# United States Court of Appeals for the Federal Circuit

02-1203, -1257

ABBOTT LABORATORIES,

Plaintiff-Appellant,

v.

SYNTRON BIORESEARCH, INC.,

Defendant-Cross Appellant.

Lee Carl Bromberg, Bromberg & Sustein LLP, of Boston, Massachusetts, argued for plaintiff-appellant. With him on the brief were Joel R. Leeman and Eric Paul Belt. Of counsel on the brief were George C. Lombardi, Winston & Strawn, of Chicago, Illinois; and Regina M. Anderson, Office of the General Counsel, Abbott Laboratories, of Abbott Park, Illinois.

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Appealed from: United States District Court for the Southern District of California

Chief Judge Marilyn L. Huff

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DECIDED: July 10, 2003

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Before MAYER, Chief Judge, MICHEL and DYK, Circuit Judges.

DYK, Circuit Judge.

Abbott Laboratories ("Abbott" or "appellant") appeals from the judgment of the United States District Court for the Southern District of California that Syntron Bioresearch, Inc. ("Syntron" or "appellee") did not infringe the asserted claims of United States Patent Nos. 5,073,484 ("the '484 patent") and 5,654,162 ("the '162 patent"). Abbott Labs. v. Syntron Bioresearch, Inc., No 98-CV-2359 (S.D. Cal. Oct. 12, 2001) ("Judgment"). Syntron cross-appeals from the judgment that the asserted claims are not invalid.

We affirm the judgment of noninfringement as to claim 26 of the '484 patent and claims 1, 22, 29, and 30 of the '162 patent. We reverse the judgment of non-infringement as to claims 22 and 23 of the '484 patent, and remand as to those claims. We affirm the judgment that the asserted claims are not invalid.

## BACKGROUND

### I

Abbott is the exclusive licensee of the '484 and '162 patents (collectively "the patents-in-suit), respectively entitled "Quantitative Analysis Apparatus and Method" and "Chemical Analysis Apparatus and Method." The written descriptions of the '484 and '162 patents are substantially identical, being generally directed to devices and methods for performing chemical analysis. The Field of the Invention sections of both patents described the technical field disclosed in the patents as follows:

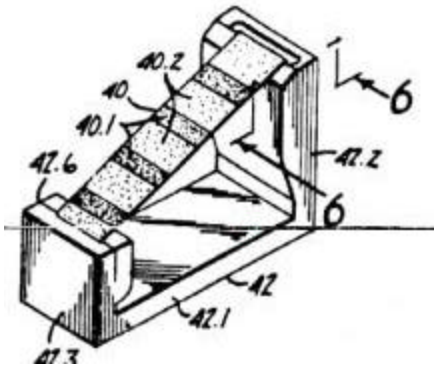
> The invention is in the field of quantitative chemical analysis, and is particularly useful in the detection and analysis of small amounts of chemical substance in such biological fluids as milk, blood, urine, etc.

'484 patent, col. 1, ll. 10-13.[1]

The technology at issue involves the reaction of three chemical constituents: a substance to be detected (called an analyte, ligand, or antigen), a substance that is complementary to and binds to the substance to be detected (called a reactant

or antibody), and an indicator (called a detector), which also binds to the substance to be detected. The patents are particularly directed to chemical analysis related to the immune system and its reactions. Proteins produced by the immune system bind to particular foreign substances as a natural defense mechanism. The technology at issue here exploits the ability of the immune system to create proteins (antibodies or reactants) that bind with particularity to a substance to be detected (ligand or analyte). The indicator and the reactant bind to the analyte. The reactant immobilizes the analyte, and the indicator provides an indication of the presence of the analyte. The indication can be one of two types, a qualitative indication or a quantitative indication. Qualitative analysis provides an indication of the presence or absence of the analyte in the sample. A quantitative indication provides information about the quantity of the analyte present in the test sample. In the disclosed invention quantitative analysis is performed using a device that includes a number of analyte detection zones, wherein the number of zones in which analyte is detected is directly proportional to the amount of analyte in the sample.

