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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GERHARD TIVIG and SEBASTIAN HEBLER

Appeal 2016-005460
Application 11/721,762
Technology Center 3700

Before JEFFREY N. FREDMAN, ULRIKE W. JENKS, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal¹ under 35 U.S.C. § 134(a) involving claims to a medical monitoring system. The Examiner rejected the claims as directed to nonstatutory subject matter, as anticipated, and as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

¹ Appellants identify the Real Party in Interest as KONINKLIJKE PHILIPS ELECTRONICS, N.V. (*see* App. Br. 1).

Statement of the Case

Background

“In a clinical environment a patient monitor is used for the observation of the condition of a patient. The primary function of a patient monitor is to warn the clinical staff on changes in the status of the patient” (Spec. 1:8–10). “Typically a limit alarm mechanism is implemented in such patient monitors. Thereby an alarm is activated if a measurement exceeds a user-defined threshold” (Spec. 1:10–12).

The Claims

Claims 4, 6, 13–20, 22, and 24–31 are on appeal. Independent claim 24 is representative and reads as follows:

24. A medical monitoring system for observing a condition of a patient and warning medical staff of changes in a status of the patient, the system comprising:

a plurality of sensors which acquire medical data from the patient, the medical data being indicative of a plurality of vital signs including heart rate, oxygen saturation and respiration;

at least one memory configured to store the medical data;

a display device;

one or more processors configured to:

receive the medical data;

analyzing the medical data for an occurrence of trigger conditions, the trigger conditions including the medical data corresponding to each of the vital signs crossing a selected threshold for a selected duration,

analyzing the trigger conditions to determine if one or more of a plurality of event parameters are satisfied,

each event parameter including a different predefined combination of two or more trigger conditions,

analyzing the event parameters to determine if one or more event groups are satisfied, each event group including a combination of a plurality of event parameters,

in response to one of the event groups being satisfied, controlling the display device to display an event notification including medical content information.

The Issues

- A. The Examiner rejected claims 4, 6, 13–20, 22, and 24–31 under 35 U.S.C. § 101 as directed to nonstatutory subject matter (Final Act. 4–5).
- B. The Examiner rejected claim 24 under 35 U.S.C. § 102(a)/§ 102(e) as anticipated by Hutchinson² (Final Act. 5–7).
- C. The Examiner rejected claims 4, 6, 13, 14, 16, 18–20, 22, 25, and 27 under 35 U.S.C. § 103(a) as obvious over Hutchinson and Rosenfeld³ (Final Act. 8–15).
- D. The Examiner rejected claims 15 and 26 under 35 U.S.C. § 103(a) as obvious over Hutchinson, Rosenfeld, and Schradi⁴ (Final Act. 15–17).
- E. The Examiner rejected claims 17 and 23 under 35 U.S.C. § 103(a) as obvious over Hutchinson, Rosenfeld, and Reed⁵ (Final Act. 17–18).
- F. The Examiner rejected claims 28–31 under 35 U.S.C. § 103(a) as obvious over Hutchinson and Schradi (Final Act. 19–22).

² Hutchinson et al., US 2005/0020886 A1, published Jan. 27, 2005.

³ Rosenfeld et al., US 6,804,656 B1, issued Oct. 12, 2004.

⁴ Schradi et al., US 5,860,918, issued Jan. 19, 1999.

⁵ Reed et al., US 6,524,239 B1, issued Feb. 25, 2003.

A. 35 U.S.C. § 101

The Examiner finds the claims “are directed to analysis of medical data, which is directed to an abstract idea” (Final Act. 4). The Examiner finds the “claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the additional elements of a physiological data sensor, processor, memory, and display are all generic hardware performing generic computer functions or are insignificant extrasolution activities” (*id.*).

In *Alice*, the Supreme Court applied a two-step framework for analyzing whether claims are patent-eligible under section 101. First, we determine whether the claims at issue are “directed to” a judicial exception, such as an abstract idea. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S.Ct. 2347, 2355 (2014). If not, the inquiry ends. If the claims are determined to be directed to an abstract idea, we next consider under step two whether the claims contain an “inventive concept” sufficient to “‘transform the nature of the claim’ into a patent-eligible application.” *Id.* (citation omitted).

Alice Step One

Claims 13, 20, 24, and 28 of the instant application are directed systems and methods for monitoring patients for “user-defined trigger conditions” that, in combination, “generate an event parameter notification signal” (*see, e.g.*, claim 13). The claims also recite generic sensors, display devices, and processors configured to perform the method.

