United States Court of Appeals for the Federal Circuit

03-1630

LIFESTREAM DIAGNOSTICS, INC.,

Plaintiff-Appellant,

v.

POLYMER TECHNOLOGY SYSTEMS, INC.,

Defendant-Appellee,

and

JAMES M. CONNOLLY,

Defendant-Appellee.

DECIDED: August 25, 2004

Before LOURIE, LINN, and PROST, Circuit Judges.

PROST, Circuit Judge.

Lifestream Diagnostics, Inc. ("Lifestream") appeals a judgment of noninfringement granted by the United States District Court for the District of Idaho to Polymer Technology Systems, Inc. and James M. Connolly (collectively "Polymer Tech") regarding United States Patent No. 5,135,716 ("the '716 patent"). Because we reverse-in-part and affirm-in-part the district court's claim construction, we vacate the ju dgment of noninfringement and remand the case for further findings to determine whether Polymer Tech infringes claim 1 under the correct claim construction.

BACKGROUND

Lifestream commenced a lawsuit against Polymer Tech for allegedly infringing claim 1 of the '716 patent.[1] The '716 patent is directed to a device for determining HDL cholesterol from whole blood using HDL test strips and dry chemistry. At the trial level, the parties disputed the proper claim construction of the terms "physical transport medium" and "microporous plasma separation membrane." After conducting a Markman hearing, the district court concluded that "physical transport medium" means:

> A structure or device that moves at least a portion of blood laterally from one location to the microporous plasma separation membrane.

(Emphasis added). The district court construed "microporous plasma separation membrane" to mean:

> A thin, soft pliable layer having a surface against the physical transport medium that receives blood from its underside and separates plasma from whole blood by at least a portion of lateral flow and tangential filtration, thereby delivering plasma to the next adjacent layer.

(Emphasis added). Lifestream contends that the text underlined in the definitions above is inconsistent with the ordinary meaning of the construed terms. Lifestream timely appealed the district court's judgment of noninfringement based on the allegedly erroneous claim construction. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Lifestream's appeal of the noninfringement judgment hinges on whether the district court correctly construed claim 1 of the '716 patent. We review a district court's claim construction de novo. Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1330 (Fed. Cir. 2004).

I.

The parties dispute whether a patent applicant's arguments, in regard to the meaning of claim

terms in the parent application to overcome patentability rejections, may limit the scope of claims that contain the same terms in a continuation-in-part ("CIP") application, even though the Patent Office rejected those arguments during prosecution of the parent application. According to Lifestream, a court may apply argument-based estoppel only if it may be reasonably inferred that the Patent Office relied on the arguments advanced by the patent applicant. Because the arguments from the patent applicant were rejected, Lifestream takes the position that the district court should not have applied argument-based estoppel to limit the claimed invention to embodiments requiring tangential filtration. Instead, Lifestream contends that the claim terms should have been construed according to their ordinary meaning, which is allegedly not limited to any particular method of filtration.

Lifestream summons support for its argument from our statement that "the prosecution disclaimer standard 'is the same standard applicable, in the context of doctrine of equivalents, to the doctrine of argument-based estoppel . . . and that our precedent has recognized a relation between the doctrines of argument-based estoppel and prosecution disclaimer.'" Cordis Corp. v. Medtronic Ave., Inc., 339 F.3d 1352, 1363 (Fed. Cir. 2003) (quoting Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1326 n.1 (Fed. Cir. 2003) (emphasis added)). Lifestream attempts to draw further support from our statement that "if [prosecution history] estoppel is to rest upon argument made during the examination process, the circumstances must be such as to permit the inference that such reliance in fact occurred." Zenith Lab., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1425 n.8 (Fed. Cir. 1994). Lifestream deduces from Zenith, Cordis, and Omega Engineering that argument-based estoppel, like prosecution history estoppel, requires a reasonable basis to infer reliance by the examiner upon the arguments made.

Lifestream misreads our cases. The "standard" mentioned by Cordis and Omega Engineering was in regard to our precedent "requir[ing] that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable," not in regard to whether reliance is necessary for both argument-based and prosecution history estoppel. See Cordis, 339 F.3d at 1363; Omega Eng'g, 334 F.3d at 1325-26 & n.1. Furthermore, our statement in Zenith requiring reliance was in regard to prosecution history estoppel, not argument-based estoppel. By arguing that the standards for prosecution history estoppel and argument-based estoppel are identical, Lifestream attempts to confuse

their respective requirements.

