

# United States Court of Appeals for the Federal Circuit

01-1188

INVERNESS MEDICAL SWITZERLAND GmbH and  
UNIPATH DIAGNOSTICS, INC.,

Plaintiffs-Appellants,

v.

PRINCETON BIOMEDITECH CORPORATION,

Defendant-Appellee.

J. Anthony Downs, Goodwin Procter LLP, of Boston, Massachusetts, argued for plaintiffs-appellants. Of counsel were Paul F. Ware, Jr. and Roland H. Schwillinski. Also of counsel was Keith A. Zullo, Goodwin Procter LLP, of New York, New York.

Richard L. DeLucia, Kenyon & Kenyon, of New York, New York, argued for defendant-appellee. Of counsel were Elizabeth A. Gardner and Stefan C. Grant, M.D.

Appealed from: United States District Court for the District of New Jersey

Judge Katharine S. Hayden

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DECIDED: October 31, 2002

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Before RADER, BRYSON, and DYK, Circuit Judges.

DYK, Circuit Judge.

Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. (collectively “Unipath”)

appeal from the decision of the United States District Court for the District of New Jersey granting summary judgment of non-infringement of U.S. Patent Nos. 5,622,871 (“the ‘871 patent”), 5,602,040 (“the ‘040 patent”), and 5,656,506 (“the ‘506 patent”) (collectively “the patents-in-suit”). Conopco, Inc. v. Princeton Biomeditech Corp., No. 97-6254 (D.N.J. Dec. 18, 2000) (“Order”). In construing the claims of the patents-in-suit, we conclude that the phrase “mobility . . . is facilitated” is not limited to release of the labelled reagent, but rather must be given its ordinary meaning of capacity to make movement easier at any stage. Under this claim construction, issues of material fact remain regarding infringement of the ‘871, ‘040, and ‘506 patents. Therefore, we vacate the grant of summary judgment of non-infringement in favor of Princeton Biomeditech Corp. (“Princeton”) and remand for further proceedings.

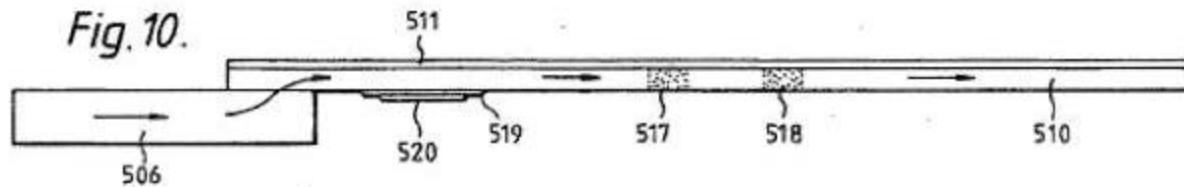
## BACKGROUND

Unipath is the assignee of the ‘871, ‘040, and ‘503 patents, respectively entitled “Capillary Immunoassay and Device Therefor Comprising Mobilizable Particulate Labelled Reagents,” “Assays,” and “Test Device for Detecting Analytes in Biological Samples.” The patents all claim original priority back to U.S. Patent App. No. 294,146 (“the ‘146 application”). The disclosures of the three patents are substantially identical, and are generally directed to the field of analytical testing devices.

A preferred embodiment of the disclosed invention is as a pregnancy-testing device. The urine of pregnant women includes human chorionic gonadotropin (hCG), a protein indicative of pregnancy. In the preferred embodiment a portion of the device is placed in contact with a test subject’s urine. If the woman is pregnant a colored label binds with high specificity to the hCG protein. Two binding zones are located on the device. The first binding zone includes a reagent that binds solely to the protein, such that when the protein is present it (and its colored label) provide a visual indication of the presence of the protein. The second zone (a control zone) includes a reagent that binds to the colored label, so that whether or not the hCG protein is present a visual indication is provided in the control zone. Thus, the test subject is able to determine whether the device is operating properly.

