

United States Court of Appeals for the Federal Circuit

IN RE ABBOTT DIABETES CARE INC.

2011-1516, -1517

(Reexamination Nos. 90/007,903, 90/007,910)

Appeal from the United States Patent and Trademark
Office, Board of Patent Appeals and Interferences.

Decided: September 28, 2012

GREGORY A. CASTANIAS, Jones Day, of Washington, DC, argued for appellant. With him on the brief were THOMAS E. FRIEBEL, of New York, New York; and ALYSON G. BARKER, of Irvine, California. Of counsel on the brief was LAURA A. THOMAS, Landau Gottfried & Berger LLP, of San Francisco, California.

SYDNEY O. JOHNSON, JR. Associate Solicitor, United States Patent and Trademark Office, of Alexandria, Virginia argued for appellee. With him on the brief were RAYMOND T. CHEN, Solicitor, and AMY J. NELSON, Associate Solicitor.

Before LOURIE, PROST, and WALLACH, *Circuit Judges*.

PROST, *Circuit Judge*.

Abbott Diabetes Care, Inc. (“Abbott”) appeals from ex parte reexamination proceedings in which the Board of Patent Appeals and Interferences (“Board”) rejected numerous claims of U.S. Patents Nos. 6,175,752 (“’752 patent”) and 6,565,509 (“’509 patent”). *Ex parte Abbott Diabetes Care Inc.*, No. 2010-006873, 2011 WL 180171 (B.P.A.I. Jan. 18, 2011) (“’752 BPAI Op.”), *reh’g denied*, 2011 WL 1661489 (B.P.A.I. Apr. 29, 2011) (“’752 Reh’g Denial”); *Ex parte Abbott Diabetes Care Inc.*, No. 2010-009711, 2011 WL 180180 (B.P.A.I. Jan. 18, 2011) (“’509 BPAI Op.”), *reh’g denied*, 2011 WL 1661491 (B.P.A.I. Apr. 29, 2011) (“’509 Reh’g Denial”). Because the Board’s rejections were based on unreasonable claim constructions and because the U.S. Patent and Trademark Office (“PTO”) concedes that the examiner’s official notice rejections should be withdrawn, we vacate-in-part and remand.

I. BACKGROUND

Abbott owns the ’752 patent and the ’509 patent. Both patents share a common specification that describes methods and devices “for the in vivo monitoring of an analyte using an electrochemical sensor to provide information to a patient about the level of the analyte” in the bloodstream. ’752 patent col.1 ll.8-10; ’509 patent col.1 ll.11-14. Specifically, the specification describes methods and devices for monitoring glucose levels for diabetics. ’752 patent col.1 ll.13-21; ’509 patent col.1 ll.17-25. The specification notes that a variety of devices exist for monitoring glucose levels in the blood stream, but some of these devices include sensor guides that are “typically bulky and do not allow for freedom of movement.” ’752 patent col.1 ll.51-54; ’509 patent col.1 ll.55-59. According

to the “Background of the Invention” portion of the specification, these prior art systems also feature external wires and cables connecting the various components that restrict the movements and daily life activities of the user:

[T]he sensor guides or the sensors include cables or wires for connecting the sensor to other equipment to direct signals from the sensor to an analyzer. The size of the sensor guides and presence of cables and wires hinders the convenient use of these devices for everyday applications. There is a need for a small, compact device that can operate the sensor and provide signals to an analyzer without substantially restricting the movements and activities of a patient.

'752 patent col.1 ll.55-63; '509 patent col.1 ll.58-67.

The first claims of each patent are representative. Claim 1 of the '752 patent recites:

1. A sensor control unit comprising: a housing adapted for placement on skin and adapted to receive a portion of an *electrochemical sensor* extending out of the skin having a plurality of contact pads; a plurality of conductive contacts disposed on the housing and configured for coupling to the plurality of contact pads on the electrochemical sensor; and an rf transmitter disposed in the housing and coupled to the plurality of conductive contacts for transmitting data obtained using the electrochemical sensor.

