IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 00-001-RRM
	)	
INVERNESS MEDICAL TECHNOLOGY, INC.,	)	
	)	
Defendant.	)	

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MEMORANDUM OPINION

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Richard L. Horwitz, Esquire, Potter Anderson & Corroon LLP, Wilmington, Delaware; Jesse J. Jenner, Esquire and Kevin J. Culligan, Esquire, Fish & Neave, New York, New York; Brian C. Cannon, Esquire, Fish & Neave, Palo Alto, California; counsel for plaintiff.

Patricia Smink Rogowski, Esquire, Connolly Bove Lodge & Hutz LLP, Wilmington, Delaware; Michael A. O'Shea, Esquire, Leiv H. Blad, Esquire, Heather F. Auyang, Esquire, Julie N. Ambrose, Esquire and Mary Walters, Esquire, Clifford Chance Rogers & Wells LLP, Washington, D.C.; counsel for defendant.

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December 20, 2001

Wilmington, Delaware

McKELVIE, District Judge

This is a patent case. Plaintiff Becton, Dickinson and Company ("BD") is a New Jersey corporation with its principal place of business in Franklin Lakes, New Jersey. Defendant Inverness Medical Technology Inc., formerly known as Selfcare, Inc., is a Delaware corporation with its principal place of business in Waltham, Massachusetts. In its complaint, BD claims ownership of the two patents it asserts in this suit, United States Patent No. 4,703,017 (the '017 or "Campbell" patent) and United States Patent No. 5,591,645 (the '645 or "Rosenstein" patent). BD's complaint, filed January 3, 2000, alleges that Inverness has infringed both patents by making, using, selling or offering for sale home pregnancy and ovulation tests, such as the "Inverness Medical, Inc., Early Pregnancy Test."

Following the filing of BD's complaint, the United States Patent and Trademark Office ("PTO") conducted an interference proceeding to determine whether the Rosenstein patent had an earlier priority of invention than an invention made by Carter-Wallace, Inc. BD and Carter-Wallace agreed to arbitrate the priority of invention and the arbitrator ruled in favor of Carter Wallace. As a result, the PTO determined BD was not entitled to patent the 23 claims of the Rosenstein patent. Accordingly, BD has moved to amend its complaint to withdraw its claim that Inverness infringes the Rosenstein patent.

On August 29, 2001, Inverness moved for summary judgment of noninfringement of the Campbell patent. Inverness argues that because its product is a "lateral flow assay" and not a "spot assay," as is disclosed in the Campbell patent, it does not infringe. The court

heard oral argument on Inverness's motion on November 8, 2001.

This is the court's decision on BD's motion to amend its complaint and Inverness's motion for summary judgment.

I. FACTS AND PROCEDURAL HISTORY

The court draws the following facts from the Campbell and Rosenstein patents, their prosecution histories, and the affidavits and documents submitted by the parties.

A. General Description of the Technology

The patents at issue relate to immunoassays. Immunoassays are tests used to detect the presence or quantity of a particular substance in a sample of bodily fluid by using principles derived from the immune system of humans or animals. Specifically, ammunoassays detect the presence of a substance by utilizing the binding relationship of an antibody and an antigen. Antibodies are protein molecules that attach to target molecules, or antigens. Antibodies can be custom-designed to attach to a specific designated antigen. The antigen being analyzed in an immunoassay is called an "analyte."

Some immunoassays test for the presence of an analyte by introducing a labeled antibody, called a "tracer," to the sample being tested. The tracer antibody contains a label or tag that permits the user to visually evaluate the presence of tracer in a sample. If the liquid sample contains the particular analyte being tested, the tracer will bind to the analyte.

Another kind of antibody used in immunoassays is called a binder. A binder is an antibody that is attached to a solid support that, like the tracer, will bind to the analyte if

present in a sample. Unlike a tracer antibody, the binder is immobile.

Pregnancy tests are a common application of immunoassays, although the technique has many uses. When a woman is pregnant, her urine contains increased levels of a particular hormone called human chorionic gonadotropin ("hCG"). The hCG is the analyte. Because hCG is an antigen, it will bind to an antibody, if present. Thus, immunoassays might use a tracer antibody, a binder antibody, or both to test for the presence of hCG in a sample.

B. The Campbell patent

The '017 patent is entitled "Solid Phase Assay with Visual Readout." Its inventors are listed as Robert L. Campbell, Daniel B. Wagner, and James P. O'Connell and its assignee is BD. The application for the Campbell patent was filed on February 14, 1984 and the patent issued on October 27, 1987.

