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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* Abbott Diabetes Care Inc.,  
Patent Owner and Appellant

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Appeal 2010-006837  
Reexamination Control 90/007,910  
Patent 6,175,752 B1  
Technology Center 3900

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Before RICHARD E. SCHAFER, RICHARD M. LEBOVITZ, and  
JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

ROBERTSON, *Administrative Patent Judge*.

DECISION ON APPEAL<sup>1</sup>

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<sup>1</sup> The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” shown on the PTOL-90A cover letter attached to this decision.

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Abbott Diabetes Care Inc. (hereinafter “Appellant”), the owner of the patent under reexamination (hereinafter “the ‘752 Patent”), appeals under 35 U.S.C. §§ 134(b) and 306 from a final rejection of claims 1-35, 38-46, 49-51, 53, 54, 58-65, 74-86, 88-90, 92-94, 96, 98, 107, 125, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and 251 (Supplemental Appeal Brief filed September 3, 2009, hereinafter “App. Br.,” at 4; Final Office Action mailed October 2, 2008).<sup>2</sup> We have jurisdiction under 35 U.S.C. §§ 134(b) and 306.

We AFFIRM.

#### STATEMENT OF THE CASE

This reexamination proceeding arose from a third-party request for *ex parte* reexamination filed by Dexcom, Inc. (Request for *Ex Parte* Reexamination filed February 1, 2006, hereinafter “the Request”). The ‘752 Patent issued on Jan. 16, 2001 from Application 09/070,677 filed on April 30, 1998, which is related to Application 09/667,199 filed on September 21, 2000, now United States Patent 6,565,509 B1 (hereinafter “the ‘509 Patent”), the latter which is the subject of Reexamination Control 90/007,903 (Appeal No. 2010-009711). Appellant informs us that there are a number of other related patents that have undergone or are currently undergoing reexamination. (Second Supplemental Appeal Brief filed October 18, 2010, 4-5.) We also understand that the ‘752 and ’509 Patents,

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<sup>2</sup> Claims 36, 37, 47, 48, 52, 55-57, 66-73, 87, and 91 have not been subjected to reexamination. (App. Br. 4.)

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as well as the other related patents have been the subject of various patent infringement actions, identified at pages 3-4 of the Second Supplemental Appeal Brief, which have been consolidated and stayed pending the outcome of the reexamination proceedings. (Order in the litigation styled *Abbott Diabetes Care, Inc. v. Dexcom, Inc.* (C.A. No. 06-514 GMS, Del.), dated September 30, 2007, signed by Chief United States District Judge Gregory M. Sleet; App. Br, App'x C.)

We heard Patent Owner's oral arguments on October 20, 2010, a written transcript of which will be entered into the record in due course.

The '752 Patent involves a sensor control unit, a sensor assembly, and an analyte monitoring system. (Col. 2, ll. 18-61.)

Claims 1 and 33 on appeal read as follows (underlining and brackets indicate changes made relative to the issued claims of the '752 Patent):

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.

33. A sensor assembly, comprising:

a sensor comprising a flexible substrate with at least one working electrode, at least one counter electrode, and at least one contact pad coupled to each of the working and counter electrodes, the sensor being adapted for implantation of a

portion of the sensor comprising the working and counter electrodes through skin; and

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;

a plurality of conductive contacts disposed on the housing and configured for coupling to the contact pads of the sensor; and

an rf transmitter disposed in the housing and coupled to the plurality of conductive contacts for transmitting data obtained using a sensor.

(Claims App'x.)

The Examiner relied upon the following as evidence of unpatentability (Examiner's Answer mailed November 19, 2009, hereinafter "Ans.," 8-9):

Shichiri (Shichiri I)	EP 0 098 592	Jan. 18, 1984
Fischell	US 4,494,950	Jan. 22, 1985
Rogoff	US 4,538,616	Sep. 3, 1985
Skotheim	EP 0 390 390 A1	Oct. 3, 1990
Lord (Lord II)	US 5,390,671	Feb. 21, 1995
Cheney	WO 96/25089	Aug. 22, 1996 <sup>3</sup>
Lord (Lord I)	US 5,569,186	Oct. 29, 1996
Heller	US 5,593,852	Jan. 14, 1997

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<sup>3</sup> Although relied upon in the rejections of record as detailed below, the Examiner did not list Cheney or Cormier in the Evidence Relied Upon section of the Answer. (Ans. 8-9.)

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Besson US 5,957,854 Sep. 28, 1999

Cormier US 6,219,574 B1 Apr. 17, 2001

Shichiri, et al., “Telemetry Glucose Monitoring Device with Needle-Type Glucose Sensor”, *Diabetes Care*, Vol. 9, no. 3, May-June 1986, pp. 298-301. (Shichiri II).

Shichiri, et al., Ch. 15 “Needle Type Glucose Sensor for Wearable Artificial Endocrine Pancreas” Ko et al., (Ed.), Implantable Sensors for Closed-Loop Prosthetic Systems (1985) pp. 197-210. (Shichiri III).