An exemplary embodiment of a test device as shown in figure 5 of the '484 patent is reproduced below. The test device includes a test medium comprised of a filter paper strip (40) that permits a liquid test sample to flow downward therethrough. The test medium contains reaction zones (40.1), which include therein reactant, bound to the medium within the reaction zones. As the test solution flows through the reaction zone, the reactant bound therein reacts by binding with the analyte (if any) present within the test sample. An indicator also reacts with the analyte (e.g., by binding therewith), thus providing a "moiety derived from [the] analyte, and desirably . . . a tagged or labeled form of the analyte" called an "analyte derivative" that functions as an indication of the presence of the analyte.




In operation, the liquid sample is applied to the test strip and flows downward. The labeled or tagged analyte in the liquid sample is trapped by the reactant in the test zones. The label or tag associated with the analyte provides an indication of the analyte. The number of zones within which analyte is indicated provides a measurement of the concentration of the analyte within the liquid sample.

II

On December 30, 1998, Abbott filed a complaint for patent infringement against Syntron alleging infringement of

both patents-in-suit and seeking damages and a permanent injunction. At trial the allegations of infringement were narrowed to claims 22, 23, and 26 of the '484 patent (of which claims 22 and 26 are independent) and claims 1, 22, 29, and 30 of the '162 patent (of which claims 1 and 22 are independent). Claim 22 of the '484 patent is exemplary of the asserted claims of that patent, and provides:

> A method for the analysis of an analyte which is a member of a ligand-antiligand binding pair in a test solution comprising the steps of:
>
> (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); and
>
> (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 persence of analyte in the solution.

Claim 1 of the '162 patent is exemplary of the asserted claims of that patent, and provides:

> 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.

On January 4, 2001, the district court issued an order resolving disputed issues of claim construction. Abbott Labs. v. Syntron Bioresearch Inc., No. 98-CV-2359 (S.D. Cal. Jan. 4, 2001) ("Claim Construction Order"). On September 25, 2001, the district court issued an order adopting supplemental claim constructions. Abbott Labs. v. Syntron Bioresearch Inc., No. 98-CV-2359 (S.D. Cal. Sept. 25, 2001) ("Supplemental Claim Construction Order"). The constructions provided in the supplemental order were used as the basis for the jury instructions as to the claim terms "non-diffusively immobilized"; "non-diffusively bound"; "specific for"; "predetermined amount"; and "analyte."

On October 4, 2001, the jury returned a special verdict form finding the asserted claims of the patents-in-suit valid but not infringed. Abbott Labs. v. Syntron Bioresearch Inc., No. 98-CV-2359 (S.D. Cal. Oct. 4, 2001) ("Special Verdict"). The jury found with respect to all of the asserted claims that Abbott failed to prove that the accused products included a "non-diffusively immobilized" or "non-diffusively bound" reactant. Id. at 1-3. The jury found that Abbott failed to prove that the accused products included "a reactant bound [to the reaction zone] which is specific for . . . the analyte" as recited claims 1,

22, 29, and 30 of the '162 patent. Id. at 3. With respect to claim 26 of the '484 patent and claims 22, 29, and 30 of the '162 patent, the jury found that Abbott failed to prove that the accused products included "a predetermined amount of reactant" in the reaction zone. Id. at 2-3. The jury also found with respect to claim 26 of the '484 patent that Abbott failed to prove that "detection occurs . . . only if analyte is present in the test solution in a predetermined amount." Id. at 2. As to validity and enforceability, the jury returned verdicts that Syntron failed to prove by clear and convincing evidence that the claims were anticipated, obvious, invalid due to inventorship error, lacked enablement or written description support, or were unenforceable due to inequitable conduct. Id. at 4-7.

On October 12, 2001, the district court entered judgment in favor of Syntron as to infringement and in favor of Abbott as to validity and unenforceability in accordance with the special verdict. Abbott Labs. v. Syntron Bioresearch Inc., No. 98-CV-2359 (S.D. Cal. Oct. 12, 2001) ("Judgment"). Following judgment, Abbott and Syntron filed motions for JMOL and a new trial, which were denied. Abbott Labs. v. Syntron Bioresearch Inc., No. 98-CV-2359 (S.D. Cal. Jan. 10, 2002) ("Order Denying JMOL"). Abbott filed a timely appeal of the final judgment. Syntron filed a timely cross-appeal. We have jurisdiction over the appeal and the cross-appeal under 28 U.S.C. § 1295(a)(1).

## DISCUSSION

We review the jury's factual determinations for substantial evidence. Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1177, 64 USPQ2d 1545, 1551 (Fed. Cir. 2002). This court reviews issues of claim construction and the propriety of jury instructions without deference. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998) (en banc). We review "[the] jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence." LNP Engineering Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353, 61 USPQ2d 1193, 1197 (Fed. Cir. 2001).

