United States District Court,
D. Delaware.

DADE BEHRING MARBURG GMBH, Syva Company and Behring Diagnostics, Inc,
Plaintiffs.
v.
BIOSITE DIAGNOSTICS, INC,
Defendant.

No. Civ.A. 97-501 MMS

July 24, 1998.

David J. Baldwin, and Joanne Ceballos, of Potter Anderson & Corroon, Wilmington, Delaware; Herbert F. Schwartz, Kenneth B. Herman, Marta E. Gross and Keith D. Agisim, of Fish & Neave, New York, New York; for plaintiffs, of counsel.

Josy W. Ingersoll, and John W. Shaw, of Young, Conaway, Stargatt & Taylor, Wilmington, Delaware; Richard G. Greco, of Kaye, Scholer, Fierman, Hays & Handler, LLP, New York, New York; for defendants, of counsel.

MEMORANDUM OPINION

SCHWARTZ**, Senior J.**

I. Introduction

Dade Behring Inc., Syva Company, and Dade Behring Marburg GmbH (collectively "Dade Behring") brought a patent infringement suit against Biosite Diagnostics, Inc. ("Biosite"), alleging infringement of its United States Patent No. 4,366,241, as originally issued and as reexamined and issued under Reexamination Certificate B1 4,366,241 (collectively the " '241 Patent" '), entitled "Concentrating Zone Method In Heterogeneous Immunoassays." FN1 Biosite answered the complaint and counterclaimed against Dade Behring alleging the '241 Patent is invalid, unenforceable, and not infringed, and that Dade Behring's actions against it constitute anticompetitive or predatory conduct in violation of the Sherman Act, 15 U.S.C. s. 1.

FN1. The '241 Patent issued on December 28, 1982, to the inventors, Henry K. Tom and Gerald L. Rowley, who then duly and legally assigned the patent to Syva Company. Since that date, Dade Behring Marburg GmbH has become the owner of the '241 Patent, but all the plaintiffs retain certain rights to the '241 Patent, including the right to sue and recover for infringement. *See* Docket Item ("D.I.") 66 at para. 6.

Jurisdiction is proper pursuant to 28 U.S.C. s.s. 1331 and 1338(a). Having received briefs and heard argument on the proper construction to be given disputed claim language in the '241 Patent, the Court now

engages in a claim construction for each of the disputed claim terms as required by Markman v. Westview Instruments, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

II. Factual Background

Both Dade Behring and Biosite design, manufacture, market, and sell immunoassays, devices which allow a quick and easy determination of whether a patient's bodily fluids, such as blood or urine, contain a drug or other chemical. Immunoassays operate by utilizing antibody or antigen specificity to detect the presence (or absence thereof) of a compound of interest.FN2 This substance detected by the antibody or the antigen is called the analyte. FN3 Immunoassays employ the known ability of antibodies and antigens to latch on to, or bind to, their complementary antigen or antibody, respectively, as a means of detection.FN4

FN2. Antibodies are proteins made by the immune system of mammals in response to the invasion of a foreign substance, such as a virus or toxin, which are also referred to as antigens. On the surface of the antibodies are specific sites which bind with only specific antigens, the two together being referred to as members of an immunological pair or "mips." In this manner, the virulent aspects of the antigen are rendered innocuous by interaction with its complementary antibody.

In addition, antibodies can either be of a polyclonal or monoclonal variety. Polyclonal antibodies are the product of many different antibody-producing cells and hence differ somewhat in their precise affinity to the antigen because different forms of similar antibodies bind to different parts of the antigen and bind with differing strengths. Monoclonal antibodies, on the other hand, are homogenous because a single cell produces the antibody meaning that all antibodies bind to the antigen at the same specific site within the antigen and with the same strength. Because of their preciseness as an analytical tool, monoclonal antibodies are mostly used in present-day immunoassays.

FN3. Typically, the analyte is the antigen being measured by the immunoassay. Although the analyte may also be the antibody, for simplicity sake the Court will henceforth use the antigen as the analyte and the antibody to that antigen as the molecule which binds to the analyte.

FN4. The primary physical interaction between an antibody and an antigen can be described as either fitting two pieces of a puzzle together, or as a lock and key. If the puzzle piece does not fit properly or the key cannot open the lock, the antibody will be unable to bind the antigen.

The immunoassay method and device covered by the '241 Patent has two distinct structures.FN5 First, there is an "immunosorbing member" and/or an "immunosorbing zone", which is relatively small compared to the other distinct part of the invention, the "liquid absorbing member" and/or "liquid absorbing member." FN6 The immunosorbing structure serves both as the place where a sample solution is added and the location where the detection of the analyte takes place. On the immunosorbing structure there is a member of an immunological pair ("mip"), for purposes of this opinion an antibody, which is non-diffusively bound. It is the mip, with its ability to bind a specific, sought-after analyte, that allows the immunoassay to function as a means for detection.

FN5. Although this opinion properly focuses on the construction of claims within the patent and not on the invention itself, the Court provides a cursory structural review of the invention covered by the '241 Patent so that the claim construction analysis is given proper context. Additionally, although it is improper during a

claim construction to analyze the accused product, *see* Young Dental Mfg. Co., Inc. v. Q3 Special Products, Inc., 112 F.3d 1137, 1141 (Fed.Cir.1997), the particular accused product is kept in mind, for it is efficient to focus on the construction of only the disputed elements of the claims. *See* Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1580 (Fed.Cir.1991).

FN6. As part of the claim construction dispute between the parties revolves around whether the immunosorbing member and the immunosorbing zone are synonymous or are subsumed one in the other, the Court refrains during its recitation of the factual background to promote either view and instead uses the neutral term "immunosorbing structure." The Court will also treat the other major structure of the device, the "liquid absorbing member" and/or "the liquid absorbing zone," in the same manner.

The second distinct part of the immunoassay device is the "liquid absorbing member" and/or "liquid absorbing zone." The liquid absorbing structure operates by drawing or pulling solutions through the immunosorbing structure in order to concentrate the analyte, which has become bound to its mip counterpart in the immunosorbing structure. Concentration in the immunosorbing zone is insured because the liquid absorbing structure is enclosed in an impermeable enclosure to inhibit contact with solutions except through the immunosorbing structure. With such concentrated levels of analyte in a relatively small area, it is then easier to use various detection methods to ferret out the sought-after analyte.

Because the actual binding of antigens to their complementary antibodies is not detectable by the human eye, detection in an immunoassay usually involves a signal label attached to one component of the binding reaction, i.e., either to the antibody or analyte/antigen. The signal label is usually a substance capable of detection, e.g., radioactive isotopes or enzymes which generate color when exposed to particular chemicals. There are two major types of immunoassay detection techniques: the competitive assay and the sandwich assay.

