United States District Court,
D. New Jersey.

CONOPCO, INC., d/b/a UNIPATH DIAGNOSTICS COMPANY,
Plaintiff.
v.
WARNER-LAMBERT COMPANY,
Defendant.

No. CIV.A. 99-101(KSH)

Dec. 12, 2000.

OPINION (REDACTED)

HAYDEN**, D.J.**

Plaintiff filed this lawsuit on grounds that defendant committed and continues to commit willful acts of patent infringement by making, using, selling and offering for sale its e.p.t.(R) home pregnancy test kits. Defendant has moved for summary judgment of noninfringement, contending that plaintiff's patent claims, when properly construed, do not cover the e.p.t.(R) test. Its position is that resolution of the parties' dispute about the meaning of just two prepositions in Claim 1 will resolve the issue of literal infringement in its favor. Defendant also argues that the sugar limitations in the patent claims are such that on the record before it, this Court must grant summary judgment of noninfringement.

BACKGROUND

Both plaintiff and defendant are in the business of developing, producing and selling diagnostic kits. Plaintiff owns three 1997 patents that are the subject of this lawsuit: (1) Patent No. 5,622,871 entitled "Capillary Immunoassay and Device Therefore Comprising Mobilization Particulate Labelled Reagents," issued to Keith May on April 22, 1997 and assigned to Unipath; (2) Patent No. 5,602,040 entitled "Assays," issued to Keith May on February 11, 1997 and assigned to Unipath; and (3) Patent No. 5,656,503 entitled "Test Device for Detecting Analytes in Biological Samples," issued to Keith May on August 12, 1997 and assigned to Unipath. Plaintiff claims that defendant's product, e.p.t.(R), a home pregnancy test kit, infringes all three of these patents.

A Closer Look at the Technology

According to the Background section of the May patents, the invention "relates to analytical devices which are suitable for use in the home, clinic or doctor's surgery and which are intended to give an analytical result which is rapid and which requires the minimum degree of skill and involvement from the user." U.S. Patent No. 5,622,871 ("Patent '871"), Col. 1, lines 18-22. FN1 And in the Summary section: "The present invention is concerned with adapting and improving the known techniques ... to provide diagnostic test devices especially suitable for home use which are quick and convenient to use and which require the user to

perform as few actions as possible. " Patent '871, Col. 1, lines 62-67. As such, the patents are related to a category of devices which, according to a document provided among plaintiff's exhibits, "is continuing to increase at a very quick pace. Major factors that are contributing to this growth include improvements in conjugate technology and a growing understanding among product developers of the general design principles involved." Plaintiff's Exh. 37 (Kevin D. Jones, *Troubleshooting protein binding in nitrocellulose membranes,* at 1 (viewed on August 18, 2000) available at http://www.devicelink.com/ivdt/archive/99/03/009.html).

FN1. Each of the three patents at issue in this case involve the same immunoassay technology. For purposes of consistency throughout this opinion, the Court will reference U.S. Patent No. 5,622,871 when citing to the "Background of the Invention," "Summary of the Invention," and the "Brief Description of Drawings." The portions cited by the Court are identical in each of the three patents.

Into this busy universe have come the May patents, which describe a sample application method for use in diagnostic kits suitable for home use. These kits are immunochromatographic devices combining features of the human immune system and chromatography. The latter is the technique of separating compounds that are in liquid or gaseous phase by passing them through a device that separates them according to size, chemistry, electric charge, or-as in these diagnostic tests-by using antibody binding techniques. The devices that must be understood here involve an immobile support, a nitrocellulose strip, which has the ability to bind to proteins, so that specific proteins (reagents) can be applied to the strip and they will stay where applied, that is become immobilized where they are put down. Also, the chemistry of nitrocellulose is such that water will flow through the strip and carry along anything dissolved or suspended in the water. As the Jones article describes, the nitrocellulose strip used in home pregnancy kits features "the lateral flow or dipstick design." Id.; *see* Patent '871, Fig. 10.

As the liquid material permeates the nitrocellulose strip, drawn into and flowing through it by capillary action, the molecules in the liquid can be caused to bind to the zones on the strip where reagents have been laid down and immobilized in the strip. In immunochromatographic assays, these reagents are specially engineered antibodies chosen for their affinity for the protein molecules in the liquid sample. As Jones usefully terms them, they are "capture reagent[s] for the target analyte in the sample," and nitrocellulose acts as "a protein-binding membrane." Id. at 2 Interestingly, Jones indicates that despite considerable research, the exact mechanism for protein binding to nitrocellulose remains unknown; what his article stands for beyond peradventure is that the chemistry behind the engineering for useful and reliable binding is complex.