The Specification teaches “data of a number of different medical parameters, e.g. heart rate and blood pressure, is acquired” and “any measurement can be set up as an event parameter” (Spec. 3:12–16). The Specification teaches “trigger conditions [are] assigned to the event

parameters” and “up to four event parameters (e.g. heart rate, blood pressure, respiration, . . .) with corresponding trigger conditions can[]be clustered to an event group” (Spec. 3:19–23).

The Specification explains that using “this method different diseases can be assigned to different event groups in a defined way. In other words an event surveillance is provided, which allows to define event groups expressing specific clinical situations. The user can be informed about these groups and the user can review these events” (*id.* at 3:23–27).

Therefore, both the claims and Specification are directed to systems and processes of obtaining medical information and analyzing that data to display a particular result. No special rules or details of the computer processors, sensors, display devices, or even algorithms are recited. We note that “[c]laims directed to the ‘process of gathering and analyzing information of a specified content, then displaying the results,’ without ‘any particular assertedly inventive technology for performing those functions,’ were held ineligible in *Electric Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016).” *Trading Techs. Int’l, Inc. v. CQG, Inc.*, 675 Fed. App’x 1001, 1005 (Fed. Cir. 2017).

We find the instant claims analogous to the claims held patent ineligible in *Electric Power*. The claims are not limited by rules or steps that establish how the focus of the system or methods are achieved. Instead, the claims embrace the abstract idea of using medical data obtained by sensors to allow users to set trigger signals and display alerts in real time. Because the claims are directed to an abstract idea, we turn to the second step of the *Alice* inquiry.

Alice Step Two

In step two, we consider whether the elements of the claims transform the nature of the claim into a patent-eligible application of the abstract idea. *Content Extraction & Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1347 (Fed. Cir. 2014). This inquiry is the search for an inventive concept, which is sufficient to ensure that the claim amounts to significantly more than the abstract idea itself. *Id.*

“Merely requiring the selection and manipulation of information . . . by itself does not transform the otherwise-abstract processes of information collection and analysis.” *Electric Power*, 830 F.3d at 1355. Appellants do not identify any technological advance to the process of analyzing the medical data, but simply provide a particular approach for data manipulations (*see, e.g.*, Spec. 6:23 to 7:2). Thus, we agree with the Examiner that the claim limitations, analyzed alone and in combination, fail to add “something more” to “transform” the claimed abstract idea of manipulating sensor data to trigger and display alerts into “a patent-eligible application.” *See Alice*, 134 S. Ct. at 2354, 2357.

Appellants contend the “Examiner has not made a *prima facie* showing that the claims are patent ineligible under 35 U.S.C. § 101 by providing a detailed analysis” (App. Br. 10; *cf.* App. Br. 14).

We find these arguments unpersuasive.

[T]he PTO carries its procedural burden of establishing a *prima facie* case when its rejection satisfies 35 U.S.C. § 132, in “notify[ing] the applicant . . . [by] stating the reasons for [its] rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of [the] application.” 35 U.S.C. § 132.

In re Jung, 637 F.3d 1356, 1362 (Fed. Cir. 2011). The Examiner has properly applied and explained the *Alice* test, identifying the abstract idea within the claim and finding the absence of “something more” that transforms the abstract idea into a patent-eligible application. The sufficiency of the Examiner’s prima facie case is not defined by the number of words written but by whether the Examiner provides a reasoned statement that provides the underlying rationale and supporting reasons. The Examiner has done so here (*see* Final Act. 4–5; *cf.* Ans. 3–8).

Claim 13

Appellants contend that claim 13 “has set forth a detailed and specific combination which sets forth the elements of an improved medical monitoring system and not merely an abstract idea, such as a medical monitoring system” (App. Br. 11).

We are not persuaded. The five operations listed by Appellants in the Appeal Brief as elements of claim 13 are entirely focused on the abstract idea of medical monitoring (*see id.* at 10–11). These five operations simply involve the abstract idea of using medical data obtained by sensors to allow users to set trigger signals and display alerts in real time. The operations do not differ, in principle, from a physician, (1) aware of symptoms (i.e., physiological parameters) that require treatment, (2) observing a patient “in real time” for symptoms, (3) analyzing the severity of the symptoms to make a diagnosis, (4) informing the treatment team of the diagnosis and (5) displaying the information on a medical record.⁶ Therefore, we are not

⁶ “[1] Minnie May, aged three, was really very sick. She lay on the kitchen sofa feverish and restless, while her hoarse breathing could be heard all over

persuaded that the combination of elements in claim 13 is anything other than an abstract idea implemented on routine and conventional medical equipment.