In the competitive assay, an analyte is labeled. Thereafter, both a sample solution containing the labeled analyte and a test solution suspected of containing unlabeled analyte are prepared. Antibodies, specific for the sought after analyte, are fixed to a solid surface in the immunosorbing structure. If the sample solution contains the analyte of interest, both the labeled and unlabeled analytes will compete for the limited number of antibody binding sites on the immunosorbing structure. The magnitude of the signal detected from the labeled analyte bound to the solid surface is thus inversely proportional to the amount of unlabeled analyte in the test solution. In other words, if there is no analyte in the test solution, all the labeled analyte will bind and there will be a strong signal detected; contrariwise, if there is the sought-after analyte in the test solution, the solid surface to which the antibodies are attached will display proportionate levels of both labeled and unlabeled analyte, and therefore send a less strong signal. In this type of assay, therefore, the lower the level of detected labeled analyte, the more likely the specimen contains the analyte of interest.

In the sandwich assay, the antibodies are again fixed to a solid surface in the immunosorbing structure. The test solution, suspected of containing the analyte of interest, is applied to the solid surface of the immunosorbing structure. If the test solution contains the desired analyte, the analyte will bind to the antibodies, and thereby also be attached to the immunosorbing structure as an analyte-antibody pair. A second solution containing a labeled antibody specific for a different site on the same analyte is then added. The labeled antibody will only bind to analyte which has become bound to the unlabeled antibody fixed on the immunosorbing structure, making a antibody-antigen-antibody sandwich. The level of the analyte in the

specimen is therefore directly proportional to the magnitude of the signal given off by the labeled antibodies; labeled antibody will only bind to the immunosorbing structure if the sought after antigen has bound to the mip on the immunosorbing structure first. The greater the signal given off by the labeled antibody, therefore, the greater the amount of analyte the specimen has.

Having briefly set forth the underlying methods and devices in dispute in the '241 Patent, the Court confronts the claim language in dispute, which cover Dade Behring's immunoassay methods, devices, and kits. The disputed claim language falls into three distinct groups: method claims (claims 1, 2, and 5); device claims (claims 25, 27, 35, 37, 69 and 71); and kit claims (claims 32, 46, 48, 80 and 82). However, only claims 1, 2, 25, and 32 need be analyzed, as they are representative of the claim disputes found in the other disputed claims.FN7 The claims will be construed according to the well-developed body of claim construction law set forth in detail below.

FN7. There are no terms in claim 5, aside from those discussed in claim 1, that are in dispute. Likewise, there are no terms in claims 27, 35, 37, 69, and 71, aside from those discussed in claim 25, that are in dispute. Lastly, there are no terms in claims 2, 46, 48, 80, and 82, aside from the one discussed in claim 32, that are in dispute.

III. Claim Construction Law

Patent infringement litigation involve two stages: "First, the claim language must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1476 (Fed.Cir.1998) (quoting Carroll Touch, Inc. v. Electro Mechanical Sys., Inc., 15 F.3d 1573, 1576 (Fed.Cir.1993)). The first phase, which is the concern of the present Opinion, is commonly referred to as claim construction and is exclusively a matter of law to be determined by the Court. *See* Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1455 (Fed.Cir.1998)(*in banc*); Eastman Kodak Co. v. Goodyear Tire and Rubber Co., 114 F.3d 1547, 1552 (Fed.Cir.1997).FN8

FN8. Although Biosite attempts to argue that a claim construction should consider Section 112 support, in the form of the written description requirement and enablement requirement, the Court declines to consider these sections of Section 112 during claim construction. Biosite appears to have confused the patent principle "a court [should] seek to interpret claims to preserve, rather than defeat, [patent] invalidity," *see* Eastman Kodak Co., 114 F.3d at 1555, with permitting an out and out invalidity analysis during the claim construction phase of the litigation. This claim construction principle, however, was enunciated in the context of explaining why extrinsic evidence of the subjective intent of parties is disfavored. *See* Markman v. Westview Instr., Inc., 52 F.3d 967, 986 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

First, as the Court does not rely on extrinsic evidence for its claim construction, it is not necessary to consider the enablement requirement under s. 112, para. 1 and interpret claim language narrowly so as to preserve its validity. *See* Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1998 WL 394371 at *6- *7 (Fed.Cir. July 2, 1998) ("[I]f after consideration of the intrinsic evidence there remains a doubt as to the exact meaning of claim, consideration of extrinsic evidence may be necessary to determine the proper construction. If a claim falls into this latter category," questions of enablement under s. 112, para. 1 would support adoption of a narrower claim construction.) Second, the Federal Circuit has explicitly made clear

that a validity argument is generally not part of claim construction. *See* Intervet Am., Inc. v. Kee-Vet Labs., Inc. ., 887 F.2d 1050, 1053 (Fed.Cir.1989) ("Ambiguity, undue breadth, vagueness, and triviality are matters which go to claim *validity* for failure to comply with 35 U.S.C. s. 112, para. 2, not to interpretation or construction.") (emphasis in original). Accordingly, the Court declines to consider arguments of validity during the claim construction phase without more clear guidance from the Federal Circuit.
Proper claim construction is based on a hierarchy that assigns different weights to various parts of the intrinsic record: first in importance is the claim language itself, next the specification, and finally the prosecution history. *See* CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1152 (Fed.Cir.1997), *cert. denied sub nom.,* Marchon Eyewear v. Tura LP, 522U.S. 1109, 118 S.Ct. 1039, 140 L.Ed.2d 105 (1998); Eastman Kodak, 114 F.3d at 1552. The Court therefore starts its claim construction by "look[ing] to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Vitronics,* 90 F.3d at 1582. Claims are construed from the point of view of the person of ordinary skill in the field of the invention at the time of the invention. *See* Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed.Cir.1998); Eastman Kodak, 114 F.3d at 1555. Unless a special definition is stated in the specification or prosecution history, claim language is interpreted according to its ordinary and customary meaning. *Vitronics,* 90 F.3d at 1582 ("[P]atentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history."); *see also* Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed.Cir.1997) (if the specification does not use a term in a special or unique way, "its ordinary meaning to one skilled in the art controls."). Additionally, claims in the same patent should be interpreted with reference to one another, *see* Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed.Cir.), *cert. denied,* 516 U.S. 987, 116 S.Ct. 515, 133 L.Ed.2d 424 (1995), and "each claim is an entity which must be considered as a whole." General Foods Corp. v. Studiengesellschaft Kohle, 972 F.2d 1272, 1274 (Fed.Cir.1992).

Second in importance to the claim language in determining the meaning and scope of the patent is the specification. The specification acts as a dictionary when it either expressly, or by implication, defines terms used in the claims. *See Vitronics,* 90 F.3d at 1582. It is thus unsurprising the specification has been described as "often the single best guide to the meaning of a disputed term...." *See id.* Indeed, when the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term. *See* Multiform Desiccants, 133 F.3d at 1478. However, the specification cannot be used to import language into the claim in a wholesale fashion. Although, "examples disclosed in the preferred embodiment may aid in the proper interpretation of a claim term, the scope of a claim is not necessarily limited by such examples." Ekchian, 104 F.3d at 1303; Intervet Am., 887 F.2d at 1053 ("[I]nterpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.").