As described in the parties' briefs, immunoassays depend upon how the immune system functions, which is that when something is recognized by the system as "not me," the system reacts by doing something about the situation, which is to produce an antibody to bind to what is "not me." By definition, if an antibody binds to something (that is, recognizes and grabs on), that something is an epitope, the smallest part of the molecule that the antibody recognizes. Extrapolating, if the goal is to detect the presence of a specific molecule, the scientist finds an epitope that is invariable to that molecule, and finds an antibody that is invariably going to recognize and grab onto (bind to) the epitope.

In the home pregnancy detection kits marketed by the parties, chemical reactions take place by means of different capture reagents (specifically engineered antibodies) located in three places along the nitrocellulose strip. The first involves labelled antibodies, that is antibody molecules anchored to particles (hence, the "label"; because of the particulate, there will be a visible signal created depending upon the

outcome). This labelled antibody recognizes the hormone human chorionic gonadotropin (hCG), which is present in elevated levels in the urine of a pregnant woman. It is different from the other antibodies working in the device because it is labelled and because it is mobile. It is evident from the patent claims and the description of the e.p.t.(R) device that these attributes are critical: the labelling permits the user to read the results of the test; the mobility makes the test work. As will be seen, it is how each of the parties has solved the problem posed by a "protein binding membrane" when it is used with a protein that the scientist wants to make and keep mobile, that led to this lawsuit.

Returning to the test strip: the other antibodies are located in two areas downstream from the labelled reagent-immobilized in the test zone, and immobilized in the control zone, making use of the affinity of nitrocellulose for binding with proteins. When the liquid sample is applied to the test strip, using a wicking device, it first makes contact with the labelled reagent and releases the labelled antibodies. Through capillary action the liquid, now carrying the labelled reagent, is drawn along the nitrocellulose strip through the test zone and then to the control zone. The chemical reactions that take place are first, a binding in the liquid stream of the labelled reagent with hCG present in the urine; second, in the test zone, a binding of labelled reagent with the immobilized antibodies present there, which serve as a capture reagent which recognizes specifically and only the complex of hCG bound to the labelled reagent. There will be a positive signal in the test zone if the capture reagent recognizes and binds to the complex of hCG and labelled reagent, and no signal if no hCG is present because the labelled reagent will not bind to anything. Finally, the third reaction happens in the control zone, where a binding occurs between the labelled reagent and the antibodies immobilized there. Those antibodies serve as a capture reagent that recognizes the labelled reagent, whether or not it is bound to hCG, and when that occurs the particulate will show up, signaling that the test worked because the liquid sample made it through the test zone.

This system permits the following responses. The woman whose urine was used as the liquid sample is pregnant; or the woman is not pregnant; with the variables that she is pregnant and the test worked or didn't work; or she is not pregnant and the test worked or didn't work.

As can be seen by the patent claims, the way the May patents provide for release of the labelled reagent when the liquid stream hits it is by one of two methods: "1) coating at least a portion of said test strip upstream from said test result zone, or 2) drying said labelled reagent onto a portion of said test strip upstream from said test result zone." It is agreed by the parties and easily discerned that the e.p.t.(R) test does not work through a mechanism like option one. As plaintiff describes the workings of e.p.t.(R) on page of its brief:

The product includes a wick which delivers the urine to a test strip from the left. The test strip includes two components of interest here, a nitrocellulose membrane and a fiberglass pad. The fiberglass pad includes first, mobile monoclonal antibodies FN* each bound to a label (gold sol), sugars * and proteins *. The label + M_{ab1}, sugars and proteins are soaked into the fiberglass pad and then dried together. Besides the label, M_{ab1} also binds to an eptipe on hCG and a receptor on an antibody * that is permanently affixed ("immobilized") to a test strip beneath a control window. A second monoclonal antibody * is immobilized on the test strip under the test window-and has an affinity to bind to a secound epitope on the hCG.

FN* Material redacted pursuant to Protective Order
The mobile antibody begins at a test strip location not visible to the user (to the left of the test window and obstructed from view by the plastic case).

In use during a test, the urine resuspends the label + M_{ab1}, and transports it through the test strip to the test and control zones. If the woman is pregnant, a four-part complex or sandwich is formed at the test location on the strip containing colored particles (gold sol), first monoclonal antibody, hCG and second monoclonal antibody bonded to each other in the sequence listed. This results in a colored line across the width of the strip indicating pregnancy.

If the woman is not pregnant, there is no substantial amount of the hCG hormone. hCG is the "glue" which connects the labelled M_{ab1} and the test zone immobilized M_{ab2}. Absent the hCG, the labelled M_{ab1} is not captured in the test zone. Thus, no colored line appears at the test window indicating that the user is not pregnant.