Claims 14–19

Appellants contend “claim 14 further calls for the one or more processors to generate the event notification signals in real time. Thus, claim 14 is more specific, more clearly does not set forth only an abstract idea” (App. Br. 12). Appellants similarly claim the limitations of claims 15–19 are also not drawn to abstract ideas (*see id.* at 12–14).

We find these arguments unpersuasive because each of the additional limitations of claims 14–19 involves “the selection and manipulation of information”, whether “event notification signals in real time” (claim 14), displaying an “episode window including a time . . . [and] physiological parameters responsible” (claim 15), programming processors “to dynamically adopt new trigger conditions” (claim 16), including “a level of priority” (claim 17), defining “medical context information” (claim 18), or identifying types of triggers (claim 19). None of these information processing or routine medical components “transform[s] the otherwise-abstract processes of information collection and analysis.” *Electric Power*,

the house. . . . [2] ‘Minnie May has croup all right; [3] she’s pretty bad, but I’ve seen them worse. [4] First we must have lots of hot water . . . I’m going to give her a dose of ipecac first of all’ . . . [5] ‘That little redheaded girl they have over at Cuthbert’s is as smart as they make ‘em. . . . I never saw anything like the eyes of her when she was explaining the case to me.’” Lucy Maud Montgomery, *Anne of Green Gables*, <https://www.gutenberg.org/files/45/45-h/45-h.htm#link2HCH0018>, originally published June 1908. Though we find this reference exemplary of the claimed steps, we do not, however, rely upon it in our analysis.

830 F.3d at 1355. These claims are drawn to iterations of the abstract idea of using medical data obtained by sensors to allow users to set trigger signals and display alerts in real time.

Claims 20, 4, 6, 22, and 25–31

Appellants contend

claim 20 sets forth additional limitations that, when considered as an ordered combination, demonstrates a technologically rooted solution to a problem and thus amounts to significantly more. For example, claim 20 calls for the computer processors to be programmed to perform five specific operations which, as an ordered combination, are significantly more than merely monitoring a patient.

(App. Br. 16.)

We find this argument unpersuasive because, as with claim 13 discussed above, each of the five processes recited in claim 20 (*see also id.* at 15) is drawn to the selection and manipulation of medical information for diagnosis and treatment and does not “transform the otherwise-abstract processes of information collection and analysis.” *Electric Power*, 830 F.3d at 1355.

We also find the existence of the additional limitations in claims 4, 6, 22, and 25–31 unpersuasive because the limitations also involve “the selection and manipulation of information”, whether using mathematical or logical operators to combine triggers (claim 4), to adapt the trigger based on data (claim 6), to include medical data in the medical context information (claim 22), to perform the process using the system of claim 13 (claims 24 and 28), to display trend vs. time data (claims 25 and 30), to display medical data regarding vital signs from particular time periods (claims 26 and 29), or to alter the analysis based on a user input device (claims 27 and 31).

We, therefore, affirm the Examiner’s rejection of the claims as drawn to patent-ineligible subject matter.

B. 35 U.S.C. § 102(a)/§ 102(e) over Hutchinson

The Examiner finds Hutchinson teaches

sensors which acquire medical data from the patient . . . including heart rate, oxygen saturation and respiration . . . at least one memory configured to store the medical data . . . a display device . . . [and] processors configured to . . . receive the medical data.

(Final Act. 6.) The Examiner also finds Hutchinson teaches processors for analyzing the received data where “*the logic is adapted to receive[] a physiologic data stream . . . further adapted to cross-reference the plurality of physiologic variables with a set of logic rules*” (*id.*). The Examiner further finds Hutchinson teaches “*within each logic rule set is a plurality of logic rules . . . these logic rules are comprised of diagnostic algorithms that allow the plurality of physiologic variables to be correlated with a diagnostic interpretation*” (*id.* at 6–7). The Examiner finds Hutchinson teaches “analyzing the event parameters to determine if one or more event groups are satisfied” and “controlling the display device to display an event notification” (*id.* at 7).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that Hutchinson anticipates claim 24?

Findings of Fact

1. Hutchinson teaches a “method and apparatus for patient physiologic monitoring is provided. The method includes receiving a real-

time physiologic data stream from a patient. The real-time physiologic data stream includes a plurality of physiologic variables. The method further includes processing the plurality of physiologic variables using a rules engine” (Hutchinson ¶ 7).