Shichiri et al., “Glycaemic Control in Pancreatectomized Dogs with a Wearable Artificial Endocrine Pancreas” *Diabetologia* (1983). (Shichiri IV).

Appellant relied on certain parts of the following (App. Br. 138):

App. B: Decl. of James Say dated April 11, 2008.

#### THE REJECTIONS

The Examiner rejected claims 1-35, 38-46, 49-51, 53, 54, 58-65, 74-86, 88-90, 92-94, 96, 98, 107, 125, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and 251 as follows:

- I. Claims 33, 96, 98, 107, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and 251 under 35 U.S.C. § 305 as not being proposed for a proper purpose (Ans. 8-11);
- II. Claims 1-25, 27, 28, 32-34, 38-40, 42-44, 49-51, 53, 54, 58-65, 76-84, 88-90, 92, 96, 98, 107, 125, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and 251 under 35 U.S.C. § 103(a) as being obvious over Shichiri I in view of Lord II (Ans. 11-28);

- III. Claims 26, 31, 41, 45, 46, 85, and 86 under 35 U.S.C. § 103(a) as obvious over Shichiri I in view of Fischell and Benson (Ans. 28-32);
- IV. Claims 29, 74, and 75 under 35 U.S.C. § 103(a) as obvious over Shichiri I and Lord II, further in view of Fischell, Besson, and Heller (Ans. 32-33); and
- V. Claims 93 and 94 under 35 U.S.C. § 103(a) as obvious over Shichiri I and Lord II, further in view of Heller (Ans. 33-34);
- VI. Claims 30 and 35 under 35 U.S.C. § 103(a) as obvious over Shichiri I and Lord II, further in view of Skotheim (Ans. 34-35).

Relying on the Request, the Examiner also sets forth the following additional rejections (Ans. 35-47):

- VII. Claims 1-12, 14-16, 20-25, 27, 28, 30-35, 38-40, 42-45, 49-51, 53, 54, 58-64, 76-86, 88-90, 92-94, 96, 98, 107, 125, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and 251 under 35 U.S.C. § 103(a) as being obvious over Shichiri I in view of Cheney (similar rejections are set forth over Shichiri II, Shichiri III, or Fischell in view of Lord I or Cheney);
- VIII. Claims 9, 10, and 17-19 under 35 U.S.C. § 103(a) as obvious over Shichiri I, Shichiri II, Shichiri III, or Fischell in view of Lord II or Cheney and further in view of Cormier;
- IX. Claims 17-19, 29, 45, 74, and 75 under 35 U.S.C. § 103(a) as obvious over Shichiri I, Shichiri II (claims 17-19, 74, and 75),

Shichiri III (claims 17-19), or Fischell (claims 17-19) in view of Lord II or Cheney and further in view of Besson;

- X. Claim 65 under 35 U.S.C. § 103(a) as obvious over Shichiri I in view of Cheney and further in view of Rogoff; and
- XI. Claim 74 under 35 U.S.C. § 103(a) as obvious over Shichiri I or Shichiri II in view of Lord II or Cheney and further in view of Fischell.

At the outset, we note that the positions of both the Examiner and Appellant regarding the base references, Shichiri I, Shichiri II, Shichiri III, and Fischell are each very similar if not the same. Accordingly, we provide a detailed discussion of the rejections based on Shichiri I, with the understanding that our comments apply equally to the rejections based on Shichiri II and Fischell. We address the rejections based on Shichiri III separately.

#### ISSUES

The dispositive issues in this appeal are:

1. Were claims 33, 96, 98, 107, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and 251 properly amended or added consistent with 35 U.S.C. § 305?
2. Does the transcutaneous electrochemical sensor recited in the claims include wires and cables?
3. Does Shichiri I in view of Lord II disclose the sensor control unit structure with a housing, a plurality of contacts, and an rf transmitter as recited in claim 1?

4. Did the Examiner err in concluding that it have been obvious to modify the sensor disclosed in Shichiri I to include at least one contact pad in view of Lord II as required in the sensor assembly recited in claim 33?
5. Does Shichiri I in view of Lord II suggest the mounting unit as recited in claim 3?
6. Did the Examiner properly take Official Notice that certain aspects recited in the claims were well known in the art?
7. Did the Examiner err in concluding that it would have been obvious to modify the sensor control unit of Shichiri I and Besson to include an rf receiver in view of Fischell and Benson as recited in claim 26?
8. Did the Examiner err in determining that Shichiri I inherently discloses a calibrator as recited in claim 45 or that including a calibrator in an analyte monitoring system would have been obvious to one of ordinary skill in the art?
9. Would the analyte system of claim 65, including at least two alarms, have been obvious in view of Shichiri I, Cheney and Rogoff?

#### FINDINGS OF FACT (“FF”)

##### *The ‘752 Patent*

1. The ‘752 Patent discloses that “sensors include cables or wires for connecting the sensors to other equipment to direct the signals to an analyzer.” (Col. 1, ll. 54-57.)