### I.

Abbott requests review of the jury findings as to four claim recitations: "non-diffusively bound"; "non-diffusively immobilized"; "specific for"; and "predetermined amount." Abbott argues that under the proper claim construction the judgment of noninfringement cannot stand and that judgment of infringement should be entered in its favor or, alternatively, a new trial should be granted.

We must sustain the judgment of noninfringement as to an asserted claim if any one of the noninfringement findings as to that claim is based on proper jury instructions and is supported by substantial evidence. See Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1328, 63 USPQ2d 1374, 1383 (Fed. Cir. 2002). Thus, in order to prevail as to a particular claim,

Abbott must establish as to each ground of noninfringement that either (1) the jury instruction as to that element was erroneous and prejudicial, Ecolab Inc. v. Paraclipse, Inc., 285 F.3d 1362, 1373, 62 USPQ2d 1349, 1356 (Fed. Cir. 2002), or (2) the jury verdict was not supported by substantial evidence, Cybor, 138 F.3d at 1454, 46 USPQ2d at 1172.

A. Non-Diffusively Bound and Non-Diffusively Immobilized

Abbott argues that the jury's finding of noninfringement based on the failure to satisfy the claim terms "non-diffusively bound" and "non-diffusively immobilized" is not sustainable because of error in the jury instruction.

All of the asserted claims require a reactant that is either "non-diffusively bound" or "non-diffusively immobilized." The parties agree that these recitations as properly construed have the same meaning. The district court adopted, and instructed the jury using the following definition of "non-diffusively bound":

> Nondiffusively bound means a reactant immobilized in the reaction zone so as to provide a detectable signal indicating the presence or absence of analyte in the solution, and the reactant is not capable of detaching from the medium, spreading out, and moving along the test strip . . . . [A] reactant is nondiffusively bound only if it is found in such a manner that a sufficient and reproducible amount of reactant remains bound in the reactive zone or zones to conduct both quantitative and qualitative assays.

(Tr. at X-132.) Abbott objected to the district court's construction, urging instead that the disputed recitations "require only that the reactant be immobilized sufficiently to permit detection of the analyte in the reaction zone." (Appellant's Br. at 25.).

On appeal Abbott urges that the adoption of an instruction including the underscored language was error because it interpreted the claim to require quantitative analysis. Syntron urges that the inclusion of the "quantitative" language in the jury instruction was proper.

The first step in the analysis is to determine the ordinary meaning of the claim terms. Tex. Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1817 (Fed. Cir. 2002); see also Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1378, 64 USPQ2d 1933, 1936 (Fed. Cir. 2002); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996). Dictionary definitions provide evidence of a claim term's "ordinary meaning." Inverness, 309 F.3d at 1378, 64 USPQ2d at 1936. The parties have conceded that the recitations "non-diffusively bound" and "non-diffusively immobilized" are to be construed consistently. Starting with the words themselves, "non-diffusively" is an adverb defining the verbs "immobilized" and "bound." Webster's defines "bound" as "held in chemical or physical combination : COMBINED." Webster's Third International Dictionary 260 (1968) ("Webster's"). Webster's defines "immobilize" as "to make immobile : fix in place or position : render incapable of movement." Id. at 1130. The plain meaning of "immobilized" requires that the reactant not move relative to the medium, and the recitation "bound" further defines how that immobilization is provided, by requiring that the reactant be chemically or physically combined with the medium so as to be immobilized.

"Diffusively" defines the degree or character of the recitations "bound" and "immobilized." "Diffusive", the adverb form of which is "diffusively", means "having the quality of diffusing: tending to diffuse: characterized by diffusion." Id. at 631. Webster's defines diffusion as "the process whereby particles (as molecules and ions) of liquids, gases, or solids intermingle as the result of their spontaneous movement caused by thermal agitation and in dissolved substances move from a region of higher concentration to one of lower concentration." Id. at 631 (emphasis added). Thus, a dissolved substance that moves diffusively moves from a region of high concentration to one of lower concentration within the liquid, i.e., disperses within the liquid.

