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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ALAN CHMIEL, HEATHER GORNIK,
JOHN R. BARTHOLOMEW, CARLOS GRODSINSKY,
and JONATHAN SCHAFFER

Appeal 2013-011068
Application 12/857,118[1]
Technology Center 3600

Before BIBHU R. MOHANTY, MEREDITH C. PETRAVICK, and BRADLEY B. BAYAT, *Administrative Patent Judges*.

PETRAVICK, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Alan Chmiel, et al. (Appellants) seeks our review under 35 U.S.C. § 134 of the final rejection of claims 1–5, 7–16, and 18–32.[2] We have jurisdiction under 35 U.S.C. § 6 (b).

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[1] The real parties in interest, identified by Appellants, are ZIN Technologies, Inc. and the Cleveland Clinic Foundation. Appeal Br. 3.

[2] The Claims Appendix submitted with the Appeal Brief includes amendments presented in an After Final Amendment filed on May 24, 2013. The Examiner, however, denied entry of the amendments. *See* Advisory Action entered May 31, 2013. Our decision refers to the currently pending

SUMMARY OF DECISION

We AFFIRM-IN-PART the rejection of claims 1–5, 7–16, and 18–32.[3]

THE INVENTION

Claims 1, 18, 23, and 29 are independent. Claims 1, 18, and 23 are reproduced below and are illustrative of the subject matter on appeal. Claim 29 is similar to claim 1.

1. A patient monitoring system comprising:

a patient unit configured as a server in a network to read and write data in a remote database, the patient unit comprising:

a device interface configured to provide for data communication with a measurement device, the patient unit being programmed to selectively retrieve results data indicative of at least one patient condition from the measurement device;

a communication module configured to provide two-way communication via the network with the remote database, the server being configured to employ the communication module to retrieve encounter instruction data for the patient unit from the remote database for a given patient encounter, the encounter instruction data comprising a plurality of main sequence steps that include at least one set of predetermined queries, at least one of the plurality of main sequence steps being programmed to

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claims, which can be found in the Replacement Claims Appendix attached to the Reply Brief.

[3] We reference the Appellants' Appeal Brief ("App. Br.," filed May. 28, 2013), Appellants' Reply Brief ("Reply Br.," filed Sept. 6, 2013), the Final Office Action ("Final," mailed Dec. 27, 2012), and the Examiner's Answer ("Ans.," mailed July 9, 2013).

trigger a conditional branch of sequence steps in response to detecting an off-nominal condition at the at least one of the plurality of sequence steps, the conditional branch of sequence steps being programmed to obtain additional information about the off-nominal condition and to return to complete the plurality of main sequence steps, the server being configured to employ the communication module to send response data to the remote database for the given patient encounter, the response data comprising stored user responses, including the additional information about the off-nominal condition, and the results data; and

a user interface programmed to present at least one of the predetermined queries to a user and to receive user responses to the each of the predetermined queries for the given patient encounter, the user responses for each of the predetermined queries being stored in memory of the patient unit as the response data for the given encounter; and

a back office system programmed to access the remote database and to retrieve the response data from the remote database for at least one patient unit, the back office system further being programmed to at least one of add or modify the encounter instruction data in response to retrieved response data for the given encounter, the encounter instruction data being stored in the remote database for a next patient encounter at the patient unit.

18. A patient monitoring system comprising:

a patient unit configured as a server in a network to read and write data in a remote database, the patient unit comprising:

a device interface configured to provide for data communication with a measurement device, the patient unit being programmed to selectively retrieve results data indicative of at least one patient condition that is measured by the measurement device;

a communication module configured to provide two-way communication with the remote database via the network, the server configured to employ the communication module to retrieve encounter instruction data for the patient unit from the remote database for a given patient encounter that includes a plurality of predefined sequence steps that involve at least one set of predetermined queries to be presented to the user for the given patient encounter, the server also being configured to employ the communication module to send response data to the remote database for the given patient encounter, the response data comprising at least one of stored user responses and the results data;