2. Figure 1 of Hutchinson is reproduced below:

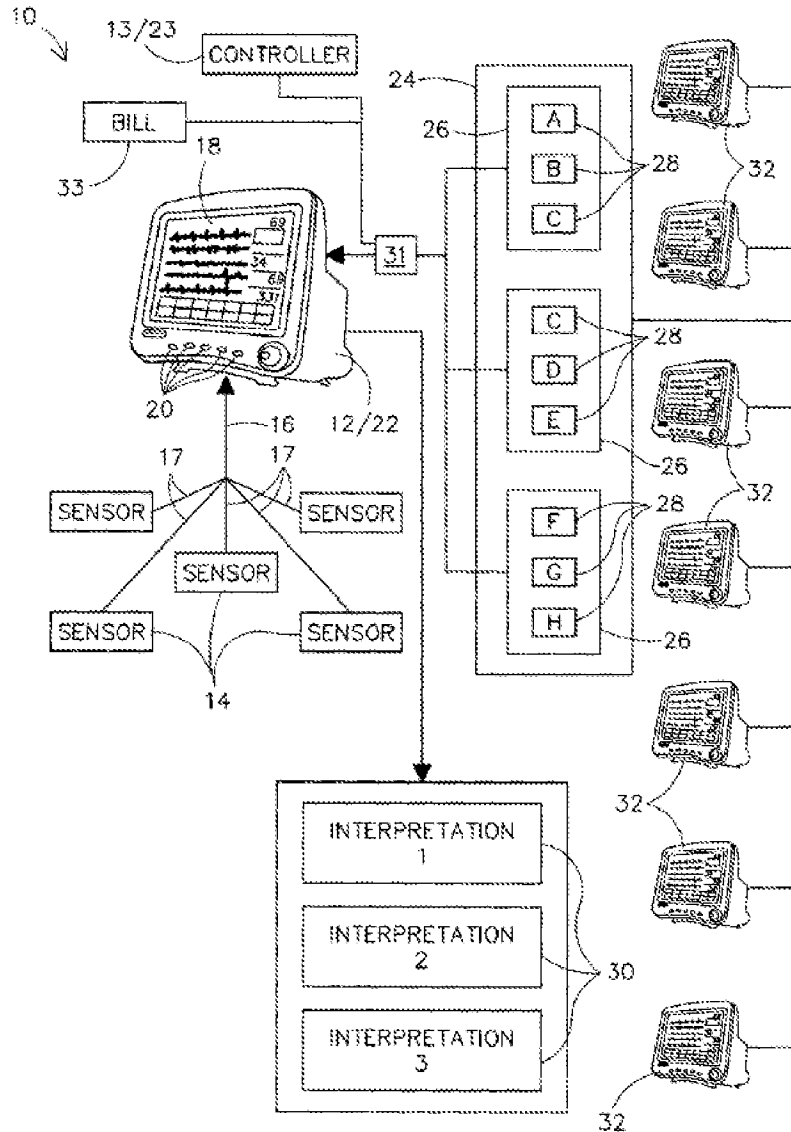


FIGURE 1

Figure 1 illustrates “a patient physiologic monitoring assembly 10 . . . [that] includes a controller 12 in communication with a plurality of patient sensors 14” (*id.* ¶ 18).

3. Hutchinson teaches “patient sensors **14** and real-time physiologic data stream **16** may encompass a wide variety of patient monitoring physiologic characteristics/variables **17**. These variables include, but are not limited to, heart rate, arterial blood pressure, SpO₂, CO₂, respiration rate, and a variety of other patient physiologic responses” (Hutchinson ¶ 18).

4. Hutchinson teaches “the use of a data storage device **24**” (*id.* ¶ 19).

5. Hutchinson teaches “controller **12** may be utilized in combination with a variety of interactive elements such as a display **18** and user interface **20**” (*id.* ¶ 18).

6. Hutchinson teaches “logic **22** is adapted to receive a physiologic data stream including a plurality of physiologic variables **110** of the patient. The logic **22** is further adapted to cross-reference the plurality of physiologic variables with a set of logic rules **120**” (*id.* ¶ 19).

7. Hutchinson teaches:

These logic rules **28** are comprised of diagnostic algorithms that allow the plurality of physiologic variables **17** to be correlated with a diagnostic interpretation **30**. By way of example, one physiologic variable **17** may indicate a drop in oxygen in a patient’s blood. Another physiologic variable **17** may indicate the level of CO₂ that a patient exhales is dropping as well. A logic rule **28** can be adapted such that these physiologic variables **17** in combination correlate with a diagnostic interpretation **30** indicating a reduction in a patient’s circulation.