Taking the words together, the plain meaning of "non-diffusively bound" and "non-diffusively immobilized" is – a chemical or physical combination of the reagent and the medium, such that the reagent does not dissolve and move within the liquid from a region of high concentration to a region of low concentration. This definition closely mirrors the first portion of the construction adopted by the district court – the reactant is not capable of detaching from the medium, spreading out, and moving along the test strip – but bears no resemblance to the underscored portion of the instruction. None of the pertinent dictionary definitions supports the underscored portion. The plain meaning of the claim recitation, therefore, does not support the district court's narrowing construction.

The usage of the disputed claim terms in the context of the claims as a whole also informs the proper construction of the terms. See RF Del., Inc. v. Pac. Keystone Techs., Inc., 326 F.3d 1255, 1263-64, 66 USPQ2d 1593, 1598 (Fed. Cir. 2003). Here, the language of the asserted claims suggests that quantitative analysis should not be read as a requirement of the recitations "non-diffusively bound" or "non-diffusively immobilized." In claim 22 of the '484 patent, for example, element (c) requires "detecting the presence of analyte." Similar language is found in each of the asserted claims. This language is broad enough to encompass both qualitative and quantitative analysis, and therefore, militates against the narrow definition used to instruct the jury. Syntron appears not to argue to the contrary on appeal. Rather, Syntron urges that the underscored language, in fact, broadens rather than narrows the construction of "non-diffusively bound." (Appellee's Br. at 20.) According to Syntron, the jury instruction did not require "quantitative analysis," but rather defined the quality of binding between the reactant and the test strip. We cannot agree, as the language "sufficient and reproducible amount of reactant remains . . . to conduct both quantitative and qualitative assays" is an additional requirement beyond the ordinary meaning of the claim language.[2]

Thus, the construction adopted by the district court and used to instruct the jury was erroneous insofar as it included the underscored language requiring a sufficient amount to conduct quantitative assays. Because we have found that the jury was improperly instructed, and Syntron does not argue that the instruction was harmless error, we cannot affirm the judgment of noninfringement on the basis of the accused products' not incorporating a "non-diffusively bound" and "non-diffusively immobilized" reactant. Abbott urges that we enter JMOL in its favor instead of ordering a new trial. However, we think the

issue of whether JMOL or a new trial should be granted is an issue best addressed in the first instance by the district court. Moreover, we must determine whether the judgment of noninfringement as to any of the claims can be sustained on other grounds.

B. Specific For

The jury also found noninfringement of claims 1, 22, 29, 30 of the '162 patent because it concluded that the accused device did not meet the "specific for" claim recitation. Abbott urges that the district court's construction of "specific for" was in error, and that JMOL of infringement in its favor as to those elements should have been entered or a new trial granted. Abbott urges that the jury instruction included two errors, the inclusion of the language "particular to" in the instruction and the failure to instruct the jury that the claim language "does not mean that the reactant must bind only one analyte." (Appellant's Br. at 50-52.)

As to the first assigned error, the inclusion of the language "particular to," Abbott waived this argument by agreeing to that portion of the adopted construction. The jury instruction for "specific for" stated that the term meant "particular to and capable of binding with the analyte or chemical moiety of interest." (Tr. at X-133.) The district court further stated that "[p]articular to means capable of preferentially reacting or binding with the analyte or chemical moiety from among the thousands of molecules potentially in the test sample." Id. The disputed phrase was present in the proposed jury instructions submitted by Abbott.[3] (J.A. at 8006.) Abbott also stated during trial "the Court has defined [specific to] to mean particular to and capable of binding with the analyte of interest, [a]nd the Plaintiff believes that that . . . claim term is properly defined." (Tr. at VIII-212.) Abbott cannot wait until after the jury returns a verdict against it and then on JMOL request a different construction by attempting to have the district court delete a portion of the construction that Abbott itself agreed to. See Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1345-46, 59 USPQ2d 1401, 1418 (Fed. Cir. 2001) (holding that the presentation of the adopted construction to the district court constituted a waiver, precluding the party from proposing a new construction either on JMOL or on appeal). Abbott, therefore, cannot assign error to the district court's use of a definition including the language "particular to." The jury in reaching its verdict was bound by the district court's instruction construing the claims. The jury was not charged with the task of reaching a new claim construction through review of the sources used in interpreting the claims such as dictionaries, the specification, or the prosecution history.

