NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

ROCHE DIAGNOSTICS OPERATIONS, INC., CORANGE INTERNATIONAL LIMITED,
Plaintiffs-Appellants

v.

LIFESCAN INCORPORATED, NOVA BIOMEDICAL CORPORATION,
Defendants-Appellees

2015-1356

Appeal from the United States District Court for the District of Delaware in No. 1:07-cv-00753-RGA, Judge Richard G. Andrews.

Decided: September 22, 2016

GRANTLAND GILBERT DRUTCHAS, McDonnell, Boehnen, Hulbert & Berghoff, LLP, Chicago, IL, argued for plaintiffs-appellants. Also represented by PAULA FRITSCH.

WILLIAM C. ROOKLIDGE, Gibson, Dunn & Crutcher LLP, Irvine, CA, argued for defendant-appellee Lifescan Incorporated. Also represented by JAYSEN CHUNG, San Francisco, CA.

BRADFORD J. BADKE, Sidley Austin LLP, New York, NY, argued for defendant-appellee Nova Biomedical Corporation. Also represented by SONA DE.

Before PROST, *Chief Judge,* MAYER, and REYNA, *Circuit Judges.*

REYNA, *Circuit Judge*.

Roche Diagnostics Operations, Inc. and Corange International Limited ("Roche") appeal from the United States District Court for the District of Delaware's grant of summary judgment in favor of Lifescan Incorporated and Nova Biomedical Corporation ("Defendants"). The district court entered judgment of non-infringement after construing the term "electrode" in a way that excluded Defendants' products. The district court's claim construction was correct and we therefore *affirm* the court's judgment of non-infringement.

BACKGROUND

I. Patents

This case involves U.S. Patent Nos. 7,276,146 ("'146 patent") and 7,276,147 ("'147 patent"). Both patents claim priority to the same provisional application and have similar specifications.[1]

The patents claim methods for determining the concentration of glucose in a blood sample. Claim 1 of the '146 patent is representative of the asserted claims:

> 1. A method of determining the concentration of glucose in a blood sample, comprising;

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[1] This opinion refers to the specification portions shared by both patents as the "shared specification."

providing a disposable biosensor test strip including a capillary chamber having a depth suitable for capillary flow of blood and holding a volume of between about 0.1 µl and about 1.0 µl of the blood sample, a working electrode and a counter or reference electrode disposed within the capillary chamber, and a reagent proximal to or in contact with at least the working electrode, the reagent including an enzyme and a mediator, the reagent reacting with glucose to produce an electroactive reaction product;

applying a blood sample containing glucose into the capillary chamber, the capillary chamber directing capillary flow of the blood sample into contact with the reagent to cause the blood sample to at least partially solubilize or hydrate the reagent;

detecting the blood sample in the capillary chamber;

following said detecting, applying or controlling the voltage or current across the working and counter or reference electrodes;

electrooxidizing or electroreducing the electroactive reaction product at the working electrode; and

within 10 seconds after said detecting, determining and providing a readout of the glucose concentration in the blood sample, said determining comprising correlating the electrooxidized or electroreduced electroactive reaction product to the concentration of glucose in the blood sample.

'146 patent col. 29 ll. 38–67.

II. Procedural History

Roche sued Defendants for infringement of the '146 and '147 patents. The parties disagreed about the proper construction of certain claim limitations that included the term "electrode." Roche initially proposed constructions describing the function of particular electrodes. For example, it argued that "working electrode" should be construed as "[a]n electrode in an electrochemical cell at which the reaction of interest occurs." J.A. 12. Roche argued that the claimed electrodes "may be of any dimension that provides useful or advantageous results with relatively small samples." J.A. 14487. Defendants argued that the term "electrode" should be construed as "microelectrode having a width of 15 to 100 µm."[2] J.A. 12. For example, Defendants proposed that "working electrode" should be construed as "[a] working microelectrode having a width of 15 to 100 µm." *Id.*

At a *Markman* hearing, Roche opposed Defendants' "electrode" constructions, alleging that "electrode" included not only microelectrodes but also macroelectrodes. Roche argued that the term "electrode" included certain electrodes with widths from 300 to 1,000 µm, which Roche asserted were macroelectrodes, not microelectrodes. Roche did not dispute that microelectrodes only included electrodes up to 100 µm in width.