(*Id.*)

8. Hutchinson teaches “sets of rule-based algorithms may be classified based on an area of interest, such as a rule set which contains a plurality of rules designed to monitor the cardiovascular system.” (*id.*).

9. Hutchinson teaches the “rule-based algorithm(s) are used to generate a response at block **210**. The response can be an alarm **218**, an indication of an abnormal event” (Hutchinson ¶ 30).

10. Hutchinson teaches “the views may be combined to generate an alarm **218**, or a series of alarms depending on the amount of agreement between the rule sets” (*id.*).

11. Hutchinson teaches the

response or responses can then be displayed at block **212**. The responses can also be stored at block **216**, such as in a record relating to the subject or the monitoring. The stored response can be used to later evaluate the effectiveness of the rule-based algorithms, and/or be used to later supply data relating to the subject.

(*Id.* ¶ 31.)

12. Hutchinson teaches “each facility and/or monitoring system could include a network interface **31** that facilitates access to the network. . . . Controller **13** could be configured to limit access to the rule-based algorithms. For instance, only people meeting a certain predetermined criteria may have access to the rule-based algorithms” (*id.* ¶ 27).

Principles of Law

“A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation.”

Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1375 (Fed. Cir. 2005).

Analysis

We adopt the Examiner’s findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 8–15; FF 1–12) and agree that the claims are anticipated by Hutchinson. We address Appellants’ arguments below.

Appellants contend: “Paragraph [0019] of Hutchinson applies rules and sets of rules, but does not disclose analyzing for trigger conditions, much less trigger conditions indicative of vital signs crossing a selected threshold for a selected duration” (App. Br. 24). Appellants also contend:

even if the selected duration is zero seconds, the first of the trigger conditions must include each of the vital signs crossing a selected threshold, whether for an infinitesimally small duration or longer. Setting the duration to zero does not take the first analyzing step or the trigger conditions out of the claim.

(Reply Br. 10).

We are not persuaded. The person of ordinary skill in the art of clinical treatment of patients would reasonably interpret the terms “alarm” and “abnormal event” (FF 9–10) as “trigger conditions” that are associated with changes in physiological variables such as “a drop in oxygen in a patient’s blood” (FF 7). In order for an algorithm to trigger an “alarm” or observe an “abnormal event”, there must necessarily be a threshold for what constitutes an “abnormal event” and some duration of time necessarily must have occurred. Therefore, Hutchinson, in teaching algorithms that generate “alarms” and detect “abnormal events” necessarily and inherently has triggers that cross a threshold for some duration. “It is well settled that a prior art reference may anticipate when the claim limitations not expressly

found in that reference are nonetheless inherent in it.” *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002).

Appellants contend “[p]aragraph [0019] of Hutchinson does call for applying two or more rules or sets of rules, but such rules are applied to the monitored physiological variables 17 in the data stream 16, not to combinations of trigger conditions” (App. Br. 24).

We find this argument unpersuasive because Hutchinson expressly teaches to generate “a series of alarms depending on the amount of agreement between the rule sets” (FF 10). Because each alarm is based on separate rules, and is necessarily caused by a “trigger condition” using the language of claim 24, Hutchinson’s teaching of a “series of alarms” is reasonably interpreted as satisfying the requirement for a combination of trigger conditions.

Appellants contend: “There is no description in these paragraphs of Hutchinson of analyzing event parameters, which event parameters were determined by analyzing trigger conditions, which trigger conditions were determined by analyzing medical data” (App. Br. 24).

We are not persuaded. Hutchinson teaches rules to analyze physiological variables such as oxygen or carbon dioxide levels (FF 7), which are reasonably interpreted as medical data, to create alarms that are reasonably interpreted as “trigger conditions” (FF 9–10). Finally, Hutchinson teaches using these alarms for later analysis of the rules and of the particular patient (FF 11), reasonably satisfying the analysis of “event parameters” requirement of claim 24.

Appellants contend “that each diagnostic interpretation is determined by applying one or a set of rules directly to the data stream in a single, not tiered, analysis” (App. Br. 24).

We find this argument unpersuasive because there is no requirement for a “tiered” operation. *See In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) (“[A]ppellant[s]’ arguments fail from the outset because . . . they are not based on limitations appearing in the claims.”)

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that Hutchinson anticipates claim 24.

