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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROBERT DAVID TIMMERMAN

Appeal 2019-003690
Application 12/620,202
Technology Center 3700

Before MICHAEL L. HOELTER, MICHAEL J. FITZPATRICK, and PAUL J. KORNICZKY, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's final decision rejecting claims 1, 2, 4–7, 9, and 12–22. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

[1] Appellant is the "applicant" under 37 C.F.R. § 1.42(a) and identifies Roche Diabetes Care, Inc., as the sole real party in interest. Appeal Br. 3.

STATEMENT OF THE CASE

The Specification

The Specification's disclosure "relates generally to hypoglycemic treatment methods and systems." Spec. ¶1.

The Claims

Claims 1, 2, 4–7, 9, and 12–22 are rejected. Final Act. 1. No other claims are pending. *Id.* Claim 1 is illustrative and reproduced below.

> 1. A method of treating hypoglycemia of a diabetic patient, comprising:
>
> detecting a hypoglycemic condition of the diabetic patient using a continuous glucose monitor, wherein the continuous glucose monitor is arranged subcutaneously in the diabetic patient and measures actual glucose levels in interstitial fluid of the diabetic patient on a continuous basis over a period of time;
>
> providing a first alarm to alert the diabetic patient of the hypoglycemic condition in response to an actual glucose level of the diabetic patient being detected by the continuous glucose monitor above a predetermined lower glucose level of the diabetic patient but below a predetermined upper glucose level of the diabetic patient, wherein the lower and upper glucose levels define a range of hypoglycemia of the diabetic patient in which the hypoglycemic condition of the diabetic patent has not reached a dangerous level;
>
> providing a second alarm different from the first alarm to alert the diabetic patient that the hypoglycemic condition has reached the dangerous level in response to the actual glucose level of the diabetic patient being detected by the continuous glucose monitor below the predetermined lower glucose level, wherein said second alarm starts a predetermined time period;
>
> providing the first alarm to alert a caregiver of the hypoglycemic condition of the diabetic patient when the actual glucose level of the diabetic patent is above the predetermined

lower glucose level of the diabetic patient but below the predetermined upper glucose level of the diabetic patient;

providing the second alarm to alert the caregiver that the hypoglycemic condition of the diabetic patient has reached the dangerous level;

detecting acknowledgement of the second alarm within the predetermined time period;

discontinuing the second alarm in response to detecting an acknowledgement of the second alarm within the predetermined time period; and

delivering glucagon automatically to the diabetic patent using an alarm and injector apparatus comprising a glucagon delivery mechanism for delivering glucagon to the diabetic patient in response to absence of an acknowledgement of the second alarm within the predetermined time period.

Appeal Br. 23–24.

The Examiner's Rejections

The following rejections, both pursuant to 35 U.S.C. § 103(a), are before us:

1. claims 1, 2, 4–7, and 22 as unpatentable over Houben,[2] Fox,[3] Asomani,[4] Brister,[5] and Lebel[6] (*id.* at 2); and

2. claims 9 and 12–21 as unpatentable over Houben, Fox, Asomani, and Brister (*id.* at 5).

DISCUSSION

Rejection 1

Appellant argues the rejection of claims 1, 2, 4–6, and 22 together. Appeal Br. 12–19. For these claims, we select claim 1 as representative. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Appellant separately presents additional arguments with respect to claim 7. Appeal Br. 19–20.

Claims 1, 2, 4–6, and 22

Houben is titled "SYSTEM AND METHOD FOR MONITORING AND CONTROLLING THE GLYCEMIC STATE OF A PATIENT." Houben, [54]. The Examiner found that Houben teaches much of the subject matter of claim 1. Final Act. 2 (citing Houben 5:8–15, 5:60–63, 11:32–24, 19:35–40, 21:41–60). One difference between Houben and claim 1 is that Houben indirectly measures (or "correlates") blood glucose levels via measured ECG and EKG signals (*see* Houben 14:42–59), whereas claim 1

[2] US 6,572,542 B1, issued June 3, 2003 ("Houben").
[3] US 2003/0125612 A1, published July 3, 2003 ("Fox").
[4] US 7,261,691 B1, issued Aug. 28, 2007 ("Asomani").
[5] US 2008/0306444 A1, published Dec. 11, 2008 ("Brister").
[6] US 2003/0055406 A1, published Mar. 20, 2003 ("Lebel").

recites "measure[ing] actual glucose levels in interstitial fluid of the diabetic patient on a continuous basis over a period of time." *See* Final Act. 3 (acknowledging this difference). Additionally, "Houben fails to teach a first alarm that is provided when the glucose level is between predetermined upper and lower levels, and a second, different, alarm if the glucose level is below the predetermined lower level, detecting actual blood glucose levels, and the delivery of glucagon if the alarm is not acknowledged." *Id.*

