IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Roche Diagnostics Operations, Inc., and **Corange International Ltd.,** Plaintiffs, v. **Abbott Diabetes Care, Inc., Abbott Diabetes Care Sales Corp., Bayer Healthcare, LLC, Diagnostic Devices, Inc., Lifescan, Inc.,** and **Nova Biomedical Corp.,** Defendants.	Civil Action No. 07-753-RGA

MEMORANDUM OPINION

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December 5, 2014

ANDREWS, U.S. District Judge:

Pending before the Court, on remand from the United States Court of Appeals for the Federal Circuit, is consideration of the construction of the term "electrode."

On September 15, 2009, the Court construed the claimed "electrode" as "microelectrode having a width of 15 μm up to approximately 100 μm." *Roche Diagnostics Operations, Inc. v. Abbott Diabetes Care*, 667 F.Supp.2d 429, 435-36 (D.Del. 2009) (the "*Markman Decision*"); (D.I. 563 & 564). Two weeks later, Roche moved for reconsideration, positing a different claim construction theory than the one it had previously advanced. (D.I. 636). On January 21, 2010, at the second pretrial conference, the Court denied the motion for reconsideration. (D.I. 852 ¶ 4). On July 27, 2010, the Court granted summary judgment of non-infringement for Defendants LifeScan and Nova. (D.I. 850 at 2 ¶¶ 2 & 3). Roche appealed the Court's summary judgment order as being predicated, in part, on the erroneous claim construction of "electrode." (D.I. 852 ¶ 2). On January 25, 2012, the Federal Circuit vacated the judgment of non-infringement and remanded to this Court to consider the parties' arguments that pertain to the scope of the term "electrode." *Roche Diagnostics Operations, Inc. v. LifeScan Inc.*, 452 F. App'x 989, 998 (Fed. Cir. 2012) (the "*CAFC Decision*"). This Court duly heard argument on the "electrode" construction. For the reasons set forth below, the Court holds that the proper construction of "electrode" is "microelectrode having a width of 15 μm up to approximately 100 μm."

I. PROCEDURAL ISSUES

Roche filed this lawsuit in 2007, alleging patent infringement, against various defendants including Lifescan and Nova. The case followed the normal course of hotly-contested patent litigation. In due course, the Court held a Markman hearing. In preparation for the hearing, the parties submitted briefing. One of the terms in dispute was "electrode."

Roche did not originally specify any proposed construction for "electrode." (D.I. 357 at

6) (listing three terms for construction, not including "electrode"). Defendants proposed that the claimed "electrode" should be construed as a "microelectrode having a width of 15 to 100 μm." (D.I. 359 at 19) (*E.g.*, "a working electrode" is "a working microelectrode having a width of 15 to 100 μm"). Roche responded to Defendants' proposed claim construction, arguing that the claims were not limited to microelectrodes (D.I. 380 at 12-14) and were not limited to "having a width smaller than 100 μm." (*Id.* at 14-23); *CAFC Decision*, 452 F. App'x at 992 ("[A]t the claim construction stage, Roche argued . . . that the term 'electrode' in the asserted patent claims includes both 'micro' and 'macro' electrodes. Roche asserted that micro-electrodes are up to approximately 100 μm wide.") .

The Court rejected Roche's proposed construction and concluded that "the claims should . . . be limited to microelectrodes." *Markman Decision*, 667 F. Supp.2d at 435; *see also id.* ("[T]he written description repeatedly confirms that the invention, and hence the claims, are directed to methods utilizing microelectrodes."); *CAFC Decision*, 452 F. App'x at 994-95 ("Roche agrees . . . that the claims do not cover all electrodes of all widths. [Roche] now concedes that the term 'electrode' only covers micro-electrodes, not macro-electrodes."). The Court also addressed the parties' arguments concerning the preferred dimensions of microelectrodes. Not surprisingly, as all parties agreed that the upper limit of a microelectrode was "approximately 100 μm," *see id.* at 992 ("Roche asserted that microelectrodes are up to approximately 100 μm, the Court concluded that the claimed 'microelectrodes' had a width of 15 μm up to approximately 100 μm. The Court also noted that the specification "does not describe the upper limit of the range as a strict cutoff" and, therefore, the construction "illuminates the

size of the microelectrode to one of skill in the art without improperly excluding microelectrodes that are *slightly* larger than the preferred dimensions." *Markman Decision*, 667 F. Supp. 2d at 436.

