UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GRAYSON SILASKI and JONATHAN D. BIRCK

Appeal 2008-2126
Application 10/640,978
Technology Center 3700

Decided: May 2, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for a sensing system for detecting analyte concentrations inside animal bodies which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Background

"Implanted medical devices frequently include a wire coil that is used to receive an electromagnetic wave broadcast from outside the body. Often

the transmitted signal is used for information content and to power the embedded device" (Spec. 1). The Specification notes that "electromagnetic coupling has been used for communications between an ex vivo device and an implantable device" (Spec. 2). However, the Specification indicates that "this has typically been for actuators that communicate with an ex vivo transceiver only occasionally, or for instances in which the ex vivo portion can be retained directly on the other side of the skin from the in vivo portion" (Spec. 2).

Statement of the Case

The Claims

Claims 1-3, 6, 8, 10-16 are on appeal. We will focus on claims 1 and 14, which are representative and read as follows:

> 1. A sensing system for determining the concentration of an analyte inside an animal body, said system including:
> an analyte sensing and reporting assembly, including:
> an in vivo portion, adapted to reside inside said animal body and including a sensing element adapted to produce a sensing signal; and
> a wearable ex vivo portion coupled to said in vivo portion, including a first inductor adapted to receive a varying electro-magnetic signal and having a pair of terminals and further including a variable load assembly adapted to present a load across said pair of terminals and adapted to vary said load in response to said sensing signal, said ex vivo portion further including memory adapted to store one or more sensing signals, as memory content, from said in vivo portion;
> and an electronic monitoring unit that is physically separate from said assembly and including a second inductor, which is adapted to be magnetically coupled to

> said first inductor and adapted to transmit a varying electro-magnetic signal to detect changes in load across said terminals of said first inductor and further adapted to direct said ex vivo portion to vary said load based at least in part on said memory content.
>
> 14. The sensing system of claim 10, further comprising a stationary electronic monitoring unit including a third inductor coil adapted to direct the ex vivo portion to vary the variable resistance between the pair of terminals based at least in part on the stored digital samples.

The prior art

The Examiner relies on the following prior art reference to show unpatentability:

Causey	US 6,248,067 B1	Jun. 19, 2001
Ishikawa	US 6,546,268 B1	Apr. 8, 2003
Say	US 6,175,752 B1	Jan. 16, 2001

The issues

The rejections as presented by the Examiner are as follows:

A. Claims 1-3, 6, 8, 10-13, 15 and 16 stand rejected under 35 U.S.C. § 103(a), as being obvious over Causey and Ishikawa.

B. Claim 14 stands rejected under 35 U.S.C. § 103(a), as being obvious over Causey, Ishikawa, and Say.

A. 35 U.S.C. § 103(a) rejection over Causey and Ishikawa

The Appellants argue that

> Causey fails to teach an ex vivo portion of an analyte sensing and reporting assembly, the ex vivo portion including (1) a first inductor adapted to receive a varying electro-magnetic signal and having a pair of terminals; and

> (2) a variable load assembly adapted to present a load across the pair of terminals and adapted to vary the load in response to the sensing signal.

(App. Br. 5-6). Appellants then contend that "Ishikawa fails to remedy the deficiencies of Causey" (App. Br. 7). Appellants argue that "[e]ven if one were to consider Ishikawa's external CPU 1120 to be an electronic monitoring unit, Ishikawa's external CPU 1120 cannot be said to be an electronic monitoring unit as claimed in claims 1 and 10" (App. Br. 7). In addition, Appellants contend that "nowhere does Ishikawa teach or disclose its external CPU 1120 being adapted to transmit a varying electro-magnetic signal to direct an ex vivo portion (or any portion of Ishikawa's glucose sensor) to vary a load based at least in part on sensing signals stored as memory content" (App. Br. 7).

The Examiner responds that

> Causey, in col. 4, ll. 1-2, generally discloses a 'wireless transmitter for downloading the data to a data processor 200, computer, communication station, or the like...[h] Holter-type recorder [100] can transmit the data by wire, or wireless signals including infrared frequencies, optical frequencies, audio frequencies, hyper-audio frequencies, ultrasonic frequencies, RF frequencies, or the like', and does not explicitly disclose the specific structures involved with wireless, electromagnetic transmission and reception between the Holter-type recorder 100 and the data processor 200.