The third part of the intrinsic record, the prosecution history, also informs, as needed, the understanding of terms found in both the specification and the claim. *See* Multiform Desiccants, 133 F.3d at 1478 ("The evolution of restrictions in the claims, in the course of examination in the [Patent and Trademark Office], reveals how those closest to the patenting process-the inventor and the patent examiner-viewed the subject matter."). Indeed, the prosecution history may limit, through prosecution history estoppel, the interpretation of the disputed language to meanings not disclaimed by the inventor during the prosecution of the patents. *See* CVI/Beta Ventures, 112 F.3d at 1155 (quoting Southwall, 54 F.3d at 1579). Nevertheless, "[a]lthough the prosecution history can and should be used to *understand* the language used in the claim, it too cannot enlarge, diminish or vary the limitations in the claims." *See* Markman, 52 F.3d at 980 (emphasis added).

Once the Court completes its examination of the claim language, the specification, and prosecution history, the Court may consider extrinsic evidence, "if necessary to aid the court's understanding of the patent." *See* Wright Medical Technology, Inc. v. Osteonics Corp., 122 F.3d 1440, 1443 (Fed.Cir.1997). Although such extrinsic evidence may include expert testimony or the testimony of the inventor, technical treatises and dictionaries are the favored forms of extrinsic evidence. *See Vitronics,* 90 F.3d at 1584 n. 6. FN9 If the intrinsic evidence, however, unequivocally describes the meaning and scope of the disputed language, reliance on extrinsic evidence is improper. *See id.* at 1583; Bell & Howell Document Management Products Co. v. Altek Systems, 132 F.3d 701, 705 (Fed.Cir.1997) ("The intrinsic evidence should usually be sufficient to enable one to determine the meaning of a claim term."). Consequently, the testimony of an inventor, his attorney, or one skilled in the art concerning claim construction is entitled to little or no consideration. *See* Bell & Howell, 132 F.3d at 706.

FN9. Technical treatises and dictionaries may not, however, contradict anything in the patent documents. *See Vitronics,* 90 F.3d at 1584 n. 6.

With the above-enunciated claim construction principles in mind, the Court analyzes the disputed claim language in the '241 Patent.

IV. Claim Construction of the '241 Patent

A. Disputed Claim Language in Claims 1, 2, and 32 FN10

FN10. Citations to claim language throughout this opinion, with the exception of a citations to Claims 2 and 32, will refer to the reexamination patent which amended Claims 1 and 25 in the initially issued patent. However, all references to the specification of the '241 Patent refer to the initially issued patent because the reissue patent in no way affected the specification.

The following claim terms or phrases in Claim 1 are in dispute between the parties: (1) "immunoassay," (2) "analyte," (3) "mip," (4) "immunosorbing zone," (5) "to at least a portion of the bibulous support," (6) "serving as an inlet port for liquids into said device," (7) "liquid absorbing zone," (8) "one component conjugated to a mip," (9) "amount of signal label producing said detectable signal in said immunosorbing zone is related to the amount of analyte in said sample," (10) "(a) a solution of a sample suspected of containing said analyte; and (b) a solution of components of said signal producing system," (11) "immersed," and (12) "flowing said sample solution of substantially constant composition through said immunosorbing zone." FN11 Additionally, the term "assay device" is in dispute in Claims 2 and 32. FN12

FN11. Claim 1 of the '241 reads in pertinent part:
1. An immunoassay method for determining an analyte which is a member of an immunological pair, defined as a mip, consisting of ligand and its homologous antiligand, said method employing in combination an assay device and a signal producing system;
said assay device characterized by an immunosorbing zone comprising mips non-diffusively bound to at least a portion of a bibulous support serving as an inlet port for liquids into said device; and a liquid absorbing zone in liquid receiving relationship with said immunosorbing zone, and

a signal producing system ... having one component conjugated to a mip to provide a signal label-mip conjugate, wherein the amount of signal label producing said detectible signal in said immunosorbing zone is related to the amount of analyte;

said method comprising:

contacting said assay device in a predetermined order with: (a) a solution of a sample suspected of containing said analyte; and (b) a solution of components of said signal producing system ... wherein said immunosorbing zone is immersed in said sample solution;

flowing said sample solution of substantially constant composition through said immunosorbing zone;

whereby said solutions migrate through said immunosorbing zone into said liquid absorbing zone resulting in an amount of signal label-mip conjugate becoming bound to said mip bound to said support in relation to the amount of analyte in said sample....

See Col. 1, lines 28-62.
FN12. Claim 2 reads:
2. A method according to claim 1, wherein said signal label-mip conjugate is contacted with said assay device in a solution not earlier than concurrently with said sample solution.

See Col. 41, lines 11-14.

Claim 32 reads in pertinent part:
32. An immunoassay kit comprising an assay device according to claims 25, 26, 27, or 30 in combination with a labeled mip separate from said assay device....
See Col. 44, lines 37-39.

1. Terms Expressly Defined in the Specification

Although claim language, in most instances, is interpreted according to its ordinary and customary meaning,

see Vitronics, 90 F.3d at 1582, the general rule yields to the exception when a special definition is stated in the specification. *See id*. In such cases, the inventor acts as a lexicographer and the specification is a specialized dictionary expressly defining the terms used in the claims. In the '241 Patent, the following disputed terms are expressly defined in the specification:

"Analyte-the compound or composition to be measured, which is a mip and may be a ligand, which is mono- or polyepitopic, that is, having one or plurality of determinant sites, haptenic and antigenic, a single compound or plurality of compounds which share at least one common epitopic or determinant site; or a receptor." Col. 3, lines 58-64.FN13

FN13. This definition, and other supporting specification language, makes clear that the analyte must be a mip which binds to an antibody bound in the immunosorbing zone. *See, e.g.,* Col. 3, lines 37-40; Col. 5, lines 60-64. The Court finds that the specification definition of "analyte" does not also include labeled analyte or antibody used for detection purposes, even though it is literally a compound being measured by the immunoassay. In short, the labeled analyte or antibody is not the compound for which the immunoassay is testing.

"Mip-a member of an immunological pair, consisting of two different molecules, where one of the molecules has an area on the surface or in a cavity which specifically binds to a particular spatial and polar organization of the other molecule. The members of the immunological pair are referred to as ligand and receptor (antiligand) and members of a specific pair are referred to as homologous." Col. 3, line 65 through Col. 4 line 4.
"Assay device-the assay device has at least one bibulous layer, normally having two or more layers, which will be relatively free of non-specific adsorptivity for the materials of interest. The device has as one element a relatively small immunosorbing zone having a mip non-diffusively fixed in the zone. The mip remains substantially immobilized on a bibulous solid support during the course of the assay; and as a second element a reservoir zone, either directly or indirectly in liquid-receiving relationship with the immunosorbing zone." Col. 4, lines 39-48.

"(a) Immunosorbing zone-a bibulous solid film, layer or sheet to which a mip is non-diffusively bound; the immunosorbing zone has a relatively small fluid capacity as compared to the total assay device capacity. One or more members of the signal producing system may be bound directly or indirectly to the immunosorbing zone. The immunosorbing zone has specific binding capability for the homologous mip.

Within the immunosorbing zone may be one or more zones in tandem or overlapping. Included within the immunosorbing zone will be a detection zone, which may be the same or different from the zone to which the mip is bound. Col. 4, lines 49-61.

"(b) Liquid Absorbing Zone-a bibulous solid material either directly or indirectly in liquid receiving relationship with the immunosorbing zone and acting as a reservoir or storage zone capable of storing a substantially greater liquid volume than the immunosorbing zone. The zone acts as a pump to pull liquid through and out of the immunosorbing zone." Col. 4, lines 62-68.