2. The '752 Patent discloses that the "on-skin sensor control unit 44 usually includes no additional cables or wires to other electronic components or other devices." (Col. 29, ll. 60-62.)
3. The '752 Patent discloses that the sensor control unit may be mated with a mounting control unit, and that the mounting control unit may further contain a support structure for "holding the sensor 42 in place." (Col. 32, ll. 59-62.)

*Shichiri I*

4. Figure 1 of Shichiri I is reproduced below:

**FIG. 1**

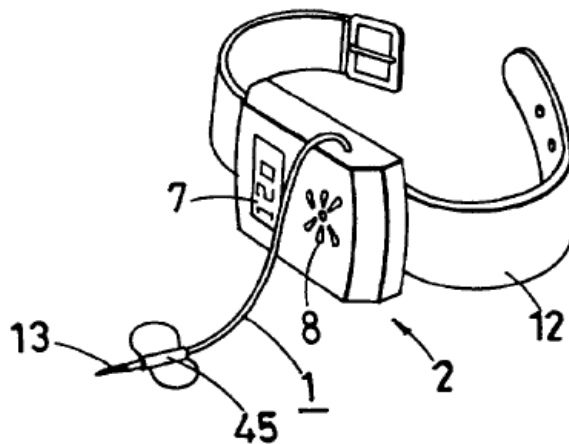


Figure 1 depicts a watch-shaped transmitting assembly 2, including a blood sugar detecting unit 1 including an electrode means 13 and catheter 45, blood sugar display 7, alarm buzzer 8, and transmitting aerial 12. (P. 7, l. 21- p. 8, l. 5; p. 9, ll. 23-25.)

5. Figure 2 of Shichiri I is reproduced below:

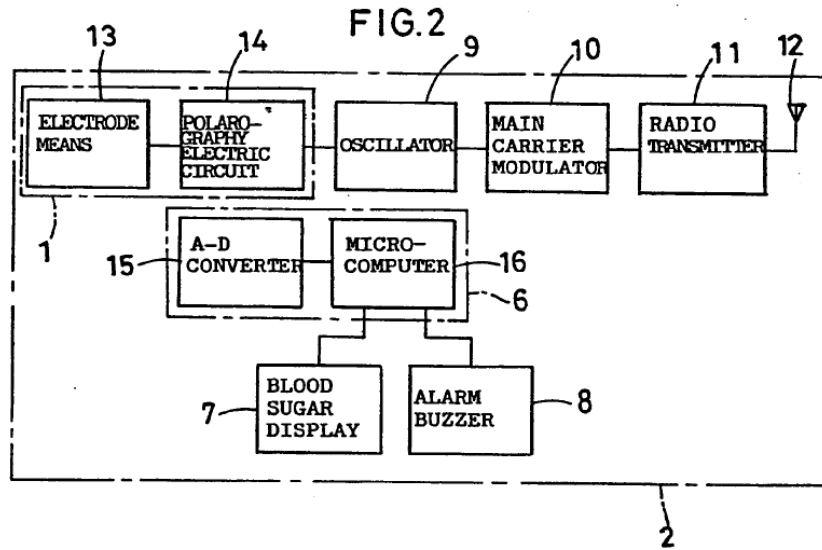


Figure 2 depicts an overall block diagram, which shows blood sugar detecting unit 1, electrode means 13, and polarography electric circuit 14, along with transmitting assembly 2, which includes radio transmitter 11. (P. 6, l. 5, p. 7, l. 21 – page 8, l. 6.)

6. Figure 3 of Shichiri I is reproduced below:

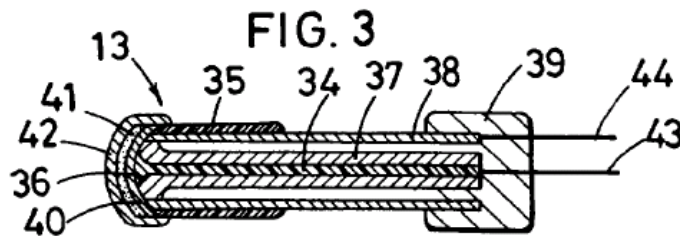


Figure 3 depicts an electrode means 13 (sensor) including platinum electrode 34 and cylinder 38, which are fixed together by plastic plug 39, and connected at their rear ends to lead wires 43 and 44. (p. 8, l. 19- p. 9, l. 23.)