"The fact that an examiner placed no reliance on an applicant's statement distinguishing prior art does not mean that the statement is inconsequential for purposes of claim construction." Laitram Corp. v. Morehouse Indus. Inc., 143 F.3d 1456, 1462 (Fed. Cir. 1998) (emphasis added). As we explained at length in Springs Window Fashions LP v. Novo Industries, L.P.:

> The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent. A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement. "The prosecution history constitutes a public record of the patentee's representations concerning the scope and the meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct. . . . Were we to accept [the patentee's] position, we would undercut the public's reliance on a statement that was in the public record and upon which reasonable competitors formed their business strategies."

323 F.3d at 995 (quoting Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 957 (Fed. Cir. 2000)). Like in Springs Window, in which we found that argument-based estoppel applies, the patent applicant in our case provided detailed, consistent and repeated arguments distinguishing Vogel, et al., from the claimed invention on the basis that the claimed invention operates using tangential filtration. See id. at 996. Moreover, the patent applicant never retracted any of his statements nor explicitly acquiesced to the Patent Office's rejection by amending the pending claims to insert the missing element alleged to be present by the applicant, but found absent by the Patent Office. See id. at 995; cf. Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1054 (Fed. Cir. 1989) (patent applicant amended three of the pending claims to include the element alleged to be missing by the examiner). If the patent applicant in our case mistakenly disclaimed coverage of claim terms during the prosecution of the parent application, which carried forward in the CIP, "then the applicant should have amended the file to reflect the error, as the applicant is the party in the best position to do so." Springs Window, 323 F.3d at 995; see also Desper Prods., Inc. v. QSound Labs, Inc., 157 F.3d 1325, 1335 (Fed. Cir. 1998) (stating that the prosecuting attorney is presumably "in the best position at the time to understand the true nature of the invention").

Lifestream further argues that the presumption of validity of a patent, which was given on the assumption that the Patent Office properly performed its duty of examining the patentability of a patent application, Applied Materials, Inc. v. Advanced Semiconductor, 98 F.3d 1563, 1569 (Fed. Cir. 1996), requires that we likewise presume that it correctly assessed the accuracy of the patentee's arguments regarding the alleged claim scope. But, as noted above, reliance is not a necessary element for argument-based estoppel to apply in claim construction. Laitram, 143 F.3d at 1462. "Regardless of the examiner's motives [for rejecting the patent applicant's arguments], arguments made during prosecution shed light on what the applicant meant by its various terms." Id. Lifestream complains that holding it to the patent applicant's arguments as to what has been disclaimed while condoning the Patent Office's rejection of those same arguments would constitute a "legal whipsaw." We warned in Springs Window that because the Patent Office has the duty to police claim language by giving it the broadest reasonable interpretation, parties should not be surprised that the Patent Office "would not be satisfied with the applicant's insistence that particular claim language distinguishes a prior art reference, but that a court would later hold the patentee to the distinction he [unsuccessfully] pressed during prosecution." 323 F.3d at 995. We agree with the district court that arguments deliberately and repeatedly advanced by the patent applicant in regard to the scope of a claim term during prosecution may be used for purposes of claim construction even though the Patent Office rejected the arguments.

II.

Lifestream additionally contends that the patent applicant's prosecution statements concerning tangential filtration were factually incorrect and inconsistent with the application's disclosure and that, under Intervet America v. Kee-Vet Laboratories, 887 F.2d 1050, 1054 (Fed. Cir. 1989), such factually incorrect statements cannot result in a disclaimer.

Lifestream claims that the statement in the written description of the parent application that the "ideal separation membrane . . . should not allow the red blood cells to migrate to the top surface" would be understood by those of ordinary skill in the art to mean that the plasma separation membrane performs depth filtration and not tangential filtration, as claimed by the patent applicant during

prosecution of the parent. Lifestream refers to the testimony of Polymer Tech's expert as evidence. In addition, Lifestream claims that "the '716 patent itself explicitly and unmistakably describes the microporous plasma separation membrane as a depth filter" because the '716 patent discloses that:

> Essentially, tangential flow of blood on the underside of microporous plasma separation membrane 4 is facilitated by components 2 and 3. The capillary pull draws the blood on the underside and through the cross-section of membrane 4 which retains the red cells while delivering clean plasma on the top surface which can be drawn into the subsequent filtering membrane 5 and/or carrier precipitant membrane 13.