(Ans. 9.)

The Examiner argues that "[i]t is well known in the art that wireless communication between two remote units can be made by sending a modulated signal through inductive coupling of two inductor antennas/coils,

each contained in two remote units. Ishikawa is an example of such technology" (Ans. 10).

In view of these conflicting positions, we frame the obviousness issues before us as follows:

Would it have been obvious to a person of ordinary skill to substitute the inductive coupling data transmission method of Ishikawa into the data transmission method of Causey and would the resultant combination have taught each of the elements of the claimed invention?

Findings of Fact

1. Causey teaches a "Holter-type monitor system coupled to a subcutaneous implantable analyte sensor set to provide continuous data recording of the sensor readings for a period of time" (Causey 3:24-27).

2. Causey teaches an in vivo portion which is an "implantable subcutaneous analyte sensor set 10 is provided for subcutaneous placement of a flexible sensor 12 (see FIG. 2), or the like, at a selected site in the body of a user" (Causey 5:13-16; Fig. 1-2).

3. Causey teaches that the sensor 12 can monitor blood glucose levels and "may monitor other analytes to determine viral load, HIV activity, bacterial levels, cholesterol levels, medication levels, or the like" (Causey 5:36-40).

4. Causey teaches a wearable ex vivo portion, a Holter-type recorder 100, which "includes a housing 106 that supports a printed circuit board 108, batteries 110, memory storage 112, and the cable 102 with the connector 104" (Causey 7:23-25).

5. Causey teaches that the ex vivo portion is preferably "sized in the range of 1.5 inches squared by .25 inches thick to minimize weight, discomfort and the noticeability of the Holter type recorder 100 on the body of the user" (Causey 7:40-44).

6. Causey teaches that

> in one embodiment, the Holter-type recorder 100 communicates with an RF programmer (not shown) that is also used to program and obtain data from an infusion pump or the like. The RF programmer may also be used to update and program the recorder 100, if the recorder 100 includes a receiver for remote programming, calibration or data receipt. The RF programmer can be used to store data obtained from the sensing portion 18 and then provide it to either an infusion pump, characteristic monitor, computer or the like for analysis.

(Causey 9:39-49.)

7. Causey teaches that in "alternative embodiments, a wired connection, ultrasonic frequencies, optical, RF or other transmission protocol may be used" (Causey 11:47-50).

8. Ishikawa teaches a "device, and outlines the fabrication process of the device to make a wireless glucose sensor" (Ishikawa 1:59-61).

9. Ishikawa teaches a sensor 100 on which "the transponder circuitry is disposed, and includes an antenna/coil 1111, which serves the dual purpose of receiving signal energy from a remote central processing unit 1120 and transmitting signal energy thereto" (Ishikawa 7:12-15).

10. Ishikawa teaches that the remote central processing unit 1120, which interacts with sensor 100 "includes an antenna/coil 1121 that serves the dual purpose of generating the electrogmagnetic wave for transmitting

power to the ball 100, and receiving the RF data signal transmitted by the ball 100" (Ishikawa 7:49-52).

11. Ishikawa teaches adapting the load in response to the sensing signal, in that the remote central processing unit 1120 uses an RF modulator 1118 to modulate "onto the carrier frequency signal one or more of the sensor data corresponding sensor(s) 1109 via an analog to digital (A/D) converter 1110" (Ishikawa 7:32-35).

12. Ishikawa teaches that the remote central processing unit 1120 also can store information where "the memory 1115 may have the capacity to store more information, such as the date, time, patient name and address, physician name, etc., to facilitate the recording of pertinent patient/doctor information" (Ishikawa 7:37-40).