The district court found that the claimed electrodes were limited to microelectrodes by assertions in the shared specification about "the invention" and arguments during prosecution distinguishing prior art. *Roche Diagnostics Operations, Inc. v. Abbott Diabetes Care*, 667 F.

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[2] The unit of measurement is µm, the abbreviation for micrometer, which is a millionth of a meter and is also referred to as a micron.

Supp. 2d 429, 435 (D. Del. 2009). It construed "electrode" to mean "microelectrode having a width of 15 µm up to approximately 100 µm." *Id.* at 442–43.

Roche moved for reconsideration. While Roche conceded that the claim term "electrode" did not include macroelectrodes, Roche argued that microelectrodes included electrodes up to 1,000 µm in width.

The district court denied Roche's motion for reconsideration, but said "[i]t's a great point for the Federal Circuit, and I actually think you might have a point. But it will be interesting to see what they say." J.A. 35. The court entered summary judgment of non-infringement on the basis that Defendants' products contain electrodes larger than 100 µm.

Roche appealed to this court and repeated the argument it had first raised in its motion for reconsideration: it asserted that microelectrodes included electrodes up to 1,000 µm in width. *Roche Diagnostics Operations, Inc. v. Lifescan Inc.*, 452 F. App'x 989, 994–95 (Fed. Cir. 2012) (*Roche I*). Defendants opposed Roche's arguments, but did not challenge whether these arguments were properly before the court. *Id.* at 994–97.

As the district court had not previously addressed the parties' arguments regarding 1,000 µm microelectrodes, we declined to address them and remanded so that the district court could consider them in the first instance. *Id.*

On remand, the district court considered the parties' arguments and affirmed its earlier decision that "electrode" meant "microelectrode having a width of 15 µm up to approximately 100 µm." *Roche Diagnostics Operations, Inc. v. Abbott Diabetes Care, Inc.*, No. CV 07-753-RGA,

2014 WL 6871579, at *4–6 (D. Del. Dec. 5, 2014) ("*Remand Op.*").[3]

This appeal followed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

Roche challenges the district court's claim construction. We review a district court's claim construction *de novo*. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). If a district court makes factual findings

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[3] On appeal previously, this court noted uncertainty as to whether Roche's motion for reconsideration was procedurally appropriate. *Roche I*, 452 F. App'x at 994. On remand, the case was assigned to a different district court judge. The district court judge stated that it appeared that Roche's motion for reconsideration had originally been denied on procedural grounds, but that it was uncertain whether Defendants waived procedural challenges to arguments first asserted in Roche's reconsideration motion by not raising them before this court on appeal. *Remand Op.*, 2014 WL 6871579, at *3–4.

On appeal now, Defendants contend that Roche's current claim construction arguments, which are premised on microelectrodes including electrodes up to 1000 μm in width, are procedurally barred because they were first raised in Roche's reconsideration motion, and Roche did not appeal the district court's denial of that motion in the prior appeal. Roche asserts that Defendants have waived procedural challenges to these arguments by not raising them when this case was previously on appeal. Roche also argues that the district court erred in applying the Third Circuit's standards for motions for reconsideration.

We need not address these procedural issues, because we affirm the district court's claim construction even when we consider Roche's arguments.

about extrinsic evidence that underlie its construction, we review the factual findings for clear error. *Id.* at 842.

Claim terms are "generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). A term's ordinary meaning is "its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321. A specification may define claim terms expressly or by implication. *Id.* at 1320–21.

The district court construed "electrode" to mean a "microelectrode having a width of 15 µm up to approximately 100 µm." *Remand Op.*, 2014 WL 6871579, at *6. It interpreted part of the shared specification as indicating "that an electrode might be characterized as a microelectrode in one of two situations: (1) where there is greater than 50% non-planar diffusion, or (2) where the electrode has a width less than 100 µm." *Id.* at *4–5 (referencing '146 patent col. 4 ll. 29–48 and '147 patent col. 4 ll. 10–29). The district court explained that converting the diffusion characteristic into a size was difficult, and its construction of which electrodes are microelectrodes relied on the 100 µm width description. *Id.* at *5.

The only aspect of the district court's construction of "electrode" that Roche challenges on appeal is the upper width limit of "up to approximately 100 µm."[4] Roche

[4] Roche does not appeal the district court's determination that Roche disclaimed macroelectrodes during the patents' prosecution. Roche also does not dispute that the claimed microelectrodes should be distinguished from macroelectrodes on the basis of their width or that the lower limit for width should be 15 µm. *See* Roche Br. 62 (arguing that "electrode" should be construed as "microe-

argues that the claimed electrodes include electrodes up to 1,000 µm. Defendants disagree.