Regarding the second error urged by Abbott – the failure to instruct the jury that "'particular to' does not mean that the reactant must bind only one analyte" – the instruction adopted by the district court implicitly incorporated this portion of the proposed instruction. Specifically, the jury instruction stated that "[p]articular to means capable of preferentially reacting or binding with." (Tr. at X-133) (emphasis added). The jury instruction did not require that the reaction occur solely with the analyte, but rather that the reaction with the analyte be the preferred reaction. Thus, the additional language urged by

Abbott was redundant of language that it also proposed and which the court used to instruct the jury. There was no error, therefore, in failing to instruct the jury that "'particular to' does not mean that the reactant must bind only one analyte."

In addition to errors in the jury instruction, Abbott also argues that substantial evidence does not support the jury verdict and that judgment of infringement is required under the district court's instruction. Even where a party proposes the adopted instruction, that party is not estopped from arguing that the jury failed to properly apply that instruction. Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1314, 66 USPQ2d 1429, 1434 (Fed. Cir. 2003). In Moba the district court refused to grant JMOL based on the jury's implicit interpretation of the agreed-upon claim construction. Id. On appeal, Moba argued that because Diamond had agreed to the construction used to instruct the jury, it was estopped from contesting the verdict. Id. This court reversed, holding that Diamond was not so estopped because it was simply arguing that there was a lack of substantial evidence to support the verdict under the district court's own instructions. Id. As the court explained, "Diamond [did] not wish to alter the district court's claim construction on appeal, but [sought] enforcement of the trial court's claim construction." Id.

Here, under the district court's claim construction, the jury found that the accused devices did not include "a reactant . . . which is specific for . . . the analyte." The undisputed evidence showed that the reactant employed in the accused devices binds identically to the analyte (human chorionic gonadotropin - "hCG") and to another protein called luteinizing hormone ("LH") that possesses an identical protein binding site to that of hCG. Order Denying JMOL at 23. The agreed upon claim construction, however, required the reagent to be "capable of preferentially reacting or binding with the analyte . . . from among the thousands of molecules potentially in the test sample." (Tr. at X-133.) The undisputed fact, as admitted by Abbott's own witness, is that the reactant employed by Syntron in the accused devices binds identically with the analyte (hCG) and another substance (LH). (Tr. at III-116). Thus, the jury could have reasonably concluded that the reagent did not preferentially bind with the analyte from among the thousands of molecules. The issue here is solely whether the jury could have reasonably concluded that the reagent did not meet the recitation as construed by the district court in the instructions. We conclude that it could have. On this ground, therefore, we affirm the judgment of noninfringement as to claims 1, 22, 29, 30 of the '162 patent.

C. Predetermined Amount[4]

The jury found noninfringement of claim 26 of the '484 patent, concluding that the accused device did not meet the "predetermined amount" claim recitation. The district court defined "predetermined amount" as "an amount determined beforehand" and instructed the jury accordingly. (Tr. at X-133.) Abbott does not challenge the instruction as such (having agreed to the instruction at trial), but for purposes of JMOL seeks to interpret the claim language more broadly, i.e., "[t]he amount of analyte or bound reactant need not be precisely known or reproducible." (Appellant's Br. at 37.) As we have

discussed above, Abbott cannot seek to modify an agreed claim construction on appeal. See Interactive Gift Express, 256 F.3d at 1345-46, 59 USPQ2d at 1418.

The jury found that the accused devices did not include an "an amount determined beforehand" as required under the construction adopted for this recitation. Special Verdict at 2-3. The district court refused to grant JMOL that Syntron infringed this limitation. Order Denying JMOL at 28. As stated by the district court:

> The record suggests that the amount of bound antibody [in the accused devices] is unknown and variable from test to test. . . . Syntron's manufacturing process merely involves placing the 1001 capture antibody solution on the test strip, and "eyeballing" it to make sure that the solution is on it.

Id. at 29. Based on this evidence the district court concluded that a reasonable jury could have found that the amount of reactant was not determined beforehand.[5] Id. We agree with the district court that a reasonable jury could have found that the amount of reagent was not determined beforehand. Thus, we affirm the judgment of noninfringement as to claim 26 of the '484 patent.

D. Analyte

Syntron seeks to alternatively support the judgment of noninfringement as to claims 22 and 23 of the '484 patent based on the argument that the district court's construction of the claim term "analyte" in those claims was erroneous, and that under the proper claim construction no reasonable jury could have found that the limitation was satisfied.