Because the specification is acting as a dictionary, expressly defining terms used in the claims, it is "the single best guide to the meaning of the disputed term...." *See Vitronics,* 90 F.3d at 1582. Additionally, claim construction principles recognize that a "patentee may choose to be his own lexicographer and use terms in

a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Id*. Because special definitions are clearly stated in the patent specification, the Court adopts the specification definitions for "analyte," "mip," "assay device," "immunosorbing zone," and "liquid absorbing zone." FN14

FN14. Biosite seeks to "interpret" these definitions explicitly set out in the specification. Presumably, if the definition of the specification was also unclear, that too would have to be "interpreted," and so on *ad infinitum*. The task before the Court, however, is not to construe ambiguous or unclear specification language, and the Court declines to undertake such a potentially, interminable chore.

2. "Immunoassay"

Biosite contends an "immunoassay" is a test that uses antibody specificity to detect the presence (or absence) of a compound of interest in a test sample. Although Dade Behring does not disagree with Biosite's definition, it believes the definition is incomplete. Dade Behring additionally states that the "immunoassay" performed in the '241 Patent is non-chromatographic in that it does not require the flow of fluid for a distance along a membrane to obtain the result; rather the assay involves the immediate contact of the sample solution with the bound mips. The dispute between the parties therefore revolves around whether this claim language should be limited by the descriptive terminology, "non-chromatographic."

Starting, as the Court must, with the language of the claim, there is no mention of the term "non-chromatographic." *See* Col. 1, lines 28-32. Nevertheless, the specification describes the invention as "[n]ovel non-chromatographic assay devices and methods employing such devices are described for the determination of members of an immunological pair (mip)." *See* Col. 2, lines 20-22. As the Federal Circuit Court of Appeals has observed, "interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." *See* Ekchian, 104 F.3d at 1303; *see also* Electro Medical Systems v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994) ("claims are not to be interpreted by adding limitations appearing only in the specification."); *See* Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1422 (Fed.Cir.), *cert. denied,* 513 U.S. 995, 115 S.Ct. 500, 130 L.Ed.2d 409 (1994) ("[I]t is axiomatic that terms in the specification cannot simply be read into the claims where they do not appear.").

The parties do not dispute that an immunoassay may be either chromatographic or non-chromatographic. Consequently, interpreting the term "immunoassay" in the claim does not inherently require a distinction to be made between chromatographic and non-chromatographic techniques. By appending the limitation "non-chromatographic" to the definition of "immunoassay," the Court would be impermissibly adding an extraneous limitation only appearing in the specification. As the Federal Circuit has warned district courts in performing claim constructions, "no matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them." *See* Intervet Am., 887 F.2d at 1053 (Fed.Cir.1989). Accordingly, the Court finds the specification cannot be used to import the term "non-chromatographic" into the definition of the claim term "immunoassay."

Dade Behring next argues that the prosecution history supports its position. Specifically, in an Amendment dated February 18, 1982, the patent applicants stated: "Deutsch and Grubb [prior art references] are both chromatographic techniques.... In the subject invention, there is a different kind of movement of the sample." *See* D.I. 129, Ex.3 at 9. Further, in an Amendment dated August 28, 1981, applicants described Grubb as "immunochromatography," while "the technique employed in the subject invention is contrary to

the manner in which Grubb's invention is performed." D.I. 129, Ex.4 at 5. In spite of this seemingly compelling evidence, the Court adheres to the well-established claim construction principle that "although the prosecution history can and should be used to understand the language used in the claim, it too cannot enlarge, diminish or vary the limitations in the claims." *See* Markman, 52 F.3d at 980. The Court therefore declines to enlarge the claim limitations by importing *post hoc* explanations, and inferences therefrom, from the prosecution history into the claim language.

In short, the simple fact of the matter is that the patentees left out of the claims, for one reason or another, the word "non-chromatographic." It is not proper, nor the Court's role, to supply an extraneous limitation appearing only in the specification and/or the prosecution history. *See* Intervet Am., 887 F.2d at 1053. Accordingly, the Court declines to add "non-chromatographic" to the definition of the "immunoassay" claim term. The Court therefore holds an "immunoassay" is a test that uses antibody specificity to detect the presence (or absence) of a compound of interest in a test sample.

3. "To At Least A Portion Of A Bibulous Support"

Dade Behring argues that this phrase simply means that the mip is bound to some or all of the bibulous support, which is equivalent to the "immunosorbing member." In other words, Dade Behring believes that both the immunosorbing member and immunosorbing zone are bibulous and that the immunosorbing member is the "bibulous support" for the immunosorbing zone. Additionally, Dade Behring contends there might be areas of the immunosorbing zone that contain no mips. Biosite, on the other hand, argues that the immunosorbing zone is equivalent to the bibulous support and that the immunosorbing zone must be completely covered with mips.

The Court agrees with Biosite that the claim language "bibulous support" in Claim 1 refers to the "immunosorbing zone," as there is no support anywhere in the record that the "immunosorbing member" must also be a part of this structure. The claim language, in context, states: "said assay device characterized by an immunosorbing zone comprising mip non-diffusively bound to at least a portion of a bibulous support...." *See* Col. 1, lines 33-35. It has already been established that the "immunosorbing zone" is where the mips are non-diffusively bound. The Court observes that as the mips are also bound "to at least a portion" of the "bibulous support," it is clear that the terms "bibulous support" and "immunosorbing zone" are synonymous. Accordingly, the Court finds the claim term "bibulous support" in Claim 1 refers to the "immunosorbing zone."

However, the Court is persuaded by Dade Behring that a solid covering of mips on the immunosorbing zone is not required by the claim language. The claim language merely states mips must be "non-diffusively bound." Col. 1, line 34. Non-diffusive means concentrated or not spread out, *see Webster's Dictionary* at 630-631; it does not mean a substance must completely cover a surface. Nor is this construction at odds with the proper operation of the invention, as a heavy concentration of mips will equally insure that a sufficient amount of analyte is pulled out of the test solution for detection purposes. Lastly, nothing in the specification or prosecution history suggests that this claim language should be interpreted in a contrary manner. Thus, the Court agrees with Dade Behring and construes this claim language to allow insignificant portions of the test solution not to come into contact with any mips while transversing the immunosorbing zone.

In conclusion, the Court construes the claim language "to at least a portion of a bibulous support" to mean that mips must be bound to the immunosorbing zone in a concentrated matter; however, the immunosorbing

zone need not be completely covered.

4. "Bibulous Support Serving As An Inlet Port for Liquids Into Said Device"

On this claim construction issue, the parties dispute whether the test solution must pass through the immunosorbing zone before entering the liquid absorbing zone. Dade Behring argues that since there can be parts of the solid support to which no mips are bound, solution may pass through portions of the solid support without going through the immunosorbing zone. Biosite, on the other hand, contends the test solution must pass through the immunosorbing zone before continuing on to the liquid absorbing structure.

The Court is persuaded that the test solution must pass through the immunosorbing zone before entering the liquid absorbing zone. To properly determine the immunoassay method established in Claim 1, the Court must construe the entire following phrase:

[I]mmunosorbing zone comprising mip non-diffusively bound to at least a portion of a bibulous support serving as an inlet port for liquids into said device.

