

United States Court of Appeals for the Federal Circuit

03-1370

HOME DIAGNOSTICS, INC.,

Plaintiff-Appellee,

v.

LIFESCAN, INC.,

Defendant-Appellant.

Barbara C. McCurdy, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for plaintiff-appellee. With her on the brief were Herbert H. Mintz and Kathleen A. Daley.

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

Judge James Ware

United States Court of Appeals for the Federal Circuit

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v.

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Defendant-Appellant.

DECIDED: August 31, 2004

Before RADER, DYK, and PROST, Circuit Judges.

RADER, Circuit Judge.

The United States District Court for the Northern District of California held that Home Diagnostics, Inc.'s (HDI's) Prestige blood glucose meters do not infringe LifeScan, Inc.'s (LifeScan's) patent on the use of reflectance to measure analyte concentration in a colored biological fluid. Home Diagnostics, Inc. v. LifeScan, Inc., No. 5:01-cv-20725-JW (N.D. Cal. Oct. 2, 2002) (Claim Construction Order); Diagnostics, Inc. v. LifeScan, Inc., No. C 01-20725 JW (PVT) (ADR) (N.D. Cal. Apr. 14, 2003) (Order Entering Judgment). Because the district court did not give the claim language its full scope and customary meaning, this court reverses the district court's claim construction order, vacates the order

entering judgment, and remands for determination of validity and infringement.

I.

LifeScan's U.S. Patent No. 6,268,162 (the '162 patent) claims a method for determining the concentration of an analyte in colored biological fluids. '162 patent, col. 1, ll. 31-35. Thus, the claimed invention detects the concentration of glucose in whole blood, an important measure for diabetics. This technology facilitates both medical diagnosis and treatment of conditions where less than a microgram per deciliter of an analyte has clinical significance. *Id.* at col. 1, ll. 37-39.

Claim 4 of the '162 patent claims a method of measuring glucose concentration in whole blood with a reflectance-reading device. The prior art teaches a minimally automated process that requires the user to place a drop of blood on a test strip, simultaneously start a timer, wait a specified period of time, and then blot the test strip to remove excess blood. Finally the prior art requires the patient to stop the reaction between the glucose in the blood and the chemicals on the test strip. These somewhat complex steps can cause measurement inaccuracies that could result in improper treatment. The claimed invention relieves the patient of timing the operation while blotting excess blood. Claim 4 of the '162 patent recites:

A method for measuring glucose concentration in a sample of whole blood using a reflectance-reading device which comprises the steps of:

- (a) providing a test strip for placement in the reflectance reading device, the test strip having a matrix pad with a sample receiving surface and a testing surface opposite the sample-receiving surface, which matrix pad further comprises a reagent for reacting with the glucose in the blood sample and creating a change in reflectance at the testing surface indicative of the glucose concentration in the sample;
- (b) applying a sample of whole blood to the sample-receiving surface and allowing at least a portion of the sample to travel to the testing surface and react with the reagent;
- (c) taking a sequence of reflectance readings from the testing surface of said matrix at specified time intervals upon detecting a predetermined drop in reflectance sufficient to indicate that said sample has reached said first surface; and
- (d) upon detection of a suitably stable endpoint, calculating said glucose concentration in said sample from one of said reflectance readings, without having determined the time at which the sample was initially applied to the matrix pad.

Id. at col. 22, l. 59 – col. 23, l.18 (emphases added).

HDI initiated this suit by seeking a declaratory judgment that its Prestige blood glucose meters do not infringe the '162 patent either directly or under the doctrine of equivalents. LifeScan filed a counterclaim for infringement. The parties dispute the meaning of four claim terms, but the issue central to these disputes focuses on the meaning of “upon detection of a suitably stable endpoint.” LifeScan construes this claim language to mean, “when the stated reaction between glucose in the blood sample and reagents in the test strip is sufficiently complete that the glucose concentration of the sample can be calculated ‘accurately,’ i.e., without an error of clinical significance.” HDI construes the same language as, “at the expiration of a predetermined time period.”