The district court construed "analyte" to mean "the substance of interest, i.e., the substance that the test is designed to detect if present in the liquid being tested." Syntron objected to this construction before the district court and urges on appeal that the district court should have instructed the jury that the "analyte" limitation required quantitative analysis. Syntron does not argue that the plain meaning of the word "analyte" requires quantitative measurement. Nor could it. Although the word "analyte" is not defined in general dictionaries of the English language, the term is used in specific fields of technology including analytical chemistry, and within that field is defined as the component of a sample that is to be determined. See, e.g., Douglas A. Skoog et al., Fundamentals of Analytical Chemistry 1 (7th ed. 1996) ("The components of a sample that are to be determined are often referred to as analytes."). This definition corresponds closely to the definition adopted by the district court, that is, "the substance that the test is designed to detect if present in the liquid being tested."

The law is clear, however, that a patentee may be his own lexicographer (see Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249, 48 USPQ2d 1117, 1121 (Fed. Cir. 1998)), and Syntron argues that Abbott did so here, defining analyte to require quantitative analysis because the patentee explicitly defined the term in the specification as "any chemical moiety which is to be measured quantitatively." (Appellee's Br. at 40.). However, "[t]he patentee's lexicography must, of course, appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim." Id. (emphasis added)

(quoting In re Paulsen, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994)). Thus, the issue is whether the patentee here defined "analyte" with reasonable clarity, deliberateness, and precession. The definition cited by Syntron is provided in the Summary of the Invention section of the patents-in-suit, and provides in its entirety:

> As used herein, "analyte" refers not only to the particular chemical moiety for which analysis is desired, but also to chemical moieties that are reaction products of the moiety to be determined with another chemical moiety. For example, a biological fluid containing an unknown amount of a chemical moiety may be reacted in solution or otherwise with another chemical moiety to provide a product, the concentration of which is related to the initial concentration of the chemical moiety to be measured. The resulting product, then, may become the "analyte" for use in the apparatus and method of the invention. Accordingly, "analyte" refers to any chemical moiety which is to be measured quantitatively.

'484 patent, col. 3, ll. 18-31.

We hold that the passage cited by Syntron, taken in context, does not provide reasonable clarity, deliberateness, and precision sufficient to narrow the definition of the claim term in the manner urged. The first portion of the cited passage defines the word "analyte" in terms of the "moiety for which analysis is desired" and "reaction products of the moiety." Id. at col. 3, ll. 18-22. This portion of the definition comports with the district court's definition of the word as the substance of interest. The last sentence provides a different definition. Because the specification provides two alternative definitions for the term at issue, the specification does not define the claim term in the manner required under Renishaw. As correctly construed, therefore, the ordinary meaning of "analyte" as used to instruct the jury is the proper construction, and there is no basis for setting aside the verdict of noninfringement of claims 22 and 23 of the '484 patent on this ground.

E. Doctrine of Equivalents

On August 20, 2002, Abbott filed its reply brief on appeal, arguing for the first time that a new trial should be granted on the issue of infringement under the doctrine of equivalents. Abbott bases this argument on the issuance of the Supreme Court's decision in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002), rejecting the complete bar approach to prosecution history estoppel adopted by our earlier decision in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000) (en banc). (Appellant's Reply Br. at 17-19.) Abbott argues that it could not have addressed this issue any earlier than May 28, 2002, the date of the Supreme Court's decision. Abbott was on notice that our decision in Festo might be reversed by the Supreme Court, and was obligated to present the issue if it wanted to have the benefit of the Supreme Court's decision.[6] Abbott has waived the doctrine of equivalents argument by failing to raise it in its opening brief. Amhil Enters. Ltd. v. Wawa, Inc., 81 F.3d 1554, 1563, 38 USPQ2d 1471, 1477 (Fed. Cir. 1996) (stating that a reply brief should "reply to the brief of the appellee" and "is not the appropriate place to raise, for the first time, an issue for appellate review") (internal citation omitted).[7]

In summary, we affirm the judgment of noninfringement as to claims 1, 22, 29, and 30 of the '162 and as to claim

26 of the '484 patent. However, remand is necessary as to claims 22 and 23 of the '484 patent on the issue of infringement because of the erroneous claim construction.

II.