a user interface programmed to present at least one of the predetermined queries to a user and to receive user responses to the each of the predetermined queries for the given patient encounter based on the encounter instruction data, the user responses for each of the predetermined queries being stored in memory of the patient unit as the response data for the given encounter; and

a back office system programmed to access the remote database and to retrieve the response data from the remote database for at least one patient unit, the back office system further being programmed to at least one of add or modify the encounter instruction data that is stored in the remote database for a next patient encounter at the patient unit, wherein the back office system comprises a rules engine that includes predetermined rules programmed according to a predetermined patient procedure protocol, the back office system employing the rules to generate the encounter instruction data that is retrieved by the patient unit during the given encounter to modify at least one of the plurality of predefined sequence steps;

wherein the sequence of predefined steps comprises an update dosage sequence step, the patient unit retrieving

an updated dosage instruction for the given encounter from the remote database during execution of the update dosage sequence step of the given encounter, a dosage query being presented as part of the update dosage sequence step, based on the instruction data, requesting that the user enter a dosage confirmation response via the user interface of the patient unit, the dosage confirmation response being stored as response data in the remote database to indicate that the user has received the updated dosage instruction for a next treatment interval.

23. A method for remote patient management, comprising:

initiating a given encounter at a patient unit in response to a user input provided at the patient unit;

opening a two-way wireless communication channel between the patient unit and a remote database, such that the patient unit operates as a server to retrieve encounter instruction data for the given encounter from the remote database, the encounter instruction data defining a sequence of steps to be executed at the patient unit for the given encounter according to a predetermined patient procedure protocol;

executing each of the sequence of steps at the patient unit, at least some of the sequence of steps requesting responses from the user to confirm compliance with the respective step and at least one of the sequence of steps corresponding to test subroutine;

executing the test subroutine at the patient unit to receive results data indicative of a patient condition;

sending response data for the given encounter from the patient unit to the remote database via a communication channel; and

retrieving by the patient unit updated encounter instruction data from the remote database for a next encounter at the patient unit, the updated encounter instruction data being generated based on the response data, which is sent to and stored in the

> remote database for the given encounter, and based on historical patient data, corresponding to response data from at least one previous encounter at the patient unit, to provide a sequence of steps to be executed at the patient unit for the next encounter at the patient unit.

THE EVIDENCE

The Examiner relies upon the following as evidence of unpatentability:

Bossi	US 2008/0059228 A1	Mar. 6, 2008
Brown	US 2008/0097170 A1	Apr. 24, 2008
Valk	US 2008/0194924 A1	Aug. 14, 2008

THE REJECTIONS

The following rejections are before us for review:

claims 1, 3–5, 7–16, and 18–32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bossi and Brown,

claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Bossi, Brown, and Valk, and

claims 29–32 are rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

ISSUES

The first major issue is whether claims 1, 3–5, 7–16, 21–22 and 29–32 are unpatentable over Brown and Bossi. Specifically, whether Brown discloses a patient unit that has a communication control module that is

configured to retrieve encounter instruction data for the patient unit from the remote database for a given patient encounter and that the encounter instruction data comprises

> a plurality of main sequence steps that include at least one set of predetermined queries, at least one of the plurality of main sequence steps being programmed to trigger a conditional branch of sequence steps in response to detecting an off-nominal condition at the at least one of the plurality of sequence steps . . . .

Reply Br. 9.

The second major issue is whether claims 18–20 and 26 are unpatentable over Brown and Bossi. Specifically, whether Brown and Bossi teaches an update dosage sequence step that includes a dosage query requesting that the user enter a dosage confirmation response via the user interface.

The third major issue is whether claims 23–25, 27, and 28 are unpatentable over Brown and Bossi. Specifically, whether the combination of Brown and Bossi teaches

> retrieving by the patient unit updated encounter instruction data from the remote database for a next encounter at the patient unit, the updated encounter instruction data being generated based on the response data, which is sent to and stored in the remote database for the given encounter, and based on historical patient data, corresponding to response data from at least one previous encounter at the patient unit, to provide a sequence of steps to be executed at the patient unit for the next encounter at the patient unit.