(Emphasis added).

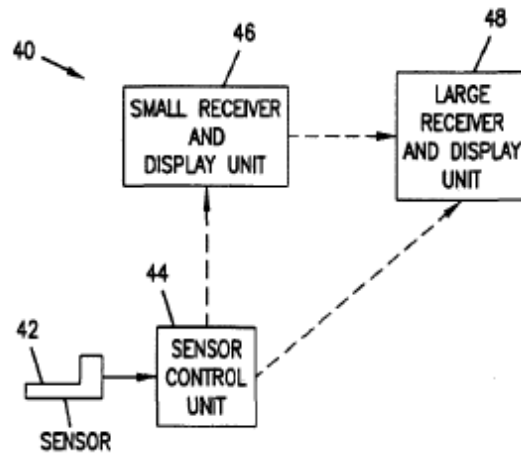
Claim 1 of the '509 patent, which was amended during reexamination, recites the following:

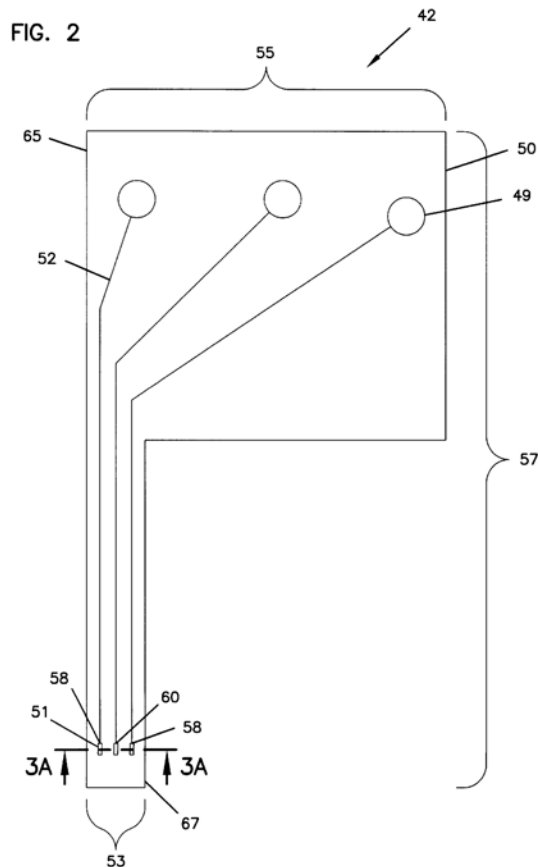
1. A sensor assembly to monitor an analyte, the sensor assembly comprising: a flexible transcutaneous *electrochemical sensor* comprising non-leachable, analyte-responsive enzyme, the sensor having a distal end and a proximal end defining the length of the sensor, such that a portion of the sensor lies above the skin when transcutaneously positioned; and a sensor control unit adapted for placement on skin and adapted for receiving a portion of the proximal end of the transcutaneous electrochemical sensor, the sensor control unit comprising a rf transmitter that is configured and arranged to intermittently and repeatedly transmit data related to analyte-dependent signals generated by the electrochemical sensor, wherein the portion of the sensor above the skin is maintained in a *substantially fixed* position relative to the position of the sensor control unit when the sensor control unit is placed on the skin and receives the proximal end of the sensor transcutaneously positioned.

(Emphasis added).

The specification describes the claimed “electrochemical sensor” as “a device configured to detect the presence and/or measure the level of an analyte in a sample via electrochemical oxidation and reduction reactions on the sensor.” ’752 patent col.5 ll.47-50; ’509 patent col.5 ll.64-67. As depicted in Figures 1 and 2 of Abbott’s patents, the electrochemical sensor (42) uses conductive traces (52) and contact pads (49) to transfer signals to a sensor control unit (44).