Roche presents several arguments why the district court improperly construed "electrode." First, Roche argues that the district court based the construction on a width the shared specification describes as a preferred embodiment. Second, Roche asserts that the district court erred in its analysis of diffusion, examples 3–5 of the '146 patent, and claim 48 of the '146 patent. Finally, Roche claims that "microelectrode" has an ordinary meaning of any electrode measured in micrometers or µm, up to 1,000 µm. We address these arguments in turn.

I

According to Roche, the district court improperly limited "electrode" based on a width the shared specification describes as a preferred embodiment. The district court's construction was based on a portion of the shared specification which stated, in part, that "[i]t is also understood that some electrode configurations can cause diffusion to take place by a mix of planar and non-planar paths, in which case the electrodes can be considered a microelectrode array, *especially* if the diffusion occurs predominantly (e.g., greater than 50%) according to a non-planar path, or if the size of the electrodes is less than 100 µm, e.g., less than 50 µm." *See, e.g.*, '146 patent col. 4 ll. 42–48 (emphasis added).

Roche argues that the word "especially" in the paragraph's final sentence means that this paragraph merely describes a preferred embodiment. We disagree.

Roche is correct that a claim term expressed in general descriptive words typically will not be limited to a

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lectrode[] having a width of 15 µm up to approximately 1,000 µm.").

numerical range described in the written description as referring to a preferred embodiment. *RF Del., Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003). But the paragraph the district court's construction relies on includes the only mention of macroelectrodes in either patent's specification. The paragraph distinguishes microelectrodes from macroelectrodes based on the type of diffusion they cause. An electrode that causes "a mix of planar and non-planar" diffusion will be considered a microelectrode especially when the diffusion is predominantly nonplanar or the electrode's size is less than 100 µm. '146 patent col. 4 ll. 42–48; '147 patent col. 4 ll. 23–29.

Considering the specifications as a whole, we agree with the district court that the language it cited defines how a microelectrode can be distinguished from a macroelectrode. *See*, *e.g.*, *Phillips*, 415 F.3d at 1315 (The specification is "the single best guide to the meaning of a disputed term."). While other parts of the shared specification refer to various widths including 100 µm as being "preferred," *see, e.g.*, '146 patent col. 3 ll. 9–12, this does not prevent the portion of the shared specification that the district court's interpretation relied on from providing a definition of microelectrodes.

II

Roche also argues that the shared specification's discussion of diffusion precludes a 100 µm limit for microelectrode width. However, Roche states that "diffusion alone does not provide a clear demarcation of where a microelectrode ends and where a macroelectrode begins." Roche Br. 41. Roche also admits that "diffusion simply depends on far too many variables to be limited to any particular size electrode." *Remand Op.*, 2014 WL 6871579, at *5.

Roche fails to provide a persuasive rationale for why its proposed 1,000 µm width limit is more consistent with

the shared specification's discussion of diffusion than any other width limit. We disagree that the shared specification's discussion of diffusion precludes a 100 μm limit.

III

Roche further argues that certain examples in the '146 patent show that microelectrodes can have a width greater than 100 μm. Examples 3, 4, and 5 of the '146 patent disclose electrodes that are wider than 100 μm. While the '146 specification does not identify the electrodes in these examples as microelectrodes, Roche asserts that an inventor declaration filed during the prosecution of the patents identified electrodes that either are the same electrodes or are "similar to" these electrodes as being microelectrodes. Roche Br. 11, 42–43.

On remand, the district court noted that, while the parties agreed that the term "electrode" was to be construed the same way for both patents, the examples from the '146 patent were not included in the '147 patent. *Remand Op.*, 2014 WL 6871579, at *5. The district court decided that these examples "must be read in light of the microelectrode definition" in the shared specification. *Id.* For this principle, the district court cited *Sinorgchem Co., Shandong v. International Trade Commission*, 511 F.3d 1132, 1138 (Fed. Cir. 2007), and quoted *Sinorgchem's* statement that "[w]here . . . multiple embodiments are disclosed, we have previously interpreted claims to exclude embodiments where those embodiments are inconsistent with unambiguous language in the patent's specification or prosecution history." *Id.*