C. 35 U.S.C. § 103 over Hutchinson and Rosenfeld

The Examiner finds Hutchinson teaches “a physiological data sensor . . . computer processors . . . a first tier of hierarchical analysis . . . wherein the rules can be pre-assigned or modified by the individual user . . . in a second tier, in response to detecting a plurality of the event notifications, generate a group event notification” (Final Act. 8–9). The Examiner finds Hutchinson also teaches “multiple logic sets can [be] use[d and] applied at the same time” (*id.* at 9).

The Examiner acknowledges “Hutchinson is not clear on whether the trigger could include a deviation trigger” (Final Act. 9). The Examiner finds Rosenfeld “teaches a system for remote patient monitoring, wherein rules are used for the detection of impending problems. The thresholds can be set as an absolute or as a deviation” (*id.*). The Examiner finds Rosenfeld “teaches a specific type of threshold dependent on the patient, disease, and/or setting” (*id.* at 10).

The Examiner finds it obvious “to modify Hutchinson with the thresholds of Rosenfeld because it is the use of a known technique to improve similar devices in the same way” (Final Act. 10).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that Hutchinson and Rosenfeld render the claims obvious?

Findings of Fact

13. Rosenfeld teaches:

The monitoring system at each ICU bedside comprises a monitoring system for monitoring the vital signs for the patient. The vital sign monitoring system **450** captures vital sign data **452** and transmits that vital sign data **454** The processor at the ICU processes the vital sign data for transmission and storage purposes and transmits that information to the remote location. Vital sign data is then loaded into the data base **458**. The data base for each individual patient is then reviewed and process rules are applied **460** to the vital sign data. These process rules relate to certain alarming conditions which, if a certain threshold is reached, provides an alarm to the intensivist on duty. The vital sign alarm **462** is then displaced to the intensivist who can then take appropriate action. A typical type of rule processing of the vital sign data might be if blood pressure remains at a certain low level for an extended period of time, or if heart rate remains high for an extended period of time. In addition a wide range of other rules are provided which will provide an audible alarm to the intensivist before a critical situation is reached. In addition to the information being provided to the alarming system for the intensivist, the vital sign data **464** is also transmitted **466** into a database warehouse **468**.

(Rosenfeld 21:35–58).

14. Rosenfeld teaches the “smart alarm system constantly monitors physiologic data (collected once per minute from the bedside monitors) and all other clinical information stored in the database” (*id.* at 24:44–47).

15. Rosenfeld teaches: “One family of alarms looks for changes in vital signs over time, using pre-configured thresholds. These thresholds are patient-specific and setting/disease-specific” (Rosenfeld 24:57–59).

16. Rosenfeld teaches: “Physiologic alarms can be based on multiple variables. For example, one alarm looks for a simultaneous increase in heart rate of 25% and a decrease in blood pressure of 20%, occurring over a time interval of 2 hours” (*id.* at 25:5–8).

17. Rosenfeld teaches: “Alarms also track additional clinical data in the patient database. One alarm tracks central venous pressure and urine output, because simultaneous decreases in these two variables can indicate that a patient is developing hypovolemia” (*id.* at 25:15–19).

18. Rosenfeld teaches: “For this alarm, current heart rate, calculated each minute based on the median value over the preceding 5 minutes, is compared each minute to the baseline value (the median value over the preceding 4 hours)” (*id.* at 25:1–4).

Principles of Law

“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).

Analysis

We adopt the Examiner’s findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 8–15; FF 1–18) and agree that

the claims are rendered obvious by Hutchinson and Rosenfeld. We address Appellants' arguments below.

Claims 13 and 20

Appellants contend "Hutchinson describes a non-tiered operation in the sense that all of the logical operation sets are performed concurrently" (App. Br. 21).

We find this argument unpersuasive. For claim 13, there is no requirement for a "tiered" operation. *See Self*, 671 F.2d at 1348.

Claim 20 does recite "a first tier of a hierarchical analysis" that involves analysis of medical data for event parameters, and a "second tier" that involves event notifications. Claim 20 is reasonably interpreted as a system with processors performing a method of analyzing medical data to obtain at least two trigger conditions, user-defined threshold and a user-defined deviation triggers. If at least two triggers are detected, the system sends a notification (i.e. "event notification") to the medical staff, with the second tier analysis causing a notification to be sent to multiple people if two notifications are generated at the same time.