In either case (pregnant or not pregnant) some or all of the labelled M_{ab1} (with or without hCG) passes to the control zone. The antibody fixed at the control zone binds to the labelled M_{ab1} (whether or not there is any hCG also attached to the labelled M_{ab1}). Thus, the test presents a colored line at the control zone whether or not the user is pregnant (Label + M_{ab1} + A_{b3} = colored control line). This equation should always occur absent failure of the immunoassay.

Plaintiff's Opposition Brief, at 25-26.
Plaintiff's lawsuit claims that the e.p.t.(R) test kit infringes on the May patent because of sugar is present in the buffer solution into which the labelled reagent mixed before it is dried into the fiberglass pad. Plaintiff argues that the sugar limitations in the patent claims cover the presence and function of sugar in e.p.t.(R). Defendant denies this and, as indicated above, has moved for summary judgment of noninfringement contending that proper construction of the patent claims of necessity resolves the issue of literal infringement in its favor, and further that the sugar limitations in the claim do not and cannot cover the way the e.p.t.(R) device works even as plaintiff explains those workings.

STANDARD OF REVIEW

Summary judgment is appropriate where the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, reveal no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c). The court's responsibility is not to resolve disputed issues of fact, but to determine whether there exist any factual issues to be tried. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-49 (1986). The presence of "a mere scintilla of evidence" in the nonmovant's favor will not avoid summary judgment. Williams v. Borough of West Chester, 891 F.2d 458, 460 (3d Cir.1989). Rather, the Court will grant summary judgment unless "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248.

The Federal Circuit has made clear that summary judgment is appropriate in patent infringement actions, *see* Spectra Corp. v. Lutz, 839 F.2d 1579, 1581 (Fed.Cir.1988); Nike Inc. v. Wolverine World Wide, Inc., 43 F.3d 644, 646 (Fed.Cir.1994), and has upheld district court determinations on the issue of noninfringement. K-2 Cirp. v. Salomon S.A., 191 F.3d 1356, 1362 (Fed.Cir.1999); Cortland Line Co. v. Orvis Co., 203 F.3d 1351, 1357-60 (Fed.Cir.2000). A dispute over the meaning and scope of asserted patent claims, a question of law; does not preclude summary judgment when there is no material dispute about the structure and operation of the accused device. *See* Phonometrics, Inc. v. Northern Telecom Inc., 133 F.3d 1459, 1464 (Fed.Cir.1998).

DISCUSSION

Patent infringement occurs when a device that is covered by patent claims, either literally or under the doctrine of equivalents, "is made, used, or sold, without the authorization of the patent holder, during the term of the patent." Stairmaster Sports/Med. Prod., Inc. v. Groupe Procycle, Inc., 25 F.Supp.2d 270, 278 (D.Del.1998). Before the Court can weigh the question of infringement or non-infringement, the claims of the patent must be construed as a matter of law. Markman v. Westview Instruments, Inc ., 52 F.3d 967, 979 (Fed.Cir.1995); Smithkline Diagnostics, Inc. v. Helena Labs. Corp., 859 F.2d 878 (Fed.Cir.1988).

A. *Claim Construction*

As earlier indicated, defendant contends in this motion for summary judgment that resolution of claim construction resolves the issue of literal infringement in its favor. On literal infringement, the movant takes the position that how this court interprets the prepositions "on" and "onto" as they appear in Claim 1 is determinative.

Claim 1, which contains the claim language that all agree serves as the focus of this motion is reproduced below in pertinent part, with the critical words emphasized in bold:

We claim:

1. An analytical test device for detecting an analyte suspected of being present in a liquid biological sample, said device comprising:

a) a hollow casing having a liquid biological sample application aperture and means permitting observation of a test result;

b) a test strip comprising a dry porous carrier contained within said hollow casing, said carrier communicating directly or indirectly with the exterior of said hollow casing through said liquid biological sample application aperture to receive applied liquid biological sample, said carrier having a test result zone observable via said means permitting observation, said test strip in the dry unused state, containing a labelled reagent capable of specifically binding with said analyte to form a first complex of said labelled reagent and said analyte, said label being a particulate direct label, wherein said labelled reagent is dry on said test strip prior to use and is released into mobile form by said liquid biological sample,

wherein mobility of said labelled reagent within said test strip is facilitated by at least one of 1) coating at least a portion of said test strip upstream from said test result zone with, or 2) drying said labelled reagent onto a portion of said test strip upstream from said test result zone in the presence of, a material comprising a sugar, in an amount effective to reduce interaction between said test strip and said labelled reagent;

said carrier containing in said test result zone a means for binding said first complex, said means for binding comprising specific binding means and being immobilized in said test result zone;

migration of said applied liquid biological sample through said dry porous carrier conveying by capillarity said first complex to said test result zone of said dry porous carrier whereat said binding means binds said first complex thereby to form a second complex;

said second complex being observable via said means permitting observation, thereby to indicate the

presence of said analyte in said liquid biological sample.