A diagram of the operative portion of an assay device in accordance with the disclosed invention

is shown in figure 10 of the patents (reproduced below), which depicts a cross-sectional view of the interior of the device. The device includes a porous member 506 in contact with a strip of porous material 510. Strip 510 contains three reagent zones disclosed as follows:



Test zone 517 incorporates [an] immobilised specific binding reagent, and control zone 518 contains a reagent to indicate that the sample has permeated a sufficient distance along the test strip. A portion of the test strip surface . . . carries a glaze [of sugar] 519 on which is deposited a layer 520 of labelled specific binding reagent.

'871 patent, col. 13, ll. 42-48. The labelled reagent is a direct-labelled antibody that binds with high-specificity to an analyte (e.g. hCG). *Id.* at col. 4, ll. 21-22. The fixed specific binding reagent in zone 517 also binds with high-specificity to the same analyte, but is unlabelled. *Id.* at col. 11, ll. 49-53. Finally, the reagent in zone 518 is an unlabelled fixed reagent that will bind to the labelled reagent without regard to the presence of the analyte in the sample. *Id.* at col. 11, ll. 55-60.

In operation a liquid sample is brought into contact with porous member 506, which carries the liquid sample so as to permeate test strip 510. *Id.* at col. 12, ll. 43-51. As the liquid sample moves through test strip 510 it releases the labelled reagent and dissolves the sugar, both of which are then carried along the strip to test and control zones. *Id.* at col. 13, ll. 57-62. The sugar assists in the “mobility” of the labelled reagent. If present in the sample, the analyte will bind to the labelled reagent and thereafter to the fixed unlabelled reagent in the test zone, thereby providing a visual indication (the label) of the analyte. Regardless of the presence of the analyte in the test sample, the labelled reagent will bind to the reagent in the control zone, thereby providing a visual indication in the control zone. *Id.* at col. 11, ll. 45-60.

Unipath initiated an action against Princeton in the District of New Jersey on December 23, 1997, for infringement of the claims '871, '040, and '503 patents. Claim 1 of the '871 patent is representative and provides:

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 applied 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.

(emphases added).

On February 27, 1998, Princeton answered and counterclaimed by denying infringement, asserting that all of the claims are invalid, and asserting that the patents are unenforceable. On September 15, 1998, Princeton filed a motion for summary judgment of non-infringement. The motion requested the court to construe the claim recitation “wherein mobility of said labelled reagent . . . is facilitated by . . . a material comprising sugar, in an amount effective to reduce interaction between said test strip and said labelled reagent” as requiring an amount of sugar greater than that required by the

prior art for use of sugar as a stabilizer. Based on its proposed construction, Princeton argued that the amount of sugar used in its product corresponded to the prior art use of sugar as a stabilizer and was therefore outside the scope of the claim. It urged that summary judgment of non-infringement should be granted.

The district court initially denied the motion on September 28, 2000. Conopco, Inc. v. Princeton Biomeditech Corp., No. 97-6254 at 9 (D.N.J. Sept. 28, 2000) (“Opinion”). In denying the motion, the district court (without having been requested to by appellee), construed the phrase “mobility . . . is facilitated . . .” to mean “sugar, or a material that includes sugar as an ingredient . . . must help or improve the release of the labelled reagent from the test strip.” Id. at 8 (emphasis added). On reconsideration the court granted summary judgment in favor of Princeton, finding that “the issue of release is critical to the sugar limitations as I’ve viewed them, not facilitating mobility standing alone.” Conopco, Inc. v. Princeton Biomeditech Corp., No. 97-6254 at 58 (D.N.J. Dec. 18, 2000) (“Motion Hearing”). The court placed specific emphasis on the use of the word “upstream,” which the court noted was “[recited] twice in the patent claim with respect to the sugar limitations, suggesting . . . very strongly that the activity and the chemical reaction being described there that involves the sugar, takes place at the point of release upstream . . . .” Id. at 50. The court also dismissed problems of protein “sticking” and “snagging,” which the court found was not encompassed by the recited mobility. The court found that in the accused product sugar did not facilitate mobility at the point of release, and that therefore, the accused product did not infringe the asserted claims. The district court entered a final judgment of non-infringement on January 22, 2001.

Unipath timely filed this appeal.

