone after binding to an immobilized antibody specific to the analyte. (Abbott's Lodgments, Ex. BB, col 17, ln. 16 to col. 18, ln. 9). Syntron's products incorporate all of these features.

Syntron's use of colloidal gold simply means that Syntron is using a particular type of labeled antibody, perhaps even an improved type of labeled antibody which warranted the issuance of a separate patent for the labeling procedure. However, colloidal gold is still a labeled antibody. Even Syntron's President, Dr. Lee, defines a labeled antibody as "any substance which is attached to a specific binding member and which is capable of producing a signal that is detectable by visual ... means." (Abbott's Lodgments, Ex. I, at 184-85). Colloidal gold serves this function, and its use does not excuse Syntron's infringement of the Abbott patents.

Syntron further argues that because labeling processes using colloidal gold were not developed until after the filing dates of the Abbott patents, the Abbott patents could not have contemplated colloidal gold as a labeling procedure within the meaning of the patents. However, articles on immunochemistry have discussed the use of colloidal gold as early as 1971. *See* W. Page Faulk and G. Malcolm Taylor, *An Immunochemical Method for the Electron Microscope*, 8 *Immunochemistry* 1081-83 (1971). Consequently, Syntron's contention appears to be incorrect.

### ***5. Syntron Alleges That Its Labeled Antibody is Not Diffusively Bound***

Syntron argues that its devices do not use labeled antibodies which are "diffusively bound." To support their contention, Syntron primarily relies on the assertion that the phrase "diffusively bound" requires that the labeled antibody mix with the analyte solution on a molecular level. (Syntron's Non-Infringement Mtn. at 21-22). As discussed *supra*, in Part III .A of the Discussion section, the plain language of the terms "diffusively bound" and the patent history indicates that the terms merely require that the labeled antibody be both capable of separating from the solid medium and of flowing through the remaining portions of the medium. The patent does not require movement on a molecular level.

The labeled antibodies in Syntron's devices clearly detach from the medium and flow along the medium. (Abbott's Lodgments, Ex. R) ("Urine sample migrates ... mixing with labeled antibody").

### ***6. Syntron's Devices Do Not Utilize a Single Liquid-Permeable Solid Medium***

Syntron argues that its products do not infringe because the labeled antibodies on its devices are placed on a different solid medium than the medium which contains the reaction zones. In contrast, Abbott's patents discuss the use of only one unitary solid medium in which all of the reactions occur.

However, a product still infringes a patent if that product "make[s] unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough ... [to evade] the reach of the law." *See* Hilton Davis Chemical Co. v. Warner-Jenkinson Co., Inc., 62 F.3d 1512, 1517 (Fed.Cir.1995) (quoting Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U .S. 605, 607, 70 S.Ct. 854 (1950)) (alterations in the original). "In applying the doctrine of equivalents, [the Court] must assess whether the claimed and accused products or processes include substantially the same function, way, and result." Hilton Davis Chemical Co., 62 F.3d at 1518.

Syntron has presented no evidence explaining the necessity of separating the device described in the Abbott patents over different liquid permeable solid media. The function of the medium in the patents is to allow a place for the reactions to occur and to allow the analyte solution to flow from one end of the medium to the other end. Syntron's separate pieces are connected in a manner where the analyte flows across the media, which are kept together with an outer plastic casing, in the same manner as it would if only one solid medium is used. (Abbott's Lodgments, Ex. I, at 50, lns. 14-18). Furthermore, the labeled antibodies and reaction zones are placed along the separate solid media in the Syntron patents and the reactions necessary for the device to create a detectable signal occur in the same manner as it would if only one medium is used.

### ***C. Abbott's Arguments***

Abbott points to the language in Claim 22 of the '162 patent and offers evidence indicating that each element of the claim language is infringed. The Court will now discuss each element and its accompanying



language and compare the element to Syntron's products.FN5

FN5. The full language of Claim 22 of the '162 patent appears in Part IV.B of the Discussion section.

**1. "A device for detecting the presence of an analyte in a carrier liquid suspected of containing said analyte"**

Syntron's products are undoubtedly made for the purpose of detecting the presence of an analyte. Syntron admits this fact in its response to Abbott's request for admissions. (Abbott's Lodgments, Ex. X, at 11).