*Lord II*

7. Figure 1 of Lord II is reproduced below:

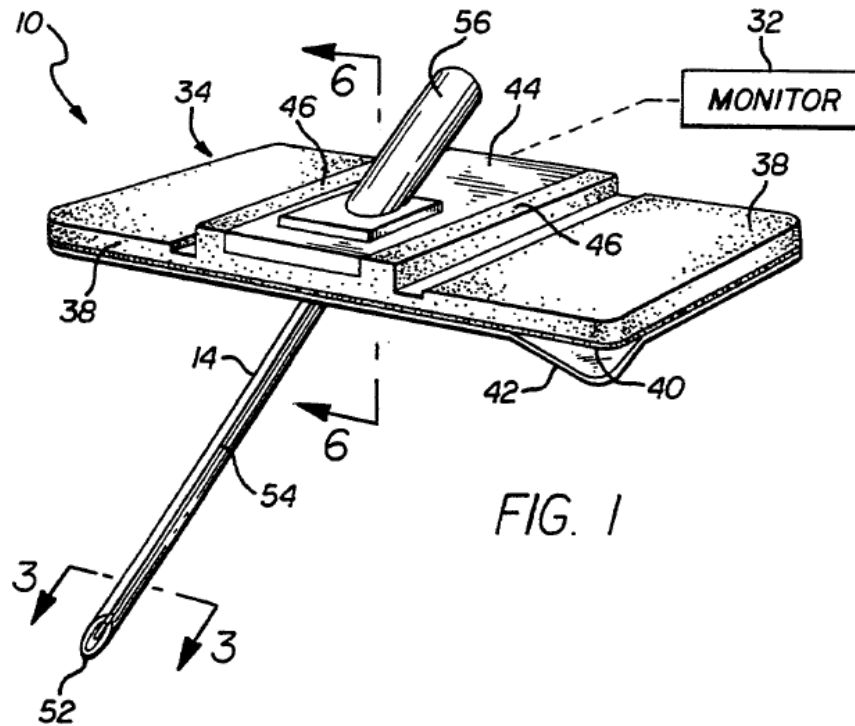


Figure 1 depicts a perspective view of a transcutaneous insertion set including a mounting base 34 adapted for placement on the skin holding a support plate 44. (Col. 2, ll. 49-51; col. 3, l. 55 – col. 4, l. 20.)

8. Figure 2 of Lord II is reproduced below:

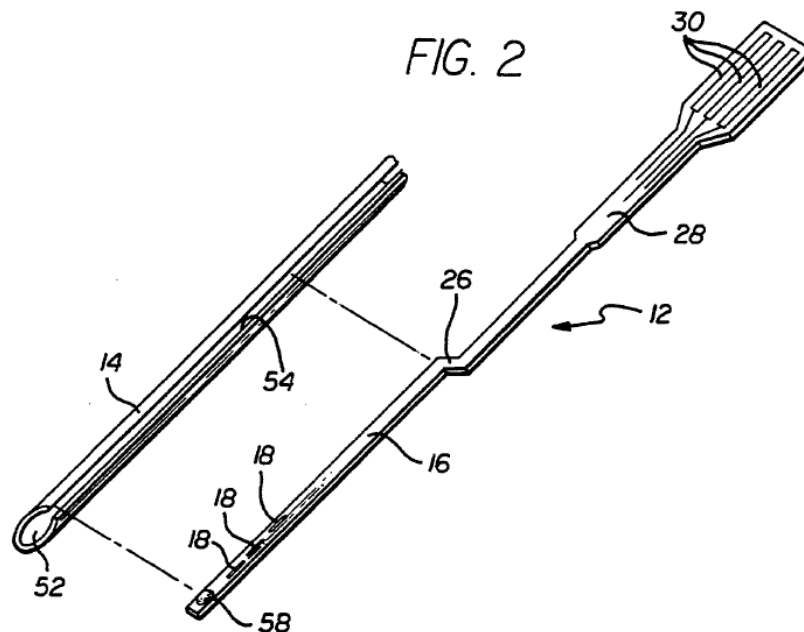


Figure 2 depicts a transcutaneous flexible sensor 12 having contact pads 30 and sensor electrodes 18. (Col. 3, ll. 32-40, 46-47.)

9. Lord II discloses: “As is known in the art . . . these contact pads 30 are adapted for electrical connection to a suitable monitor . . . .” (Col. 3, ll. 45-47.)

*Fischell*

10. Fischell discloses a sensor control unit, which may include both a telemetry antenna (transmitter) and receiving antenna (receiver). (Col. 7, ll. 5-28; Fig. 4.)

*Besson*

11. Besson discloses a sensor module having both a transmitting unit and a receiving unit. (Col. 20, ll. 52-59; Fig. 2c.)

*Rogoff*

12. Rogoff discloses operation of an insulin pump in response to a high blood sugar alarm, and a glucose pump in response to a low sugar alarm. (Col. 3, l. 63 – col. 4, l. 7; Fig. 1.)

*Shichiri II/III*

13. Shichiri II discloses a continuous glucose monitoring system where the transmitter is fixed to a forearm or anchored to a waste belt. (Para. bridging p. 298-299.)
14. Shichiri III does not disclose a glucose monitoring system fixed to a forearm.

## PRINCIPLES OF LAW

Section 305 does not require the patent owner to include an express statement that the new claims distinguish the prior art or remarks indicating how the new claims distinguish the prior art references. If the claims fail to distinguish the prior art, the claims will be rejected on the appropriate grounds; for that reason, it may frequently be in the patent owner's interest to include such remarks, but they are not necessary to satisfy section 305. For purposes of assessing validity under section 305, the MPEP directs the examiner to determine only whether any added claims impermissibly “enlarge the scope of the original claims.” 37 C.F.R. §1.552(b).

*Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157, 1185 (Fed. Cir. 2008).