## DISCUSSION

### I. Jurisdiction and Standard of Review

We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(1). We review a district court’s grant of a motion for summary judgment without deference. Ethicon Endo-Surgery, Inc. v.

United States Surgical Corp., 149 F.3d 1309, 1315, 47 USPQ2d 1272, 1275 (Fed. Cir. 1998).

Claim construction is determined as a matter of law and is reviewed on appeal without deference. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998) (en banc).

## II. Claim Construction

The sole issue of claim construction here is the proper interpretation of the phrase “mobility of said labelled reagent within said test strip is facilitated by . . . a material comprising a sugar, in an amount effective to reduce interaction between said test strip and said labelled reagent.” The parties argue for two different definitions of the term “mobility.” The appellee (alleged infringer) asserts that mobility must be facilitated at the time of release of the reagent. The appellant (owner of the patent) asserts that mobility need only be facilitated either at the time of release or during the subsequent transit of the reagent, i.e., at some time during the operation. The claim construction adopted by the district court and now supported by appellee requires the sugar to “help or improve the release of the labelled reagent from the test strip.” Opinion at 8 (emphasis added).

We begin claim construction analysis with the ordinary meaning of the disputed claim term. Tex. Digital Sys., Inc. v. Telegenix, Inc., No. 02-1032, slip op. at 8 (Fed. Cir. Oct. 16, 2002); Vitronics Corp. v. Conceptor, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996). It is well settled that dictionaries provide evidence of a claim term’s “ordinary meaning.” Tex. Digital Sys., No. 02-1032, slip op. at 9; CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366, 62 USPQ2d 1658 (Fed. Cir. 2002) (citing Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344, 60 USPQ2d 1851, 1855 (Fed. Cir. 2001)). Such dictionaries include dictionaries of the English language, which in most cases will provide the proper definitions and usages, and technical dictionaries, encyclopedias and treatises, which may be used for established specialized meanings in particular fields of art. The parties here do not argue that the term “mobility” has an established specialized meaning in technical dictionaries, encyclopedias, or treatises of the relevant field of art, and we agree that “mobility” has no such specialized meaning. Accordingly, standard dictionaries of the English language are the proper source of ordinary meaning of the phrase.

We may look, therefore, to the dictionary definition of the claim term “mobility” as of the date the patents issued.<sup>[1]</sup> As with most words, the standard dictionaries offered multiple definitions.<sup>[2]</sup> “[W]here there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meaning.” Renishaw PLC v. Marposs Societa’ per Axioni, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998); see also Tex. Digital Sys., No. 02-1032 slip op. at 11. Here, our examination of the available definitions and the specification suggest that there is only one relevant definition, namely “the quality or state of being mobile: the capacity or facility of movement: MOVABILITY.” Webster’s at 1450. The pertinent definitions of the word “mobile”<sup>[3]</sup> are fully consistent with the second portion of the definition provided for “mobility,” namely “the capacity or facility of movement.” The claim term “facilitate” means “to make easier or less difficult.” Id. at 812. Accordingly, the ordinary meaning of the phrase “mobility . . . is facilitated” is properly interpreted as: the capacity to make movement easier.<sup>[4]</sup>

Contrary to appellee’s contention, there is nothing in the remainder of the claim language that introduces an ambiguity. In its analysis of the claim language, the district court found other language, which, it said, required that the term “mobility” be limited to mobility at the point of release. The district court concluded that “[a]ccording to the claim language, ‘release of the labelled reagent into mobile form’ is caused by a liquid biological sample. The labelled reagent, therefore, becomes mobile when released from the test strip by urine or some other biological sample.” Opinion at 5 (emphasis in original). The portion of the claim language cited by the district court, however, is not concerned with the expressly recited facilitation of mobility in the presence of sugar. The cited recitation merely states the obvious – that mobility is commenced by the application of a liquid biological sample. The claim language relied upon by the district court does not restrict the meaning of “mobility” to the point of release. Indeed the language appears also to contemplate mobility after release. The recitation “release of the labelled reagent into mobile form,” therefore, does not render the phrase “mobility . . . is facilitated” ambiguous. Similarly, contrary to the district court’s view, the use of the claim term “upstream” to describe the position of the sugar prior to use does not limit mobility to the point of release, but rather simply limits the position of the sugar prior to use.