The invention disclosed in the Campbell patent, according to the patent specification, is an immunoassay "which would permit determination of an analyte by use of a tracer wherein the tracer can be visually determined without instrumentation and without further treatment of the tracer." That is, the Campbell patent discloses an invention that permits a user to test for the presence of an analyte with a tracer and binder, resulting in an indication that is visible to the naked eye. While the patent specification goes on to discuss various types of assays that can be created using a tracer, analyte, and binder, the parties focus on one type, described as a "sandwich" assay. In a sandwich assay, "the binder . . . supported on the solid support is a binder for only the analyte" and "the tracer is a tracer

which is specific for the analyte." If the analyte is present in the solution being tested, the "tracer [becomes] bound to the analyte which [then becomes] bound to the supported binder." Because the binder antibody is immobile and the tracer antibody has a tag, the result is a visible reaction in the binder area of the solid support that designates the existence of the analyte in the sample. In the absence of the analyte, neither the tracer antibody nor the binder antibody will have an analyte with which to bond and there will be no visual reaction in the binder area.

The Campbell patent is comprised of 62 claims, of which three are independent process claims (1, 14, 59) and one is an independent product claim (38), described by Inverness as a "kit" claim. Claim 1 states in part:

> A process for assaying for an analyte, comprising: contacting a binder supported on a test area of a solid with a solution of analyte and a tracer, said binder being a binder for at least the analyte, said tracer being comprised of a ligand labeled with a visible particulate label wherein when said particulate label is a sac including a visable [sic] dye, . . .

Claim 14 contains similar introductory language to that of claim 1. Claim 14 begins as follows:

> A process for assaying for an analyte, comprising: contacting a binder supported on a test area of a solid support with a solution analyte and a tracer, said binder being a binder for at least the analyte, said tracer being comprised of a ligand labeled with a visible particulate label wherein when said particulate label is a sac including a visible dye, . . .

Claim 59 is also similar to claims 1 and 14, but discusses only the contacting of a binder and the solution of analyte, rather than also including the tracer. It begins as follows:

> A process for assaying for an analyte, comprising: contacting a binder for an

> analyte supported on a test area of a solid support with a solution of analyte to bind analyte to said binder; . . .

Thus, all three independent process claims begin with similar language describing the contacting of a binder for an analyte on a solid support with a solution of analyte and, in the case of claims 1 and 14, also a tracer.

The product or "kit" claims include claims 38 through 45 and claims 52 and 53. The only independent product claim, claim 38, states the following:

> A reagent kit for determining an analyte in solution comprising: a solid support in a concentration of at least 1 $\mu g/cm^2$; and a tracer, said binder being a binder for at least the analyte, said tracer being comprised of a ligand labeled with a visible particulate label wherein when said particulate label is a sac including a visible dye, . . .

The Campbell patent contains a number of examples that illustrate uses of the patent's technology. Example III, for example, is an immunoassay for testing pregnancy by examining the presence of hCG in urine. The procedure in the example calls upon the user to cut a 1 cm disk of nitrocellulose paper, which serves as the solid support. The user then pipets 3 ul of 1:50 dilution hCG antibody to the center of the disk and allows the antibody to dry. After further treatment, the user pipets 200 ul of urine onto the disc and incubates for one hour at room temperature. The disc is then decanted and the user pipets 300 ul of 1:12 dilution of tracer on the disc. After incubating the disc for an hour, decanting and washing it, a visible spot where the antibody was placed is a positive test for pregnancy.

While Inverness has submitted the file history of the Campbell patent, its present motion does not rely on statements made during its prosecution.

Inverness distinguishes its product from the Campbell patent by describing the claims of the patent as only covering a species of assay called a "spot assay." Inverness's expert, Dr. Claude R. Gunter, states that in a "spot assay,"

> [a] binder is affixed on a solid support such as a paper strip forming a 'spot.' A sample suspected of containing analyte is then directly applied to the 'spot' of binder. If the sample contains the analyte, the analyte will bind to the binder, forming an *analyte/binder* complex, and thereby become immobilized on the 'spot.' A solution containing tracer that binds to the same analyte is also directly applied to the 'spot' of binder . . . The tracer binds to the *analyte/binder* complex, making a 'sandwich' of *tracer/analyte/binder*. The sample and tracer contacted to the 'spot' remain localized within the vicinity fo the 'spot.' Detection of tracer on the 'spot' where the sample and tracer were applied indicates existence of the analyte in the sample.

Declaration of Dr. Claude R. Gunter, ¶ 22. While the word "spot assay" is not contained in the Campbell patent, Dr. Gunter's description of a spot assay is similar to the procedure delineated in Example III, in which the result is described as a "visual spot." In describing the Campbell patent as limited to a "spot assay," Dr. Gunter seeks to distinguish it from what he calls a "lateral flow assay." He describes Inverness's products as "one-stop lateral flow assays."

Before addressing Dr. Gunter's description of lateral flow assays, the court will examine the claims contained in the Rosenstein patent, which, according to Inverness, also disclose a lateral flow assay.

C. The Rosenstein patent

The '645 patent is entitled "Solid Phase Chromatographic Immunoassay." Its inventor is Robert W. Rosenstein and its assignee is BD. The application for the patent was

filed April 20, 1993 and the patent issued on January 7, 1997.