Roche moved for reconsideration of the claim construction, not seeking to reargue that the asserted claims read only on microelectrodes (D.I. 636, p.1), but arguing that microelectrodes may have widths up to 1000 μm. In support of the motion, Roche identified five bases – one being "[n]ewly obtained extrinsic evidence" and the other four being various "[e]rror[s] of apprehension ([l]aw])." (*Id.*, pp. 2-3). At a pretrial hearing on January 14, 2010, the Court stated, "I've read the briefing. I'm not convinced that I made a mistake or that I didn't consider all the arguments. So what I'm saying is that I would maintain the claim construction, but I'm going to give you an opportunity to put something in place to tell me that I shouldn't." (D.I. 858 at 47:7-13). After the hearing, the Court entered an order inviting an opposition brief to the Court's tentative denial of Roche's motion for reconsideration of the claim construction order. (O.O., Jan. 14, 2010).

Roche submitted the requested briefing on January 19, 2010. (D.I. 774). The briefing dealt solely with a prosecution history argument based on *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363 (Fed. Cir. 2009), which was decided less than two weeks before the Court's claim construction ruling. (D.I. 774 at 4). Roche contended that *Martek* required the Court to consider prosecution history as a whole, rather than in a piecemeal fashion, and set forth the rule that preferred examples do not limit the claims to those preferred examples. (*Id.* at 5). *Martek* was not cited in any of Roche's previous briefing regarding reconsideration of the claim

construction ruling. Thus, this briefing was essentially a second motion for reconsideration. The Court held a second pretrial hearing on January 21, 2010, during which the Court stated, "I've looked at the paper on reconsideration. It'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. So we will be moving ahead with that Rule 54 judgment." (D.I. 859 at 5:24-6:6). The Court then denied the motion for reconsideration and entered summary judgment of non-infringement based on the "electrode" construction. (D.I. 850). Roche appealed. (D.I. 852).

The unique procedural posture presented an interesting set of circumstances on appeal. The Federal Circuit stated, "The district court did not address whether reconsideration was procedurally appropriate, and, if so, whether Roche's argument has merit." *CAFC Decision*, 452 F. App'x at 994. It is not clear to me which reconsideration argument (or arguments) the Federal Circuit was addressing when it made this statement. Under Third Circuit law, reconsideration is appropriate if there is: "(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *Max's Seafood Café v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999) (citing *North River Ins. Co. v. CIGNA Reins. Co.*, 52 F.3d 1994, 1218 (3d Cir. 1995)). The District Court considered Roche's initial argument for reconsideration and initially determined that it did not meet the standards for reconsideration. (D.I. 858 at 47:7-13) ("I'm not convinced that I made a mistake or that I didn't consider all the arguments."). The Court then allowed Roche to submit more briefing, which Roche did, making one argument that was not in the original motion for reconsideration. Roche

used the opportunity to present a second motion for reconsideration (even if not denominated as such). It seems clear to me that it was this subsequent argument that the District Court described as making "a great point." I say that both because the District Court had already rejected the arguments raised in the first motion for reconsideration, and because the language "a great point" seems more appropriate for a one point argument than a five point argument. The District Court followed up by entering an order denying without discussion the motion for reconsideration. The second argument for reconsideration appears to have been a non-starter in the Federal Circuit, as *Martek* and its related argument are not mentioned in the *CAFC Decision*.

The Federal Circuit thus appears to have conducted its review based on the content of the first motion for reconsideration combined with the Court's comment on the second argument for reconsideration. *CAFC Decision*, 452 F. App'x at 993 ("Roche moved the district court for reconsideration, positing a different claim construction theory. This time, Roche . . . argued that micro-electrodes may indeed be up to 1,000 μm wide. Roche also submitted new extrinsic evidence to support its motion for reconsideration. At the hearing for the motion for reconsideration, the district court remarked that Roche's new claim construction argument raised 'a great point.'").

After remand, at the September 5th hearing, I asked the parties to address (1) whether Roche's motion for reconsideration was procedurally appropriate, and (2) if so, whether Defendants waived any procedural objections to Roche's new claim construction argument by not addressing them on appeal to the Federal Circuit. Defendants argue that Roche did not appeal the Court's denial of reconsideration, *see* D.I. 1008, pp. 5-6, and therefore should be

foreclosed from now rearguing the claim construction. Defendants do acknowledge that Roche listed the denials of reconsideration in the notice of appeal, *see* D.I. 852, at ¶¶(3) & (4), but state that since Roche did not brief those issues on appeal, Defendants were under no obligation to raise the issue, and have waived nothing. (D.I. 1008 at pp. 11-13).