Col. 1, lines 33-36.

The claim language grammatically intimates that the structure serving as the "inlet port" is the "bibulous support" because the verb "serving" directly modifies the "bibulous support." As it has already been determined that the "bibulous support" refers to the "immunosorbing zone," the "immunosorbing zone" serves as the "inlet port." This construction makes perfectly good sense because the test solution sample is in fact applied to the immunosorbing zone, which acts as an inlet for the device.

This interpretation is also consistent with other claims in the patent and considering Claim 1 as a whole. *See* Southwall, 54 F.3d at 1579; General Foods, 972 F.2d at 1274. With regard to other claims found in the '241 Patent, similar language is found in Claim 25 in which a "immunosorbing member is enclosed in an impermeable enclosure to inhibit contact with solutions except through said immunosorbing member...." Col. 2, lines 8-11. Although Claim 1 concerns an "immunosorbing zone" and Claim 25 concerns a "immunosorbing member," it is clear these structures operate in a similar fashion, i.e., they both promote the binding of the analyte to a mip by concentrating the analyte in a relatively small area of the assay device.FN15 Although all the test solution may not come into contact with mips in the immunosorbing zone as they are non-diffusively bound, the fact of the matter is that the immunosorbing zone acts as the inlet port for the test solution, and therefore, the test solution must enter the immunosorbing zone before coming into contact with the liquid absorbing zone, regardless of whether the analyte in the test solution actually comes into contact with individual mips. The crucial distinction is that the claim language refers to the fact that the test solution must enter the "immunosorbing zone," and does not require contact with mips non-diffusively bound therein.

FN15. The Court's reasoning for construing immunosorbing zone and immunosorbing member consistently is discussed below. *See* infra p. 34.

Accordingly, finding nothing in the specification and prosecution history to indicate otherwise and construing this claim language with reference to similar language found in Claim 25, the Court finds the structure that serves as the "inlet port" is the "immunosorbing zone," and therefore the test solution must

come into contact with the immunosorbing zone before coming into contact with the liquid absorbing zone

Combining the previous two claim constructions, the Court construes the claim language "immunosorbing zone comprising mip non-diffusively bound to at least a portion of a bibulous support serving as an inlet port for liquids into said device" as covering an immunoassay method where the test solution must enter the immunosorbing zone before proceeding to the liquid absorbing zone, but not all of the solution must necessarily come into contact with mips while in the immunosorbing zone.

5. "Signal Producing System ... Having One Component Conjugated To A MIP To Provide A Signal Label-MIP Conjugate"

In this claim dispute, Dade Behring seeks to establish that the analyte may be conjugated directly with the signal label. Biosite construes this claim language as requiring one component of the signal system to be attached to either the analyte or an antibody to the analyte. Although both parties seem to agree that the analyte may be conjugated directly with the signal label, the Court will nevertheless construe this claim language, as the specification provides a ready definition for this Claim language.

It appears clear from the claim language itself that the "one component" of the "signal producing system" which conjugates to a mip to form a "signal label-mip conjugate" is self-definitionally the "signal label." This interpretation is also consistent with the specification definition of a "signal producing system" which reads in part, "the signal producing system may have one or more components, at least one component being conjugated to a mip." *See* Col. 5, lines 1-3. Further, the specification provides an express definition for the "signal label-mip conjugate": "a member of the signal producing system, which is directly or indirectly bound to a mip, which is or becomes bound to the immunosorbing zone to provide for production of a detectible signal in the detection zone." Col. 5, lines 39-43. This definition clearly contemplates that the analyte, which may be a member of the signal producing system, may be directly or indirectly bound to a mip. As the specification acts as a dictionary when it expressly defines terms used in the claim, *see Vitronics,* 90 F.3d at 1582, and there is no ambiguity or incompleteness after consulting the specification definition, *see* Multiform Desiccants, 133 F.3d at 1478, there is no need to search further for the meaning of the term. The Court thus adopts the definition for "signal label-mip conjugate" as found in the specification.

6. "The Amount Of Signal Label Producing Said Detectable Signal In Said Immunosorbing Zone Is Related To The Amount of Analyte"

This claim dispute boils down to whether a signal label need only indicate the presence of analyte, or whether the signal label must indicate the amount or intensity of the signal given off by a test solution.FN16 Biosite argues the claim, specification, and prosecution history all require that the signal intensity change, directly or inversely, with the amount of analyte in the test solution. On the other hand, Dade Behring contends the specification of the '241 Patent confirms its interpretation that the signal produced by the signal producing system must relate in only some way to the amount of analyte present. Such relationship, Dade Behring, asserts can be quantitative, semi-quantitative, or qualitative.

FN16. The parties also dispute the meaning of the following closely-related claim language: "an amount of signal label-mip conjugate becoming bound to said mip bound to said support in relation to the amount of analyte in said sample...." Col. 1, lines 59-62. However, because this claim dispute involves the exact same issues presently being analyzed, this claim language will be construed in the same fashion as the claim language presently being analyzed in this section of the Opinion.

The Court begins, as before, with the language of the claim itself, which requires the "amount of signal label producing said detectible signal ... is related to the amount of analyte." Col. 1, lines 44-46. Because the nature of the relationship between the amount of signal label and the amount of analyte is not expressly defined in the claim, it is necessary to search the specification and the prosecution history in order to further the Court's understanding of this claim language. Significantly, the specification states in various places that, "the devices of the subject invention ... provid[e] for qualitative or quantitative results." Col. 3, lines 28-31; *see also* Col. 8, lines 67-68; Col. 9, lines 23-24; and Col. 11, lines 4-5 (measurement may be "qualitative, semi-quantitative, or quantitative."). Additionally, the specification summarizes the invention by explaining that, "[i]n accordance with the subject invention, a simple rapid technique is provided whereby ligands and their receptors may be qualitatively or quantitatively determined by employing various techniques." Col. 40, lines 28-31. Accordingly, the specification envisions for the relation between the amount of signal and the amount of signal to be manifested in any number of quantitative or qualitative ways.

Although the language of the specification describes quantitative techniques whereby "standard or charts" relate "color intensity to the particular concentration of the analyte," *see* Col. 14, lines 3-17, Col. 38, lines 33-36, there is no support for Biosite's contention that the signal response must be graduated. The specification merely provides examples or preferred embodiments of how its immunoassay technique may be performed. As discussed previously, however, "examples disclosed in the preferred embodiment may aid in the proper interpretation of a claim term, [but] the scope of the claim is not necessarily limited by such examples." *See* Ekchian, 104 F.3d at 1303.

Similarly, the prosecution history cited by Biosite does not change the scope or meaning of the patent. Although in numerous places throughout the prosecution history Dade Behring distinguished its invention from prior art by explaining, "it is the level of the detectable signal which is the distinctive factor," *see* D.I. 127, Ex.2 at 110, 111, and 117, the prosecution history cannot "enlarge, diminish, or vary the languages in the claims." *See* Markman, 52 F.3d at 980. The claim language only requires some relation between the amount of signal produced and the amount of analyte.FN17 The specification further makes clear that quantitative, semi-quantitative, and qualitative methods of detection were contemplated by the patent applicant at the time of the invention. It is not now proper to use the prosecution history to diminish the scope of the claim language to include only quantitative or semi-quantitative methods, especially since the claim language is broader than such embodiments.FN18 *See* Electro Medical Systems, 34 F.3d at 1054.