'716 patent, col. 5, ll. 23-30. According to Lifestream, the '716 patent's disclosure quoted above shows that whole blood cells and not just plasma may travel into and through the cross-section of the separation membrane, and therefore the membrane operates by depth filtration, as allegedly defined by Polymer Tech's expert.

The principal differences between depth filtration and tangential filtration arise from the direction of the flow of fluid being filtered relative to the separation membrane. In dead-end filtration, which Lifestream calls "depth filtration," the fluid stream, carrying the material to be filtered, flows perpendicularly to the separating membrane. Particles smaller than the membrane pores, i.e., plasma, seep through to the opposite side of the membrane, while the larger particles, e.g., blood cells, are blocked from passage. By contrast, in tangential flow filtration, the fluid stream flows in a direction parallel to the separating membrane. The pressure differential from the tangential flow pushes the plasma through to the opposite side of the membrane. In principle, the larger particles are swept clean away by the tangential flow of the fluid stream to prevent "caking."

The expert testimony cited by Lifestream provides a description of an example of depth filtration not a definition as Lifestream contends. The prosecution history of the parent application informs us that the term "'microporous plasma separation membrane' as used in this application is . . . only capable of functioning properly utilizing tangential or lateral flow." (Emphasis added). The claimed separation filter works most effectively if it excludes red blood cells from diffusing into the membrane so that they

can be swept away by the flow of blood. The '716 patent explains that, although the bulk of the blood flows tangentially relative to the microporous plasma separation membrane, some of the blood cells, in practice, may diffuse into the cross-section of the membrane as a result of capillary pull. '716 patent, col. 5, ll. 22-30. The parent application informs us that, in the preferred embodiment, the "separation membrane . . . should not allow the red blood cells to migrate to the top surface" of the membrane and thereby traverse the membrane. Thus, the parent application acknowledges that clogging of the membrane by blood cells from tangential filtration, while "substantially reduced" in comparison to depth filtration, is nonetheless not eliminated completely in practice. In view of the patent documents associated with the parent application and '716 patent, we are not persuaded that the applicant's disclaimer of depth filtration is either factually incorrect or inconsistent with the patent documents here. We find no error in the district court's conclusion that the patent applicant disclaimed coverage to embodiments that do not separate plasma from blood at least by tangential filtration.

III.

If we conclude that argument-based estoppel applies, Lifestream concedes that the disclaimer supports reading the term "laterally" into the definition of "physical transport medium." The only claim term that remains in dispute is "microporous plasma separation membrane." Lifestream challenges whether this disputed term requires that it separate plasma from whole blood "by at least a portion of lateral flow and tangential filtration" and whether it receives blood from its "underside."

A. "By at least a portion of lateral flow and tangential filtration"

Lifestream contends that the district court misunderstood the disclaimer as it applies to the term "microporous plasma separation membrane." Lifestream asserts that the term tangential filtration "does not appear anywhere in the '716 patent or in the applicant's statements in the prosecution history of the parent application." Additionally, Lifestream complains that "lateral flow" occurs only through the physical transport medium, and that its mention in the definition of the claimed separation membrane is "unjustified" because "it relies on the improper disclaimer and because it is inconsistent with the factual record."

Although Lifestream may be correct that the exact term, "tangential filtration," does not appear within the '716 written description, the prosecution history of the predecessor application clearly paints a picture of how the plasma separation membrane in the claimed invention operates. The prosecution history of the parent application informs us that the plasma separation membranes in the invention "work poorly" in depth filtration mode, and that the described device laterally flows blood through the physical transport medium, which is in contact with a suitable microporous plasma separation membrane, to tangentially filter the plasma. The CIP application that later follows describes a device "similar to that described in the parent application . . . except that specific dry chemistry for HDL cholesterol determination is used." '716 patent, col. 2, l. 67 – col. 3, l. 5. We find the comments in the prosecution history of the '716 parent instructive to understanding the scope of the claimed device. For the reasons expressed earlier, we agree with the district court that the disclaimer in the parent application should apply to the CIP. We are unpersuaded by Lifestream's argument that the separation membrane does not perform its function at least by the "lateral flow" of blood for "tangential filtration."

