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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/486,708	06/17/2009	Martin Cantwell	115.P005	5726

98204 7590 11/17/2016  
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EXAMINER
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BOSQUES, EDELMIRA

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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11/17/2016

PAPER

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* MARTIN CANTWELL, H. BUD CLARK, and  
GARRY M. STEIL

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Appeal 2015-000088  
Application 12/486,708  
Technology Center 3700

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Before JAMES P. CALVE, MICHAEL L. WOODS, and  
FREDERICK C. LANEY, *Administrative Patent Judges*.

WOODS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Martin Cantwell et al. (“Appellants”) seek our review under 35 U.S.C. § 134(a) of the final rejection of claims 1–27, 45, and 46. *See* Appeal Br. 6. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

### CLAIMED SUBJECT MATTER

Appellants' invention relates to "monitoring and/or controlling blood-glucose levels in patients." Spec. ¶ 1. Claims 1 and 15 are independent and claim 1 is reproduced below with emphasis to a certain claim limitation at issue in this appeal.

1. A method comprising:  
determining a recommended therapy for a patient derived from signals representative of blood-glucose sensor measurements; and  
*generating a signal to initiate an alarm to an attendant in response to detection of a suggested change in said recommended therapy based, at least in part, on signals representative of subsequent blood-glucose sensor measurements and a predisposition for hypoglycemia in said patient.*

Appeal Br. 37 (Claims App.) (emphasis added).

### THE REJECTIONS

I. Claims 1, 2, 15, 16, 45, and 46 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ackerman (US 2003/0208114 A1, published Nov. 6, 2003). Final Act. 2.

II. Claims 3–14 and 17–27 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ackerman and Steil (US 2006/0224109 A1, published Oct. 5, 2006). Final Act. 5.

### ANALYSIS

*Rejection I: Claims 1, 2, 15, 16, 45, and 46 as Anticipated by Ackerman*

The issue before us is whether Ackerman's disclosure of generating an alarm upon reaching a glucose level satisfies the claim limitation of

initiating an alarm “in response to detection of a suggested change in [a] recommended therapy.”

In rejecting independent claims 1 and 15, and their respective dependent claims 2, 16, 45, and 46, the Examiner finds that Ackerman discloses the claimed method (claim 1) and apparatus (claim 15) comprising, *inter alia*, generating a signal to initiate an alarm “in response to detection of a suggested change in [a] recommended therapy” in a patient. Final Act. 2, 3 (citing Ackerman Abst., ¶ 11). The Examiner explains that Ackerman “teaches the generation of a signal in response of a change in blood glucose levels . . . [and that] the alarm suggests a change in the delivery of an amount of therapy provided.” Adv. Act. 2 (citing Ackerman ¶ 78); *see also* Ans. 12 (“Ackerman explains that the monitoring blood glucose device would generate an alarm when certain predetermined threshold values of glucose levels in an individual are detected”).

In contesting the rejection, Appellants assert that the Examiner’s interpretation of the claimed limitation is not consistent with the ordinary and customary meaning of the terms. *See* Appeal Br. 11. In particular, Appellants argue that the claims explicitly recite that the alarm signal is generated in response to “a suggested change in [a] recommended *therapy*,” (*id.* at 12 (emphasis omitted, emphasis added)), and—contrary to the Examiner’s finding—this suggested change in therapy “is distinct from blood-glucose measurements” (*see id.* at 13 (emphasis omitted)). In support of this argument, Appellants submit a definition of “therapy” as “treatment of disease or any physical or mental disorder by medical or physical means.” *Id.* at 14 (citing WEBSTER’S NEW WORLD COLLEGE DICTIONARY 1485 (4th ed. 2010)).

In addition to arguing the claims' ordinary and customary meaning, Appellants further argue that the Examiner's interpretation is inconsistent with the Specification, which sets forth several examples of "recommended change in therapy" to include, for example, "discontinuing, increasing or decreasing medication" and "other sources of glucose" and "initiation or cessation of renal replacement therapy." *Id.* at 13 (citing Spec. ¶¶ 136, 137).

