

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID L. THOMPSON

Appeal No. 2006-0412
Application No. 09/999,827

ON BRIEF

Before MCQUADE, CRAWFORD, and LEVY, Administrative Patent Judges.
LEVY, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-5, which are all of the claims pending in this application.

We AFFIRM.

BACKGROUND

The appellant's invention relates to a non-implantable monitoring device for sensing and storing physiologic events with no intrusion into a human/patient body (specification, page 1). A

pick-up electrode may be positioned at a "stand-off" location, spaced from intimate contact with the surface of the body (specification, page 10).

Claim 1 is representative of the invention, and is reproduced as follows:

1. A non-tissue contacting electrode monitor system for sensing physiologic signals from a patient, the system comprising:

a flexible substrate with electronic sensors having data storage and a communication module incorporated thereon; and

at least one electrode operably positionable at a location spaced from intimate contact with a surface of the patient's body;

said substrate having an adhesive backing to enable wearability by the patient for sensing the physiologic signals via said at least one electrode when operably positioned at said spaced location and for storage in said data storage and transmission, to a remote location from the patient, via said communication modules.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

DeLuca et al. (DeLuca)	6,238,338	May 29, 2001
Ferguson et al. (Ferguson)	6,454,708	Sep. 24, 2002
		(filed Jun. 9, 2000)
Brun Del Re	WO 01/16607	Mar. 8, 2001

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ferguson in view of Brun Del Re.

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over DeLuca in view of Brun Del Re.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the final rejection¹ (February 25, 2004), the answer (mailed October 7, 2004) and the supplemental answer (mailed August 11, 2005) for the examiner's complete reasoning in support of the rejections, and to the brief (filed August 30, 2004) and reply brief (filed October 29, 2004) for the appellant's arguments thereagainst.

Only those arguments actually made by appellant have been considered in this decision. Arguments which appellant could have made but chose not to make in the brief have not been considered. See 37 CFR § 41.37(c)(1)(vii) (eff. Sept. 13, 2004).

OPINION

¹ The rejections set forth in the final rejection were incorporated by reference into the examiner's answer (answer, page 2).

In reaching our decision in this appeal, we have carefully considered the subject matter on appeal, the rejections advanced by the examiner, and the evidence of obviousness relied upon by the examiner as support for the rejections. We have, likewise, reviewed and taken into consideration, in reaching our decision, appellant's arguments set forth in the briefs along with the examiner's rationale in support of the rejections and arguments in rebuttal set forth in the examiner's answer.

Upon consideration of the record before us, we make the determinations which follow. We observe at the outset appellant's statement (brief, page 3) that the claims stand or fall together. Consistent with this statement, the claims have been argued as a group. Accordingly, we select claim 1 as representative of the group. In addition, we note that although the examiner lists the rejections separately, both the appellant and the examiner have argued the two rejection together. Accordingly, we will address the rejections together in our Decision.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the examiner to establish a factual basis to support the legal conclusion of obviousness. See In re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the examiner is expected to make the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467

(1966), and to provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985); ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the examiner are an essential part of complying with the burden of presenting a prima facie case of obviousness. Note In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). If that burden is met, the burden then shifts to the applicant to overcome the prima facie case with argument and/or evidence. Obviousness is then determined on the basis of the evidence as a whole. See id.; In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986); In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); and In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

The examiner's position (final rejection, page 2) is that Ferguson and DeLuca fail to disclose the use of non-contact electrodes in the system. To overcome this deficiency of Ferguson and DeLuca, the examiner turns to Brun Del Re for a teaching of non-contact electrodes. The examiner asserts (id.) that such electrodes are well known in the art and that it would have been an obvious design expedient to a skilled artisan to use Brun Del Re's non-contact electrode in the systems of Ferguson and DeLuca.

Appellants' position (brief, page 4) is that:

Brun Del Re teaches an electric field sensor that may be spaced from contact with the body, but otherwise has no relevance to the references or claimed invention. [O]ne of ordinary skill in the art would not have been motivated to make the Examiner's proposed modification because it would result in a less operative or inoperative product. The only "motivation" provided is the Examiner's hindsight and desire to craft a rejection using the present claims as a roadmap. The Examiner's sole response to the previously presented arguments, in the Final Office Action of February 25, 2004, was a standard form paragraph suggesting that "bodily incorporation" is not a requirement for an obviousness rejection and that "the test is what the combined teachings of the references suggest."