For a patent under reexamination, “the PTO must give claims their broadest reasonable construction consistent with the specification . . . . Therefore, we look to the specification to see if it provides a definition for claim terms, but otherwise apply a broad interpretation.” *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007). “[A]s applicants may amend claims to narrow their scope, a broad construction during prosecution creates no unfairness to the applicant or patentee.” *ICON Health*, 496 F.3d at 1379.

Our reviewing court’s predecessor court has stated “Patent Office appellate tribunals, where it is found necessary, may take notice of facts beyond the record which, while not generally notorious, are capable of such instant and unquestionable demonstration as to defy dispute.” *In re Ahlert*, 424 F.2d 1088, 1091 (CCPA 1970) (citing *In re Knapp-Monarch Co.*, 296 F.2d 230 (1961)). “With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on

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its own understanding or experience — or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.” *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001).

In *KSR*, the Supreme Court explained, “[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). “A person of ordinary skill is also a person of ordinary creativity, not an automaton.” *Id.* at 421.

## ANALYSIS

### *Issue 1 – 35 U.S.C. § 305*

In rejecting the claims under §305, the Examiner’s position is that reexamination is not the proper forum for the amendments to claim 33, because Appellant stated that the claim was amended for clarity and precision of language. (Ans. 9.) For the newly added claims, the Examiner stated that “the claims are either dependent on one of claims 1, 32, 33, 88, 89, or independent claims that include the limitation of one of claims 1 or 39, as well as additional minor limitations.” (Ans. 9.) For the newly added claims subject to this ground of rejection, the Examiner stated that the claims differ from the original claims only by subject matter that is old and well known in the art, and Appellant has not pointed out the novelty of the recited limitations of the claims as required by 37 C.F.R. §1.111. (Ans. 9-10.)

Appellant contends that the proposed amendments and new claims are proper because they distinguish the invention as claimed from the prior art or are in response to a decision adverse to the patentability of the claims, and do not enlarge the scope of any claim of the '752 Patent. (App. Br. 16-17, 19-21.)

We agree with Appellant that the claims comply with 35 U.S.C. § 305. As stated by our reviewing court, section 305 does not require the Patent Owner to provide remarks as to how the claims distinguish the prior art. *Cordis Corp.*, 511 F.3d at 1185. Rather, if the claims do not distinguish the prior art, they will be rejected on appropriate grounds. *Id.* The Examiner need only determine whether the claims impermissibly enlarge the scope of the issued claims in order to comply with section 305. *Id.* In the instant case, the Examiner expressly stated that the claims are either dependent from original independent claims (and therefore incorporate all the latter's limitations) or were independent claims that include all the limitations of the original independent claims. (Ans. 9.) Thus, the Examiner determined that the new and amended claims do not enlarge the scope of the issued claims, which is the only inquiry required for determining compliance with section 305.

37 C.F.R. §1.111(b) requires in relevant part, that a patent owner "present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references." Once again, the Examiner has stated that the claims are either dependent from original independent claims or were independent claims that include all the limitations of the original independent claims. As

briefly detailed above and further discussed below, Appellant has presented numerous arguments as to why the claims are believed to be patentable over the cited prior art of record. Accordingly, we do not support the Examiner's position that Appellant has failed to comply with 37 C.F.R. § 1.111.

Therefore, we reverse the Examiner's decision to reject claims 33, 96, 98, 107, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and 251 under 35 U.S.C. § 305.

*Issue 2-Claim Interpretation*

Appellant contends that the term "electrochemical sensor" as interpreted in light of the '752 Patent does not include external cables and wires because the '752 Patent describes external cables and wires as separate components used to connect the sensor to other equipment, and further describes elimination of external cables and wires from the system. (App. Br. 30.) However, the '752 Patent expressly states that the "sensors include cables or wires." (FF 1.) Thus, although the *function* of the cables or wires may be to connect the sensor to other pieces of equipment, the '752 Patent expressly states that cables or wires are included as part of the sensor.

In addition, the elimination of additional cables and wires described in the '752 Patent is with respect to the sensor control unit and not the sensor. (FF 2.) Moreover, even if elimination of cables or wires to "other electronic components or other devices" is broad enough to include a sensor, we view the express disclosure in the '752 Patent that sensors include cables and wires as controlling because the former uses the term "usually" and is consequently open to either configuration. Therefore, when giving the term

“electrochemical sensor” the broadest reasonable interpretation in light of the Specification, the electrochemical sensor includes wires and cables.

Further, the phrase “a plurality of conductive contacts disposed on the housing configured for coupling to the plurality of contact pads on the electrochemical sensor” recited in claim 1 does not impose any particular type of connection between the housing and the sensor, such as a direct connection, and therefore includes situations in which the wires of the sensor join the contact pads of the sensor, directly or indirectly, to the conductive contacts disposed on the housing.

We now turn to the issues identified by Appellant of whether the claims were properly rejected by the Examiner in view of the prior art of record. We limit our discussion to claims 1, 3, 26, 33, 45, 65, and 96, which are representative of Appellant’s arguments pursuant to 37 C.F.R. § 41.37(c)(1)(vii).