FN17. Although Biosite points to the claim language "*amount* of signal label produc[ed]" and "*amount* of analyte," *see* Col. 1, lines 43 and 45 (emphasis added) as proving the claim only contemplates quantitative methods, there is nothing in the claim language which prevents a qualitative method being employed to analyze the relationship between the amount of signal produced and the amount of analyte. Absent express language limiting the type of analysis to be performed on these two related amounts, the Court declines to read in extraneous limitations. *See* Intervet Am., 887 F.2d at 1053.

FN18. Nor is this a case in which Dade Behring has specifically disclaimed during the prosecution of the '241 Patent an interpretation of this claim language which would preclude qualitative methods of analysis. *See* Southwall, 54 F.3d at 1576. Dade Behring only sought to distinguish prior art by showing its invention was capable of determining the level or intensity of a signal.

The Court therefore construes "amount of signal label producing said detectible signal in said immunosorbing zone is related to the amount of analyte," as allowing for quantitative, semi-quantitative or qualitative analysis of the relation between the amount of signal produced and the amount of analyte in the test solution.

7. "Contacting Said Assay Device In A Predetermined Order With: (A) A Solution Of A Sample Suspected Of Containing Said Analyte; And (B) A Solution Of Components Of Said Signal Producing System...."

The parties' disagreement concerning this claim language revolve around whether if there is one solution, whether the components of solutions (a) and (b) must remain distinguishable or whether they can essentially become one component. Dade Behring contends that solutions (a) and (b) can form a homogeneous solution, while Biosite asserts there may be one solution, but that solution has to be heterogeneous in that there has to be two distinct components in the solution.

Starting with the language of the claim, the claim provides for two solutions with different components to be contacted with the assay device. Claim 2, a dependent claim, adds: "A method according to claim 1, wherein said signal label-mip conjugate is contacted with said assay device in a solution not earlier than concurrently with said sample solution." *See* Col. 41, lines 11-14. It is therefore also clear that the two solutions can be applied to the assay device concurrently, i.e., at the same time or in conjunction with one another. *See* Webster's at 472. Not surprisingly, therefore, there is no dispute between the parties that one solution may be used. However, "concurrently" does not mean that the two components have to combine into one component so that a homogeneous solution is formed. As an analysis of the relevant claim language proves inconclusive in this respect, it is necessary to consider the relevant portions of the patent specification.

Dade Behring, in order to support its construction that one homogenous solution is possible, points to that part of the specification which states that "while the device may be contacted with only one solution, usually it will be contacted with at least two solutions." *See* Col. 10, lines 30-32. However, this language must be read in the context of the whole specification. The specification clarifies what it means by this sentence when it states:

Normally, after contacting the device with the signal label-mip conjugate, a subsequent contact with a wash solution containing reagents, such as enzyme substrates will often be employed. In this way, one can ensure the substantial absence of nonspecific binding and occlusion of the signal label-mip in the immunosorbing zone.

See Col. 10, lines 32-38. Thus, the second solution referred to in this passage is a reagent wash. This passage illustrates that the two solutions set out in the claim language, i.e., the test solution and signal solution, and the two solutions referred to in this portion of the specification, i.e., a signal solution and a reagent wash, do not correspond. This suspicion is later confirmed by specification language which states that the assay device always must come into contact with solution containing signal label-mip conjugate *and* solution containing the analyte sample. There, the specification reads:

By employing two steps, first contacting the assay device with the sample, followed by contacting the assay device with the signal label-mip conjugate, the amount of signal label-mip conjugate greater than a predetermined minimum will not significantly affect the assay result, when a *subsequent step* is employed to

reduce occluded and non-specifically bound signal label-mip.

See Col. 11, lines 12-19 (emphasis added). This "subsequent step" refers to the language cited above by Dade Behring for the proposition that a second washing step is usually employed, but need not be. However, whether the assay is conducted with this subsequent washing step or not, the fact remains that the assay device must be contacted by two separate components. In fact, the competition assay would not work properly if the labeled analyte and the sample analyte were to become one component; two different components could no longer compete for the limited number of antibody binding sites in the immunosorbing zone as a competition assay requires.

Dade Behring also directs the Court's attention to a sentence in the specification which states, "[p]rotocols having various number of steps, including as few as one can be employed for a determination of analyte." Col. 40, lines 31-33. Protocol 2, disclosed in the specification, in fact "involves combining the sample and mip components of the signal producing system and contacting the assay device with the resulting solution." Col. 8, lines 2-4. This part of the specification just makes clear that the solution of labeled analyte and solution of sample analyte may be mixed together before adding the combined solution to the assay device. However, there is no intrinsic evidence that the two components become indistinguishable from one another in the process. In fact, for reasons elucidated above, the two components' separateness within the same solution seems crucial for the competition assay to work properly.

Finding nothing in the intrinsic record that the immunoassay method described in Claim 1 could be performed with a homogeneous solution, i.e., containing one component, the Court construes "contacting said assay device in a predetermined order with: (a) a solution of a sample suspected of containing said analyte; and (b) a solution components of said signal producing system ...." as requiring the immunoassay to be contacted with at least two separate components, though those two components may be combined in one solution.

8. "Immunosorbing Zone Is Immersed In Said Sample Solution"

This claim dispute boils down to what "immersed" means. Biosite maintains the claim language must be construed to mean the immunosorbing zone must be dipped into solution, while Dade Behring contends the Claim language is not limited to a dipping process, but allows any process by which the immunosorbing structure is completely covered or surrounded.

In support of its limited reading, Biosite asserts the specification explicitly distinguishes its use of the word "immersion" from an alternative process of dropping or pouring liquid onto the immunosorbing zone. The relevant specification reads:

... the assay device may be conveniently immersed in a solution.

Alternatively, the solutions may be applied to the immunosorbing zone in a horizontal position, either dropwise, as a slowly flowing stream, or in a container surrounding the immunosorbing zone.

Col. 6, lines 33-39 (emphasis added). The specification explicitly contrasts the immersion method from other horizontal methods, such as dropping or pouring liquid on the immunosorbing zone. Dade Behring contends the word "alternatively" just refers to methods of immersion and does not contrast immersion by plunging and immersion by the dropwise or pouring method. The Court is not persuaded. The word

"alternatively" commences a new paragraph and is being used as a conjunction to signify that the terms connected are to be taken not together but one in place of the other. *See* Webster's at 63. The specification therefore supports limiting the word "immerse" to dipping the immunoassay into solution.

However, because neither the specification nor the prosecution history FN19 provides a special or unique definition for immersion, the Court will adopt the customary and ordinary meaning of immersion. *See Vitronics,* 90 F.3d at 1582. "Immerse" is defined as "to plunge or to dip into liquid." *See* Webster's Dictionary at 1130. Thus, as it turns out, the dictionary definition is consistent with the use of "immersion" in the specification.