Discussion of 35 U.S.C. § 103(a) over Causey and Ishikawa

Causey teaches a sensing system for determining the concentration of analytes, particularly glucose, in animal bodies using an analyte sensing and reporting assembly along with an electronic monitoring unit (FF 1-7). In particular, Causey teaches an in vivo portion and a wearable ex vivo portion of an assembly, along with a remote electronic monitoring unit (FF 2-7).

The Examiner acknowledges that Causey does not teach transmission of the information between the in vivo sensing unit and the ex vivo monitoring unit using electromagnetic inductance (Ans. 6-7). The Examiner relies upon Ishikawa for the disclosure that electromagnetic inductance can be used to transmit information between a sensor, including a glucose sensor, and a remote central processing unit (FF 8-12).

The obviousness case rests on whether a person of ordinary skill in the art would have considered it obvious to substitute the Ishikawa mode of transferring information between a sensor and remote device using electromagnetic inductance into the Causey device in the place of cables (*see* FF 7). Causey teaches that in "alternative embodiments, a wired connection, ultrasonic frequencies, optical, RF or other transmission protocol may be used" (Causey 11:47-50). Therefore, Causey is expressly suggesting that alternative means of communication between the in vivo sensing unit and the monitoring unit are known in the art.

We conclude that the Examiner has set forth a prima facie case that claim 1 would have been obvious to the ordinary artisan in view of Causey and Ishikawa. In *KSR*, the Supreme Court indicated that "[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 v. Teleflex Inc*., 127 S. Ct. 1727, 1740 (2007). In the instant case, using Ishikawa's method of transmitting information between a sensor and a monitoring unit in the device of Causey would have been a known and predictable variant transmission protocol (*see* FF 7, 11).

We are not persuaded by Appellants' arguments that Causey "does not teach an electronic monitoring unit adapted to magnetically couple to an ex vivo portion of an analyte sensing and reporting assembly" (App. Br. 6). The connection of elements by electromagnetic inductance is disclosed by Ishikawa (*see* FF 8-12). Appellants' conclusion that Causey "fails to teach

each and every limitation set forth therein" (App. Br. 5) is not to the point, since Causey is not relied upon as anticipatory reference, but rather as part of an obviousness rejection.

We also reject Appellants' argument that "nowhere does Ishikawa teach or disclose its external CPU 1120 being adapted to transmit a varying electro-magnetic signal to direct an ex vivo portion" (App. Br. 7). Here again, Appellants' argument fails to combine the teachings of Causey and Ishikawa. Ishikawa certainly teaches transmission of an electromagnetic signal between a sensor and a remote unit (FF 10) while Causey teaches transmission of that signal to an ex vivo portion (*see* FF 4-5). Such a combination is merely a "predictable use of prior art elements according to their established functions." *KSR*, 1727 S. Ct. at 1740.

We disagree with Appellants' conclusion that "one skilled in the art would not be motivated to make the combination suggested in the Office Action" (App. Br. 8). We think that the Examiner has provided some motivation, noting that

> it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Causey's wireless communication means to use electro-magnetic inductance to transmit data between two locations because Causey specifically discloses that other forms of communication can be used to transmit data wirelessly.

(Ans. 8). The Examiner thus provides a reason for why a person of ordinary skill in the art would have been motivated to substitute one mode of transmission for another. This substitution from Ishikawa to Causey would predictably permit transmission of information and the "combination of

familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 1727 S. Ct. at 1739.

We affirm the rejection of claim 1 as obvious over Causey and Ishikawa. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 2, 3, 6, 8, 11-13, 15, and 16 as these claims were not argued separately.

B. 35 U.S.C. § 103(a) rejection over Causey, Ishikawa and Say

Claim 14 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Causey, Ishikawa and Say.

The Examiner relies on the combination of Causey and Ishikawa as discussed above. The Examiner relies on Say to reach the limitations of claims 14, drawn to the use of a stationary electronic monitoring unit which depends from claim 10. We will affirm this rejection since Appellants do not separately argue this claim and rely upon overcoming the primary rejection over Causey and Ishikawa, which was affirmed above.

CONCLUSION

In summary, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a). Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 2, 3, 6, 8, 11-13, 15, and 16 as these claims were not argued separately. We also affirm the rejection of claim 14.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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