

# United States Court of Appeals for the Federal Circuit

01-1147, -1177

INVERNESS MEDICAL SWITZERLAND GmbH and  
UNIPATH DIAGNOSTICS, INC.,

Plaintiffs-Appellants,

v.

WARNER LAMBERT COMPANY  
(now known as Pfizer Inc.),

Defendant-Appellee.

J. Anthony Downs, Goodwin Procter, LLP, of Boston, Massachusetts, argued for plaintiffs-appellants. Of counsel were Ronald H. Schwillinski and Paul F. Ware, Jr. Also of counsel was Keith A. Zullo, Goodwin Procter LLP, of New York, New York; and Edwin F. Chociey, Jr., Riker, Danzig, Scherer, Hyland & Perretti LLP, of Morristown, New Jersey.

Charles P. Kennedy, Lerner, David, Littenberg, Krumholz & Mentlik, LLP, of Westfield, New Jersey, argued for defendant-appellee. With him on the brief was Jonathan A. David.

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

Judge Katharine S. Hayden

# United States Court of Appeals for the Federal Circuit

01-1147, -1177

INVERNESS MEDICAL SWITZERLAND GmbH and  
UNIPATH DIAGNOSTICS, INC.,

Plaintiffs-Appellants,

v.

WARNER LAMBERT COMPANY,

(now known as Pfizer Inc.),

Defendant-Appellee.

---

DECIDED: October 31, 2002

---

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 5,656,503 (“the ’503 patent”) (collectively “the patents-in-suit”). Conopco, Inc.

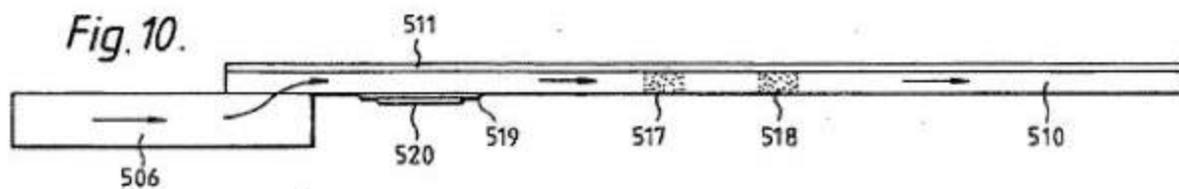
v. Warner-Lambert Co., No. 99-101 (D.N.J. Nov. 22, 2000) (“Opinion”). In construing the claims of the patents-in-suit, we hold that the claim recitations “on” and “onto” encompass both surface and internal positioning and that the claim recitation “mobility . . . is facilitated” means the capacity to make movement easier at any stage. Under this claim construction, issues of material fact remain regarding infringement of the ’871, ’040, and ’503 patents. Therefore, we vacate the grant of summary judgment for Warner Lambert Co. (now known as Pfizer, Inc.) (“Pfizer”) of non-infringement 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, being 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. human chorionic gonadotropin or 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 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.

The disposition of the labelled specific binding reagent as a “surface layer” is disclosed as “assist [ing] the free mobility of the labelled reagent when the porous carrier is moistened with the sample, [and is therefore] preferable . . . [to] being impregnated in the thickness of the carrier.” *Id.* at col. 6, ll. 59-

62. The use of sugar as a glazing material between the labelled reagent and the test strip is disclosed as a “preferred embodiment.” Id. at col. 6, ll. 64-66.

Unipath initiated an action against Pfizer in the District of New Jersey on January 8, 1999, for infringement of the '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).

After answering, Pfizer filed a motion for summary judgment, requesting a construction for the asserted claims and summary judgment of non-infringement based on that construction. (Pfizer's Mot. for Summ. J. at 2-3.) The district court granted summary judgment of non-infringement both literally and under the doctrine of equivalents. Opinion at 1. In granting summary judgment the district court

construed disputed claim language “on said test strip” and “onto a portion of said test strip” as requiring surface disposition and the phrase “mobility . . . is facilitated” as requiring an improvement in the release of the labelled reagent from the test strip. Id. at 10. The district court construed the phrase “mobility . . . is facilitated” to require the sugar to “help or improve the release.” Id. at 10 (citing the court’s decision in the related case Conopco, Inc. v. Princeton Biomeditech Corp., No. 97-6254 (D.N.J. Sept. 28, 2000) (“Motion Hearing”)). The district court entered a final judgment of non-infringement on December 22, 2000, and dismissed without prejudice Pfizer’s counterclaim for declaratory judgment of invalidity.