The Rosenstein patent discloses a solid phase immunoassay. The solid phase immunoassay is based on a single solid support, described as a "dip-stick," divided into various portions. The solution being tested can flow across the portions of the solid support by means of capillary flow. The second portion of the solid support contains a binder for at least the analyte. Another portion of the solid support contains a tracer. The tracer is supported on the solid support, either on the first portion of the support or elsewhere, in a manner such that when the support is wetted, "the tracer is capable of being transported by capillarity to the second portion of the solid support," where the binder is immobilized. The patent specification discloses several different types of assays that can be conducted using the invention, including a "sandwich assay format." In a sandwich assay format, "the first portion of the solid support is contacted with the sample containing the analyte, and the tracer portion of the solid support is wetted to cause both the tracer and analyte to flow by capillarity to the binder supported by the second portion of the support." If the analyte is present in the sample, the tracer and analyte both become attached to the binder. Additional tracer flows through to a third portion of the solid support and can be used as "a measure of the presence and/or amount of analyte in the sample." Additionally, the sandwich assay format can be used in a "yes or no" type of test by which the amount of tracer and binder used is such that no detectable amount of tracer flows through to the third portion of the solid support when the analyte is present.

Claim 1 of the Rosenstein patent describes the basic structure of the invention. It

describes:

> A test strip for determining the presence of an analyte in a liquid sample comprising a solid support, said solid support comprising at least a first portion and a second portion, said portions being in the same plane so as to permit capillary flow communication with each other;
>
> said first portion being the site for application of the liquid sample and further comprising a tracer site, said tracer site consisting of a tracer movably supported therein wherein said tracer comprises a ligand, which specifically binds to the analyte, conjugated to a visible particulate marker; and
>
> said second portion being the site for visually determining the presence of the visible particulate marker, said second portion consisting of a binder immobilized therein which specifically binds to the analyte.

The Rosenstein patent contains 22 other claims, most of which are dependant either upon Claim 1 or Claim 11, which contains a similar description of a portioned test strip using a tracer and immobilized binder to test for the analyte.

Inverness has submitted a number of statements made by BD during the prosecution of the Rosenstein patent that distinguish the Rosenstein patent from the Campbell patent. Inverness contends the statements show that the Rosenstein patent claims a one-step lateral flow assay, while the Campbell patent does not disclose this technology. According to Dr. Gunter, in a lateral flow assay,

> [t]he user . . . simply applies a sample suspected of containing the analyte [to the solid support] upstream from the binder. The sample moves by capillary action first encountering the tracer, releasing the tracer from the solid support. If the sample contains the analyte, the analyte and tracer will bind, and then continue to move downstream on the support to the binder. The *tracer/analyte* complex will bind to the binder, thereby becoming immobilized, making a "sandwich" of *tracer/analyte/binder*.

Declaration of Dr. Claude E. Gunter, ¶ 24. In prosecuting the Rosenstein patent, BD made a number of statements distinguishing the Rosenstein patent from the Campbell patent on the basis that the former is a lateral flow assay. For example, in distinguishing the prior art to the patent examiner in a July 21, 1988 letter, BD stated that

> although Campbell discloses an assay which employs a tracer labeled with a sac, Campbell is not directed to a chromatographic-type of assay, and contains no suggestion that it would be possible to impregnate a strip with a tracer labeled with a sac and in the assay, have such tracer move by capillary action, as in the present invention.

Similarly, in a letter dated April 10, 1989, BD again states that "[a]lthough Campbell discloses an assay which includes a tracer labeled with a sac, Campbell contains no suggestion that such a tracer may be effectively employed in an assay wherein it is required that the tracer be caused to flow across a binder." On March 13, 1999, BD stated in another letter that although Campbell teaches the use of a tracer,

> [BD] fails to understand how such a disclosure permits the Examiner to <u>leap</u> to the conclusion that one of ordinary skill in the art would have found it to be obvious that the application of such tracers to absorbent material would result in chromatographic flow of the tracer in a manner such that there could be provided an effective assay, particularly where [another patent] contains a specific teaching that a ligand conjugated to a particulate material does not chromatographically flow.

(emphasis in original). Last, on March 18, 1993, BD provided its most complete explanation of the relationship between the Campbell patent and the Rosenstein patent.

> Campbell et al. disclose the use of visible particulate markers of type claimed herein; however, there are no examples in the specification that disclose the capillary flow of a visible particulate marker.
> The majority of the specification in Campbell et al. is devoted to a single zone, flow-through device. Campbell et al., however, do describe a multiple

> zone device where the zones are arranged in linear manner. . . In each zone, there is "spotted" a different concentration of "binder." Simultaneously (or sequentially), sample and tracer are applied to each spot individually or to the entire device collectively. There is no capillary flow between spots. Each of the zones, in the example, is configured for an independent flow-through read-out. Thus, the multi-zone device described in Campbell et al. does not exemplify a planar flow type device of the type claimed herein.

BD made similar comments distinguishing the Campbell patent when it prosecuted the Rosenstein European Patent, EP-284232. Inverness asserts the Rosenstein European Patent is essentially identical to the Rosenstein '645 patent.