Patent '871, Col. 19, lines 50-67 and Col. 20, lines 1-23 (emphasis added).

Before construing the contested prepositions, it is useful to articulate the plain meaning of other relevant claim language in Claim 1.

Claim Language:

1. " *Said labelled reagent is dry on said test strip prior to use* "

The May patents state that the labelled antibodies are dry, as opposed to liquid, on the test strip prior to use. The meaning of the term "on" as used in this clause is contested by the parties.

2. " *Released into mobile form by said liquid biological sample* "

This Court previously recognized in its opinion in *Conopco v. Princeton Biomeditech,* Civil Action No. 97-6254 (decided September 28, 2000) at p. 5, that the labelled antibodies are released from their dry state into mobile form by the application to the test strip of the liquid biological sample, in this case a woman's urine.

3. " *Mobility of said labelled reagent within said test strip is facilitated by* "

In construing this portion of Claim 1 in *Princeton Biomeditech,* the Court found that "facilitating mobility" of the labelled reagent means to "help or improve the release" of those antibodies. *Id.* as p. 8.

4. " *Coating at least a portion of said test strip upstream from said test result zone with* "

The facilitation of the labelled reagent's mobility is accomplished by one of two options. The first is "coating" a portion of the test strip with a material comprising a sugar. Coating, as defined by its ordinary meaning, is to "cover or spread with a finishing, protection or enclosing a layer." *Merriam Webster's Collegiate Dictionary* (10th ed.1997). The meaning of "coating" is not disputed by the parties; further the parties agree that this option is not applicable to the operation of the defendant's e.p.t.(R) test.

5. " *Drying said labelled reagent onto a portion of said test strip upstream from said test result zone in the presence of* "

The second of the two options used to make or improve release of the labelled antibodies is to dry them "onto" a portion of the test strip in the presence of a material comprising a sugar. The meaning of "onto" here is contested by the parties.

6. " *A material comprising a sugar* "

The Court found in *Princeton Biomeditech,* p. 6, that "a material comprising a sugar is simply a material that includes sugar as at least one of its ingredients."

7. " *In an amount effective to reduce interaction between the test strip and the labelled reagent* "

Finally, this Court has determined that this claim term means an amount of sugar or material comprising a sugar "sufficient to reduce the mutual action between the test strip and the labelled reagent." *Id.*

Construing the meaning of "on" and "onto":

As indicated above, the Court is asked to construe two disputed and undefined prepositions, "on" and "onto."

When construing a patent claim, the Court first looks to the "intrinsic" evidence of record, including the language of the claims themselves, the specification, and the prosecution history. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996); *see also* Markman, 52 F.3d at 979. This intrinsic evidence is "the most significant source of the legally operative meaning of disputed claim language." Vitronics, 90 F.3d at 1582-83. "In most situations, an analysis of the intrinsic evidence alone resolves any ambiguity in a disputed claim term." *Id*. If a review of the intrinsic evidence reveals no ambiguity, it is improper for the Court to use or rely on extrinsic evidence when construing the claims. Bell & Howell Document Management Products v. Altek Systems, 132 F.3d 701, 705 (Fed.Cir.1997); Vitronics, 90 F.3d at 1583-1584. The claims are considered alone and not in light of the accused product or any other physical device. *See* S.R.I. Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1118 (Fed.Cir.1985). At oral argument, the parties agreed that claim construction may proceed in this case based upon intrinsic evidence.

1. ***Plain meaning***

A review of the intrinsic evidence begins with a plain meaning construction of the claim language, which defines the scope of the claim. York Prods., Inc. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed.Cir.1996). According to the claim language: "said labelled reagent is dry on said test strip prior to use" and mobilization of that labelled reagent is facilitated by "drying said labelled reagent onto a portion of said test strip." In analyzing the claim language the Court must employ "normal rules of syntax," Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F .3d 1547, 1553 (Fed.Cir.1997), and must read the claims in accordance with their ordinary dictionary meaning absent some contrary expression in the specification. Northern Telecom Ltd. v. Samsung Electronics Co., 215 F.3d 1281, 1295 (Fed.Cir.2000).

The preposition "on" is "used as a function word to indicate position in contact with and supported by the top surface of" or the "outer surface," according to *Merriam Webster's Collegiate Dictionary* (10th ed.1997). The term "onto" means "to a position on." *Id*. Substituting this plain dictionary meaning, the claim language would read: "said labelled reagent is dry in a position in contact with the top or outer surface of said test strip prior to use" and "drying said labelled reagent to a position in contact with the top or outer surface of a portion of said test strip."