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 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

Appellants raise two issues of claim construction. First, appellants urge that the court misconstrued the phrase “mobility of said labelled reagent within said test strip is facilitated by . . . a material comprising a sugar.” We have decided today in Inverness Medical Switzerland GmbH v. Princeton Biomeditech Corp., No. 01-1188, slip. op. at 13 (Fed. Cir. Oct. 31, 2002), that the proper construction of the phrase “mobility . . . is facilitated” is “the capacity for movement is made easier by a material comprising a sugar . . . .” Id. at 13. For the reasons stated in our companion case, the same construction applies here. [\[1\]](#)

The second issue of claim construction raised by appellants is that the district court incorrectly construed the phrases “said labelled reagent is dry on said test strip” and “drying said labelled reagent onto a portion of said test strip.” (Emphasis added). The claim construction adopted by the district court required disposition “in contact with the top or outer surface of said test strip.” Opinion at 12. Appellants argue, however, that the phrase should be more broadly construed to include disposition of the labelled reagent within the test strip.

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. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996). It is well settled that dictionary definitions 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, 1662 (Fed. Cir. 2002) (citing Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344, 60 USPQ2d 1851, 1855 (Fed. Cir. 2001)). Potentially relevant dictionaries include dictionaries of the English language (providing general definitions and usages) and technical dictionaries, encyclopedias, and treatises (providing specialized meanings as used in particular fields of art). The parties here do not argue that the terms “on” and “onto” have established specialized meanings, and we agree that “on” and “onto” have no such specialized meanings. Accordingly, standard dictionaries of the English language are the proper source of ordinary meaning of the phrase.

We may look, therefore, to the dictionary definitions of the claim terms “on” and “onto” as of the date the patents issued.<sup>[2]</sup> Webster’s provides the relevant definition of “onto” as “to a position or point on or upon . . . in position on.” Webster’s 3d Int’l Dict. 1577 (1968) (“Webster’s”). The Oxford English Dictionary provides a substantially identical definition, “[t]o a position on or upon.” 2 The Shorter Oxford English Dictionary 1371 (3d ed. 1947) (“OED”). The definition of “onto,” therefore, refers to the word “on” as part of its definition, such that both prepositions are properly addressed through the interpretation of “on.”

In reaching its construction of the word “on” the district court referred to the definition “used as

a function word to indicate position in contact with and supported by the top surface of.”

Opinion at 12 (citing Merriam Webster’s Collegiate Dict. (10th ed. 1997)). The standard dictionaries provide a number of definitions of “on” in positional, functional, and temporal contexts. “[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 meanings.” Renishaw PLC v. Marposs Societa’ per Azioni, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998); see also Tex. Digital Sys., No. 02-1032, slip op. at 11. It is simple to rule out many of the definitions of “on” as contextually irrelevant, e.g., “occurrence during the course of a specified day.” Webster’s at 1574. Here there are two possibly pertinent definitions. One is the definition supported by appellee and adopted by the district court: “used as a function word to indicate position over and in contact with that which supports from beneath.” Id.; 2 OED at 1368 (“Above and in contact with, above and supported by; upon.”). The other is a definition of the term “on” encompassing internal positioning, providing: “used as a function word to indicate presence within.” Webster’s at 1574; 2 OED at 1369 (“Of position within. Within the limits or bounds of.”).

In such situations, a word that has an ordinary meaning encompassing two relevant alternatives may be construed to encompass both alternatives. Rexnord, 274 F.3d at 1343, 60 USPQ2d at 1855 (holding that the claim term “portion” may be interpreted to encompass both “separate” or “integral”). However, before finally concluding that the term encompasses both meanings, we must determine whether the specification or prosecution history clearly demonstrates that only one of the multiple meanings was intended. See Renishaw, 158 F.3d at 1250, 48 USPQ2d at 1122.[\[3\]](#)

Appellee asserts that the specifications of the patents-in-suit show that the term “on” was used in a limited sense to mean only surface deposition. Specifically, appellee argues that:

the specification clearly shows by Fig. 10 and otherwise describes the labelled reagent dried on the test strip as a surface layer in the presence of sugar: “[T]he labelled reagent [is] applied to the carrier as a surface layer” (A70, col. 6, lns. 58-63); “the test strip surface . . . carries a glaze 519 on which is deposited a layer 520 of labelled . . . reagent” (A74, col. 13, lns. 45-48); “labelled antibody . . . [is] applied . . . directly on top of the [sugar] sublayer” on the test strip (A76, col. 17, ln. 63 to col. 18, ln. 4).