D. Inverness's products

Inverness produces over-the-counter home pregnancy and ovulation immunoassays. Dr. Gunter describes them as one-step "later flow" assays. Inverness produced an example of its "Inverness Medical, Inc. Early Pregnancy Test," a product alleged by BD to infringe the Campbell patent. A woman uses the Early Pregnancy Test by applying the sample urine directly to an "absorbent wick" that serves as the solid support. The sample then "migrates" along the lateral direction of the solid support by "capillary flow." The sample first reaches the tracer, which is alleged to be dried to the solid support, and then reaches the binder. If hCG is present in the sample, the tracer will bind to the hCG and the two, in turn, will adhere to the binder, resulting in a visible colored line on the solid support.

E. Procedural History

On January 3, 2000, BD filed its complaint in this action, alleging Selfcare, Inc., Inverness's predecessor, infringes the Campbell and Rosenstein patents. Selfcare filed an answer and counterclaim for declaratory relief on May 30, 2000. On June 12, 2000,

Selfcare moved to stay the proceedings pending the outcome of the interference proceeding on the Rosenstein patent. On February 22, 2001, the court denied Selfcare's motion to stay. On March 7, 2001, the court granted a motion submitted by Selfcare to substitute Inverness as defendant in this action.

On August 9, 2001, following the conclusion of the interference action in the PTO, BD filed its motion for leave to amend its complaint to withdraw its claims of infringement of the Rosenstein patent. Inverness responded to that motion on August 24, 2001 and filed its own motion for leave to amend its answer and counterclaims on October 4, 2001. Inverness's motion sought to add claims for alleged violations of federal and Massachusetts antitrust law. Following a teleconference with the parties on November 20, 2001, the court granted Inverness's motion for leave to amend its answer and counterclaims and bifurcated trial on Inverness's new counterclaims for consideration following trial on BD's infringement claims and Inverness's initially-filed counterclaim seeking declaratory relief of non-infringement.

Inverness submitted a motion of summary judgment of non-infringement of the Campbell patent on August 29, 2001. Following the filing of BD's answer and Inverness's reply, the court heard oral argument on November 8, 2001.

Trial is currently scheduled to begin April 15, 2002.

II. DISCUSSION

A. BD's Motion for Leave to Amend its Complaint

BD lost the interference proceeding before the PTO on the Rosenstein patent. Therefore, it admits that it has no rights to enforce the 23 claims in that patent and has moved to withdraw from its complaint the claim that Inverness infringes that patent. Federal Rule of Civil Procedure 15(a) requires that, after the adverse party has filed its responsive pleading, a party wishing to amend its pleading seek leave to amend from the court. In such cases, "leave [to amend] shall be freely given when justice so requires." Fed. R. Civ. P. 15(a).

Furthermore, BD's motion to amend its complaint includes a covenant that it will not sue Inverness for infringement of the Rosenstein patent. According to BD, this covenant is sufficient to remove any reasonable apprehension of suit that Inverness might have on this patent. Thus, Inverness cannot seek a declaratory judgment that the Rosenstein patent is invalid, uninfringed, or unenforceable. See Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999) (holding patentee's covenant not to sue divests the court of the actual controversy necessary for a declaratory judgment action).

Inverness filed a response to BD's motion stating that it does not oppose granting BD's motion to amend its complaint. Yet Inverness stated that it could not make an informed decision whether to support the motion because it had not received sufficient discovery from BD regarding the interference proceeding.

Because Inverness does not oppose BD's request to amend its complaint, the court will grant the motion. The court is unaware of any reason "such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by

amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." upon which the court may exercise its discretion to deny BD's motion to amend. Foman v. Davis, 371 U.S. 178, 182 (1962). Inverness's concern that removal of the Rosenstein patent from this action could deprive it of discovery on the Campbell patent is neither supported nor a proper grounds for denying BD's motion to amend.

B. Claim Construction

Evaluation of whether Inverness infringes the claims of the Campbell patent requires a two step analysis. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must construe the claims of the Campbell patent. Id. at 976. Second, the court must compare the claims, as construed by the court, to the Inverness products or process that BD alleges infringe to determine whether all of the claim limitations are present. Id. This second step, analyzing the allegedly infringing product or process, presents a question of fact. Tanabe Seiyaku Co. v. United States Int'l Trade Comm'n, 109 F.3d 726, 731 (Fed. Cir. 1997). If the court finds that there is no genuine issue of material fact regarding the allegedly infringing products, then the court's analysis of infringement reduces simply to construing the claims and applying that construction to the allegedly infringing products on summary judgment. Athletic Alternatives Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1578 (Fed. Cir. 1996).

In construing a patent's claims, the court must begin with intrinsic evidence, such as the patent itself, the patent specification, and the prosecution history. Vitronics Corp. v.

Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). First, the court examines the patent claims and must accord the words of the claim their plain and ordinary meaning to one of skill in the art. Id.; Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387 (Fed. Cir. 1992). Technical terms included in the patent claims are to be furnished the meaning given by those experienced in the field of the invention. Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed.Cir. 1996). The plain and ordinary meaning of the words of the claim may be avoided, however, if patentee chooses to be his own lexicographer and assigns a different meaning to the claim terms in either the patent specification or prosecution history. Vitronics, 90 F.3d at 1582.

After consideration of the patent claims, courts consider the remaining intrinsic evidence, including the patent specification and prosecution history. Interactive Gift Express, Inc. v. CompuServe Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001). "If the claim language is clear on its face, then [the court's] consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified." Id. Such a deviation would include a patentee using a term in a manner other than its plain and ordinary meaning or if the prosecution history reveals that the patentee forfeited a particular claim construction to distinguish a prior art reference. Id.

If the language of the claim is unclear on its face, then the court may consider the claim specification and prosecution history to resolve the claim's ambiguity. Id. Patent claims should be construed in a manner that is consistent with the its specification, for "[t]he construction that stays true to the claim language and most naturally aligns with the

patent's description of the invention will be, in the end, the correct construction." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). The specification should not be used, however, to read into the patent claims a limitation that exists only in the specification or the preferred embodiment of the invention. Intervet Am., Inc. v. Kee-Vet Lab., Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989). In contrast, a patentee's statements disclaiming a more expansive scope of the claims during the patent's prosecution can be used to limit the claim's breadth. Southwall Techs. Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.").

Evidence other than the patent claims, the specification, and prosecution history is considered extrinsic evidence. Extrinsic evidence may be used to assist the court in understanding the underlying technology. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999). A dictionary is extrinsic evidence that may be used to aid the court's analysis of the plain meaning of claim terms. Interactive Gift Express, 256 F.3d at 1332 n.1. Any other use of extrinsic evidence, however, is limited to those situations in which the intrinsic evidence is inadequate to unambiguously construe the patent's claims. "Relying on extrinsic evidence to construe a claim is 'proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence.'" Id. at 1332 (quoting Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997)). Even in this situation, "extrinsic evidence may never

be used 'for the purpose of varying or contradicting the terms in the claims.'" Id. (citing Markman, 52 F.3d at 981.).

1. The process claims – "contacting"

Inverness contends that the proper construction of the term "contacting," as that term is used in independent claims 1, 14, and 59 of the Campbell patent, is "directly applying the sample and tracer to the binder." Its argument in favor of this construction is twofold. First, Inverness argues, with the support of its expert, Dr. Gunter, that the claims of the Campbell patent teach only the direct application of sample and tracer to the binder to create a "spot assay." Second, Inverness argues that because "lateral-flow" technology of the Rosenstein patent and the Inverness products was not developed at the time the Campbell patent issued in 1987, the term "contacting" should not include this later developed technology.

Dr. Gunter contends that the Campbell patent discloses only a "spot assay" and that therefore "[a] person of ordinary skill in the art would understand that the proper way to interpret 'contacting' is that the user must directly apply the sample and tracer to the 'spot' of binder." He draws support for this conclusion from the patent's specification, and states, "[a]fter a thorough review of the Campbell patent, it is my opinion that the specification is directed to and only discloses 'spot' assays . . . ." Similarly, he states that "the specification describes that in use, the sample must be directly applied to the 'spot' of binder. . . . The specification also explains that the tracer is in a solution which is also directly applied to the 'spot' of binder." Dr. Gunter also finds support for his interpretation

of "contacting" in the only figure of the Campbell patent, which depicts three spots of binder on a rectangular solid support, and in Example III of the patent, which teaches the user to pipet both urine and the tracer directly onto the spot of binder. According to Dr. Gunter, it is clear from the patent's examples and specification "that if the user does not directly apply the sample and tracer to the 'spot,' the assay would not work."

Inverness also finds support for his conclusion that "contacting" must mean "directly contacting" from the prosecution history of the Rosenstein patent. As set forth above, during the prosecution history of the Rosenstein patent, BD repeatedly acknowledged that the Campbell patent does not disclose the transfer of the tracer and sample to the binder across the solid support by capillary action.

Last, in support of Dr. Gunter's construction of the term of "contacting," Inverness argues that any other construction that might result in the inclusion of its one-step lateral flow assays within the bounds of the Campbell patent is untenable. According to Inverness, because lateral flow assays were unknown at the time the Campbell patent issued, the term "contacting" must be construed to prevent its application to this later-developed technology. Inverness finds support for this argument in this court's opinion in IPPV Enters., LLC, v. Echostar Communications Corp., 106 F. Supp. 2d 595, 605 (D. Del. 2000). In IPPV Enters., the plaintiff's patent was addressed to encrypting television program signals. At the time of the invention, the television industry was broadcasting its signals in analog form. The patent exclusively discussed the encrypting of analog television signals. Subsequently, the industry began commercial broadcasts of digital signals. The defendants