B. "Underside"

Bearing in mind that it is "[t]he claim language [that] defines the bounds of claim scope," Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed. Cir. 2002), we find that neither the term "microporous plasma separation membrane," the ordinary meaning of the words that compose the disputed claim term, nor any of the claim language surrounding the disputed claim term compels reading the term to mean that it can only receive blood from its underside. Indeed, as explained by Polymer Tech's own expert, "[i]n tangential filtration, the actual location of the filter is really of no consequence. . . . The flow of fluid is primarily . . . tangential to the filter so the filter can either be above or below . . . where the blood is flowing." (Emphasis added). Although the specification and file history appear to speak only of placing the physical transport medium under the separation medium, none of the statements contain "words or expressions of manifest exclusion or restriction, representing clear disavowal of claim scope." Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002). Moreover, we find no place within the patent documents where the patentee may have acted as a lexicographer to narrow the scope of the claim term. See id. We therefore find no basis to conclude that

the reference to the "underside" of the separating membrane is a proper limitation and reverse the district court on its inclusion of that limitation within the definition of "microporous plasma separation membrane."

IV.

Lifestream adds that the district court appeared to unduly limit the claim scope because of concern that the claim language was overly broad. We disagree that such concern, if present, lead to it to erroneously conclude that the arguments of the patent applicant should apply to the claims at issue.

Each side levels charges that the other has waived arguments that both press on appeal. We find the charges are either without merit or moot. Lifestream also complains that the district court improperly relied upon testimony from Polymer Tech's expert, Dr. Smith, to support the claim construction. As far as we can tell, the district court neither cites nor mentions Dr. Smith as a basis for its analysis. We find no merit to Lifestream's complaint.

Lastly, Lifestream contends that the district court, as a result of clerical error, confused the definition of "test membrane" with the term "filtering membrane."[2] Polymer Tech submitted no argument to rebut Lifestream's contention. We agree that it appears that the district court confused the two types of membranes. The '716 patent informs us that the filtering membrane blocks "LDL and VLDL precipitates and prevents them from reaching the plasma collecting test membrane." '716 patent, col. 4, ll. 23-25. "[I]ts function is to block the precipitated particles from reaching the test zone." Id., col. 3, ll. 26-31. Thus, Lifestream is correct in asserting that the filtering membrane "receives blood or plasma, retains LDL and VLDL precipitates from the blood or plasma, and passes filtered plasma to the next adjacent level." By contrast, the test zone, corresponding to the test membrane, "contains enzymes and chromogens for cholesterol assay so that plasma reaching it (now devoid of LDL and VLDL components) reacts with the reagents in plasma collecting test membrane 6, producing a colored reaction, the intensity of color being proportional to HDL cholesterol concentration." Id., col. 4, ll. 34-41. In other words, the test membrane "gathers filtered plasma without LDL or VLDL precipitates and performs a measurable reaction with the filtered plasma." We agree with Lifestream that the district

court confused "filtering membrane" with "test membrane." The term "filtering membrane" should have been construed to mean: "A thin, soft pliable layer that receives blood or plasma, retains LDL and VLDL precipitates from the blood or plasma, and passes filtered plasma to the next adjacent level."

CONCLUSION

We hold that reliance by the Patent Office upon arguments made by the patentee during prosecution is not necessary to find argument-based estoppel. We affirm the district court's claim construction construing "physical transport medium" and "microporous plasma separation membrane" to require lateral flow for tangential filtration, but reverse the district court for its inclusion of the "underside" limitation in the definition of "microporous plasma separation membrane" and its reading of "filtering membrane." Because we reverse some of the district court's claim construction, we vacate the court's judgment of noninfringement, and remand the case for a determination of whether Polymer Tech infringes claim 1 of the '716 patent under the correct claim construction, which excludes the "underside" limitation and has the correct membrane definition.

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[1] Claim 1 reads as follows:

> A device for determining HDL cholesterol by obtaining plasma from whole blood and determining HDL level from the plasma which comprises:
>
> (a) a physical transport medium;
>
> (b) a microporous plasma separation membrane having a first surface against said physical transport medium and having a second surface opposite and away from said physical transport medium;
>
> (c) a filtering membrane having a first surface and a second surface and being capable of filtering LDL and VLDL precipitates from a blood or plasma flow containing these, said filtering membrane having its first surface in contact with said microporous plasma separation membrane;
>
> (d) at least one plasma collecting test membrane in contact with a portion of said second surface of said filtering membrane and having one or more

reactants therein capable of reacting with said plasma to display at least one characteristic of HDL cholesterol; and,

(e) LDL and VLDL reactants to form LDL and VLDL precipitates, said reactants being located in one or more of said microporous plasma separation membrane, said filtering membrane and said physical transport medium.

[2] The district court had construed "filtering membrane" to mean:

A thin, soft pliable layer that gathers filtered plasma without LDL or VLDL precipitates and performs a measurable reaction with the filtered plasma.