**2. "[W]hich device comprises a liquid permeable solid medium which defines a path for fluid flow capable of supporting capillary flow"**

Dr. Lee ("Dr.Lee"), Syntron's President, admitted that Syntron's devices utilize a "liquid permeable" medium and that the test liquid flows along the medium through "capillary migration." (Abbott's Lodgments, Ex. I, at 244).

**3. "[A]long which are: i) a site for application of the carrier liquid"**

Syntron admits that "its test kits have a location of the application of a sample." (Abbott's Lodgments, Ex. X, at 3).

**4. "ii) [A] diffusively bound labeled antibody specific for the analyte or a chemical moiety which is itself the reaction product of the analyte with another chemical moiety, said antibody being capable of flow along the flow path"**

Dr. Lee admits in his deposition testimony that Syntron's products utilize a labeled antibody which is dried onto the solid medium. (Abbott's Lodgments, Ex. I, at 51-54). Dr. Lee further admits that when the test sample encounters the diffusively bound labeled antibody, it can detach from the solid medium and flow along the medium. ( Id. at 58-59). Moreover, the labeled antibody which Syntron uses is specific to the analyte as described in the instructions provided in Syntron's products. (Abbott's Lodgments, Ex. R) ("hCG present in the specimen" binds to the "labeled antibody-dye conjugate").

**5. "iii) [O]ne or more zones spaced along said flow path, each zone having a predetermined amount of a reactant bound to it which is specific for either the analyte or a chemical moiety which is itself the reaction product of the analyte with another chemical moiety"**

Syntron's instructions in its products clearly indicate a "reaction zone" in which a reactant which is specific to the analyte is bound to the solid medium. (Abbott's Lodgments, Ex. Q) ("Anti-hCG antibody immobilized in the test zone of the membrane captures the complex and a visible pink-rose color band forms indicating a positive result."). Moreover, Quan Trinh ("Trinh"), Syntron's production manager, indicated that the amount of reactant placed on the medium is "determined in advance." (Abbott's Lodgments, Ex. J, at 131-33).

**6. "[W]herein said device can be used by contacting a carrier liquid with said application site in such a manner that permits said liquid to pass along the flow path by capillary flow such that analyte or reaction product of the analyte with another chemical moiety becomes bound to both the labeled antibody and the reactant bound to the solid medium"**

Dr. Lee admitted in his deposition testimony that the carrier liquid flows along the medium by capillary action. (Abbott's Lodgments, Ex. I, at 244). Trinh also admitted that the labeled antibodies used in its products are specific to hCG and that the antibodies bound to the solid medium are also specific to hCG. (Abbott's Lodgments, Ex. J, at 72-73) (indicating that the labeled antibody is specific to hCG and that the antibody bound to the "test line" is also specific to hCG").

**7. "[W]herein the labeled antibody, with the reactant bound to the solid medium, sandwiches the analyte or a chemical moiety which is itself the reaction product of the analyte with another chemical moiety"**

Trinh, Syntron's production manager, admitted in his deposition testimony that Syntron's tests utilize a "sandwich reaction." (Abbott's Lodgments, Ex. J, at 74). Furthermore, Dr. Lee also admits that Syntron's products utilize a "sandwich assay." (Abbott's Lodgments, Ex. I, at 222).

### ***C. Conclusions Concerning Infringement***

The Court has interpreted the Abbott patents and found that Syntron's challenges to the patent do not warrant summary judgment in Syntron's favor. Furthermore, the Court finds that there are no issues of material fact remaining in this matter. As discussed throughout this order, Syntron's products infringe each element of Claim 22 of the '162 patent. Consequently, Abbott is entitled to summary judgment. *See British Airways Bd. v. Boeing Co.*, 585 F.2d 946, 951 (9th Cir.1978), *cert. denied*, 440 U.S. 981 (1979).

## **CONCLUSION**

For the aforementioned reasons, the Court orders the following:

- (1) The Court DENIES Syntron's motion for summary judgment under 35 U.S.C. section 102.
- (2) The Court DENIES Syntron's motion for summary judgment under 35 U.S.C. section 112.
- (3) The Court DENIES Syntron's motion for summary judgment for non-infringement.
- (4) The Court GRANTS Abbott's motion for summary judgment for infringement.
- (5) This order supersedes the order issued by the Court that was dated June 28, 2000.

IT IS SO ORDERED.

S.D.Cal.,2000.

Abbott Laboratories v. Syntron Bioresearch Inc.

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