Plaintiff disagrees. As defined by Webster's Third New International Dictionary, "on" includes the term "within," as in "rode there on a train" or "booked passage on an ocean liner." Thus plaintiffs argues for an alternative claim construction that would read that the "labelled reagent is dry on and within said test strip prior to use" and mobility of the labelled reagent is facilitated by "drying said labelled reagent onto and within a portion of said test strip."

In considering this construction, it is significant to note that the language of Claim 1 describes an invention "wherein mobility of said labelled reagent within said test strip is facilitated by ... drying said labelled reagent onto a portion of said test strip." Plaintiff's construction would use "on" and "onto" interchangeably with "within" and thereby require the Court impermissibly to construe different words used in the claims so they have identical meanings. *See* Senmed, Inc. v. Richard-Allan Medical Indus., 888 F.2d 815, (Fed.Cir.1989)(when two terms are clearly intended to have "different meanings within the context of the

claim language," it is impermissible to construe these terms to have the same meaning).

Moreover, and contrary to plaintiff's construction, the patent specification reinforces the use of "on" and "onto" as position words being used here to describe something in cont act with a surface.

2. ***Patent Specification:***

Patent specification is one of source of intrinsic evidence used to give context to the claim language. As the Federal Circuit explained in Vitronics, 90 F.3d at 1582:

[T]he specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication .... As we have repeatedly stated, "claims must be read in view of the specification, of which they are part." ... The specification contains written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Thus, the specification is always relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of the disputed term.

Id. The specification in the May patents supports only one of the possible meanings for "on." In each of three instances, the specification clearly describes the labelled reagent as applied *on* the surface of the test strip.

Column 6 of the specification reads as follows:

To assist the free mobility of the labelled reagent when the porous carrier is moistened with the sample, it is preferable for the labelled reagent to be applied to the carrier as a surface layer, rather than being impregnated in the thickness of the carrier. This can minimize interaction between the carrier material and the labelled reagent. In a preferred embodiment of the invention, the carrier is pre-treated with a glazing material in the region to which the labelled reagent is to be applied. Glazing can be achieved, for example, by depositing an aqueous sugar or cellulose solution, e.g. of sucrose and lactose, on the carrier at the relevant portion, and drying.

Column 6, line 48-Col. 7 line 3 (emphasis added). The ordinary meaning of "on" requires contact with the top or outer surface, and the specification reinforces this meaning by affirmatively stating that the labelled reagent should be applied to the test strip as a surface layer, rather than being impregnated within the test strip.

The application of the labelled reagent as a surface layer is also referred to in Column 13 where the specification diagram is described:

A portion of the test strip surface opposite the backing strip 511 and adjacent the porous receiving member 506, carries a glaze 519 on which is deposited a layer 520 of labelled specific binding reagent..... The essential objective of reducing any interaction between the labelled reagent and the carrier material forming the strip will be achieved.

Col. 13, lines 45-48. Again, the labelled reagent is deposited *on a glaze* and this achieves the "essential objective of reducing any interaction" between the labelled reagent and what the test strip is made out of.

Finally Column 17 describes the process of using an airbrush to apply the layer of sugar substance, and then a layer of labelled antibodies on top of the sugar layer as follows:

Prior to the deposition of dye labelled antibody, a sublayer of, for example, 60% w/v of sucrose in distilled water is applied by airbrush .... Then several passes (e.g.three) of dye labelled antibody ... are applied by airbrush directly on top of the sublayer.

Col. 17, line 63-Col. 18, line 6.

Each of the above excerpts from the specification describe what is the preferred embodiment of the May patent and clarify and strengthen the contextual meaning of the terms "on" and "onto."

In opposing this construction, plaintiff correctly states that claims are not construed to cover only a particular embodiment or example-even if that embodiment is "preferred," Northern Telecom Ltd. v. Samsung Electronics Co., 215 F.3d 1281 (Fed.Cir.2000), and offers three embodiments, also in the specification, to support a construction in which "on" means "within."

First plaintiff cites Column 8, which describes an embodiment in which the test strip area in question, Zone 12, is "loaded with a first antibody bearing a visible ('direct') label .... This reagent can freely migrate through the test strip in the presence of a liquid sample." Col. 8, lines 52-55. Plaintiff argues that the term "load" should be defined as "to put a load in or on (a means of conveyance); to fill with material, animals, or passengers to be transported (had loaded the moving van by noon)." *Webster's Third New International Dictionary,* Unabridged, Merriam Webster Inc., (1993). But plaintiff fails to point out that the very next line in the patent, Col. 8, lines 55-56, describes Zone 14, the test result zone, in which a second antibody is "impregnated" in the test strip. As defendant correctly argues, the reference to "loaded" when read in context with the reference to "impregnated" does not support plaintiff's construction. Instead it bolsters a construction that distinguishes between the zones containing impregnated immobilized antibodies and the labelled antibody zone, presumably not impregnated.