FN19. Although the prosecution history makes clear "the immunosorbing zone can be in a horizontal or vertical position," *see* D.I. 129, Ex. 11 at 29; *see also id*. at Ex. 5 at 17, the prosecution history supports the definition supplied in the specification by implication when in distinguishing prior art it states, "the immunosorbing zone of Grubb is not immersed in the sample solution. Rather, Grubb exposes only a small portion of the immunosorbing zone to the sample solution." Hence, the applicants for the '241 Patent specifically distinguished between immersion, which requires the plunging or dipping the whole assay device into solution, and only exposing a small portion of the zone, as in a dropwise method. The prosecution history therefore also supports "immersion" to mean the dipping or plunging into liquid.

Accordingly the Court construes the Claim language "immunosorbing zone is immersed in said sample solution" as requiring the immunosorbing zone to be plunged or dipped into the sample solution.FN20

FN20. Dade Behring attempts to point to Biosite's own documents to support its broad construction of "immersed." The Court is at a loss, however, to understand why the accused infringer's documents should be relevant to how claim language in the allegedly infringed patent should be interpreted. Nor does the Court find it proper to rely on a former case construing this claim language, *see* Syva v. Hybritech, 1989 WL 418546 (S.D.Cal. June 29, 1989), inasmuch as such extrinsic evidence is improper to consider when the intrinsic evidence of the patent record unambiguously and completely defines this term. *See* Bell & Howell, 132 F.3d at 706.

9. "Flowing Said Sample Solution of Substantially Constant Composition Through Said Immunosorbing Zone"

It is not clear what is in dispute between the parties as concerns this claim language. Although Dade Behring extensively sets out its construction in its brief, Biosite only suggests possible constructions and concludes the terms are too indefinite to reach a single definitive position. As previously discussed, the Court finds that Biosite's invalidity argument is more properly made after claim construction. *See supra* note 8. The Court will therefore interpret this Claim language according to claim construction principles.

The claim language itself requires that the solution, which flows through the "immunosorbing zone," have "substantially the same composition." However, it is unclear whether substantially the same composition refers to a solution having substantially the same concentration when it first contacts the immunosorbing zone, or has substantially the same composition after it flows through the immunosorbing zone.

The specification states: "In the subject invention, the mip containing layer in contact with the solution

continuously contacts substantially the same composition as the solution diffuses through the layer." *See* Col. 6, lines 18-21. This relatively constant concentration is contrasted with prior art where, "the layer encounters a continuously changing solution composition as solute becomes bound to the layer or dissolves into the liquid." *See* Col. 6, lines 15-18. Furthering elucidating this claim's meaning, the prosecution history states: "In the subject invention, one is continually exposing the immunosorbing zone to a solution of the same composition." *See* D.I. 129, Ex.3 at 10; *see also id.,* Ex. 5 at 17; *id.,* Ex. 11 at 28.

The intrinsic evidence of the patent indicates therefore that the inventors of the patent contemplated that the immunosorbing zone would be exposed to a solution of substantially the same solution. As a result, there is only way to interpret the claim consistent with the purpose of the invention, which is to concentrate the analyte in the immunosorbing zone: The claim must be referring to the composition of the solution when it first makes contact with the immunosorbing zone. Indeed, because the analyte in the sample solution must bind with mips in the immunosorbing zone for the invention to function properly, it would make no sense to interpret this claim language as requiring the sample solution to have substantially the same composition even after the analyte is removed from the sample by the mip layer in the immunosorbing zone. *See* D.I. 129, Ex. 11 at 30 ("As the sample continuously flows through the immunosorbing zone, the analyte is removed from the sample and concentrated in the immunosorbing zone.").

Accordingly, the Court construes "flowing said sample solution of substantially constant composition through said immunosorbing zone" as requiring only the sample solution to have substantially the same composition when it first comes into contact with the mips in the immunosorbing zone, not thereafter.

B. Disputed Claim Languages In Claim 25

Before proceeding to construe disputed claim language in Claim 25,FN21 the Court first observes that "immunoassays," "mip," and "at least a portion of a bibulous support," are claim terms that have already been construed in Claim 1 and thus, require no further construction under this claim. The Court now proceeds to interpret the terms "immunosorbing member," "liquid absorbing member," "bibulous material," "extending transversely," and "about," which appear in Claim 25, but do not appear in Claim 1.FN22

FN21. Claim 25, in pertinent part, recites:

An assay device for performing immunoassays which comprises:
an immunosorbing member comprising a member of an immunological pair, defined as a mip, non-diffusively bound to at least a portion of a bibulous support; and

a liquid absorbing member comprising a bibulous material in *fixed* liquid receiving relationship *throughout the duration of said immunoassay* with said immunosorbing member and extending transversely therefrom, wherein at least the portion of said liquid absorbing member about said immunosorbing member is enclosed in an impermeable enclosure to inhibit contact with solutions except through said immunosorbing member....

See Col. 1, line 65 through Col. 2, line 11.
FN22. The parties previously disputed the claim language: "enclosed in an impermeable enclosure to inhibit contact with solution except through said immunosorbing member." However, both parties now agree this claim language means the liquid absorbing member is enclosed at least in part by an impermeable case, such that the impermeable case prevents the test solution from entering directly into contact with the liquid absorbing member. The only other dispute concerning this language is whether the solution must not touch the immunosorbing member or immunosorbing zone. As will be discussed more fully below, because the immunosorbing member and immunosorbing zone are construed in identical fashion, there remains no dispute between the parties. Accordingly, the Court will adopt the agreed upon definition stated above.

1. "Immunosorbing Member" and "Liquid Absorbing Member"

The crux of this claim dispute is whether "immunosorbing member" should be construed identically with "immunosorbing zone" and whether "liquid absorbing member" should be construed identically to "liquid absorbing zone." First, the Court confronts the immunosorbing terminology. Dade Behring explains that while the "immunosorbing zone" is where the mips are bound, the "immunosorbing member" may be identical in scope or may subsume within it the "immunosorbing zone," as the "immunosorbing member" acts as a support for the "immunosorbing zone." Biosite, on the other hand, argues that the "immunosorbing member" and "immunosorbing zone" should be construed in the same manner, as they refer to the same aspect of the '241 invention.

The Court is persuaded that the "immunosorbing member" and the "immunosorbing zone" should be construed in the exact same manner. Claim 1 contains an "immunosorbing zone" whose definition is adequately set out in the definitions portion of the specification, while the "immunosorbing member" of Claim 25 is not defined in the specification. In fact, the latter term is not even mentioned in the specification or the prosecution history. It appears that there was no need to refer to the "immunosorbing member" separately in the specification or the prosecution history because it had no separate meaning from "immunosorbing zone," which had already been explicitly defined in the specification. Importantly, neither the specification drawings nor the prosecution history make reference to a separate immunosorbing member which supports the immunosorbing zone. Further, the "immunosorbing member," like the "immunosorbing zone" is comprised of mip, non-diffusively bound to at least a portion of a bibulous support. *See* Col. 1, lines 33-35 (Claim 1); Col. 1, line 66 through Col. 2, line 2 (Claim 25).