The Examiner relies on Fox for teaching a continuous glucose monitoring device placed subcutaneously to directly measure actual glucose levels in the interstitial fluid that has several thresholds (proportional to urgency) and distinct alarms pertaining to the different thresholds. *Id.* (citing Fox ¶¶ 53, 54, 56, 89, 90, Fig. 4). The Examiner relies on Asomani for teaching a glucose monitoring device that automatically administers glucose upon failure of the patient to acknowledge an alarm condition within a predetermined time period. *Id.* at 4 (citing Asomani 2:51–60). The Examiner relies on Brister for teaching a diabetes monitoring device wherein information can be monitored remotely by the patient's physician using a portable device. *Id.* (citing Brister ¶276). The Examiner relies on Lebel for teaching a medical communications device, wherein alarms are set to go off for a predetermined time period, until it is acknowledged. *Id.* (citing Lebel ¶¶356–358, 368). The Examiner provides reasons for why a person of ordinary skill in the art would have incorporated each of these features into Houben. *Id.* at 3–5.

Appellant argues that "the Examiner wholly failed to explain how or why the method for measuring glucose levels in interstitial fluid using a subcutaneously arranged sensor as taught by Fox would be incorporated into

a system that monitors glucose levels by processing ECG and EEG signals as seen in Houben." Appeal Br. 14. Appellant specifically challenges that a person of ordinary skill in the art would have incorporated Fox's "more invasive" manner of measuring blood glucose levels, particularly in light of Houben's statement that "ideally, glucose monitoring would be continuous and non-invasive." *Id.* at 14–15 (quoting Houben 2:25–26). The Examiner responds that, despite Houben's stated ideal, its teachings explicitly extend to using "subcutaneous electrodes, or intracardiac or intracranial electrodes." Ans. 4–5 (quoting Houben 11:32–35). Accordingly, Appellant's argument does not apprise us of error.[7]

Appellant also argues that

> the Examiner's reasoning focusing solely on the subsequent alarms and automatic corrective actions is inapposite when *Fox* is silent regarding the application of the automated and semi-automated medication infusion devices. *See Fox,* para. [0053]. As such, the skilled artisan would have no basis for determining a relationship between the multiple alarms and the automated and semi-automated medication infusion devices and as noted above obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the claimed invention.

[7] In its Reply, Appellant ultimately concedes that Houben contemplates subcutaneous electrodes, but argues that such electrodes do not measure blood glucose levels of interstitial fluid. Reply Br. 2 ("Although the ECG and EEG electrodes may be subcutaneous electrodes, such sensors measure electrical signals and do not measure glucose levels of interstitial fluid."). That argument is inapposite, as the Examiner does not rely on Houben for teaching directly measuring actual glucose levels in the interstitial fluid. For that limitation, as already discussed above, the Examiner relies on Fox. Final Act. 3.

Appeal Br. 15. Appellant's argument is vague with respect to "the Examiner's reasoning focusing solely on the subsequent alarms and automatic corrective actions." *Id.* As best we can discern from this argument, Appellant is challenging the Examiner's reason for combining Houben and Fox—it is not clear from Appellant's argument—based on the isolated teachings of Fox. However, the Examiner relies on Fox solely for teaching a means to monitor blood glucose levels that is an alternative to Houben's ECG- and EKG-based means. Final Act. 3. That Fox does not teach other aspect of the claimed subject matter does not undermine the rejection. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. . . . [The reference] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole."). Appellant's argument does not apprise us of Examiner error.

Appellant points out that, in Houben, certain data within the EKG and ECG data must be identified and correlated with glucose or insulin levels to determine if an alarm should be triggered. Appeal Br. 15–16. Thus, Appellant argues, "the processing method for identifying and delivering alerts and therapies is necessarily dependent upon the collection method." *Id.* Appellant does not explain how the change in blood glucose collection method might be nonobvious. Rather, Appellant merely implies that Fox's blood glucose collection method could not be substituted into Houben thoughtlessly (i.e., without also making some changes to the device's programming). *See id.* ("As such, the processing method for identifying and delivering alerts and therapies is necessarily dependent upon the collection

method and actual collected data."). Whatever the specific contours of this argument, however, it is not persuasive of error. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007); *see also id*. at 417 ("[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

Appellant argues that "it is unclear why one having ordinary skill in the art would be motivated to combine the passive monitoring system of Asomani (and/or Houben) with the more invasive method as taught by Fox." Appeal Br. 17. This argument does not apprise us of error for multiple reasons. First, its factual premise is erroneous. On the one hand, Appellant asserts that Fox's blood glucose collection method in which "the sensor is subcutaneously placed" (Fox ¶54) is "more invasive" than Asomani. Appeal Br. 17. But, on the other hand, Appellant concedes that Asomani teaches an equally invasive method of collecting blood glucose measurements (i.e., "through the patient's skin"). *Id.* (quoting Asomani 4:30–31). Second, the Examiner does not rely on Asomani for its collection method. Rather, the Examiner relies on Asomani for its feature of automatically administering glucose upon failure of the patient to acknowledge an alarm condition within a predetermined time period. Final Act. 4 (citing Asomani 2:51–60).