It is further argued (reply brief, page 4) that to incorporate the Brun Del Re sensor would require modification of the sensors of Ferguson and DeLuca in such a manner as to

preclude their ability to perform their intended use, and (reply brief, page 5) that the examiner's proposed combining of the references illustrates the use of Applicant's invention and claims as a roadmap for forging a rejection based upon hindsight.

It is further argued (id.) that "there is no motivation to combine the Brun Del Re reference with Ferguson or DeLuca and even if combined, the resultant combination would be inferior, less functional, and likely inoperative."

From our review of Ferguson we find that the reference is directed to a system and method for monitoring vital signs and capturing data from a patient (col. 1, lines 14 and 15). The vital signs include electro-cardiogram (ECG), blood pressure, etc. (col. 1, lines 21 and 22). A component of the invention is an adhesive, cordless, disposable sensor band with electrode patches (col. 4, line 62). The sensor band is designed to be worn for 24 hours, at which time it may be discarded and replaced by a new sensor band (col. 5, lines 6-8). As illustrated in figure 2, "the patient only has to prepare his or her skin, peel back a protective strip over the hydrogel and hydrocolloid adhesive layers which are, in turn, placed over the electrodes, signal processing circuitry 12, and battery and stick the sensor band 10 to the prepared skin in a position for measurement of the

vital signs such as ECG.” (col. 9, lines 16-21). Thus, we find from Ferguson that the hydrogel and adhesive layers are applied over the electrodes, such that the electrodes do not directly contact the skin of the patient.

Turning to DeLuca, we find that the reference is directed to a system for monitoring biosignals (col. 1, lines 6 and 7). The biosignals include Electrocardiographic (EKG) signals (col. 1, line 14). As shown in figure 3b, sensor contacts 51 extend through slots 55 in adhesive bottom surface 27 of adhesive interface 44 (col. 3, lines 30-50). From the disclosure of DeLuca, we find that although the contacts (electrodes) 51 extend through the adhesive layer and contact the surface of the user, the contacts 51 are not positionable at a location spaced from intimate contact with the user, as recited in claim 1.

Turning to Brun Del Re, we find that the reference is directed to electric field sensors in the medical field for detection of alternating electric fields emanating from within a body to produce e.g., electrocardiograms (ECGs) (page 1). It is disclosed (id.) that:

An extensive science has been established on the basis of coupling conductive electrodes to the human body to sense the low-level electrical signals that the body is able to generate. A feature of this

technology in the past has been to focus on reducing electrical resistance at the skin/electrode interface. For this purpose ECG electrodes are often used in conjunction with conductive gels and suction cup attachment mechanisms. These arrangements are uncomfortable for the user, restrict mobility, and have limited useful life.

Brun Del Re further discloses (id.) that in the prior art, dry electrodes were used that had capacitive pickups to detect electrostatic potentials on the skin of a patient. As set forth on pages 3-5:

[T]he prior art has addressed the problem of capacitive dry electrodes in terms of developing high capacitive values for insulated electrodes placed in intimate contact with the surface being monitored. These prior investigative efforts have been focused on maximizing the coupling between the electrode and the skin surface carrying the potential to be detected. . . . However, when placed proximate to the human skin, the dead layer of the skin acts effectively as an insulating spacer, removing the plate of the pickup electrode further from the source of the electric field being sensed. . . . One problem that has arisen is the extensive sensitivity of these capacitive electrodes of prior design to variations in the gap or intimacy of contact between the electrode and the skin. When intimate contact is the objective, even the presence of hair or sweat can cause variations in the value of capacitive coupling being established. The procedure of pressing dry electrodes against the body has presented similar inconveniences to those arising in the use of conductive electrodes, e.g., discomfort and limited mobility due to intimate contact protocols. . . . Further difficulties associated with the use of dry electrodes pressed into intimate contact with the skin of a person a tribo-electric effects - electrical charges created by sliding friction and

pressure. Tribo-electric effects deliver large, essentially static charges, to the pickup electrode.

As set forth on pages 8 and 9:

According to the invention in one aspect, an electric field sensor is provided that includes a first pickup electrode for placement next to a surface whose electrical field is to be sensed through capacitive coupling. This may be achieved by avoiding intimate contact with the body e.g. by positioning the plate of the pickup electrode at a "stand-off" location that reduces the sensitivity of the measured output to motion efforts i.e. variations in the separation of the pick-up electrode from the surface of the body being sensed. And it may be achieved by placing a limiting capacitor in series with the input to the sensing amplifier. To ensure that "standoff" effort of the invention first arrangement is achieved, an insulating layer may be provided over the electrode to separate it from a body by a gap that ensures that capacitive coupling does not vary sensitivity with separation. . . .