Motions to reconsider are disfavored. *See* D. Del. LR 7.1.5(a) ("Motions for reargument shall be sparingly granted."). The motion for reconsideration (D.I. 636) was based on "new extrinsic evidence" and four legal arguments. The "new extrinsic evidence" was mostly new only in the sense that it had not been presented by Roche before. For example, Roche relied primarily upon a 1993 U.S. patent (*id.*, p. 5), a 2001 standard text and a 2008 technical dictionary (*id.*, pp. 6-7), and a 1939 journal article. (*Id.*, p.8). It also found support in the 2008 reexamination proceedings. (*Id.*) It also claimed support from snippets of Defendants' experts' depositions, although the experts disagreed with Roche's position. The experts' depositions carry no independent weight, and everything else was available to Roche before the claim construction hearing. Roche offers no explanation why it should be getting a second bite at claim construction based on its "new extrinsic evidence." In my opinion, the "new extrinsic evidence" was not new and therefore was not a proper ground for reconsideration.

Roche raised four legal arguments. Roche couched them as errors of apprehension. Yet I do not think that is a fair characterization. The District Court understood Roche's argument. Indeed, it understood the importance of "electrode" among the mass of terms the parties wanted construed, *see Markman Decision*, 667 F. Supp. 2d at 434, and understood the parties' different positions. In my opinion, it is fair to say that the error of apprehension was Roche's, not the

Court's, as Roche argued a position in the claim construction hearing that it has subsequently partially abandoned. It is true that it raises new lines of analysis in support of its legal conclusion, but it is no different than moving for reconsideration of a point based on non-controlling authority one could have raised in the first instance. "Rolling claim construction" is not justified by a party's considered claim construction choices that it later regrets. There was no intervening change in the controlling law, and there was no clear error of law. I think to some extent the Federal Circuit's decision shows that there was no clear error of law. The Court's extensive and detailed analysis shows a host of unanswered questions. Thus, in my opinion, the Motion for Reconsideration (D.I. 636) was properly denied on procedural grounds. *See, e.g., Golden Bridge Tech., Inc. v. Apple Inc.*, 758 F.3d 1362, 1369 (Fed. Cir. 2014) ("An argument made for the first time in a motion for reconsideration comes too late and is ordinarily deemed waived."). Thus, on that basis alone, I adopt the District Court's original claim construction. I think such a decision is particularly warranted here where Roche is not only raising an argument it did not make, but an argument that is contrary to the argument it did make.

I do not, however, decide this issue in a vacuum. I am cognizant that a district court must respect any controlling decision of a court of appeals. The Federal Circuit noted, "Nova and Lifescan do not dispute on appeal, however, that Roche's argument should be addressed on the merits." *CAFC Decision*, 452 F. App'x at 994. That statement could be interpreted as either (1) any procedural issues about the propriety of the motion to reconsider are waived, or (2) despite any procedural issues about the propriety of the motion to reconsider, the parties have argued the merits without any objection. On the one hand, the Federal Circuit's statement sounds like a

conclusion that any procedural objections were waived. On the other hand, Defendants have represented that they did not waive the arguments in their briefing. (*See* D.I. 1021, at 38 ("[W]e were very clear in our briefs."). When I pressed them on the point, the response was underwhelming. Defendants cite to places in their briefs before the Federal Circuit where they "preserved and did not waive their arguments about the reconsideration standard not being met," (D.I. 1023 at 2), but the provided citations do not show any argument at all about reconsideration being procedurally improper. (*See* D.I. 1009-3 at 13, 15, 35; D.I. 1009-4 at 18-19, 21). I do not see any evidence that Defendants put the Federal Circuit on notice that Defendants were arguing that the Federal Circuit should affirm the claim construction on the basis of a waiver argument. As a result, the Federal Circuit cited no Third Circuit cases, or indeed any cases at all, in connection with either how the district court treats a motion to reconsider, or how a court of appeals treats the denial of a motion to reconsider. Exactly what the Federal Circuit decided, if anything, about the continuing ability of this Court to address procedural failures in the way the claim construction issue was handled is a question that I have pondered without coming to a conclusion in which I am confident during the unforgivably long period of time that this decision has been under advisement.