After a Markman hearing, the district court interpreted claim 4 as limited to predetermined timing methods. In accordance with this understanding, the trial court construed “suitably stable endpoint” to mean “at the expiration of a predetermined time period.” This claim construction effectively precluded LifeScan from seeking infringement of its '162 patent because HDI's accused infringing device does not use a predetermined timing methodology. Instead, the accused infringing device uses a rate methodology that monitors the rate at which the chemical reaction between glucose from the sample and the reagent occurs. Under the rate methodology, an endpoint is reached when the rate at which the chemical reaction is occurring falls below a certain level. In an effort to facilitate this appeal, LifeScan stipulated that it could not prove infringement given the trial court's claim construction. Accordingly, the district court entered a judgment of noninfringement for HDI and dismissed LifeScan's infringement counterclaim. The district court's order was rendered final under Federal Rule of Civil Procedure 54(b). Given this sequence of events, the procedural posture of this appeal is analogous to an appeal of summary judgment. That is, if the claim construction is in error, this court will vacate the judgment and remand the case for disposition on the merits.

LifeScan timely appeals. This court has jurisdiction under 28 U.S.C. § 1295(a)(1).

II.

This court reviews claim construction without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). LifeScan's appeal focuses solely on claim construction. At

the center of the debate between the two parties is the claimed method of stopping the measurement period, step (d) of claim 4 of the '162 patent. LifeScan argues the district court erred by overlooking the accepted contextual meaning of the claim term and limiting claim 4 to a preferred embodiment which utilizes a predetermined timing method to determine the end of the measurement period. HDI argues that LifeScan has clearly disavowed claim scope by disclosing only predetermined timing methods.

As always, the claim language itself governs the meaning of the claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). This court construes the meaning of claim language according to its usage and context. ResQNet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1378 (Fed. Cir. 2003). The touchstone for discerning the usage of claim language is the understanding of those terms among artisans of ordinary skill in the relevant art at the time of invention. See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). Indeed, normal rules of usage create a "heavy presumption" that claim terms carry their accustomed meaning in the relevant community at the relevant time. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (citing Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999)). The patent applicant may also define a claim term in the specification "in a manner inconsistent with its ordinary meaning." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 (Fed. Cir. 2003) (citing Teleflex, Inc. v. Ficoso N. Am. Corp., 299 F.3d 1313 at 1325-26 (Fed. Cir. 2002)). In other words, a patent applicant may define a term differently from its general usage in the relevant community, and thus expand or limit the scope of the term in the context of the patent claims. Id.

Another tool to supply proper context for claim construction is the prosecution history. As in the case of the specification, a patent applicant may define a term in prosecuting a patent. CCS Fitness, 288 F.3d at 1366 (a "claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term" in the specification or prosecution history). This court also acknowledges the relevance of extrinsic evidence, often presented in the form of expert testimony. Vitronics, 90 F.3d at 1585; Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999) ("[C]onsultation of extrinsic evidence is particularly appropriate

to ensure that [the court's] understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art.”). Other useful references for construing disputed terms include dictionary definitions and treatises. See, e.g., Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002) (“[D]ictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms.”).

As noted before, these claim construction aids inform the court's task of ascertaining the meaning of the claim terms to one of ordinary skill in the art at the time of invention. Moba v. Diamond Automation, Inc., 325 F.3d 1306, 1315 (Fed. Cir. 2003) (“Moreover, as this court has repeatedly counseled, the best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention.”); Ferguson Beauregard v. Mega Sys., LLC, 350 F.3d 1327, 1338 (Fed. Cir. 2003) (“The words used in the claims must be considered in context and are examined through the viewing glass of a person skilled in the art.”); Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1332 (Fed. Cir. 2001) (“[I]t is important to bear in mind that the viewing glass through which the claims are construed is that of a person skilled in the art.”); Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995) (*en banc*) (“[T]he focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean.”).

In this case, this court must ascertain the meaning of the claim language “upon detection of a suitable stable endpoint.” The claim language does not explicitly require a predetermined time for the reaction, but instead measures the endpoint by the stability of the reflectance. Thus, according to this language, the endpoint coincides with a suitable stability in the reflectance readings. At this stable endpoint, the method calculates the glucose concentration. The claim limitation emphasizes that the method does not require any determination of a starting point for application of the blood sample to the matrix. In sum, the claim language limits the endpoint by reference to suitable stability in the reflectance readings, not by reference to a predetermined time.

The specification contains further enlightenment on the accustomed usage of “upon detection of

a suitably stable endpoint” among artisans of ordinary skill at the time of invention. In discussing the invention as a whole, the specification states that the concentration of an analyte in a sample: “may be determined by measuring the change . . . between two or more points in time.” *Id.* at col. 7, ll. 57-59 (emphasis added). This language shows that a “suitably stable endpoint” varies between unspecified points in time. A predetermined timing method is simply one means of determining when a “suitably stable endpoint” has been reached. In discussing a single embodiment of the invention that used a predetermined reaction time, the ’162 patent specifically states: “[u]sing the preferred embodiments described herein, the endpoint is not particularly stable and must be precisely timed.” *Id.* at col. 14, ll. 42-44. Thus, the specification limits its discussion of predetermined timing methods to preferred embodiments. Nevertheless, the invention as claimed permits detection of the endpoint with reference to the stability of the reflectance readings.

