United States Court of Appeals for the Federal Circuit

01-1428

HOME DIAGNOSTICS, INC.,

Plaintiff-Appellee,

v.

LIFESCAN, INC.,

Defendant-Appellant.

DECIDED: May 29, 2002

Before MAYER, Chief Judge, MICHEL and DYK, Circuit Judges.

PER CURIAM.

Lifescan, Inc. appeals from the judgment of the United States District Court for the Northern District of California granting Home Diagnostics Inc.'s motion for summary judgment of no infringement, either literal or under the doctrine of equivalence. Home Diagnostics Inc. v. Lifescan, Inc., No. C 99-21269 (N.D. Cal. April 23, 2001). Because the district court properly construed the disputed claim terms and correctly concluded there was no infringing activity, we affirm.

Home Diagnostics Inc. ("HDI") filed a declaratory relief action seeking a judgment that its blood glucose monitoring systems do not infringe United States Patent No. 5,843,692 owned by Lifescan. Claim 1, from which all of the asserted

claims depend, reads:

> A method for measuring a 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) initiating a predetermined incubation period upon a change in reflectance at the testing surface sufficient to indicate that at least a portion of the sample has reached the testing surface;
> (d) taking a reflectance measurement at the end of the predetermined incubation period, without having determined the time at which the sample was initially applied to the matrix pad; and
> (e) determining the glucose concentration in the sample from the reflectance measurement.

U.S. Patent No. 5,843,692, col. 23, ll. 1-27 (emphasis added). The district court construed the phrase "a predetermined incubation period" to mean "a time period determined in advance, which requires presetting the length of time of the incubation period, either directly or by reference criteria such as glucose concentration." The court later clarified that this requires knowledge of the duration of the incubation period prior to the test. Lifescan argues that the correct construction defines the incubation period by a set of events that define the beginning and the end of the period, in which the precise duration of the period is not necessarily known and set in advance. This proposed claim construction is unsupported by the intrinsic evidence. The specification only refers to the incubation period in terms of time, only discloses time-based measurements, and from the correspondence between the examiner and the applicant, it is clear that the claim was prosecuted based upon an understanding that incubation period meant time.*

The district court construed the phrase "determining the glucose concentration in the sample" to mean "ascertaining the amount of glucose contained per unit volume in the sample." It further determined that the phrase meant the actual concentration of the sample, not a premature or intermediate measurement. Lifescan argues that because the open-ended article "a" is used to refer to "glucose concentration" in the preamble, and the specification discloses embodiments in which intermediate glucose determinations are made, a proper construction would not exclude intermediate or premature measurements. Lifescan's argument fails because such a claim construction would conflict with the plain meaning of the claim. The claim requires determining the glucose concentration of the blood sample; the blood sample can have only one glucose concentration. The intermediate measurements that Lifescan seeks to encompass within "glucose concentration" are not measurements of the glucose in the sample; they are measurements of the rate of reaction of the glucose in the sample with the chemicals found on the testing strip.

The properly construed claim requires predetermining the length of the incubation period. Because HDI's device has no method for predetermining the incubation period, there is no literal infringement. Moreover, there can be no infringement

under the doctrine of equivalence because no equivalent exists in HDI's device for predetermining the incubation period.

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* Alternatively Lifescan argues, based on the specification, that even if the patent is construed to refer to a time period, the length of the predetermined time period may depend on the glucose concentration that it encountered during the test (20 seconds for one concentration and 30 seconds for another), and that "predetermined incubation period" should be construed to include a choice of a time period that is affected by the results of the test while it is being conducted. Whether or not that is so, there is no contention here that the allegedly infringing product requires a choice to be made among predetermined time periods known in advance. Rather, the time period for the test in the allegedly infringing method is constantly variable, depending on the conditions encountered during the test.