Syntron also cross appeals the judgment that claims 22, 29, and 30 of the '162 patent are not invalid for lack of written description, and that the asserted claims of the '484 patent are not anticipated or rendered obvious by U.S. Patent No. 4,094,647 to Deutsch et al. ("Deutsch") issued June 13, 1978.[8] Even though we have sustained the judgment of noninfringement as to some of these claims, we must nevertheless address the issues of validity raised by the counterclaims in view of the Supreme Court's decision in Cardinal Chemical Co. v. Morton International, 508 U.S. 83, 93-94 (1993) (requiring a counterclaim of invalidity to be addressed without regard to a determination of noninfringement).

At trial the burden was on Syntron to prove by clear and convincing evidence that the written description requirement of 35 U.S.C. § 112, ¶ 1, was not met. Compliance with the written description requirement is a question of fact, which is reviewed for substantial evidence. SunTiger, Inc. v. Scientific Research Funding Group, 189 F.3d 1327, 1334, 51 USPQ2d 1811, 1815 (Fed. Cir. 1999). The dispute here centers upon whether the disclosure, as originally filed, provided support for the later added claim limitation "diffusively bound." The district court construed this recitation to mean "bound to the solid medium in such a way that the labeled antibody is capable of detaching from the medium, spreading out, and moving along the test strip." (Tr. at X-131.) Abbott cites the following text from the '162 specification as providing the necessary written description support:

> In a preferred embodiment, only a single pass through the apparatus of a single liquid material is required. An analyte may be mixed with an analyte derivative, chromogen or other material and flowed through the apparatus to yield an appropriate test result. In a further preferred embodiment, the apparatus is chemically complete in that it includes all reactants and other chemicals necessary or desirable for the quantitative analysis of an analyte; that is, all that is required is that the analyte in a liquid carrier be flowed through the apparatus. Elements of the apparatus that, if combined, would undergo reaction in the absence of the analyte may be maintained in different zones. For example, the bottom-most layer (20.2) of the strip of FIG. 2 may contain a reactant physically separated from reactants in the adjacent reaction zone. When the analyte in a carrier liquid is flowed through the layer (20.2), the reactant in this layer together with the analyte and carrier liquid is flowed into the first reaction zone. If desired, a reactant may be provided in the form of a solid and may merely be placed upon the upper layer (18.4) of the column of FIG. 1, the reactant being dissolved by and carried with the liquid carrier and analyte into the column.

'162 patent, col. 12, l. 62 - col. 13, l. 15. Thus, the cited passage teaches placing solid reactant on the upper layer of the test device to be dissolved by the liquid carrier. An expert witness for Abbott testified that in his opinion the claims of both patents were properly fully supported. (Tr. at II-156-57.) That testimony, while brief, did provide substantial evidence supporting the jury verdict. See Union Oil Co. v. Atl. Richfield Co., 208 F.3d 989, 999, 54 USPQ2d 1227, 1234 (Fed. Cir. 2000). Moreover, all issued claims are presumed valid. 35 U.S.C. § 282 (2000). The evidentiary burden, therefore, was on Syntron and not Abbott. Syntron failed to prove that, in light of the presumption of validity, no reasonable jury could have

decided that Syntron failed to prove by clear and convincing evidence that the claims are invalid for failure to meet the written description requirement.

Finally, as to the question of the validity of the asserted claims of the '484 patent over Deutsch, that reference was of record during the prosecution of both patents in suit. The presumption of validity remains the same whether or not the art relied upon at trial was before the examiner. SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp., 225 F.3d 1349, 1355-56, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000). However, the fact that a skilled examiner passed upon that very reference during prosecution may be a factor in determining whether the challenger has met the clear and convincing evidence burden. Id.; Alco Standard Corp. v. Tenn. Valley Auth., 808 F.2d 1490, 1497, 1 USPQ2d 1337, 1342 (Fed. Cir. 1986).

With respect to anticipation under 35 U.S.C. § 102, the dispute concerns whether Deutsch teaches "flowing said solution along the medium" as required by the asserted claims. As described by Syntron, Deutsch teaches using a "developing fluid" in addition to the sample solution to cause the solution to flow. (Appellee's Br. at 47.) The issue, therefore, is whether the combination of developing fluid and test sample in Deutsch meets the claim language "flowing said solution along the medium."