Reply Br. 15.

ANALYSIS

A. Ground Under 35 U.S.C. § 101

Claims 29–32 are rejected under 35 U.S.C. § 101 as being directed to subject matter which is not patent eligible. *See* Final 2. In the Appeal Brief, Appellants argue, that an After-Final Amendment submitted at the same time as the Appeal Brief overcomes the rejection. App. Br. 18. The Examiner, however, did not enter the After-Final Amendment. *See* Ans. 3, 5–6. Appellants do not make any substantive arguments contesting the rejection and indicate that Appellants intend to amend claims 29–32 to overcome the rejection after appeal. *See* Reply Br. 3. As Appellants do not contest this rejection, we summarily affirm the rejection of claims 29–32 under 35 U.S.C. § 101.

B. Grounds Under 35 U.S.C. § 103

Section 103 forbids issuance of a claim when the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 399 (2007), 35 U.S.C. § 103. The ultimate determination of obviousness under § 103 is a question of law based on underlying factual findings. *In re Baxter Int'l, Inc.,* 678 F.3d 1357, 1361 (Fed. Cir. 2012) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)). These underlying factual considerations consist of: (1) the "level of ordinary skill in the pertinent art[,]" (2) the "scope and content of the prior

art[,]" (3) the "differences between the prior art and the claims at issue[,]" and (4) "secondary considerations" of non-obviousness such as "commercial success, long-felt but unsolved needs, failure of others, etc." *KSR*, 550 U.S. at 399 (quoting *Graham,* 338 U.S. at 17–18).

i. Obviousness over Brown and Bossi

a. Claims 1, 3–5, 7–10, 12–16, 21–22 and 29–32

Independent claim 1 requires a patient unit that has a communication control module that is configured to retrieve encounter instruction data for the patient unit from the remote database for a given patient encounter and requires that the encounter instruction data comprises

> a plurality of main sequence steps that include at least one set of predetermined queries, at least one of the plurality of main sequence steps being programmed to trigger a conditional branch of sequence steps in response to detecting an off-nominal condition at the at least one of the plurality of sequence steps[.]

Reply Br. 9. Independent claim 29 requires a similar limitation. *Id.* at 16–17.

The Examiner and Appellants dispute whether Brown teaches this limitation. *See* Final 4–5, Ans. 3–4, App. Br. 19–21, App. Br. 31–35, Reply Br. 3–4.

Brown discloses a blood glucose monitoring system. Brown, Abstract. Figure 12 of Brown is reproduced below.