Brun Del Re adds (page 10) that:

This is completely counter-intuitive to the methodologies applied by the prior art experiments with capacitive, "dry" electrodes which employ extremely thin dielectric layers and then proceed to place the sensor in intimate contact with the surface of the body being sensed. Thus, the present invention, in one aspect, employs a dielectric layer for the pick-up electrode that ensures that sensing is occurring at a stand-off location which is insensitive to minor motion and/or surface irregularities as well as temporal changes in surface characteristics [sic, characteristics].

From the disclosure of Brun Del Re, we find that having dry electrodes press directly against the patient's body has various

drawbacks, as set forth, supra. We further find that to avoid the problems associated with using high capacitance, the electrodes should be positioned at a stand-off location, spaced from intimate contact with the surface of the body. Turning to Ferguson, we note that the reference does not have dry electrodes that directly contact the body of the patient. Rather, the hydrogel and adhesive layers are placed over the electrodes (col. 9, lines 16-21). Because Ferguson does not disclose the use of dry electrodes pressed directly against the patient's body, we find no suggestion of modifying Ferguson in light of the teachings of Brun Del Re.

However, as shown in figure 3b of DeLuca, the electrodes 51 extend through slots in the adhesive layer and contact the body of the patient. In view of the disclosure of Brun Del Re of replacing dry electrodes that contact the body of the patient with stand-off electrodes to overcome the problems associated with high capacitance, we find that an artisan would have been motivated to replace the contact electrodes of DeLuca with the stand-off electrodes of Brun Del Re. We note that claim 1 requires that the substrate have an adhesive backing, and that Brun Del Re discloses that adhesives should be avoided. However, from the additional disclosure of Brun Del Re (page 27) that the

pickup electrode need not be tightly fixed at a specific location on the skin, we find that although adhesives should be avoided, Brun Del Re does not preclude the use of adhesives, and that adhesives are acceptable.

We are not persuaded by appellant's assertion (brief, page 4) that aside from Brun Del Re's disclosure of a field sensor spaced from the patient's body, the reference has no relevance to the references or to the claimed invention. As we found, supra, Brun Del Re recognizes the capacitance problems associated with having electrodes directly contact the patient's body. Brun Del Re's recognition of the solution to the problem is therefore relevant to the disclosure of DeLuca and the claims by Brun Del Re's disclosure of solving the capacitance problem by spacing the electrodes from direct contact with the patient, by spacing the electrodes from the body through thin layers of clothing.

We are not persuaded by appellant's assertion (id.) that the only motivation is the examiner's hindsight and the examiner's desire to craft a rejection using the present claims as a roadmap. As we stated, supra, the motivation to combine the teachings of the references stems from the recognition by Brun Del Re that having the electrodes contact the patient's body

causes capacitance problems, and the solution to the problem is to position the pickup electrodes at a stand-off location spaced from intimate contact with surface of the body of the patient.

Nor are we persuaded by appellant's assertion (reply brief, page 4) that "[t]o incorporate the Brun Del Re sensor would require the modification of these sensors in such a manner as to preclude their ability to perform their intended use." We fail to see how replacing the contact electrodes of DeLuca with standoff electrodes as in Brun Del Re would require modification of the sensors in such a manner as to preclude their ability to perform their intended use.

Similarly, we do not agree with appellant's assertion (reply brief, page 5) that:

Additionally, De Luca details specifically shaped and configured sensors "arranged to detect a particular biosignal." Thus, while one could physically make such a combination, there is no motivation to do so; it would eliminate the benefit of this shape and arrangement advantageously provided by and relied upon by DeLuca; and like result in a wholly inoperative device.

Appellant has not indicated what benefits of the shapes and configuration of the sensors of DeLuca would be eliminated if the contact electrodes of DeLuca were replaced with stand-off electrodes as taught by Brun Del Re, and we find nothing in the

references that could conceivably support appellant's assertion of benefits of the sensor shape and configuration being eliminated. Nor we find any evidence or argument to support appellant's assertion that the combination would likely result in a wholly inoperative device.

From all of the above, we reverse the rejection of claims 1-5 under 35 U.S.C. § 103(a) as being unpatentable over Ferguson in view of Brun Del Re, and affirm the rejection of claims 1-5 under 35 U.S.C. § 103(a) as being unpatentable over DeLuca in view of Brun Del Re.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1-5 under 35 U.S.C. § 103 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv).

AFFIRMED

JOHN P. MCQUADE)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
MURRIEL E. CRAWFORD)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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STUART S. LEVY)	

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Παγε 16

Administrative Patent Judge)

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Παγε 17

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