The disputed claim language was not separately addressed by the district court, nor did the parties request a jury instruction concerning this language. The jury instructions stated that the jury "should give any terms not defined by [the court] their ordinary meaning." (Tr. at X-135.) Since Syntron did not urge a particular claim construction of the disputed language before the district court, it has waived the right to do so on appeal. We agree with Abbott that the jury could have reasonably interpreted the language of the claims standing alone as requiring that the solution itself provide the required flow. (Appellant's Reply Br. at 23.) The burden having been on Syntron to prove by clear and convincing evidence that the claims were anticipated, we cannot conclude that the jury verdict on anticipation was not supported by substantial evidence.

Syntron further argues that even if the claims required that the solution itself provide the recited flow, the claims as interpreted would be rendered obvious by Deutsch under 35 U.S.C. § 103. Syntron cites a statement by an expert for Abbott that the use of the fluid sample to drive the flow was known in the prior art. (Appellee's Br. at 51.) Knowledge in the prior art of every element of a patent claim, however, is not of itself sufficient to render claim obvious. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); Teleflex, 299 F.3d at 1333-34, 63 USPQ2d at 1386. The issue is whether substantial evidence supports the judgment (under the clear and convincing evidence standard) that a person having ordinary skill in the art would not have been motivated to replace the developing fluid/sample solution combination of Deutsch with flow provided solely by sample fluid. Upon review of the evidence presented on the issue of obviousness in view of Deutsch, and in view of the burden of proof, we sustain the judgment of non-obviousness.

# CONCLUSION

Thus, we affirm the judgment of noninfringement as to claim 26 of the '484 patent and claims 1, 22, 29, and 30 of the '162 patent. We also affirm the judgment on validity of all the asserted claims. Finally, we reverse the judgment of noninfringement as to claims 22 and 23, and remand for further proceedings consistent with this opinion.

AFFIRMED IN PART AND REVERSED AND REMANDED IN PART

COSTS

No costs.

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[1] In view of the substantial identity between the written descriptions of the two patents, citation will be made to the '484 patent as exemplary of both patents-in-suit.

[2] Syntron also cites the description of the disclosed invention in the specification as using "covalent bonding" between the reactant and the test strip as somehow supporting the district court's adopted jury instruction. (Appellee's Br. at 21-22.) The description in the specification of a particular embodiment does not require that the claims be limited to that embodiment. See Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., No. 02-1145, slip op. at 12 (Fed. Cir. June 27, 2003).

[3] Abbott's proposed jury instruction provided in full:

> "specific for" means "particular to and capable of binding with." The words "particular to" do not mean that the reactant (e.g., and antibody) will bind one and only one analyte. Rather, "particular to" means the reactant is capable of preferentially reacting or binding with the analyte (or the reaction product of the analyte with another chemical moiety) from among the thousands of molecules potentially in the test sample. The reactant may also bind with other related molecules that share common structures.

(J.A. at 8006 (emphasis in original).)

[4] The claim language "predetermined amount" is recited in a number of claims. However, only claim 26 of the '484 patent is addressed in this section, as the verdicts of noninfringement as to the remainder of the claims containing that language are being affirmed on other grounds.

[5] On appeal Abbott cites testimony from one of Syntron's witnesses purporting to prove that the amount of reagent is

determined in advance. (Appellant's Br. at 40.) That testimony, however, was in response to the following question: "isn't it true that Syntron controls the amount of each ingredient that you use in the production of your antibody solution?" (Tr. at VIII-69) (emphasis added). The cited testimony, therefore, was directed to the amount of reagent incorporated in the solution to be applied to the test strip, and not the amount of reagent that is placed on the test strip.

[6] Indeed, the district court's order granting judgment as a matter of law addressed the issue of prosecution history estoppel under both our decision in Festo, and the preexisting flexible bar approach, recognizing that certiorari had been granted in Festo. Abbott Labs. v. Syntron Bioresearch, Inc., No 98-CV-2359 slip op. at 13 (S.D. Cal. Oct. 9, 2001) ("Order Granting JMOL") ("[E]ven if the flexible bar that Festo rejected were to control again, prosecution history estoppel would bar Abbott from relying on the doctrine of equivalents for the elements in dispute.").

[7] Abbott also appears to have raised the issue of prosecution history estoppel for the first time in its reply brief during briefing on JMOL. Order Denying JMOL at 32. The district court chastised Abbott for this behavior, but "nonetheless address[ed] those arguments for the sake of completeness." Id.

[8] No issue is raised on appeal with respect to the enforceability of the patents-in-suit.