Appellee's Br. at 31. In effect, appellee argues that only surface deposition was disclosed, and that therefore, only surface deposition could have been intended by the use of the word "on."

The surface layer disposition is disclosed as a preferred embodiment of the invention, however, it is not the sole embodiment disclosed. Impregnation within the thickness of the test strip is also disclosed. The specification states, "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." '871 patent, col. 6, ll. 59-62 (emphasis added). [4] It is improper to limit the claim based on a preferred embodiment of the invention. Turbocare v. Gen. Elec. Co., 264 F.3d 1111, 1123, 60 USPQ2d 1017, 1026 (Fed. Cir. 2001) (citing Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865, 9 USPQ2d 1289, 1299 (Fed. Cir. 1988), cert. denied, 490 U.S. 1068 (1989) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations.")).

Appellee also cites to the prosecution histories of the patents as suggesting a limited use of the words "on" and "onto." Appellee argues that "[i]n rejecting broader claims, the examiner stated that the only enablement for mobilizing the labelled reagent was 'as a surface layer by means of soluble glazing techniques as instantly described.'" Appellee's Br. at 36. Appellee asserts that in response to this rejection the patentee amended the claims to require "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 with, and 2) drying said labelled reagent onto said test strip in the presence of, a material comprising a sugar." Appellee's Br. at 36. Appellee effectively argues that by amending the claim in response to the examiner's rejection, which stated that only the glazing method was enabled, appellants disclaimed any interpretation broader than the enabled glazing embodiment.

To be sure, failure to object to an examiner's interpretation of a claim ordinarily disclaims a broader interpretation. 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). The passage from the prosecution history cited by appellee, however, was not the entirety of the

examiner's rejection, which continued:

Thus, the disclosed glazing method of providing particulate labelled reagent is required for resolubilization and mobilization of the dried particulate labelled reagent. (In the alternative, Applicant is invited to provide evidence that the prior art recognized a number of equivalent pretreatment/application techniques for providing mobilizable/resolubilizable dried particulate labelled reagents in a conventional porous test strip capable of capillary transport).

Office Action of Dec. 16, 1994 at 5 (emphasis added).<sup>[5]</sup> Based on the underscored language, during oral argument appellants asserted for the first time an alternative interpretation of the prosecution history.

On September 3, 2002, appellee filed a motion to preclude consideration of the argument on the ground that appellants failed to raise the argument before the district court or in its briefs on appeal or, in the alternative, “[to] consider its response contained in the . . . motion.” (Appellee’s Mot. at 19.) “[A] waiver may occur if a party raises a new issue on appeal, as by, e.g., presenting a new question of claim scope. . . . A waiver will not necessarily occur, however, if a party simply presented new or additional arguments in support of ‘the scope of its claim construction, on appeal.’” CCS Fitness, 288 F.3d at 1370-71, 62 USPQ2d at 1665-66 (citing Interactive Gift Express, Inc. v. Compuserve Inc. 256 F.3d 1323, 1347, 59 USPQ2d 1401, 1419 (Fed. Cir. 2001)); see also Forshey v. Principi, 284 F.3d 1335, 1355-58 (Fed. Cir. 2002), cert. denied, No. 01-1826, slip op. (Oct. 7, 2002) (“[A]ppellate courts may apply the correct law even if the parties did not argue it below and the court below did not decide it, but only if an issue is properly before the court.”). Appellee argues that appellants significantly altered the scope of their claim construction on appeal. However, the argument raised during oral argument simply provided additional support for appellants’ previously argued claim construction. In a separate order issued today the motion has been denied to the extent that it seeks to preclude consideration, but has been granted in so far as it seeks to respond. In arriving at the proper claim construction we have considered the appellee’s written responses to this new argument.

As we understand it, appellants’ theory is as follows: at the time of the examiner’s rejection of the claim it failed to recite a sugar glaze as an element of the claimed device, without which the

examiner determined the claims were not enabled. While the examiner interpreted the sugar glaze as the only enabled embodiment, he invited the applicant to provide evidence of art-recognized equivalents. In amending the claim language to include the two methods finally claimed, the applicant was making reference to two prior art methods, those disclosed in European Patent No. 0 183 442 to Stiso (“Stiso”) and U.S. Patent No. 5,120,643 to Ching et al. (“Ching”).