Plaintiff's second reference to the specification identifies language from Column 13:

The thickness of these two layers as depicted in FIG. 10 is grossly exaggerated purely for the purpose of illustration. It will be appreciated that in practice, the glaze may not form a true surface layer and the glazing material will penetrate the thickness of the strip to some extent. Similarly, the subsequently applied labelled reagent may also penetrate the strip.

'871 Patent, Col. 13, lines 49-55. But this is excerpted from the specification defendant points to, discussed above: "a portion of the test strip surface ... carries a glaze on which is deposited a layer of labelled specific binding reagent," '871 Patent, Col. 13, lines 45-48, to achieve the "essential objective of reducing any interaction between the labelled reagent and the carrier material forming the strip," '871 Patent, Col. 13, lines 55-57. The fact that the glaze with the labelled reagent might "to some extent" penetrate the thickness of the strip is clearly in contrast with specification language describing antibodies in the test result zone as "impregnated throughout the thickness of the carrier." '871 Patent, Col. 7, lines 37-42. If the patent drafter intended to include labelled antibodies "within" the test strip, this language does not express it.

Plaintiff also cites to language in Column 18, which reads: "In another embodiment, the label may be dispensed/deposited into/on a restricted zone before cutting up the liquid-conductive material into strips."

'871 Patent, Col. 18, lines 18-20, offering the term "dispensed into" to support its construction that the labelled reagent and sugar material can be dried "within" the test strip. But, once again, this reference is surrounded by language describing the labelled reagent as "applied ... directly on top of the sublayer." '871 Patent, Col. 17, line 63-Col. 18, line 1. The fact that the labelled reagent could be dispensed into a "zone" does not mean it is dried into or within the thickness of the test strip.

3. ***Final Claim Construction (Resolving "On" and "Onto")***

The claim language is construed by the Court to define an invention that uses an undefined sufficient amount of material, of which sugar is an ingredient, to reduce the mutual action between the labelled reagent and the test strip by either coating the test strip with the material or drying the labelled reagent and this material together onto the surface of a portion of the test strip upstream from the test result zone. The claim is further construed to mean that the presence of this sugar material on the surface of the test strip will help or improve the release of the labelled reagent when the liquid biological sample is applied to the strip.

B. ***Noninfringement of the Patent***

Defendant claims that, based upon a proper construction of the patent claims, the e.p.t.(R) product does not have the critical limitation common to all of plaintiff's patent claims, or an equivalent thereof, and therefore does not infringe plaintiff's patents. First, defendant argues the e.p.t.(R) product does not use a sugar coating. This is uncontested. Then defendant argues that it does not dry the labelled reagent *onto* the test strip in the presence of sugar. Finally, defendant argues that the e.p.t.(R) product has no equivalent to the claimed sugar element.

The basis of the summary judgment motion is defendant's contention that plaintiff offers no record evidence to support infringement, that is its proofs do not add up to "sufficient evidence to prove that the accused product or process contains, either literally or under the doctrine of equivalents, every limitation of the properly construed claim." Seal-Flex. Inc. v. Athletic Track and Court Constr., 172 F.3d 836, 842 (Fed.Cir.1999).

1. ***Literal Infringement***

To establish literal infringement, the plaintiff must show "by a preponderance of evidence that every limitation is literally met by the accused device." Stairmaster Sports/Med. Prod., Inc. v. Groupe Procycle, Inc., 25 F.Supp.2d 270, 278 (D.Del.1998).

The patent claims require that either a sugar material be "coated" onto a portion of the test strip or the labelled reagent be dried "onto" the surface of the test strip in the presence of sugar. As the plaintiff describes in its opposition brief, the e.p.t .(R) product is produced in part by soaking a fiber glass pad in a solution containing the labelled reagent, proteins, and sugar and drying them all together. The fiberglass pad * absorbs the solution into its thickness. There is no coating of sugar or drying of the labelled reagent "onto" the surface of the test strip or the fiberglass pad. In contrast, the labelled reagent and sugar are absorbed "into" or "within" the pad. Therefore plaintiff's own description of the accused device fails, clearly, to support its claims that the e.p.t.(R) test literally infringes the May patents as construed above.

2. ***Doctrine of Equivalents***

When an accused product does not contain the literal elements of the claims, infringement can still be found

when "there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Stairmaster, 25 F.Supp.2d at 283 (*quoting* Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 520 U.S. 17, 21 (1997). Infringement under the doctrine of equivalents may be decided on summary judgment only if no reasonable jury could determine that the limitation and the element at issue are equivalent. Warner-Jenkinson, 520 U.S. at 39.