Appellee argues that the disputed language, when read in context, refers to “release,” pointing out that “migration” of the reagent is separately recited, and that, therefore, “mobility” cannot include migration, *i.e.*, movement after the point of release. That “mobility” and “migration” are used in the same claim, however, does not suggest that mobility excludes migration. The term “migration,” in context, does not refer to the effect of the sugar. The claim language is equally consistent with the notion that “migration” is subsumed within “mobility.”

Further weakening appellee’s argument is the language of claims 17 and 18, which depend from claim 1, and provide “wherein mobility of said labelled reagent within said test strip is further facilitated by blocking excess binding sites within said test strip” respectively with “polyvinyl alcohol” or “protein.” Claims 17-18 of the ’871 patent (emphasis added).<sup>[5]</sup> A claim term used in multiple claims should be construed consistently (*CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1159, 42 USPQ2d 1577, 1586 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 1109 (1998)), and it makes no difference that claims 17 and 18 refer to “mobility” facilitated respectively by polyvinyl alcohol and protein, rather than sugar. Construing the term “mobility” as used in claims 17 and 18 in the manner suggested by the district court and appellee would require the recited polyvinyl alcohol or protein to block excess binding sites at the point of release. The express language of the claims, however, requires the facilitation of mobility within the test strip. Further, the specification teaches that the polyvinyl alcohol or protein should be used throughout the test strip. ’871 patent, col. 6, ll. 45-51. In short, considering the language of the claim as a whole and the use of the term in other claims, the term “mobility” is not ambiguous, but rather encompasses both release and migration.

However, the general rule that the ordinary meaning of an unambiguous claim term controls is subject to two limitations. First, “a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification . . . .” *Vitronics Corp.*, 90 F.3d at 1582, 39 USPQ2d at 1576 (citing *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578, 38 USPQ2d 1126, 1129 (Fed. Cir. 1996), *cert. denied*, 519 U.S. 911 (1996)); *see also Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002) (“The patentee may demonstrate an intent to deviate from the

ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.”). Second, “[e]ven where the ordinary meaning of the claim is clear, it is well-established that ‘[t]he prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.’” Pall Corp. v. PTI Techs. Inc., 259 F.3d 1383, 1392, 59 USPQ2d 1763, 1769 (Fed. Cir. 2001) (citing Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 USPQ2d 1673, 1676 (Fed. Cir. 1995) cert. denied, 516 U.S. 987 (1998)), vacated on other grounds, 122 S. Ct. 2324 (2002); see also Robotic Vision Sys., Inc. v. View Eng’g, Inc., 189 F.3d 1370, 1375, 51 USPQ2d 1948, 1952 (Fed. Cir. 1999). A broader definition may be disclaimed, for example, where the examiner adopts a narrow definition and the applicant does not object. See Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979, 52 USPQ2d 1109, 1113-14 (Fed. Cir. 1999), cert. denied, 529 U.S. 1066 (2000) (holding that failure to respond to an examiner’s reason for allowance functioned as a disavowal of a different interpretation of the claim).

Appellee does not cite to a definition provided in the specification for the disputed claim term. Appellee does, however, cite to the following statement by the patentee in the prosecution history as providing a disclaimer of claim scope:

The use of sugar in the invention to facilitate mobility of the labelled reagent is advantageous over conventional methodology within the art in part because the sugar allows rapid and effective release of the water-insoluble particulate direct label from the porous carrier when liquid is applied.

Amendment After Final Rejection of Dec. 19, 1995, at 2 (emphasis added). The cited passage, however, states only that the improvement is “in part . . . rapid and effective release.” This is not a clear and unambiguous disclaimer of a claim scope that would cover mobility after release as required to deviate from the ordinary meaning of the claim recitation. See, e.g., N. Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281, 1294, 55 USPQ2d 1065, 1075 (Fed. Cir. 2000) (requiring prosecution history statements cited as narrowing claim scope to have “reasonable clarity and deliberateness.”); IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1439, 54 USPQ2d 1129, 1141 (Fed. Cir. 2000), cert. dismissed,

530 U.S. 1299 (2000) (“In light of the ambiguity of the patentee’s statements and the subject matter actually disclosed in the references, we cannot say that the patentee clearly disavowed coverage of [claim scope].”).