FIG. 1





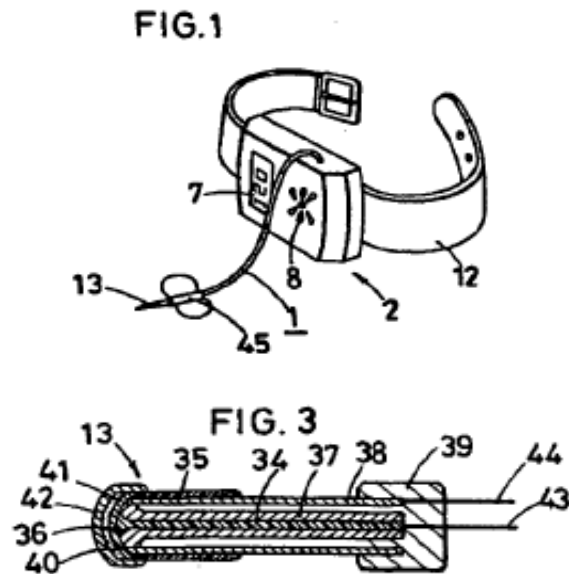
On March 27, 2006, the PTO granted third-party requests for ex parte reexamination of Abbott’s patents.¹

¹ There are currently two lawsuits pending in the United States District Court for the District of Delaware. See *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 05-590 (D. Del. filed Aug. 11, 2005); see also *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 06-514 (D. Del. filed Aug. 17, 2006). These actions have been consolidated and stayed pending the outcome of several reexamination proceedings, including the reexaminations for the ’752 and ’509 patents at issue in this appeal.

During reexamination, the examiner finally rejected all of the claims subject to the reexamination as being indefinite, anticipated, or obvious over several combinations of prior art references. Particularly, the examiner relied on European Patent Application 0 098 592 (“Shichiri I”), two articles written by Shichiri et al. (“Shichiri II” and “Shichiri III”), U.S. Patent No. 5,390,671 (“Lord II”), combinations of other prior art references, and the examiner’s official notice of certain features known in the prior art.

In reviewing the examiner’s rejections, the Board first had to determine the correct construction of “electrochemical sensor,” namely, whether “the transcutaneous electrochemical sensor recited in the claims include[s] wires and cables.” *’752 BPAI Op.*, 2011 WL 180171, at *4. The Board reasoned that even though the specification criticizes the external cables and wires of the prior art, and none of the embodiments in Abbott’s patents include external cables or wires connecting to the sensor control unit, the absence of a more express limiting statement meant that the “cables or wires” description of the prior art sensors carried through to the claimed electrochemical sensor as well. Ultimately, the Board concluded that “when giving the term ‘electrochemical sensor’ the broadest reasonable interpretation in light of the [s]pecification, the electrochemical sensor includes wires and cables.” *Id.* at *8; *’509 BPAI Op.*, 2011 WL 180180, at *7. The Board also addressed the proper construction of the term “substantially fixed” recited in amended claim 1 of the *’509* patent and concluded that the term would “be understood by the skilled worker to allow some movement of the sensor relative to the position of the sensor control unit.” *’509 BPAI Op.*, 2011 WL 180180, at *8.

Having construed the claims, the Board went on to consider whether the claims were properly rejected in view of the prior art of record. The Board limited its discussion of the prior art primarily to Shichiri I, “with the understanding that our comments apply equally to rejections based on Shichiri II and Fischell.” *’752 BPAI Op.*, 2011 WL 180171, at *4; *’509 BPAI Op.*, 2011 WL 180180, at *4. Figures 1 and 3 of Shichiri I disclose a watch-shaped transmitting assembly (2), with a blood sugar detection unit (1) that includes an electrode means (13) for measuring blood sugar. The signal from the electrode means is fed through insulated lead wires (43) and (44) through the catheter (45) to the watch-shaped assembly. Additionally, the Board agreed with the examiner’s conclusion that lead wires 43 and 44 are part of the sensor.