Rosenfeld teaches analysis of medical data for trigger conditions that are sent to the physician for review (FF 13). In addition, Rosenfeld teaches alarms (i.e. thresholds) "can be based on multiple variables" and can "also track additional clinical data" (FF 16–17). Hutchinson also teaches analysis of "a plurality of physiologic variables" that may be "correlated with a diagnostic interpretation" to create a "logic rule" regarding a patient's condition (FF 6–7). Hutchinson teaches that a plurality of rules may be "designed to monitor the cardiovascular system" (FF 8). Hutchinson also teaches the use of alarms based on the rules (FF 9–11). Finally, Hutchinson

teaches that the data may be available to multiple people on a network (FF 12).

We agree with the Examiner that it would have been obvious to the ordinary artisan to use multiple levels of analysis for the alarms because “Hutchinson teaches rule sets (26) which are a collection of logic rules. . . . The rule set is equivalent to the second tier wherein a group event notification is generated based on a plurality of event notifications” (Ans. 10). Moreover, the ordinary artisan would reasonably have found it obvious to send a group event notification for each detected medical alert to every member of the patient’s medical team, including doctors, nurses, and other relevant staff, to maintain continuity of care.

Appellants contend “Hutchinson does not analyze the acquired variable 17 and generate trigger signals in response to user-defined trigger conditions being detected. Moreover, Hutchinson does not analyze trigger signals to generate an event parameter notification in response to detecting a preselected combination of trigger signals” (App. Br. 21).

We are not persuaded. Hutchinson clearly teaches the use of alarms, which are based on defined trigger conditions based on user-defined rules (FF 7–10). Moreover, Rosenfeld also teaches the use of alarms as trigger signals where a “family of alarms looks for changes in vital signs over time, using pre-configured thresholds. These thresholds are patient-specific and setting/disease-specific” (FF 15). Appellants fail to address this combination of teachings or to explain why claim 13 is unobvious over this combination. “Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed.

Cir. 1986). In determining obviousness, furthermore, a reference “must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” *Id.*

Appellants contend “Hutchinson does not capture the physiological parameters responsible for generating the event parameter notification nor control the display device to display medical context information regarding the captured physiological parameters” (App. Br. 21).

We find this argument unpersuasive because Hutchinson expressly teaches sensors that “may encompass a wide variety of patient monitoring physiologic characteristics/variables 17. These variables include, but are not limited to, heart rate, arterial blood pressure, SpO₂, CO₂, respiration rate” (FF 3). Moreover, Hutchinson teaches a display (FF 5) and Rosenfeld teaches “the vital sign data 464 is also transmitted 466 into a database” (FF 13). These teachings reasonably render it obvious to display the physiological parameter data such as the raw vital sign data that result in “event parameter notification” along with the alarm itself. Indeed, Rosenfeld teaches “the vital sign data is displayed in real time at the ICU 472” (Rosenfeld 21:64–65), supporting this reasoning.

Claim 16

Appellants contend: “Significant by its absence is any suggestion that this evaluation is performed by a processor. Rather, it is submitted that this is a mental operation in which the user, not a processor of the monitor, determines the best balance between sensitivity and specificity” (App. Br. 22).

We find this argument unpersuasive because, to the extent that Rosenfeld teaches performing the method manually “as a mental operation”

as acknowledged by Appellants, it would have been obvious to employ a computer in order “to update it using modern electronic components in order to gain the commonly understood benefits of such adaptation, such as . . . increased reliability, simplified operation, and reduced cost.” *Leapfrog Enterprises, Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). Such a modification is particularly obvious in the current fact pattern, where the entire intent of Hutchinson is to replace manual monitoring of medical patients with automated rules that allow continuous monitoring with more accurate algorithmic interpretation of the underlying medical data (*see* Hutchinson ¶ 2).

Claim 4

Appellants contend “Hutchinson does not teach or fairly suggest the use of mathematical or logical operators” and “Rosenfeld was not cited as and does not cure this shortcoming of Hutchinson” (*id.* at 23).

The Examiner responds “Hutchinson clearly teaches the use of logic and diagnostic algorithms in the processing of the medical data. Using the example spelled out in paragraph 19, it is clear that logical and/or mathematical operators are used to create a trigger combination” (Ans. 11). The Examiner further finds “Rosenf[]eld also uses mathematical and/or logical operators in the smart alarms” (*id.*).

We find that the Examiner has the better position because Rosenfeld teaches “patients with known coronary artery disease in a surgical ICU have alarms set to detect either an absolute heart rate of 95 beats per minute or a 20% increase in heart rate over the baseline” (Rosenfeld 24:65–25:1 (emphasis added)). This is an express teaching of the logical operator “OR” in use in an alarm (i.e. trigger).