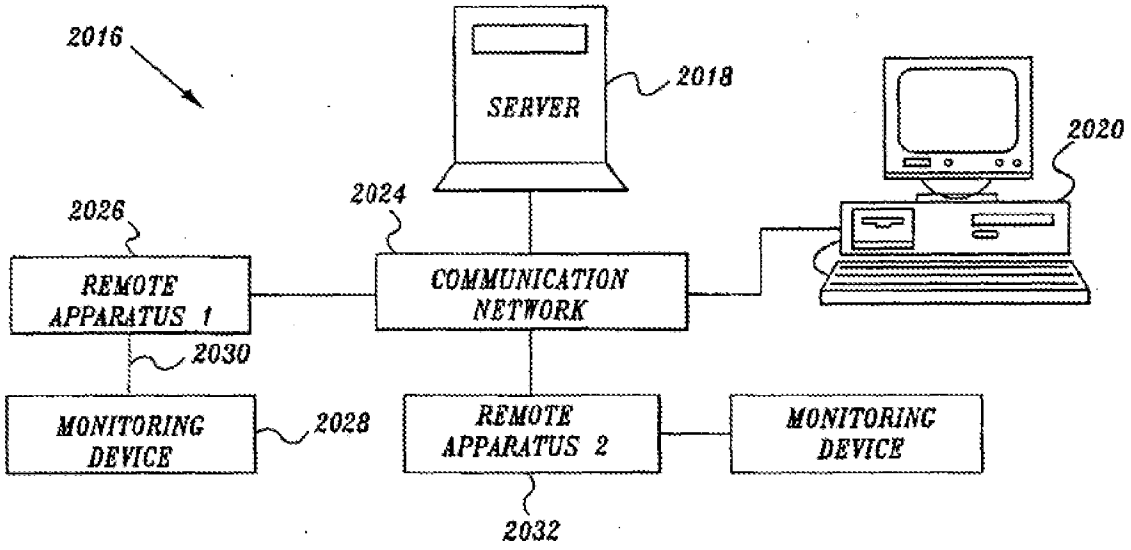

Fig. 12

Brown's Figure 12 depicts one embodiment of the blood glucose monitoring system. *Id.* ¶¶ 46, 111. The system include a server 2018 and a remote apparatus 2026 connected to a monitoring device 2028. *Id.* ¶¶ 112, 113.

The server 2018 includes a database 2038 that stores script programs 2040. *Id.* ¶ 114. The rejection cites database 2038 as equivalent to the claimed remote database. Final 4. Script programs 2040 are executed by the remote apparatus 2026 to communicate queries and messages to the patient and to receive responses. Brown ¶¶ 114, 133.

The rejection makes no mention of the limitation in dispute and does not state which element of Brown corresponds to the claimed encounter instruction data. *See* Final 4. The rejection, however, does equate the claimed patient unit to Brown's blood glucose monitor 16 or monitoring

devices 20 and 22.[4] The rejection also equates the claimed remote database to Brown's database 2038. *Id.* Given this, it is implicit that the claimed encounter instruction data, which includes the conditional branch of the sequence of steps that are triggered by an off-nominal condition, is equivalent to Brown's script program 2040. Script programs 2040 are stored and retrieved from database 2038 and script programs 2040 are executed by remote apparatus 2026 to query the patient, as required by the claim. Brown ¶¶ 114, 133.

In the Answer, the Examiner points to Figures 22A, 22B, 23A and 23B of Brown to teach the limitation at issue and, specifically, points to Figure 22A as teaching the claimed conditional branch. Ans. 4. Figures 22A and 22B depict a flow-chart showing steps, which the Answer alleges to include a conditional branch of steps. *See* Ans. 3–4. Figures 22A and 22B, however, do not depict the steps of Brown's script program 2040, which is executed by remote apparatus 2026. Figures 22A and 22B depict steps that are executed by server 2018. Brown ¶¶ 57, 132. The alleged conditional branch steps, thus, are not included in program script 2040, as required by the claim.

Figures 23A and 23B depict a flow chart showing steps of the script program 2040, which is executed by remote apparatus 2026. *Id.* ¶ 140.

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[4] In the embodiment depicted in Figure 12, monitoring device 2028 corresponds to blood glucose monitor 16 or monitoring devices 20 and 22. *Compare* Brown ¶ 71 to ¶ 113.

Figures 23A and 23B, however, do not depict any conditional branch of steps that are triggered by an off-nominal condition, as required by the claim.

Although Brown separately teaches elements of the limitation at issue, Brown does not teach the elements arranged as required by the claim. The rejection does not rely upon Bossi to cure this deficiency of Brown. *See* Final 4–5. We, thus, reverse the rejection of claims 1 and 29, and claims 3–5, 7–10, 12–16, 21–22, and 30–32, dependent therefrom, under 35 U.S.C. § 103 over Brown and Bossi.