*Rejection II-Shichiri I in view of Lord II*

The Examiner found that Shichiri I discloses a sensor control unit including a housing that is adapted to receive a portion of an electrochemical sensor extending out of the skin and an RF transmitter disposed in the housing and coupled to a plurality of conductive contacts for transmitting data. (Ans. 11-12.) The Examiner found that Shichiri I failed to teach a sensor having at least one contact pad, but that it would have been obvious to substitute contact pads as an equivalent means for making electrical connections in a well known convenient and reliable manner in view of Lord II. (Ans. 12.)

Appellant contends that the sensor disclosed in Shichiri I does not have portion extending out of the skin, as required in the claim, because the lead wires disclosed in Shichiri I are not part of the sensor. (App. Br. 27, 29-31.) Appellant argues that Lord II provides no details as to the physical connection between the electrochemical sensor and the monitor and the Examiner has provided no support for the position that the electrical connection means in Shichiri I and Lord II would be equivalent. (App. Br. 34-35.)

*Issue 3-Claim 1*

Claim 1 is directed to a sensor control unit and requires three structural features, a housing, a plurality of conductive contacts disposed on the housing, and an rf transmitter. Though the housing and conductive contacts are further structurally defined as being adapted to and configured for receiving a portion of a transcutaneous electrochemical sensor, an electrochemical sensor is not a required part of the claim. Rather, the structural elements recited must only be structurally capable of interacting with an electrochemical sensor as claimed.

The Examiner found that Shichiri I discloses a housing, a plurality of conductive contacts, and an rf transmitter. (Ans. 11; FF 4, 5.) Claim 1 does not identify a particular structure for the conductive contacts. Moreover, in light of the claim interpretation that the recited “coupling” does not identify the particular type of connection between the conductive contacts and the contact pads of the sensor, and that the sensor may include wires, we discern

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no patentable distinction between the sensor control unit disclosed in Shichiri and the sensor control unit recited in the claims.

Appellant relies on similar arguments for Rejections IV-VI, VIII, and XI. Accordingly, we affirm the Examiner's rejections for the same reasons discussed above and further discussed below. Regarding Rejection VII, and more specifically to the combination of Shichiri I in view of Cheney, Appellant relies on similar arguments to distinguish Cheney as presented for Lord II. Because we view Cheney's disclosure as cumulative to the disclosure of Lord II, we also affirm the Examiner's rejection of the claims over Shichiri I in view of Cheney for the same reasons discussed above and further discussed below.

*Issue 4-Claim 33*

Claim 33 is directed to a sensor assembly comprising a sensor including at least one contact pad. Consistent with the claim interpretation discussed above, we agree with the Examiner that lead wires 43 and 44 disclosed in Shichiri I are part of the electrochemical sensor 13. (Ans. 56; FF 6.) As acknowledged by Appellant, watch-shaped structure 2, located above the skin, receives lead wires 43 and 44. (App. Br. 31.) Lead wires 43 and 44 are connected to polarography circuit 14 (the sensor control unit.) Therefore, a portion of the electrochemical sensor 13, lead wires 43 and 44, are located above the skin. Thus, contrary to Appellant's arguments, Shichiri I discloses a transcutaneous electrochemical sensor, where a portion of the sensor extending out of the skin is received by the housing.

Although we agree with Appellant that Lord II does not identify the particular manner in which the sensor and the monitor are electrically connected, Lord II does provide for a sensor with contact pads that are electrically connected to a monitor. (App. Br. 33-34; FF 8, 9.) Thus, we do not agree with Appellant that the Examiner has failed to provide sufficient evidence that sensors including contact pads as disclosed in Lord II are equivalent to the sensor disclosed in Shichiri I. Accordingly, because Lord II provides for a sensor with contact pads that are electrically connected to a monitor, 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.

Moreover, the Say Declaration is insufficient to outweigh the Examiner's evidence of obviousness. Specifically, while the Say Declaration discusses the problems with elongated wires (para. 9-11, and 14), as we have discussed above, claims 1 and 33 do not exclude the presence of wires in the sensor. In addition, the Say Declaration provides no specific discussion of Shichiri I or Lord II.

*Issue 5-Claim 3*

Claim 3 depends from claim 1, and further recites a mounting unit in the sensor control unit. The Examiner found that Shichiri I does not specifically disclose a mounting unit within the housing, but stated that Lord II provides evidence that the recited mounting unit is well known in the art. (Ans. 13-14.) The Examiner concluded that it would have been obvious to

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include a mounting unit to allow for quick and easy placement of the sensor and monitor in a relatively simple manner. (Ans. 14.)

Appellant argues that neither Shichiri I nor Lord II provides a mounting unit that is adapted for coupling with the housing, because Shichiri I discloses a watch-shaped assembly secured by a strap and Lord II describes a monitor positioned remotely from the mounting base. (App. Br. 36.)

We disagree with Appellant. Lord II discloses a mounting base 34 adapted for placement on the skin holding support plate 44, and provides evidence to support the Examiner's position that mounting units are known in the art as aiding coupling by holding the desired components in place. (Ans. 13-14, 63-64; FF 7.) Thus, we agree with the Examiner that it would have been obvious to have included a mounting unit in the sensor unit of Shichiri I in order to allow for quick and easy placement of the sensor and monitor. (Ans. 13-14.)