The Supreme Court opined in Graver Tank & Mfg. Co., Inc. v. Linde Air Prod. Co., 339 U.S. 605 (1950), that "to permit imitation of a patented invention which does not copy every literal detail would ... encourage ... the unscrupulous copier to make unimportant and unsubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of the law." An analysis under the doctrine of equivalents turns on "whether the accused device performs substantially the same function in the same way to achieve substantially the same result [the function/way/result test]" Unidynamics Corporation v. Automatic Products Int'l, 157 F.3d 1311, 1322 (Fed.Cir.1998); Stairmaster, 25 F.Supp.2d at 283.

In considering the arguments advanced by both sides, the Court keeps in mind that the claimed device and the accused device both seek to solve a solution to a finite problem: in the ordinary immunoassay, proteins bind to nitrocellulose. In a home pregnancy kit, the labelled reagent must become mobile upon the application of urine. So some type of technology is necessary to reduce the binding affinity between these labelled antibodies and the nitrocellulose test strip. The patent actually refers to the application of the labelled reagent as a surface layer (which is how the court has construed the limitations in Claim 1) achieving "the essential objective of reducing any interaction between the labelled reagent and the carrier material forming the strip" in the specification in Column 13 referred to above. If such interaction can be reduced or eliminated, the tests are expected to work accurately, rapidly, and "with a minimum degree of skill and involvement from the user. " Patent '871, Col. 1, lines 21-22.

Considering the record before it, the court perceives that both the May patent and the e.p.t.(R) device feature sample application methodologies that enable the products to perform in the universe of immunochromatological assays. As such, the *function* of the sample application methodology in the May patent and the e.p.t.(R) test is substantially the same, to enable the immunoassay to perform reliably, rapidly, and accurately in determining pregnancy. The expected *result* for both the May patent and the e.p.t.(R) test is the same, a visible signal indicating accurately, reliably, and rapidly the presence or absence of hCG. And in achieving that function each has devised a *way* for the advancing aqueous front of the urine sample, possibly containing hCG molecules, to pick up the labelled antibodies and move them along as the urine sample flows through the test zone and the control zone. The issue is whether each has devised the same *way,* a determination that is important. A finding of functional equivalence alone cannot support a finding of infringement if the way in which the accused device accomplishes that function is substantially different from the way in which the claimed device accomplishes that function. *See* Alpex Computer Corporation v. Nintendo Company Ltd., 102 F.3d 1214, 1223 (Fed.Cir.1997).

Examining the Accused and Claimed Devices for Equivalence:

When one compares the claim language with the undisputed workings of the e.p.t.(R) test, it is apparent that the *way* in which each product accomplishes the stated function to achieve the stated result is fundamentally different. The May patent achieves this function in two ways: 1) coating a portion of the test strip with a material comprising a sugar; or 2) drying the labelled reagent onto a portion of the test strip in the presence of a material comprising a sugar. As the Court has already construed, the sugar is present because it

performs in a way that reduces the interaction between the labelled reagent and the nitrocellulose test strip. Very simply, the advancing aqueous front of the urine flow releases the labelled reagent when it causes the sugar to dissolve, and borne by the flow as it travels by capillary action through the nitrocellulose strip, the labelled reagent passes through the two capture zones.

The e.p.t.(R) test, by contrast, uses a separate fiberglass pad to reduce and eliminate any interaction between the labelled antibodies and the nitrocellulose strip by absorbing the antibodies into the pad. Dr. Robert Chang, one of defendant's experts, explains in his Declaration at para. 11 that the presence of sugar in the e.p.t .(R) test device is used in the fiberglass pad only for the well recognized function of stabilizing or preserving the antibodies. Critical evidence has been provided by defendant about the special properties of fiberglass: glass fibers have little or no affinity for labelled antibodies, so these antibodies "can be absorbed in the glass fiber material and still be freely released." Declaration of Dr. Alan Schwartz, para. 44. As Dr. Mark McDermott writes in his Declaration at para. 31, "colloidal gold [referring to the labelled reagents] does not adhere to glass fibers. It is well known in the art that colloidal gold is negatively charged and will not adhere to the negatively charged glass surfaces." And so although the fiberglass pad unquestionably contains sugar, defendant has offered evidence that the sugar present in the pad has no function in reducing interaction because the protein does not bind with fiberglass. And plaintiff has no evidence to refute this.