We agree with the district court's decision not to adopt a construction that is inconsistent with the definitional paragraph discussed above. Finding these electrodes to be microelectrodes would be inconsistent with the shared specification's explanation that the microelectrodes cause diffusion "in a non-planar fashion," and that, where electrodes "cause diffusion to take place by a mix of

planar and non-planar paths," electrodes will be considered microelectrodes when the diffusion is predominantly "according to a non-planar path" or "if the size of the electrodes is less than 100 µm." '146 patent col. 4 ll. 42–48; '147 patent col. 4 ll. 23–29. As a result, we find that these examples are unclaimed embodiments because they include electrodes larger than 100 µm.

This determination is consistent with other indications that examples 3–5 of the '146 patent are unclaimed embodiments. For example, the patents' claims are limited to methods testing blood samples, while the examples disclose embodiments that were evaluated testing saline, which is not blood. '146 patent at col. 26 ll. 10–col. 28 ll. 51; Figs. 10–12. Although Roche claims that the embodiments disclosed in the examples could be used with blood, the shared specification includes language suggesting that these embodiments could only be used for body fluids other than blood, such as serum or plasma. Specifically, all of the independent claims recite "a capillary chamber having a depth suitable for capillary flow of blood." *See*, *e.g.*, '146 patent col. 29 ll. 42–43. Examples 3–5 in the '146 patent disclose embodiments having capillary depths of 62 µm, but the shared specification suggests that a capillary depth of at least 100 µm is needed for blood:

> Capillaries with depths of greater than or equal to 100 µm have been found to allow fast fill of blood with hematocrits from 20 to 70% to reliably flow into the chamber. Capillary depths of less than 100 microns to 25 microns can be used *for other biological fluids* such as serum, plasma, intersti[t]ial fluid, and the like.

'146 patent col. 19 ll. 45–50; '147 patent col. 18 ll. 27–32 (emphasis added).

Because we agree with the district court that interpreting these '146 examples as microelectrodes would be

inconsistent with the shared specification's disclosure distinguishing macroelectrodes from microelectrodes, we need not decide whether the patents' claimed "depth suitable for capillary flow of blood" includes depths less than 100 μm. Therefore, we also need not address the district court's related determination that dependent claim 48 of the '146 patent—which claims depths below 100 μm—was not enabled, and whether it was invalid for lack of written description.

IV

Finally, Roche argues that extrinsic evidence demonstrates that the ordinary meaning of microelectrode is any electrode measured in micrometers, up to 1,000 μm. The district court found this extrinsic evidence was unpersuasive, and that it did not "trump the intrinsic evidence." *Remand Op.*, 2014 WL 6871579, at *6. To the extent that this is a factual finding, we review it for clear error.

We find that the court did not clearly err in finding Roche's extrinsic evidence unpersuasive. In fact, Roche's extrinsic sources do not demonstrate that microelectrode has an ordinary meaning of any electrode measured in micrometers, up to 1,000 μm. For example, one of the sources Roche cites is the Kirk-Othmer Encyclopedia of Chemical Technology. This encyclopedia states that "[s]mall, referring to the diameter of the electrode, is about a millimeter for microelectrodes." 9 Raymond E. Kirk et al., *Kirk-Othmer Encyclopedia of Chemical Technology*, 97, 4th ed. (1994). This statement arguably supports Roche's proposed construction, as it mentions 1,000 μm microelectrodes. (1 millimeter is equal to 1,000 μm.) However, it appears to declare that a 1,000 μm electrode is a *small* microelectrode. As Defendants note, the encyclopedia cites 15 R. Mark Wightman and David O. Wipf, *Voltammetry at Ultramicroelectrodes* (1989) as support for this statement. That article, provided by Defendants, states that "[t]he term 'microelectrode' is

already in routine use for electrodes with dimensions approaching a centimeter or greater," which is ten times larger than the 1,000 μm limit Roche proposes. J.A. 28261. The article further states that "[t]his area is still sufficiently new that a uniform nomenclature for these electrodes has not yet been developed." *Id.* Even the extrinsic evidence Roche cited is inconsistent with its assertion that 1,000 μm is an established width limit for microelectrodes.

CONCLUSION

We affirm the district court's construction of electrode as a "microelectrode having a width of 15 μm up to approximately 100 μm."

AFFIRMED

COSTS

Costs to Defendants.