Applying its construction of “electrochemical sensor” as covering sensors with external cables or wires, the

Board held that Shichiri I anticipates claim 1 of the '509 patent and also anticipates or renders obvious a large portion of the other claims. *'509 BPAI Op.*, 2011 WL 180180, at *8-9. In addressing the construction of “substantially fixed” in amended claim 1 of the '509 patent, the Board reasoned that although Shichiri I discloses wires (43) and (44) that are flexible and allow for some movement, “they are still somewhat restrained in movement, and are therefore ‘substantially fixed,’ by virtue of being tethered to the watch assembly unit.” *Id.* at *8. That is to say, the Board equated “somewhat restrained in movement” to “allow[ing] some movement.”

With respect to the '752 patent, the Board again applied its claim construction of “electrochemical sensor,” and held that claim 1 and a large portion of the other claims are unpatentable in light of Shichiri I in combination with Lord II. Although Shichiri I does not teach “at least one contact pad” as required by claim 1 of the '752 patent, the Board found that this feature was taught by Lord II, which discloses a transcutaneous sensor having sensor electrodes at one end and contact pads adapted for connection to a monitor on the other end. Moreover, the Board found that claim 1 “does not impose any particular type of connection” between the electrochemical sensor’s “contact pads” and the housing’s “conductive contacts,” such as a direct connection, and therefore allows for a cable or wire connection between the contact pads and the conductive contacts. *See '752 BPAI Op.*, 2011 WL 180171, at *8. Accordingly, the Board held that “Lord II provides evidence that the conductive contacts in the sensor control unit of Shichiri I would have been configured for coupling the equivalent contact pads of Shichiri I’s modified sensor.” *Id.* at *9. The Board also affirmed the examiner’s use of official notice in combination with other

primary references to reject 157 newly added independent and dependent claims.

Abbott filed requests for rehearing, arguing that, when construing the term “electrochemical sensor,” the Board improperly relied on the specification’s statement that “sensors include cables or wires.” According to Abbott, that statement simply criticizes the restrictive prior art sensors—it does not describe the claimed electrochemical sensor. The Board disagreed, instead holding that the statement “provides insight as to how one of ordinary skill in the art would interpret the term ‘sensor.’” *’752 Reh’g Denial*, 2011 WL 1661489, at *1; *’509 Reh’g Denial*, 2011 WL 1661491, at *1. The Board also found that nothing in Abbott’s patents explicitly disclaims sensors that include external cables or wires. Additionally, Abbott argued that the Board misapplied its own construction of “substantially fixed” and also applied an incorrect standard for official notice. But so too here, the Board rejected Abbott’s arguments.

Abbott timely appealed, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II. DISCUSSION

We review the Board’s legal conclusions de novo and its factual determinations for substantial evidence. *In re Am. Acad. Sci. Tech Ctr.*, 367 F.3d 1359, 1363 (Fed. Cir. 2004). Substantial evidence means “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Claim construction is a legal question, reviewed de novo. *Am. Acad. Sci.*, 367 F.3d at 1363. In contrast to

district court proceedings involving an issued patent, claims under examination before the PTO are given their broadest reasonable interpretation consistent with the specification. *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007).

A. “Electrochemical Sensor”

The parties’ primary dispute centers on whether the broadest reasonable construction of “electrochemical sensor” includes external cables and wires connecting the sensor to its control unit. Abbott argues that the Board improperly relied on language in its patents that was directed to the failings of the prior-art devices—failings that the claimed invention attempts to overcome. Abbott notes that all descriptions of the claimed electrochemical sensor in the specification are devoid of any mention of external cables or wires for connecting to the sensor control unit. Abbott further contends that the plain language of the claims—“contact pads” on the electrochemical sensor “coupl[ed]” to the “conductive contacts” of the sensor control unit’s housing in the ’752 patent, or having the transcutaneous electrochemical sensor “receiv[ed]” by the sensor control unit in the ’509 patent—does not support an embodiment with external cables or wires attached to the sensors.