*Issue 6-Official Notice*

Regarding claims 96, 98, 244, 246-248, 250, and 251, the Examiner took official notice that the features of these claims are well-known and would have been inherent or obvious modifications or routine design choices in view of the cited references. (Ans. 27-28.)

Appellant contends that the Examiner's taking of Official Notice was improper because the Examiner did not identify the facts being noticed and did not articulate a proper ground of rejection. (App. Br. 39-40.) Appellant further argues that Shichiri I and Lord II fail to disclose the features of claims 96, 98, 244, 246-248, 250, and 251. (App. Br. 40-44.)

We are not persuaded by Appellant's arguments that the Examiner has improperly taken official notice of the limitations recited in the claims. Specifically, the Examiner stated that "the noticed facts related only to new limitations that are of such an extremely simple nature as to be considered well known without any documentary evidence." (Advisory Action mailed February 6, 2009, p. 10; cited in the Answer 54.) In addition, the Examiner stated that documentary support may be found in the numerous references of record. (Adv. Action 9-10.) In light of the nature of the limitations for which the Examiner has taken official notice, e.g., making sensors removable (claim 96), the Examiner's position is reasonable. Moreover, Appellant lists the Advisory Action in the reexamination of the related '509 Patent in the Related Proceedings Appendix to the Appeal Brief, in which the Examiner specifically identifies references supporting the Examiner's position regarding many of the same limitations. (Appendix C3, Advisory Action in Reexamination Control No. 90/007,903, p. 8-9.) Accordingly, the Examiner's taking of Official Notice appears to be supported by documentary evidence.

In addition, Appellant's arguments that the references cited in the rejection do not disclose certain limitations of the claims, fail to consider the Examiner's position that the claim limitations were well known. To the extent that Appellant relies on the Say Declaration to demonstrate that the limitations of the claims are not well established and predictable (App. Br. 41-43), we are not persuaded. The Say Declaration does not discuss any of recited limitations at issue in detail, or provide specific reasons why the recited electrochemical sensor system would have posed technical problems

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beyond the ordinary skill in the art in light of the systems available in the prior art. (Say Declaration, para. 5, 14, & 15.).

We are also unpersuaded that the Examiner has not provided sufficient basis for obviousness in light of the noticed facts. (App. Br. 13.) The Examiner determined that such modifications would have been obvious modifications and a matter of design choice. (Ans. 28.) As *KSR* instructs, one of ordinary skill in the art is not an automaton, and is capable of applying predictable variations of prior art devices based on design needs or market pressures. *KSR*, at 417, 421. Thus, we are not persuaded that the Examiner improperly took Official Notice that certain limitations of the claims on appeal were well known.

*Rejection III-Shichiri I in view of Lord II, Fischell and Besson*

*Issue 7-Claim 26*

Claim 26 depends from claim 1, and further recites a receiver disposed in the housing. The Examiner found that Shichiri I in view of Lord II although disclosing an rf transmitter, fails to disclose a receiver in the sensor control unit. (Ans. 28.) The Examiner determined that it is known in the art to include both a transmitter and receiver in the sensor control unit as evidenced by Fischell and Besson. Thus, the Examiner concluded that it would have been obvious to modify the sensor control unit of Shichiri I and Besson to include a receiver in order to allow for the sensor to transmit data on command or in synchronization with other sensor control units as well as to receive error correction, programming and control information. (Ans. 29.)

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Appellant contends that Fischell and Besson may not properly be combined with Shichiri I or Lord II because Fischell describes a module that is in the form of a decorative belt buckle and not for placement on the skin. (App. Br. 91.) Appellant argues that Besson is from a different field and provides no motivation to combine the EEG/EKG equipment described therein with a sensor control unit operable with an electrochemical sensor. (App. Br. 92.)

We are unconvinced by Appellant's argument that Fischell and Besson may not properly be combined with Shichiri I and Lord II. Appellant's arguments focus on aspects of Fischell and Besson not relied on by the Examiner in the rejection, the aspect of a housing adapted for placement on the skin. (App. Br. 91-92.) Appellant does not dispute the Examiner's finding that Fischell and Besson illustrate that it is known in the art to include a receiver in a sensor control unit, and that adding such a receiver to the modified sensor assembly of Shichiri I in view of Lord II would have been obvious to one of ordinary skill in the art. (Ans. 28-29; FF 10-11.) Therefore, we affirm the Examiner's rejection of claim 26.

Appellant relies on similar arguments for Rejection IX. Accordingly, we affirm the Examiner's rejection for the same reasons.

*Issue 8-Claim 45*

Claim 45, which depends from claim 39, recites an analyte monitoring system that further comprises a calibrator. The Examiner found that in disclosing an arithmetic control unit and a microcomputer, Shichiri I inherently discloses a calibrator unit, or if not, that such a modification

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would have been obvious in view of the well known need for sensor calibration. (Ans. 31.)