Claim 6

Appellants contend the “Examiner concedes that this limitation is not shown by Hutchinson” and “as set forth in lines 14-15 [of Rosenfeld], once the best balance between sensitivity and specificity has been evaluated, the final thresholds are set. Because the final thresholds are set, it is submitted that they are not dynamically adapted” (App. Br. 23).

The Examiner responds “Rosenf[]eld also defines thresholds that change over time. For example, for an alarm look at heart rate, the threshold is based on the median value over the preceding 4 hours, showing the threshold can change based on the timing” (Ans. 10). The Examiner finds “Rosenf[]eld teaches the thresholds can be initially selected and changed based on patient data that yields the best balance between sensitivity and specificity” (*id.*).

We find that the Examiner has the better position. As the Examiner notes, Rosenfeld teaches that one alarm is “calculated each minute based on the median value over the preceding 5 minutes, is compared each minute to the baseline value (the median value over the preceding 4 hours)” (FF 18). Because the baseline value changes based on the acquired medical data, this exemplary embodiment of Rosenfeld teaches an alarm that is calculated by the processor and dynamically depends on the acquired medical data, satisfying the requirement of claim 6 (*see* FF 18).

In addition, as discussed above, even if Appellants correctly state that Rosenfeld’s teaching “to determine a magnitude change for each variable that yields a best balance between sensitivity and specificity . . . is a mental operation performed by the user and is not performed by one or more processors,” (App. Br. 23) it would have been obvious to employ a computer

in order “to update it using modern electronic components in order to gain the commonly understood benefits of such adaptation, such as . . . increased reliability, simplified operation, and reduced cost.” *Leapfrog Enterprises Inc.*, 485 F.3d at 1162.

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that Hutchinson and Rosenfeld render the claims obvious.

D. and E. 35 U.S.C. § 103(a)

Appellants do not separately argue these rejections. The Examiner provides sound fact-based reasoning explaining why the further combinations of Reed or Schradi with Hutchinson and Rosenfeld render the rejected claims obvious (*see* Final Act. 15–18). Having affirmed the rejections over Hutchinson and Rosenfeld for the reasons above, we affirm these further rejections for the Examiner’s reasons, which we adopt as our own.

F. 35 U.S.C. § 103(a) over Hutchinson and Schradi

Appellants contend:

claim 28 calls for: (1) analyzing medical data for the occurrence of a trigger condition, (2) analyzing the trigger conditions to determine an event parameter, (3) analyzing occurrences of the event parameter to determine one or more event groups, and (4) in response to one or more of the event groups being satisfied, displaying an event notification. Hutchinson does not show this chain of analyses. Rather, Hutchinson has sets of rules which concurrently analyze a medical data stream.

(App. Br. 25). Appellants contend “Schradi was cited to show monitoring for amplitudes. However, Schradi was not asserted to and does not cure Hutchinson’s shortcoming of failure to disclose a series of analyses performed on the results of prior analyses” (*id.*).

We remain unpersuaded for the reasons given above. In addition, as already noted, Hutchinson teaches “rule-based algorithm(s) are used to generate a response at block **210**. The response can be an alarm **218**” (FF 9), teaching the steps (1) of analyzing medical data and (2) analyzing the trigger conditions. Hutchinson further teaches the “stored response can be used to later evaluate the effectiveness of the rule-based algorithms, and/or be used to later supply data relating to the subject,” thereby teaching to (3) analyze occurrences of the event group and (4) supplying data is a type of event notification (FF 11). Consequently, we agree with the Examiner that claims 28–31 are obvious over the teachings of Hutchinson and Schradi.

SUMMARY

In summary, we affirm the rejection of claims 4, 6, 13–20, 22, and 24–31 under 35 U.S.C. § 101 as directed to a judicial exception.

We affirm the rejection of claim 24 under 35 U.S.C. § 102(a)/§ 102(e) as anticipated by Hutchinson.

We affirm the rejection of claims 4, 6, 13, 14, 16, 18–20, 22, 25, and 27 under 35 U.S.C. § 103(a) as obvious over Hutchinson and Rosenfeld.

We affirm the rejection of claims 15 and 26 under 35 U.S.C. § 103(a) as obvious over Hutchinson, Rosenfeld, and Schradi.

We affirm the rejection of claims 17 and 23 under 35 U.S.C. § 103(a) as obvious over Hutchinson, Rosenfeld, and Reed.

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We affirm the rejection of claims 28–31 under 35 U.S.C. § 103(a) as obvious over Hutchinson and Schradi.

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

AFFIRMED