The PTO argues that the specification acknowledges, albeit when disparaging the prior art, that sensors can include external cables or wires. *See Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1306 (Fed. Cir. 2011) (“In general, statements about the difficulties and failures in the prior art, without more, do not act to disclaim claim scope.”). The PTO further contends that neither the claims nor the specification explicitly require the term “electrochemical sensor” to exclude sensors that

have external cables or wires. According to the PTO, Abbott was required to make a “clear disavowal” or an “express disclaimer” of claim scope. See *Am. Acad. Sci.*, 367 F.3d at 1363 (“[A] patentee ‘may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.’”) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002)); *In re Bigio*, 381 F.3d 1320, 1325-26 (Fed. Cir. 2004) (“Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition.”).

The PTO also notes that the specification describes an embodiment of the “sensor control unit 44” that “usually includes no additional cables or wires to other electronic components or other devices.” ’752 patent col.29 ll.65-67; ’509 patent col.29 ll.60-63. Relying on this statement, the PTO argues that if the patentees had intended to disclaim an electrochemical sensor with cables or wires, they should have made a similar disclaimer with respect to the electrochemical sensor—although the PTO acknowledges that the term “usually” is less than precise. But in any event, the PTO asserts that Abbott had “the opportunity and responsibility to remove any ambiguity in claim term meaning by amending” the claims during reexamination, yet failed to do so. *Bigio*, 381 F.3d at 1324.

We agree with Abbott that the Board’s construction of “electrochemical sensor” is unreasonable and inconsistent with the language of the claims and the specification. As a preliminary matter, the claims themselves suggest connectivity without the inclusion of cables or wires: an “electrochemical sensor” having “contact pads” that are

“coupl[ed]” to “conductive contacts” (in the ’752 patent), or a “transcutaneous electrochemical sensor” that is “receiv[ed]” by the sensor control unit (in the ’509 patent). That suggestion is only reinforced by the specification. “Although the PTO emphasizes that it was required to give all claims their broadest reasonable construction, . . . this court has instructed that any such construction be consistent with the specification, and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2011) (internal citation and quotation marks omitted). Indeed, “the specification ‘is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Here, the specification contains only disparaging remarks with respect to the external cables and wires of the prior-art sensors: “[t]he size of the sensor guides and presence of cables and wires hinders the convenient use of these devices for everyday applications.” ’752 patent col.1 ll.57-59; ’509 patent col.1 ll.61-63. In fact, the primary purpose of the invention was to provide “a small, compact device that can operate the sensor and provide signals to an analyzer without substantially restricting the movements and activities of the patient.” ’752 patent col.1 ll.60-63; ’509 patent col.1 ll.64-67.

Even more to the point, every embodiment disclosed in the specification shows an electrochemical sensor without external cables or wires. Indeed, the only mention of a sensor with external cables or wires in Abbott’s patents is a single statement addressing the primary deficiency of the prior art. It is true that the specification

does not contain an explicit statement disclaiming electrochemical sensors with external cables or wires. But this is not an instance where the specification would necessarily have to disavow an embodiment that would otherwise be covered by the plain language of the claims—rather, claim terms like “coupl[ed]” and “receiv[ed]” are entirely consistent with and even support the specification’s exclusive depiction of an electrochemical sensor without external cables or wires. We have held that “[e]ven when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents.” *Iredeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004) (internal quotation marks omitted). Here, Abbott’s patents “repeatedly, consistently, and exclusively” depict an electrochemical sensor without external cables or wires while simultaneously disparaging sensors with external cables or wires. *Id.* at 1303.