To overcome the presumption biasing claim construction in favor of the accustomed usage of a term in the relevant community at the relevant time, HDI must show a clear disavowal of such scope in the specification, prosecution history, or both. The district court erred by placing too much emphasis on the specification’s discussion of the preferred embodiments, rather than the meaning of the claims themselves. Because the specification discussed only predetermined timing methods, the district court concluded incorrectly that the applicant had disavowed other ways to reach an endpoint. The specification describes a preferred embodiment of the ’162 patent that uses a predetermined twenty second time period for blood samples with glucose concentrations below 250 mg/dl and a predetermined thirty second time period for samples with glucose concentrations between 250 mg/dl and 450 mg/dl. ’162 patent, col. 14, ll. 47-49. Because the specification described no other embodiments in detail, the district court apparently interpreted the specification’s silence regarding alternative embodiments as a disavowal. However, the applicant’s choice to describe only a single embodiment does not mean that the patent clearly and unambiguously disavowed other embodiments. See *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 907-08 (Fed. Cir. 2004).

As noted earlier, the specification’s overall context shows that the endpoint “may be determined by measuring the change . . . between two or more points in time.” *Id.* at col. 7, ll. 57-59 (emphasis

added). The preferred embodiments that used the predetermined timing method simply do not limit the broader claim language. This court has previously stated that reference to a preferred embodiment does not alone undermine the customary meaning and scope of claim language. Teleflex, 299 F.3d at 1327. The meaning of the claim term “upon detection of a suitably stable endpoint” encompasses multiple methods for finding the proper endpoint. The patent’s preferred embodiment is just that – one way of using the invention. That disclosure alone does not clearly and unambiguously disavow other ways of computing the endpoint within the scope of the claim language.

A patentee may claim an invention broadly and expect enforcement of the full scope of that language absent a clear disavowal or contrary definition in the specification. Id. at 1325. The history of the ’162 patent illustrates that this applicant took this course. The ’162 patent is part of a family of patents that includes U.S. Patent Nos. 5,049,487 (the ’487 patent) and 5,843,692 (the ’692 patent). These patents stem from the same initial application and contain the same or essentially the same specifications. In place of a “suitably stable endpoint,” the ’487 patent claims recite a “predetermined time period.” ’487 patent, col. 22, l. 36. Similarly, the ’692 patent claims recite a “predetermined incubation period” rather than a “suitably stable endpoint.” ’692 patent, col. 23, l. 22. This progression, from “predetermined time period” to “predetermined incubation period” to “suitably stable endpoint,” shows that LifeScan purposefully sought in the ’162 patent claim scope broader than the predetermined timing method. Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.

The prior art identified by the ’162 patent gives additional reasons that an artisan of ordinary skill would not limit “upon detection of a suitably stable endpoint” to predetermined timing methods. See Kumar v. Ovonic Battery Co., 351 F.3d 1364, 1368 (Fed. Cir. 2003); see also Arthur A. Collins, Inc. v. N. Telecom, Ltd., 216 F.3d 1042, 1045 (Fed. Cir. 2000) (“When prior art that sheds light on the meaning of a term is cited by the patentee, it can have particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons skilled in the art, but also that the patentee intended to adopt that meaning.”).

Specifically, U.S. Patent Nos. 4,178,153 and 4,627,014 (the '153 patent and the '014 patent) show the usage of the claim terms at the time of invention. The '153 patent, entitled "Method and Apparatus for Chemical Spot Test Analysis" relates to chemical analysis of a sample with reagents on a fibrous or porous medium after a predetermined period of time. '153 patent, col. 1, ll. 46-51. The '153 patent discloses both an endpoint-seeking methodology and a predetermined-timing methodology. In disclosing an endpoint-seeking methodology, the '153 patent states that a sample can be analyzed, "by monitoring the resultant constituent manifesting reaction." *Id.* at col. 3, ll. 26-27. Alternatively, the '153 patent discloses that the analysis can utilize, "a single point measurement, i.e., with a single measurement of reaction product." *Id.* at col. 4, ll. 27-28. The '153 patent demonstrates that as early as 1979, artisans of ordinary skill in the art knew that a chemical analysis of a sample with reagents could be accomplished by either monitoring the reaction itself or by using a single measurement of the reaction product.