Appellant argues that the Examiner has not shown that a person of ordinary skill in the art would have "convert[ed] the operational alarms of *Lebel* to physiological alarms" in the asserted combination. Appeal Br. 18. This argument does not apprise us of error. Claim 1 does not recite

"physiological" alarms, nor does Appellant explain what it means by that. As best we can discern, Appellant is arguing that Lebel's alarms are triggered by an operational status of a device such as a low battery, whereas the recited alarms of Appellant's invention must be triggered by detection of hypoglycemia, either dangerous or non-dangerous. The Examiner responds to Appellant by pointing out, correctly, that "[o]ne of ordinary skill in the art would surely recognize that the concept of having an alarm that rings for a time period or until acknowledgment would not be solely limited to an alarm associated with glucose levels, as that is how many an alarm clock similarly functions." Ans. 6. Appellant's related argument that a person of ordinary skill in the art would not have a reasonable expectation of success in creating an alarm triggered by the detection of hypoglycemia (Appeal Br. 19) likewise does not apprise us of error. In view of the cited prior art teachings and the level of skill in the art as reflected in the cited prior art, we are not dissuaded that a person of ordinary skill would have had a reasonable expectation of success in combining the prior art teachings as proposed by the Examiner.

For the foregoing reasons, we affirm the rejection of claim 1, as well as claims 2, 4–6, and 22, which fall with claim 1, as unpatentable over Houben, Fox, Asomani, Brister, and Lebel.

Claim 7

Claim 7 ultimately depends from claim 1 and recites "wherein, after the step of providing the second alarm, said method further comprises the controller looking for the patient-initiated input signal provided using an input mechanism within the predetermined time period." Appeal Br. 25.

The Examiner relies on Houben for teaching such a patient-initiated input signal. Final Act. 5 (citing Houben 18:64–19–22).

Appellant argues that Houben does not disclose the "within the predetermined time period" aspect of the limitation. Appeal Br. 19–20. The Examiner responds, in part, by noting that "Asomani addresses the acknowledgment of the predetermined time period, and as Houben allows for the patient-initiated input signal, the resulting combination addresses this limitation." Ans. 6.[8] The Examiner is correct. It is claim 1 that first recites "a predetermined time period," and, in fact, the Examiner cited Asomani for that limitation. Final Act. 4 (citing 2:51–60); *see also* Asomani 2:56–57 (disclosing automatic glucose administration "upon a failure of the patient to acknowledge an alarm condition within a predetermined time period, e.g., three to five minutes, more or less"). For the foregoing reasons, we affirm the rejection of claim 7 as unpatentable over Houben, Fox, Asomani, Brister, and Lebel.

Rejection 2

Claims 9, 12–13, and 15–19

Appellant argues against the rejection of claims 9, 12–13, and 15–19 on the basis that they recite (or incorporate by reference through dependency) "similar features as independent Claim 1," and therefore are patentable "[f]or at least the reasons set forth above." Appeal Br. 20. However, as discussed above, those arguments do not apprise us of Examiner error, and Appellant does not present any additional arguments for

[8] The Examiner additionally points out that Houben's patient input would be useless if there is no time limit on its receipt. Ans. 6.

these claims. *Id.* Accordingly, we affirm the rejection of claims 9, 12–13, and 15–19 as unpatentable over Houben, Fox, Asomani, and Brister.

Claims 21 and 22

Appellant does not present arguments against the rejection of claims 21 and 22. Accordingly, we affirm the rejection of claims 21 and 22 as unpatentable over Houben, Fox, Asomani, and Brister.

Claim 14

Claim 14 depends from claim 9 and recites "wherein the first alarm signal and the second alarm signal are provided by a glucose meter receiving glucose information from the continuous glucose monitor." Appeal Br. 27. Appellant points out that "*Houben* provides that an alarm signal is generated by the processor and controller (34) and transmitted to the external device (41)." Appeal Br. 20–21 (citing Houben 13:51–62). The Examiner responds that "any part of the system that is part of receiving the glucose information and outputting an alarm can be considered a glucose meter. The claim does not necessitate the glucose meter be encased in the same housing or be connected via wires." Ans. 6. Appellant does not reply to the Examiner's response, and we discern no error in the Examiner's construction of "glucose monitor." *See generally* Reply Br.

SUMMARY

Claims Rejected	35 U.S.C. §	References/Basis	Affirmed	Reversed
1, 2, 4–7, 22	103	Houben, Fox, Asomani, Brister, Lebel	1, 2, 4–7, 22	
9, 12–21	103	Houben, Fox, Asomani, Brister	9, 12–21	
Overall Outcome			1, 2, 4–7, 9, 12–22	

TIME PERIOD FOR RESPONSE

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

AFFIRMED