Recognizing it is well settled that claims are not to be interpreted so as to render claim language meaningless, *see* Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed.Cir.1991), the Court attributes the use of the word "member" rather than the use of the word "zone" to the fact that Claim 1 is a method claim, while Claim 25 is a device claim. Whereas "zone" is defined as "one of the sections or divisions of an area created for a particular purpose," *see* Webster's Dictionary at 2660, "member" is defined as "an essential part of a *device*." *Id*. at 1408 (emphasis added). The "zone" language terminology illustrates that the immunoassay method requires an area to be set aside for immunosorbing purposes. The "member" terminology, on the other hand, explicitly recognizes that the immunosorbing attribute has been assigned to an essential part of a device.

For analogous reasons, the Court is persuaded that the "liquid absorbing member" and the "liquid absorbing zone" have the same meaning. In fact, the "liquid absorbing member," is in a "liquid receiving relationship"

with the "immunosorbing member," just as the "liquid absorbing zone" is in a "liquid receiving relationship" with the "immunosorbing zone." *See* Col. 1, lines 36-38 (Claim 1); Col 2, lines 3-6 (Claim 25). Additionally, the Court notes that counsel for Dade Behring was unable during oral argument to explain to the Court how an immunoassay, consistent with the '241 invention, could have both a "liquid absorbing member" and a separate and distinct "liquid absorbing zone." *See* D.I. 138 at 109-110.

Accordingly, the Court finds the "immunosorbing zone" of Claim 1 and the "immunosorbing member" of Claim 25 have the same meaning. The Court also construes "liquid absorbing zone" and a "liquid absorbing member" in an identical manner.

2. "A liquid absorbing member comprising a bibulous material"

Dade Behring argues the term "bibulous" is an adjective which describes a property or function of a material. Dade Behring then suggests that the property or function of the material is to pull or draw liquid through the immunosorbing member. Biosite contends the "bibulous material" refers to a physical part of the assay device which is comprised of an absorbent, porous material which allows for the flow of solutions.

Starting with the language of the claim itself, the liquid absorbing member is said to be comprised of a "bibulous material." *See* Col. 2, lines 3-4. As the term "bibulous" has not been used in a special or unique way in the specification, it is interpreted according to its ordinary and customary meaning.FN23 *See Vitronics,* 90 F.3d at 1582; Ekchian, 104 F.3d at 1303. Additionally, by adding extraneous limitations only found in the specification or prosecution history, the Court would be violating a cardinal rule of claim construction by importing limitations found only in the specification into the claim. *See* Electro Medical Systems, 34 F.3d at 1054 ("claims are not to be interpreted by adding limitations appearing only in the specification."); Zenith Laboratories, 19 F.3d at 1422 ("[I]t is axiomatic that terms in the specification cannot simply be read into the claims where they do not appear.").

FN23. Much has been made by both parties of the following specification language:
The important features of the assay device material are that they are able to absorb liquid, particularly aqueous solutions, without substantially impeding the movement of the solutes employed in the assay. In effect, the materials are bibulous; they are porous and allow the flow of solutions....

See Col. 15, lines 16-22. The Court does not believe that the term "bibulous" is being used in a special or unique way in this passage in the sense that the patentee was attempting to be his own lexicographer or a special definition of the term is clearly stated in the patent specification or prosecution history. *See Vitronics,* 90 F.3d at 1582 ("[P]atentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.") The Court therefore declines to import this specification language into the claim.
The dictionary definition of "bibulous" is "readily taking up fluids or moisture." FN24 *See* Webster's Dictionary at 212. No further gloss is required. Such words as "porous" or "absorbent" may or may not be equivalent. The important point is that for one reason or another, the patent applicant decided not to use these terms.

FN24. The dictionary definition is consistent with the definition adopted for "liquid absorbing zone," which has been previously found to be identical to the "liquid absorbing member." As the "liquid absorbing

member" is comprised of the "bibulous material," the adopted definition of "liquid absorbing zone" proves insightful. The specification relates that the "liquid absorbing zone" "acts as a pump to pull liquid through and out of the immunosorbing zone." Col. 4, lines 67-68; *see also* Col. 2, lines 32-33; Col. 3, lines 18-19; Col. 14, lines 35-37; Col. 16, lines 61-62; Col. 17, lines 1-3, 21-22.

Accordingly, the Court construes "bibulous material" as any material which is able to readily take up fluids or moisture.

3. "Extending Transversely"

The parties' dispute concerning this claim language revolves around the spatial relationship between the liquid absorbing member and the immunosorbing member. Dade Behring contends "extending transversely" means the liquid absorbing member lies or extends across from one side of the immunosorbing member to the other. Biosite asserts "extending transversely" means not parallel.

The claim language is silent as to a possible definition of "extending transversely," except to explain the liquid absorbing member is in a liquid receiving relationship with the immunosorbing member. *See* Col. 2, lines 3-7; *see also* Col. 16, lines 58-59. The specification and the prosecution history add nothing to the meaning of this claim language, outside of what is already known from the claim language itself. *See* Col. 2, lines 30-35; Col. 18, lines 22-23. As there is no special definition provided in the intrinsic evidence of the patent, this claim language will be interpreted according to its ordinary and customary meaning. *See Vitronics,* 90 F.3d at 1582.

The dictionary defines "extend" as "to cause to span an interval." *See* Webster's Dictionary at 804. "Transverse" is defined as "to lie or pass across." *Id*. at 2431. Hence, the ordinary and customary meaning of "extending transversely" is spanning an interval by lying or passing across. This dictionary definition is consistent with the requirements of the claim language because the liquid absorbing member must be in a liquid receiving relationship with the immunosorbing member. By having the liquid absorbing member span an interval, while lying or passing across the immunosorbing member, the liquid absorbing member is able to properly act as a pump to pull liquid out and through the immunosorbing member. *See* Col. 4, lines 67-68.

Accordingly, the Court construes "extending transversely" as meaning in the context of the '241 Patent that the liquid absorbing zone or member must span the entire immunosorbing zone or member by lying or passing across it.

4. "Wherein At Least A Portion Of The Liquid Absorbing Member About Said Immunosorbing Member"

As to this dispute, Dade Behring argues "about" means near or in the immediate neighborhood so that the liquid absorbing member is in a liquid receiving relationship with the immunosorbing member. Biosite contends "about" means that the liquid absorbing member must surround the immunosorbing member.

Again, the ordinary and customary meaning of "about" will be applied as there is no special or unique definition supplied in the specification or the prosecution history. *See Vitronics,* 90 F.3d at 1582. The dictionary defines "about" as "in the vicinity: NEAR ." *See* Webster's at 5. This definition is supported by the claim construction principle that, "each claim is an entity must be considered as a whole." *See* General

Foods, 972 F.2d at 1274. The "extending transversely" claim language just construed and the "about" claim language are used to describe the exact same spatial relationship between the liquid absorbing member and the immunosorbing member. *See* Col. 2, lines 3-9. Thus, because "extending transversely" has just been interpreted to mean spanning an interval by lying or passing across, "about" must be interpreted in a consistent manner in order to interpret Claim 25 consistently as a whole. The above dictionary definition is indeed consistent with the definition adopted for "extending transversely." As a result, the Court construes "about" to mean in the vicinity or near.

An appropriate order will issue.

D.Del.,1998.
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