The Stiso and Ching patents were cited by the examiner as prior art to the patents-in-suit in the Office Action just prior to the amendment in question. Stiso teaches that a disclosed testing device “can be coated with a wide variety of materials . . . [which] may include . . . sugars or the like, which are used particularly to enhance the stability of the materials . . . .” Stiso at 20-21. Appellants argue that the first alternative recitation, which provides for the “coating . . . said test strip,” corresponds to the prior art coating method of Stiso. The abstract of Ching provides:

impregnation of solid substrate materials with labile protein materials including colloidal particle and enzyme labelled reagents in the presence of meta-soluble proteins provides for the rapid resolubilization of such materials which have been dried onto such substrate materials.

(emphasis added). This passage of Ching equates the use of the phrase “impregnation . . . [of] labelled reagents in the presence of meta-soluble proteins” with being “dried onto [the] substrate materials.” Appellants argue that the prior art teaching of Ching corresponds to the second alternative recitation in the claim, which provides for the reagent being “dried onto [the] substrate.”

Appellants argue that the examiner’s rejection referred to a single enabled embodiment, but the patentee expressly amended the claim to recite two distinct embodiments, “coating at least a portion of said test strip” or “drying said labelled reagent onto a portion of said test strip.” Appellants urge that the first recitation clearly corresponds to the glazing method referred to by the examiner, and that the second recitation is distinct in language from the first and is properly construed as reciting a different aspect of the invention, namely impregnation. See CAE Screenplates Inc. v. Heinrich Fielder GmbH & Co. KG, 224 F.3d 1308, 1317, 55 USPQ2d 1804, 1810 (Fed. Cir. 2000) (“In the absence of any evidence to the

contrary, we must presume that the use of these different terms in the claims connotes different meanings.”).

Although we are not convinced that the appellants’ reading of the history is the only plausible reading,<sup>[6]</sup> we are also not convinced that the prosecution history demonstrates that the patentee clearly was using the disputed language in a limited sense that would foreclose the broader dictionary definitions that encompass both surface and internal positioning. It is inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous. As we recently said in Schwing, “[a]lthough prosecution history can be a useful tool for interpreting claim terms, it cannot be used to limit the scope of a claim unless the applicant took a position before the PTO that would lead a competitor to believe that the applicant had disavowed coverage of the relevant subject matter.” Schwing GmbH v. Putzmeister Aktiengesellschaft, No. 01-1615, slip op. at 12 (Fed. Cir. Sept. 24, 2002) (citations omitted).

Accordingly, the plain meaning of the recitations “on” and “onto” must control, whereby disposition of the labelled reagent “on” or “onto” the test strip means disposition as a surface layer or within the test strip. The claim construction used by the district court in reaching summary judgment of non-infringement having been incorrect, the judgment is vacated. 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.

---

[1] We have considered and found unpersuasive the additional arguments presented by appellee concerning the proper construction of this claim language.

[2] 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.

[3] We are not convinced with appellants' argument that the only way to differently construe the two alternative recitations is to view the first alternative as corresponding to surface positioning and the second as corresponding to impregnation. As appellee correctly points out, a difference exists between the alternatives even if both are construed as surface positioning, in that the first requires "coating . . . with . . . sugar" while the second recites that the sugar and reagent are deposited together, i.e., the reagent is deposited in the presence of the sugar.

[4] The patent also discloses that the labelled reagent, even if provided as the preferred surface layer, "may also penetrate the strip." '871 patent, col. 13, ll. 54-55. We find this particular reference to be unhelpful because it is ambiguous as to whether it is referring merely to incidental penetration or to impregnation.

[5] When the claim was amended the applicant quoted the examiner's rejection and stated that the claims were amended in response thereto, stating that:

According to the examiner,

the disclosed glazing method of providing particulate labelled reagent is required for resolubilization and mobilization of the dried particulate labelled reagent. . . .

In response, claims 39, 70, and 75 have been amended hereinabove . . . .

In making the rejection under § 112, first paragraph, the Examiner has correctly noted an existing problem within the art. That is, it is true that particle mobility may be

constrained by interactions between the particles and the surrounding surfaces. Consequently, to achieve optimal particle mobility it is important to reduce any interaction between the particulate labelled reagent and the material forming the strip. In seeking to address this problem in the instant immunoassay invention, the inventors discovered unexpectedly that sugars were effective in avoiding those interactions.

Amendment of June 9, 1995, to the '313 application at 15.

[6] As noted above, there is another plausible reading of the claim language as encompassing two alternative embodiments of surface positioning. Ante at n.3.