Instead, plaintiff has produced the Declarations of experts whose opinions are offered on the basis that sugar can facilitate mobility of the labelled reagent as it flows down the nitrocellulose strip through the testing zones. Dr. Eric Toone and Balbir Raj theorize about the function of sugar in blocking binding sites during the aqueous flow along the strip. Toone Decl. para. 23-32; Raj Decl. para. 17. As defendant points out, however, using this evidence of a possible function of sugar incorrectly construes "mobility" as used in the claim. The patent claim makes a distinction between "mobility," which involves the release of the dried labelled antibodies upon the application of a liquid biological sample, and "migration," which involves the flow of the liquid biological sample all the way down the nitrocellulose strip carrying the anchored hCG + labelled reagent compound. The opinions of Toone and Raj only focus on how sugar might be operating in the e.p.t.(R) device as a blocking device during migration and therefore do not address the issue, which is whether the accused device uses sugar to enhance mobility at the time of release. In any event, were one to examine whether the patent claims talk about the use of sugar during migration, one would find nothing. There is reference to blocking agents utilized for that purpose; patent language describes dried proteins and other substances utilized to block binding sites along the nitrocellulose strip. But the patent makes no reference to sugar being used as a blocking agent during migration. Patent '871, Col. 6, lines 48-51; Col. 9, lines 40-46; Col. 10, lines 29-34; Col. 17, lines 34-40.

It is particularly telling that in making its arguments for a function of the sugar in the e.p.t.(R) test in the opposition brief plaintiff consistently and inexactly talks about sugar as "facilitating mobility." Plaintiff's Opposition Brief sets forth, on pages 30-36, its arguments opposing noninfringement under the following headers: "e.p.t.(R) has sufficient *sugar to mobilize the labelled antibody* ... the developer of the e.p.t.(R) product acknowledges that e.p.t.(R) has more than *sufficient sugar to facilitate mobility* ... plaintiff's witnesses testify that e.p.t.(R) has more than *sufficient sugar to facilitate mobility* ... defendant's use of *sugar to mobilize* is a reasonable inference from the excessive amount employed ... defendant's withheld test does not show that the *sugar in the e.p.t.(R) product is inadequate to facilitate mobility*." Framing the argument this way completely ignores the sugar limitation set forth in Claim 1. The patent teaches there that mobility of the labelled reagent is facilitated by at least one of two options. The test strip is coated upstream from the test result with a material comprising a sugar (that is, sugar as a glaze forms a surface layer and the labelled reagent is dried onto the glaze) or the labelled reagent is dried onto a portion of the test strip upstream from

the test result in the presence of a material comprising a sugar, and as to both options, the material comprising a sugar is in an amount effective to reduce interaction between the test strip and the labelled reagent. That is what the sugar is doing there, in short: reducing the interaction of the test strip and the labelled reagent, with the consequence that the labelled reagent is mobilized. The court rejects plaintiff's efforts, based on its experts' expositions on sugar's ability to facilitate mobility pure and simple, to extend the patent claims where they do not go.

By seeking to extend the patent claims plaintiff creates the unintended result of enhancing defendant's arguments about the patent prosecution history. As defendant points out in the moving brief, pp. 16-18, plaintiff's applications were rejected several times on the theory that prior art patents "employ sugar as a stabilizer component for their reagents" and that "the use of sugars as preservatives ... is highly conventional for immunassays." Defendant's Exhibit J at 6, Exh. K at 5 (Examiner's Actions). Ultimately, plaintiff made amendments to the patents that distinguished its use of a sugar glaze from the known use of sugar to stabilize and defended the distinction, interestingly, in language that reaffirms the way the sugar works in its claimed device: "sugar has not been utilized in the prior art of record to facilitate mobility of direct particulate relabelled reagents, by reducing the expected interactions between the particles and the strip." Plaintiff's Exh. C at 16-17; Exh. N at 23; Exh. O at 31-32 (Patent Amendments).

Not surprisingly, then, the court easily rejects plaintiff's position at oral argument that when the May patent came along, the world of home pregnancy kits was transformed from the world before sugar to the world after sugar and as a consequence, sugar in the e.p.t.(R) test is by its presence evidence of infringement.

The long and short of this motion for summary judgment of noninfringement based on equivalency is defendant's challenge to plaintiff's proofs. Has plaintiff, defendant asks, produced evidence in this court record that the e.p.t.(R) device works the way the claimed device does to reduce interaction between protein and nitrocellulose so the labelled reagent will be mobilized when the liquid sample is applied to the test strip? If so, where is it? Reviewing the record, the court concludes such evidence is lacking, and will grant summary judgment of noninfringement in favor of defendant.

CONCLUSION

Accordingly, because there is a lack of evidence to support a finding that defendant's e.p.t.(R) product infringes upon the plaintiff's three patents as construed by this Court, the defendant's motion for summary judgment is granted and the complaint is dismissed.

D.N.J.,2000.
Conopco Inc. v. Warner-Lambert Co.