operated a direct broadcast satellite subscriber television service that transmitted encrypted video signals in a digital format. In response to plaintiff's infringement claim, defendants argued that because the patent exclusively discusses the encryption of analog television signals, the court should construe the phrase "television program signal" in the claim at issue as meaning "analog television program signal." The court agreed with defendants, but noted that this construction would not preclude plaintiff's claim that defendants infringed under the doctrine of equivalents. Id. at 605-06. In identifying its construction, the court relied upon two principles of claim construction; that the literal meaning of a claim is fixed at its issuance, see Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1320 (Fed. Cir. 1999), and that broadly written claims may, in certain instances, be construed to limit their scope to the technologies disclosed in the patent specification, see Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1383 (Fed. Cir. 1999). IPPV Enters., 106 F. Supp. 2d at 605. Inverness contends that the same principles are relevant here and that therefore the meaning of "contacting" must be limited to cover spot assays, because only spot assays are revealed in the patent specification and the lateral-flow technology was not yet developed when the Campbell patent issued.

BD responds by arguing that the plain meaning of "contacting" is not limited to Dr. Gunter's suggested interpretation of "directly contacting." According to BD, the court must begin with meaning of the term "contacting" as it was known to those skilled in the art at the time the patent issued. BD contends that because the term "contacting" has no specialized meaning and has not changed since the Campbell patent issued, it should be

interpreted consistently with its plain meaning. BD suggests that "contacting" is defined as "the coming together or touching of two objects or surfaces." American Heritage Dictionary of the English Language, 287 (Houghton Mifflin 1981).

Furthermore, BD notes that Inverness's suggested interpretation violates the rule of claim construction that the specification should not be used to import limitations into the claim language. According to BD, the Campbell patent's disclosure of only alleged "spot assays" cannot limit the breadth of the plain language of its claims or alter the meaning of "contacting." See Markman, 52 F.3d at 980 ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.").

In evaluating the meaning of the term "contacting," as used in claims 1, 14, and 59 of the Campbell patent, the court must begin with the plain meaning of the claims. Vitronics, 90 F.3d at 1582. Inverness has not suggested that "contacting" had a specialized meaning to those with skill in the art at the time the Campbell patent was issued. Nor has it suggested that elsewhere in the Campbell patent the patentee assigned a particular meaning to the term "contacting." Thus the court adopts the definition proffered by BD, "the coming together or touching of two objects or surfaces" as its plain meaning.

Inverness's arguments that the term contacting has a more limited definition find their root in two places: the specification of the Campbell patent and BD's statements about the Campbell patent while prosecuting its application for the Rosenstein patent. Beginning with the Campbell patent, Dr. Gunter's report finds no support for his definition

of the term in the patent claims themselves, but instead looks to the written description of the patent, a figure included with that description, and the examples given of how to employ the invention. The uses of the patent specification to define the terms of the patent claims is limited. If the claims are clear, the patent specification can only be used to determine whether a deviation from the claims is required, such as when the specification uses a term in other than its plain and ordinary meaning. Interactive Gift Express, 256 F.3d at 1331. If the claims are unclear, then the patent specification can be used more liberally to aid the court in resolving ambiguities and identifying a claim construction that properly delimits the bounds of the patentee's invention. Renishaw PLC, 158 F.3d at 1250. Inverness has not explained why the uses of the term "contacting" in claims 1, 14, and 59 are unclear or ambiguous on their face. Thus, there is no reason to use the patent specification to explain the claims and the claim language should be accorded its plain meaning.

Even were the court to find that the claim terms are ambiguous and employ the patent specification to resolve that ambiguity, Dr. Gunter's suggested definition of contacting still lacks support. Patent specifications cannot be used to import into the patent claims a limitation suggested only by the specification or the preferred embodiment of the invention. Intervet Am., 887 F.2d at 1053. In this case, Inverness is attempting to use the fact that the patent specification's written description, figure, and examples all disclose that a user should directly contact the sample and tracer to the binder. Because doing so would have the effect of diminishing or limiting the plain meaning of the claims, the court refuses to import into its claim construction a limitation purported to be required

by the patent's specification.

Inverness also finds support for its definition of "contacting" in BD's statements to the PTO during the Rosenstein patent that a person of ordinary skill in the art at the time of the Campbell patent would not have known of using capillarity through the solid support to bring the analyte, tracer, and binder into contact. However, statements made during the prosecution history of another patent are extrinsic evidence. Such statements would only be intrinsic evidence if the patentee used those statements in the prosecution of the contested patent. See Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1332 (Fed. Cir. 1999). "Relying on extrinsic evidence to construe a claim is 'proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence.'" Interactive Gift Express, 256 F.3d at 1332 (citation omitted). This court finds that the claim language is not genuinely ambiguous and thus resort to extrinsic evidence to construe the term "contacting" is unwarranted.[1]

Furthermore, Inverness's reliance on this court's opinion in IPPV Enters. is misplaced. While it is true that the literal meaning of a claim is fixed upon the issuance of the patent, Al-Site Corp., 174 F.3d at 1320, IPPV Enters., 106 F. Supp. 2d at 605, the important distinction here is the nature of the disputed term. Inverness disputes the