The '014 patent, entitled "Method and Apparatus for Determination of an Analyte and Method of Calibrating such Apparatus," reinforces this point. This prior art reference states that the measurement of an analyte can utilize "any chemical analyzer constructed to perform rate or endpoint colorimetric assays." '014 patent, col. 7, ll. 50-52.

In light of the preceding analysis, this court determines that the customary meaning in this art field of "upon detection of a suitable stable endpoint" means "when the stated reaction is sufficiently complete that the glucose concentration of the sample can be calculated without an error of clinical significance." This determination is confirmed by using the contemporary understanding of a skilled artisan to guide an inquiry into dictionary meanings. Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998). LifeScan offers a dictionary definition of the term "stable" as "not subject to sudden change: subject to relatively limited fluctuations." Webster's Third New International Dictionary 2071 (3d ed. 1986). Alternatively, Webster's also defines "stable" as "firmly established." *Id.* The first definition conforms to the usage of "stable" by one of ordinary skill in the art as manifested by the pertinent prior art references identified by the '162 patent.

In contrast, the alternative dictionary definition would import an additional limitation into the claim, namely that the analyte's reaction product and the reagent must be firmly established.

Thus, an examination of dictionary sources guided by the prior art references enlightens the meaning of "stable" and confirms this court's determination that the customary meaning in this art field of "upon detection of a suitable stable endpoint" means "when the stated reaction is sufficiently complete that the glucose concentration of the sample can be calculated without an error of clinical significance."

LifeScan also appeals the district court's construction of the claim terms: a) "specified time interval"; b) "upon detecting a predetermined drop in reflectance sufficient to indicate that sample reached said first surface"; and c) "calculating said glucose concentration in said sample from one of said reflectance readings." Because the district court read those terms as limited to predetermined timing methods, those claim terms as well require revision based on the full scope of the claim language as understood by those of skill in the art at the time of invention.

Specifically, the district court erred in construing "specified time interval" to mean "times set in advance" because it limited claim 4 of the '162 patent to a preferred embodiment. Claim Construction Order at 5. Again consulting dictionaries within the context of this field of technology at the time of invention, "interval" is "a space of time between two events or points of time." Webster's Third New International Dictionary at 1183. This definition does not carry any hint of predetermined time calculations or intervals. Because LifeScan does not clearly disavow this customary meaning of the claim term, "specified time interval" means "a space of time between two events." In this instance, the interval refers to the space of time between reflectance readings from the testing surface of the matrix.

The district court construed "upon detecting a predetermined drop in reflectance sufficient to indicate that sample reached said first surface" to mean:

[A] reflectance reading taken immediately following or very soon after detecting the point in time of a drop in reflectance, the magnitude of which is determined in advance, to be the point in time of the first breakthrough of sample to the testing surface. At that point in time, the reflectance drop must be mostly or entirely due to wetting of the testing surface and not color from chemical reaction.

Claim Construction Order at 5 (emphasis added). In sum, the district court strictly limited the claim term to the “first breakthrough of sample to the testing surface.” Because the district court restricted claim 4 of the ’162 patent to predetermined timing methods, it limited the initiation of the measuring phase to “the first breakthrough.” As discussed previously, this interpretation improperly limits claim 4 to a preferred embodiment and does not give the disputed claim terms their proper scope in this technology at the time of invention. Therefore, “upon detecting a predetermined drop in reflectance sufficient to indicate that sample reached said first surface” means “immediately following or very soon after detecting the point in time of a predetermined drop in reflectance, where the predetermined drop in reflectance is mostly or entirely due to wetting of the testing surface.”

The district court also construed “calculating said glucose concentration in said sample from one of said reflectance readings” to mean “calculating the amount of glucose contained per unit volume in the sample from the reflectance reading taken at the expiration of the predetermined time period.” Claim Construction Order at 5 (emphasis added). This construction again improperly limited claim 4 of the ’162 patent to predetermined timing methods. This court construes “calculating said glucose concentration in said sample from one of said reflectance readings” to mean “calculating the amount of glucose contained per unit volume in the sample using a reflectance reading taken when the reaction between glucose in the blood sample and the reagents in the test strip has reached a suitably stable endpoint.”

III.

This court reverses the district court’s claim construction order, vacates the order entering judgment, and remands the case for a determination of validity and infringement.

COSTS

Each party shall bear its own costs.

REVERSED-IN-PART, VACATED-IN-PART, and REMANDED