The appellee also cites a statement by the examiner assigned to the ‘675 application provided in a “Reasons for Allowance” that “[t]he prior art currently of record neither teaches nor suggests use of a material comprising a sugar . . . to facilitate the release and mobility of the labelled reagent as claimed.” (Appellee’s Br. at 30 (emphasis added).) Based on this statement, the appellee argues that “[t]he Patent Office explicitly stated that the Unipath Patents were granted because Unipath’s claims, in contrast to the prior art, taught the use of sugar to facilitate the release of the labeled antibodies.” *Id.* at 29-30. The examiner’s statement, however, contradicts the appellee’s position, as that statement does not interpret mobility as meaning the same thing as release. Instead, the examiner refers to mobility and release as two distinct concepts.

Because the plain meaning of the unambiguous recitation “mobility . . . is facilitated” is not contradicted by either the specification or prosecution history, that meaning must control. Accordingly the disputed phrase means “the capacity to make movement easier.” The district court having applied an incorrect construction of the claims when granting summary judgment, that judgment is vacated.<sup>[6]</sup> The case is remanded to the district court for consideration of any remaining issues including issues of claim construction not addressed in this opinion and issues of validity and infringement of the claims as correctly construed.

## CONCLUSION

For the foregoing reasons, the judgment of non-infringement is vacated and the case is remanded for further proceedings consistent with this opinion.

## COSTS

No costs.

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[1] Our decisions have not always been consistent as to whether the pertinent date is the filing date of the application or the issue date of the patent. Compare Tex. Digital Sys., No. 02-1032, slip op. at 9, with Schering Corp. v. Amgen, Inc., 222 F.3d 1347, 1353, 55 USPQ2d 1650, 1654 (Fed. Cir. 2000). No party here has suggested that the pertinent sources changed between the application and issuance dates.

[2] Webster's defines mobility as "1: the quality or state of being mobile: the capacity or facility of movement: MOVABILITY . . . 2 : the measure of the rate at which a solid is deformed under stress after the yield point has been exceeded 3a : the average speed at which either gaseous or electrolytic ions move under the influence of a unit potential gradient b : the average speed with which molecules in solution diffuse under the influence of a unit of osmotic pressure gradient." Webster's 3rd New International Dictionary 1450 (1968) (Webster's). The Oxford English Dictionary defines mobility as "[t]he quality or condition of being mobile." 1 The Shorter Oxford English Dictionary 1267 (3d ed. 1947) (OED).

[3] Webster's defines "mobile" as "capable of moving or being moved from one place to another . . . capable of moving or being moved about readily." Webster's at 1450. The Oxford English Dictionary defines "mobile" as "[c]apable of movement; movable . . . [c]haracterized by facility of movement." 1 OED at 1266-67.

[4] Appellee relies on part of the dictionary definition of the term "mobilize," which provides in part: "to put into movement or circulation : make mobile . . . to release (something stored in the body) for body use." Webster's at 1450. The dictionary, however, does not define the recited claim term "mobility," in terms of the word "mobilize." The definition of that term, therefore, is irrelevant.

[5] Those claims provide:

17. The test device according to claim 1, wherein mobility of said labelled reagent within said test strip is further facilitated by blocking excess binding sites within said test strip

with polyvinyl alcohol.

18. The test device according to claim 1, wherein mobility of said labelled reagent within said test strip is further facilitated by blocking excess binding sites within said test strip with a protein.

[6] Contrary to the district court's ruling of December 18, 2000, the issue of infringement is not whether the accused device "works without sugar." Motion Hearing at 54. The question of infringement to be addressed on remand is whether the capacity for movement of the labelled reagent is made easier by the use of sugar in the accused product.