In the Answer, the Examiner responds, "Ackermann explains that the monitoring blood glucose device would generate an alarm when certain predetermined threshold values of glucose levels in an individual are detected." Ans. 12 (citing Ackermann ¶ 11). The Examiner further explains that "it is *implied* that from this alarm that a change in recommended therapy is being suggested, because the patient is at risk with the therapy that is being applied." *Id.* (emphasis added).

Notwithstanding the Examiner's explanation, we find Appellants' argument persuasive. Here, we are not persuaded that an alarm triggered by a glucose level (disclosed by Ackerman) satisfies the claimed limitation of an alarm initiated "in response to detection of a suggested change in [a] recommended therapy."

Under the broadest reasonable construction standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Furthermore, this construction must be consistent with the specification. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

In the present case, the claims explicitly recite that the alarm is initiated “in response to detection of a suggested change in [a] recommended therapy.” Appeal Br. 37 (claim 1), 39 (claim 15). The ordinary and customary meaning of this claim limitation requires that it is the “detection of a suggested change in [a] recommended *therapy*” that initiates the alarm signal. Furthermore, the Specification describes that the “suggested change in a recommended therapy” may include, for example, “discontinuing, increasing or decreasing medication,” “discontinuing, increasing or decreasing other sources of glucose,” or “initiation or cessation of renal replacement therapy” (Spec. ¶¶ 136, 137), and that these changes in therapy “may initiate an alarm” (*id.* at ¶ 137 (“these are merely examples of changes in recommended therapy that may initiate an alarm”)). We further find that the Specification’s discussion regarding therapy is consistent with the dictionary definition submitted by Appellants, which defines “therapy” as “treatment of disease or any physical or mental disorder by medical or physical means.” Appeal Br. 14 (citation omitted).

Accordingly, a person of ordinary skill in the art, when interpreting the claimed limitation in light of the Specification, would not find the mere measurement of a glucose level as satisfying the claimed “suggested change in [a] recommended therapy,” as the Examiner has arguably done. *See* Ans. 12 (“Ackerman explains that the . . . device would generate an alarm when certain . . . glucose levels . . . are detected.”). Rather, a person of ordinary skill in the art would interpret the claimed limitation as requiring an alarm to be initiated upon a suggested change in therapy, which may include, for example, discontinuing, increasing, or decreasing medication.

Moreover, and in response to the Examiner's position that "it is *implied* that from this alarm that a change in recommended therapy is being suggested, because the patient is at risk with the therapy that is being applied" (*id.* (emphasis added)), this explanation appears to be premised on a finding that Ackerman *inherently discloses* the missing limitation, in that a change in therapy is suggested if an alarm is sounded. The fact that a certain result or characteristic *may* occur or *may* be present in the prior art, however, is not sufficient to establish the inherency of that result or characteristic. *See In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Rather,

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

*In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added).

In the present case, the Examiner has failed to establish that Ackerman's alarm *necessarily* suggests a change in recommended therapy, as called for in the claims. For example, even if Ackerman's alarm is triggered as a result of a glucose measurement falling outside of a predetermined range—as disclosed by Ackerman ¶ 11—we are not persuaded that the alarm necessarily suggests a change in therapy as opposed to signifying that the current therapy should continue because threshold values are met or expected rate changes have occurred. Nor does Ackerman indicate how therapy should change. Accordingly, the Examiner's inherency finding is insufficient to satisfy the claimed limitation.

Accordingly, we do not sustain the rejection of independent claims 1 and 15 and their respective dependent claims 2, 16, 45, and 46, as anticipated by Ackerman.

*Rejection II: Claims 3–14 and 17–27 as  
Unpatentable Over Ackerman and Steil*

The rejection of claims 3–14 and 17–27 as unpatentable over Ackermann and Steil is based on the same unreasonably broad claim interpretation and unsupportable finding relied on and discussed *supra* with respect to Rejection I. Final Act. 5. Therefore, we also do not sustain the rejection of claims 3–14 and 17–27 as unpatentable over Ackerman and Steil.

SUMMARY

The rejection of claims 1, 2, 15, 16, 45, and 46 under 35 U.S.C. § 102(b) as anticipated by Ackerman is reversed.

The rejection of claims 3–14 and 17–27 under 35 U.S.C. §103(a) as unpatentable Over Ackerman and Steil is reversed.

REVERSED