While Abbott’s patents define the electrochemical sensor’s connectivity by implication, the PTO argues that our case law still requires an explicit disclaimer of external cables or wires. But the PTO’s reliance on cases like *American Academy of Science* and *Retractable Technologies* is misplaced. Although the patentee in *American Academy of Science* argued that it had disparaged and therefore disclaimed the use of “multi-user computers such as mainframes” in the background of the invention section of its patent, that same background section and the “specification as whole” actually supported configurations that included multi-user computers. 367 F.3d at 1367. And in *Retractable Technologies*, the patentee’s supposed disclaimer of “cutting” in the background of the invention was undermined by an embodiment in the

specification that indicated that some forms of cutting fell within the scope of the claimed invention. 653 F.3d at 1306. In the case before us, however, nothing suggests or even hints that the claimed electrochemical sensor can include external cables or wires. Instead, Abbott's patents consistently show the opposite.

To be sure, the Board noted that Abbott's patents acknowledge that the "sensor control unit 44 usually includes no additional cables or wires." The PTO argues that a similar statement would be required to disclaim an electrochemical sensor with external cables or wires. This particular statement, however, refers to a specific embodiment where the transmission of data from the sensor control unit (44) to the receiver/display unit (46) "may also be performed using methods other than rf transmission, including optical or wire transmission." '752 patent col.52 ll.56-65; '509 patent col.52 ll.56-65. Instead of being an explicit disclaimer, the statement is actually an explicit acknowledgment that at least some embodiments of the sensor control unit can include external cables or wires. Tellingly, the specification does not contain a similar acknowledgment with respect to the electrochemical sensor.

We conclude, therefore, that under the broadest reasonable construction, "electrochemical sensor" is properly interpreted to mean a discrete electrochemical sensor devoid of external connection cables or wires to connect to a sensor control unit. Accordingly, we vacate the Board's decisions as to the patentability of Abbott's independent

claims at issue² and remand for the Board to apply the correct claim construction.

B. “Substantially Fixed”

The parties do not dispute that the correct construction of “substantially fixed” in the ’509 patent allows for “some movement of the sensor relative to the position of the sensor control unit.” Instead, the dispute between the parties lies in whether “some movement” includes the degree of movement in the Shichiri I system such that the sensor need only be “somewhat restrained.” We conclude that it does not.

The external wires of the Shichiri I sensor are only “somewhat restrained” because they are tethered to a watch-shaped assembly and therefore only restrained by human arm or wrist movement. This degree of arm and wrist movement is not only significantly greater than the movement allowable under the Board’s original construction of “substantially fixed,” it is also greater than the movement described in the specification. Indeed, the embodiments disclosed in the ’509 patent all show the above-skin portion of the electrochemical sensor maintained in a fixed position. Specifically, the specification teaches a “support structure 82” that “hold[s], support[s], and/or guide[s] the sensor 42 into the correct position.” ’509 patent col.34 ll.54-55. While the Board’s original construction is reasonable in view of the specification, the Board’s modified construction requiring only a “somewhat restrained” sensor is not. On remand, the Board should apply its original construction of “substantially fixed.”

² These include claims 1, 32, 33, 39, 88, 89, 90, 244, 247, and 248 of the ’752 patent and claims 1, 11, 26, 229, 230, 231, and 233 of the ’509 patent.

C. Official Notice

During reexamination of the '752 patent, the examiner invoked the doctrine of official notice in combination with other primary references to reject 157 newly added independent and dependent claims. The Board affirmed, and now nineteen of these official notice-rejection claims are before this court on appeal.³ The PTO, however, now agrees with Abbott that the examiner's official notice rejection of these nineteen claims should be remanded and withdrawn. Therefore, we vacate the Board's rejection of these nineteen claims and remand to the Board for appropriate further proceedings.

III. CONCLUSION

The Board's construction of "electrochemical sensor" and its modified construction of "substantially fixed" are unreasonable and inconsistent with the specification. We therefore vacate the Board's decisions as to the patentability of Abbott's independent claims at issue and remand for the Board to apply the correct claim constructions. We also vacate the Board's official notice rejection of the nineteen claims before us and remand to the Board for appropriate further proceedings.

VACATED-IN-PART AND REMANDED

³ These include claims 96, 98, 107, 125, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247-248, and 251 of the '752 patent.