Appellant contends that Shichiri I does not disclose or suggest a unit that provides a calibration value, but only refers to calculation parameters that are set with the use of a keyboard. (App. Br. 93.)

Although Appellant contends that Shichiri I does not explicitly refer to calibration or a calibrator, Appellant has not addressed the Examiner's reasoning that in light of the art recognized need for sensor calibration, the unit of Shichiri I would inherently contain a calibrator, or the addition of a calibrator to the sensor control unit of Shichiri I would have been an obvious modification of Shichiri I. Accordingly, we affirm the Examiner's rejection of claim 45.

*Rejection X-Shichiri I in view of Cheney and Rogoff*

*Issue 9-Claim 65*

Claim 65 depends from claim 39, and further recites two alarms in the analyte monitoring system, where each alarm produces a distinguishable audible signal. In rejecting claim 65 over Shichiri I, Cheney, and Rogoff, the Examiner cites to the Request pages 84-86, for the proposition that it would have been obvious to have modified Shichiri I's alarm buzzer to produce a low sugar alarm and a high sugar alarm with different sounds in view of Rogoff. (Ans. 37.)

Appellant argues that contrary to the Requestor's reasoning, Rogoff provides ample reasons for having two alarms, and as such, the concept of

providing two audibly distinguishable alarms constitutes improper hindsight reasoning. (App. Br. 99.)

We disagree with Appellant that using two audibly distinguishable alarms constitutes improper hindsight reasoning in view of Rogoff. Though Rogoff discloses operation of an insulin pump in response to a high blood sugar alarm, and a glucose pump in response to a low sugar alarm, we agree with the Examiner that the two alarms in Rogoff would reasonably suggest two different sounds in order to signal whether there is high blood sugar or low blood sugar, thus providing an auditory signal to the person or health care provider. (*See* FF 12.)

To be clear, because the positions of both the Examiner and Appellant regarding the base references, Shichiri I, Shichiri II, and Fischell are each very similar if not the same, we affirm the Examiner's rejections, enumerated above in Rejections VII-XI based on Shichiri II, and Fischell for the same reasons discussed supra with reference to Shichiri I.

### *Shichiri III*

Regarding the iterations of Rejections VII-IX based on Shichiri III, neither the Examiner nor the Requester identify with sufficient specificity where Shichiri III discloses a housing adapted for placement on the skin. (*See* App. Br. 70.) The Examiner relies on the Request for all of the rejections based on Shichiri III. (Ans.43-44.) The Request incorrectly quotes Shichiri III as disclosing a transmitter configured to be fixed to the forearm. (Req. 17.) We are unable to find such a disclosure in Shichiri III.

Rather, Requester appears to be referring to Shichiri II. (FF 13,14.) In addition, neither the Examiner nor the Requester offers an alternative rationale as to how the housing of Shichiri III would have been modified for placement on the skin. Therefore, we reverse Rejections VII-IX to the extent that they rely on Shichiri III as the base reference.

### CONCLUSION

On this record, Appellant has failed to demonstrate any error in the Examiner's factual findings and conclusions that:

the transcutaneous electrochemical sensor recited in the claims include wires and cables, i.e., the lead wires disclosed in Shichiri I;

Shichiri I in view of Lord II disclose the sensor control unit structure with a housing, a plurality of contacts, and an rf transmitter as recited in claim 1;

it would have been obvious to modify the sensor disclosed in Shichiri I to include at least one contact pad in view of Lord II as required in the sensor assembly recited in claim 33;

Shichiri I in view of Lord II suggests the mounting unit as recited in claim 3;

certain aspects recited in the claims were well known in the art;

it would have been obvious to modify the sensor control unit of Shichiri I and Besson to include an rf receiver in view of Fischell and Benson as recited in claim 26;

Shichiri I inherently discloses a calibrator as recited in claim 45 or that including a calibrator in an analyte monitoring system would have been obvious to one of ordinary skill in the art; and

the analyte system of claim 65, including at least two alarms, would have been obvious in view of Shichiri I, Cheney and Rogoff.

However, the Examiner erred in determining that claims 33, 96, 98, 107, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and 251 properly amended or added consistent with 35 U.S.C. § 305.

#### DECISION

The Examiner's rejections of claims 1-35, 38-46, 49-51, 53, 54, 58-65, 74-86, 88-90, 92-94, 96, 98, 107, 125, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and 251 under 35 U.S.C. § 103(a) with the exception of the rejections based on Shichiri III are affirmed.

The Examiner's decision to reject claims 33, 96, 98, 107, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247, 248, and under 35 U.S.C. § 305 is reversed.

The Examiner's rejections of claims 1-12, 14-19, 32-35, 38, 89, 96, 98, 107, 125, 127, 139, 157, 159, 168, 214, 216, 244, 247, 248, and 251 under 35 U.S.C. § 103(a) as being obvious over Shichiri III as the base reference are reversed.

Requests for extensions of time in this *ex parte* reexamination proceeding are governed by 37 C.F.R. § 1.550(c). *See* 37 C.F.R. § 41.50(f).

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AFFIRMED

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