The Federal Circuit recognized that the motion for reconsideration raised the issue "whether reconsideration was procedurally appropriate," *CAFC Decision*, 452 F. App'x at 994, and that the District Court did not address it. I think that, having found the District Court's handling of the reconsideration motion was insufficient for lack of explanation, it is unlikely the Federal Circuit then decided essentially the same issue with no discussion at all. Thus, on

balance, I think the Federal Circuit did not actually decide the motion to reconsider issue. Having stated my view that the "procedural appropriateness" issue is dispositive, I nevertheless think the better course is to proceed from this point as if it were not dispositive.

II. THE MERITS

While the Federal Circuit considered reaching Roche's arguments, the Court noted that the record was not fully developed. *CAFC Decision*, 452 F. App'x at 996. The District Court had a record at the Markman hearing that contained everything the parties wanted to submit. Roche submitted with its first motion for reconsideration three volumes including 28 exhibits. (D.I. 637-39). If the record after a Markman hearing, a first motion for reconsideration, and a second argument for reconsideration was insufficient to support a basis for concluding the argument in Roche's favor, why should Roche get a fourth shot at making its case? The Federal Circuit "le[ft] it to the discretion of the district court whether and to what extent each party should be allowed to supplement the record with additional briefing and evidence . . . ." *CAFC Decision*, 452 F. App'x at 997. Since it appeared that I was going to need to reconsider the claim construction in light of the issues identified by the Federal Circuit, it seemed to me to be in the interest of justice to allow the parties to supplement the record as they saw fit. They did so, raising a discovery dispute along the way. (D.I. 993-94).

The Federal Circuit noted four issues for this Court to address. First, the Federal Circuit asked this Court to address "what degree of non-planar diffusion justifies characterizing an electrode as a [microelectrode]." *CAFC Decision*, 452 F. App'x at 995. Second, the Federal Circuit asked this Court to address whether examples 3, 4, and 5 of the '146 patent are

unclaimed embodiments. *Id.* at 996. Third, the Federal Circuit asked this Court to address whether "claim 48" is enabled. *Id.* at 996-97. Fourth, the Federal Circuit asked this Court to address whether it should consider new extrinsic evidence presented by Roche in support of its new claim construction. *Id.* at 997.

With respect to the Federal Circuit's first question concerning non-planar diffusion, in my opinion, the specification answers this question. Specifically, the specification states:

> It 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.

'147 patent at col.4 ll.23-29. The specification, thus, seems to indicate 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. There is some difficulty in converting the first characterization into a size, as it gives no basis for doing so. As Roche admits, "diffusion simply depends on far too many variables to be limited to any particular size electrode." (D.I. 988, p.17). It would also make no sense to describe a microelectrode as being either (1) less than 1000 μm wide, or (2) less than 100 μm wide. The second characterization supports the Court's construction. What is clear to me is that neither characterization supports Roche's 1000 μm microelectrode construction.

Second, the Federal Circuit asked this Court to address whether examples 3, 4, and 5 of the '146 patent are unclaimed embodiments. The Court's original claim construction considered these examples and concluded that "such examples cannot pertain to claimed embodiments

because, although the claims are limited to blood samples, the examples include a capillary depth insufficient for the flow of blood." *Markman Decision*, 667 F.Supp.2d at 435. The parties agree that "electrode" should be construed the same way in the '146 and '147 patents. The '146 and '147 patents share a common specification, but examples 3, 4, and 5 only appear in the '146 patent. These examples must be read in light of the microelectrode definition in the common specification. *Sinorgchem Co., v. ITC*, 511 F.3d 1132, 1138 (Fed. Cir. 2007) ("Where, as here, multiple embodiments are disclosed, we have previously interpreted claims to exclude embodiments where those embodiments are inconsistent with the unambiguous language in the patent's specification or prosecution history."). Therefore, consistent with the Court's original claim construction, the Court concludes that examples 3, 4, and 5 are unclaimed embodiments.

The Court asked whether claim 48 of the '146 patent is enabled. Enablement is a question of law based on underlying factual findings. The issue is whether, at the time of filing the patent application, one skilled in the art, having read the specification, could practice the invention without "undue experimentation." *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013). When enablement is asserted as an invalidity counterclaim, the parties have a right to a jury trial on it, and the underlying facts have to be proved by clear and convincing evidence. I do not imagine, however, that the Federal Circuit was asking me to have a trial on claim 48 before construing the patent. Instead, I think what the Federal Circuit had in mind was more the "enablement lite" sort of analysis that sometimes arises in connection with prior art references. *See, e.g., Robocast, Inc. v. Apple Inc.,* 2014 WL 1622002, *10 n.5 (D. Del. Apr. 22, 2014); *Forest Labs,., Inc. v. Ivax Pharm., Inc.*, 438 F. Supp. 2d 479, 487 n.3 (D. Del.