[1]While the court acknowledges that the position currently taken by BD on the meaning of the claims of the Campbell patent may be inconsistent with its position during the Rosenstein prosecution, and that such inconsistency might be relevant to other relief for Inverness, it does not change the meaning of the terms the court is asked to construe for purposes of this summary judgment motion.

meaning of the term "contacting." In IPPV Enters., the parties disputed the term "television program signal." While it was asserted that the meaning of the latter had changed over time due to technological progress, the meaning of the former has not. While technological progress in the field of immunoassays may have been significant, it has not altered the meaning of the term "contacting" and therefore has not restrained the types of contacting covered by the Campbell patent.

Inverness also relies on the statement in IPPV Enters. that broadly written claims may be construed to limit their scope to the technologies disclosed in the patent specification. IPPV Enters., 106 F. Supp. 2d at 605 (citing Wang Labs., 197 F.3d at 1383).[2] The court in IPPV Enters. employed this principle to construe the phrase "television program signal" as meaning "analog television program signal." Inverness argues this case is analogous because the patent specification in this case discloses only "spot assays" and lateral-flow technology had not been developed at the time. While it may be true that lateral-flow technology is not disclosed in the specification of the Campbell patent, the court's primary inquiry is into the scope of the claims themselves. Markman, 52 F.3d at 980 ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims."). Because the court has concluded that the meaning of the term "contacting" is clear, the court need not resort to the claim

[2]For the court's discussion of the limited nature of the Federal Circuit's holding in Wang Labs., see Intel v. Broadcom, No. 00-796-RRM, 2001 WL 1388439, *27-28 (D. Del. Nov. 6, 2001).

specification unless it contains some indication that the claims do not use the term "contacting" in its ordinary sense. Interactive Gift Express, 256 F.3d at 1331.

Thus, the court finds that the term "contacting," as used in claims 1, 14, and 59 of the Campbell patent means "the coming together or touching of two objects or surfaces." The term does not require a user of the Campbell patent to directly apply the solution of analyte and the tracer to a spot of binder; it only requires that those components come together or touch.

2. The product claims – "a tracer"

Inverness claims that the proper construction of the term "tracer" in claim 38 of the Campbell patent is "a tracer that is a separate component from (*i.e.*, is not attached to) the solid support." Inverness's expert, Dr. Gunter, argues that this construction is suggested by the structure of claim 38, in which a semicolon separates the clause introducing the tracer from the clause explaining the solid support. Furthermore, Dr. Gunter notes that "kit" claims are typically understood to involve separate components. He cites Jeffrey G. Sheldon, How to Write a Patent Application, Practising Law Institute, New York City (December 1995), in support of his understanding of "kit claims." According to that publication, "[m]any products are sold unassembled or contain a variety of parts that are used together. Kit claims are particularly valuable for those products." Based on these facts, Dr. Gunter alleges that the separate listing of the two components requires an interpretation of claim 38 that the tracer not be located on the solid support. Dr. Gunter believes that this is the proper construction of claim 38 because the patent specification

never discloses a configuration in which the tracer is located on, or attached to, the solid support. He finds further support in the prosecution history of the Rosenstein patent, in which BD stated that Campbell does not disclose that the tracer can be placed on the solid support and be made to flow to the binder area, as is claimed in Rosenstein.

BD argues that the neither term "separate" nor "attached" is used in claim 38 to describe the relation between the tracer and the solid support, and thus the claim does not require any particular relation between those components of the invention. It also contests Inverness's assertion that the fact claim 38 is described as a "kit" claim provides support for the conclusion that the tracer and solid support must be separate components of the invention.

Beginning with the language of claim 38, Inverness's proposed construction is premised on the description of the claim as a "kit claim" and the use of a semicolon to divide the tracer clause from the solid support. Taking these points in order, Dr. Gunter's support for his hypothesis that "kit" claims must contain separate elements is the PLI publication by Jeffrey Sheldon. The PLI publication, however, is extrinsic evidence and thus should not be considered until the court has concluded, after considering the intrinsic evidence, that the claims remain ambiguous.[3] Second, the use of a semicolon in claim 38 is

[3]Even as extrinsic evidence, however, the PLI publication is of dubious value. It was published eight years after the Campbell patent was issued and thus cannot be said to be evidence of the meaning of terms at the time the patent was issued. See Al-Site Corp., 174 F.3d at 1320. Moreover, PLI publications are generally intended for lawyers, and thus it is unlikely that a person of skill in the art of immunoassays would be knowledgeable of the publication's contents or import. See Pall Corp. v. PTI Techs., Inc., 259 F.3d 1383, 1393

a grammatical tool for separating two independent clauses and does not necessarily indicate that the items on opposing sides of the semicolon must also be physically separated. Thus, the court finds that neither the description of the claim as a "kit," nor the use of a semicolon imparts a characterization of the physical relationship between the tracer and the solid support. Instead, the court finds that the plain meaning of the claim's use of only a semicolon to differentiate the tracer from the solid support is that claim 38 does not require any particular physical relationship between those components of the assay.