2006), *aff'd*, 501 F.3d 1263 (Fed. Cir. 2007).

Claim 48 of the '146 patent recites capillary depths of 25-200 μm and depends from claim 31. The prosecution history reveals that claim 48 is not enabled. Roche originally filed claims in both the '146 and '147 patent applications that were broadly directed to "an analyte in a test sample," rather than specifying only blood. (*See* D.I. 987, Ex. 24 at 45; *id.*, Ex. 20 at 36). On June 5, 2006, Roche cancelled the original '147 patent claims and proposed new claims directed to testing "blood or serum" in a "capillary chamber having a depth of 25-200 μm." (D.I. 987, Ex. 21 at 3). On August 28, 2006, the Examiner rejected those claims for lack of written description given the specification's capillary depth requirement, noting that the specification did not "support using a capillary depth less than 100 μm for a blood sample for determining glucose concentration in the sample within about 10 seconds after said detecting." (*Id.*, Ex. 22 at 9). The Examiner further stated that "[t]he specification in fact teaches away from this feature." (*Id.*).

On December 22, 2006, Roche narrowed both the '146 and '147 patent claims to test strips "including a capillary chamber having a depth suitable for capillary flow of blood." (D.I. 986, Ex. 20 p.4 [*see* D.I. 991-17 at 5]; D.I. 987, Ex. 21 p.4 [*see* D.I. 992-1 at 5]). In its remarks, Roche stated that the claims had been limited to testing blood using strips having "a depth suitable for capillary flow of blood." (D.I. 986, Ex. 20 pp. 25-26 [*see* D.I. 991-17 at 26-27]; D.I. 987, Ex. 21 p.28 [*see* D.I. 992-1 at 29]). However, on April 20, 2007, Roche added dependent claim 48 into the '146 application, which used the same "25-200 μm" capillary depth language that the Examiner had previously rejected for lack of written description. (D.I. 1002-6 at 100 ¶

135; *id.* at 115 ¶ 127). The claims must be read in light of their specification. The specification teaches that a capillary depth of less than 100 μm is not suitable for the capillary flow of blood. Thus, in order for a person of ordinary skill in the art to practice the invention of claim 48, that person would have to figure out how to obtain suitable capillary flow of blood in a capillary chamber which the specification teaches is not suitable. There is no information in the patent that would assist in doing this, and thus I conclude that it would take undue experimentation to practice claim 48. (It also appears, as the Examiner concluded when focusing on the issue, that claim 48 would be invalid for lack of written description.). The Court, thus, concludes that claim 48 is not enabled, and its existence does not alter the Court's construction of microelectrode.

Finally, with respect to the new extrinsic evidence presented by Roche in support of its new claim construction, the Court has considered it but does not find this evidence persuasive. A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318-19 (Fed. Cir. 2005) (en banc); *see also Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995)(en banc), *aff'd*, 517 U.S. 370 (1996). Extrinsic evidence, however, is considered less reliable and less useful in claim construction than the patent and its prosecution history. *Phillips*, 415 F.3d at 1318-19 (discussing "flaws" inherent in extrinsic evidence and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered in the context of intrinsic evidence"). The Federal Circuit

specifically has cautioned against reliance on dictionaries because "the use of [a] dictionary may extend beyond what should properly be afforded by the inventor's patent." *Id.* at 1322. Indeed, the Federal Circuit has noted that "even technical dictionaries or treatises . . . may suffer from some of these deficiencies" and that there is "no guarantee that a term is used in the same way in a treatise as it would be by the patentee." *Id.* The Court concludes that Roche's dictionary references do not trump the intrinsic evidence already considered by this Court.

Accordingly, the Court affirms its earlier construction of the term "electrode" as a "microelectrode having a width of 15 μm up to approximately 100 μm."

III. CONCLUSION

For the reasons set forth in this Memorandum Opinion, the Court affirms its earlier claim construction of the term "electrode."

An Order consistent with this Opinion will be entered.

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ORDER

This 5th day of December 2014, for the reasons stated in the accompanying memorandum opinion, IT IS HEREBY ORDERED that:

The term "electrode" is construed as "microelectrode have a width of 15 μm up to approximately 100 μm."

Richard G. Andrews
United States District Judge