Inverness's reliance on the specification of the Campbell patent and the prosecution history of the Rosenstein patent to support its construction of claim 38 is unhelpful for the same reasons this evidence does not support its argument on the construction of the process claims. While it is true that the patent specification reveals only the attachment of binder antibodies to the solid support and nowhere suggests that the tracer might also be attached, this fact does not require that the proper construction of claim 38 be limited to those immunoassays that keep the tracer and solid support separate. Once again, the patent specification cannot be used to limit a claim in a manner suggested only in the specification or preferred embodiment of the invention. Intervet Am., 887 F.2d at 1053. Neither can the prosecution history of a later patent such as Rosenstein, which is extrinsic evidence, alter the clear meaning of the terms in the claim of an earlier patent. See Interactive Gift Express, 256 F.3d at 1332. Thus, the court finds that neither the Campbell

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(Fed. Cir. 2001) ("In claim construction, a claim is interpreted from the perspective of one of ordinary skill in the art.").

patent's specification nor the Rosenstein patent's prosecution history alters the clear meaning of claim 38. Claim 38 reveals the use of a tracer and a solid support including a binder as an immunoassay, but it does not require that the tracer and solid support have any particular physical relationship. Therefore, the court finds that Inverness's suggested interpretation of claim 38, that the claim requires a tracer separate from the solid support, is unsupported.

C. Summary Judgment on Non-Infringement

Inverness's motion seeks summary judgment that its products do not infringe the asserted claims of the Campbell patent. Inverness is entitled to summary judgment if the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Rule 56 requires that Inverness, as the moving party, bear the initial burden of informing the court of the basis for its motion and demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). A genuine issue of material fact is present when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The evidence must be viewed in the light most favorable to BD, as the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986); Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1274 (Fed. Cir. 1995). Once the moving party has shown an absence of genuine issue of material fact, it is incumbent upon

the non-moving party, BD, to "come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986) (citing Rule 56(e)).

Establishing infringement will require BD to prove "that every limitation of the claims asserted to be infringed is found in the accused device." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1566 (Fed. Cir. 1997). Thus, to demonstrate its entitlement to judgment as a matter of law that its accused products do not infringe, Inverness must show that "after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue whether the accused device is encompassed by the claims." Pitney Bowes,, 182 F.3d at 1304.

In this case, Inverness contends that it is entitled to summary judgment on the product claims because the user of its products does not "directly contact" the sample and tracer to the binder area of the solid support. Rather, the user contacts the sample to the absorbent wick of the solid support and the sample migrates across the solid support, where it locates both the tracer and the binder area. Inverness also argues it is entitled to summary judgment on the process or "kit" claims because the solid support and tracer are not separate components of its product.

BD responds that Inverness is not entitled to summary judgment because both of its arguments rest on an erroneous claim construction and, in any event, there are genuine issues of material fact. BD's claim construction arguments have been summarized and addressed above. Its alleged genuine issue of material fact concerns whether the tracer is

located on the solid support in Inverness's products. According to BD, even under Inverness's proposed construction that claim 38 of the Campbell patent is only infringed if the tracer and the solid support are separate components of the product, Inverness infringes because the tracer in Inverness products is indeed on a separate pad and not the solid support.

The court finds that summary judgment of non-infringement of the asserted product and process claims of the Campbell patent is not appropriate. First, the court has concluded that claims 1, 14, and 59 do not require that the user "directly contact" the solution of analyte and/or the tracer to the binder area of the solid support. Rather, claims such as 1 and 14 require only the "coming together or touching" of the binder area of the solid support to the solution of analyte and a tracer. Similarly, claim 59, which does not explicitly require the "contacting" of the solid support and the tracer, does require the "coming together or touching" of the binder area of the solid support to the solution of analyte. Under this construction of "contacting," Inverness has not met its burden of showing non-infringement because the claim is infringed simply by permitting the solution of analyte and/or the tracer to come together with or touch the binder area of the solid support and meeting the other claim limitations. Inverness is therefore not entitled to summary judgment of non-infringement of claims 1, 14, and 59 of the Campbell patent.

Second, the court has concluded that claim 38, the process or "kit" claim, does not require that the tracer and solid support be separate components. Rather, claim 38 only requires the existence of both of those components and does not include any limitation that

they must be in some particular physical relationship to one another. Under this construction of claim 38, Inverness has not meet its burden of showing non-infringment because a product infringes to the extent that it utilizes both a tracer and solid support and meets the remaining claim limitations. Inverness is therefore not entitled to summary judgment of non-infringement of claim 38 of the Campbell patent.

III. CONCLUSION

For the foregoing reasons, BD's motion for leave to amend its complaint will be granted. Inverness's motion for summary judgment of non-infringement of the Campbell patent will be denied. The court will enter an order in accordance with this opinion.