b. Claim 11

Claim 11 depends from claim 6. Claim 6, however, is canceled. As claim 11 depends from a canceled claim, the scope of claim 6 is indefinite under 35 U.S.C. § 112. Since the claims fail to satisfy the requirements under 35 U.S.C. § 112, we are constrained to reverse, *pro forma,* the Examiner's rejection under 35 U.S.C. § 103 over Brown and Bossi. *See In re Steele,* 305 F.2d 859, 862-63 (CCPA 1962) (A prior art rejection cannot be sustained if the hypothetical person of ordinary skill in the art would have to make speculative assumptions concerning the meaning of claim language.); *see also In re Wilson,* 424 F.2d 1382, 1385 (CCPA 1970) ("If no reasonably definite meaning can be ascribed to certain terms in the claim, the subject matter does not become obvious- the claim becomes indefinite.")

c. Claims 18–20

Independent claim 18 requires that the sequence of predefined steps of the encounter instruction data includes an update dosage sequence step that is retrieved from the remote database during execution of the update dosage sequence step of the given encounter and requires that the update dosage sequence steps includes a dosage query requesting that the user enter a dosage confirmation response via the user interface. *See* Reply Br. 13.

The Examiner and the Appellants dispute whether the combination of Brown and Bossi teaches this limitation. *See* Final 10, Ans. 5, App. Br. 28–29, App. Br. 31–35, Reply Br. 4–6. The rejection cites to ¶¶ 143 and 175 of Bossi as teaching this limitation. Final 10. However, neither of the cited paragraphs teach the limitation at issue.

Bossi discloses a system that manages and delivers individual dosages of medications to a patient. Bossi, Abstract. Paragraph 143 of Bossi describes a physician, pharmacist, or other licensed healthcare practitioner reviewing relevant stored data and modifying a dosing schedule or medication regimen by entering new instructions into the system, but does not teach entering instructions that require a patient enter a dosage confirmation response via the user interface, as required by the claim. Likewise, paragraph 175 describes the dangers of a patient receiving an older dosage of medication before an update dosage is in place, but does not teach entering instructions that require a patient to enter a dosage confirmation response via the user interface. Although the cited paragraphs teach updating a patient's dosage in the system, neither paragraph teaches

instructing a patient to enter a confirmation of the updated dosage into the system. The Examiner provides no other evidence or rationale to teach the limitation at issue.

Accordingly, we reverse the rejection of claim 18, and claims 19 and 20, dependent therefrom, under 35 U.S.C. § 103 over Brown and Bossi.

d. Claims 23–25, 27, and 28

Independent claim 23 recites a method that includes a step of

> retrieving by the patient unit updated encounter instruction data from the remote database for a next encounter at the patient unit, the updated encounter instruction data being generated based on the response data, which is sent to and stored in the remote database for the given encounter, and based on historical patient data, corresponding to response data from at least one previous encounter at the patient unit, to provide a sequence of steps to be executed at the patient unit for the next encounter at the patient unit.

Reply Br. 15.

Appellants argue that neither Brown nor Bossi disclose this limitation. App. Br. 32–33. We disagree.

Brown teaches that its system allows a healthcare provide to review previously collected data in reports and to send changes and instructions to the patient. *See* Brown ¶¶ 85–87, 131. Brown's system includes a script generator 2050 that generates new script programs 2040 based upon information entered by a healthcare provider. *Id.* ¶¶ 132–134, Fig. 22A, steps 2202, 2204. Similarly, Boss teaches that a healthcare provider can

retrieve and evaluate a patient's treatment regimen and makes changes to a patient's medication regime. *See* Bossi ¶¶ 125, 143.

Given these teachings of Brown and Bossi, we agree with the Examiner that it would have been obvious to one of ordinary skill in the art to modify the system of Brown to update the next script program for a patient based upon the response and measurement data from a previous script program, in order to efficiently determine whether a patient's medication regimen should be modified. *See* Final 13.

Accordingly, we affirm the rejection of claim 23 under 35 U.S.C. § 103(a) over Brown and Bossi. We also affirm the rejection of claims 24, 25, 27, and 28, which depend from claim 23, under 35 U.S.C. § 103(a) over Brown and Bossi as Appellants do not separately argue these claims. *See* App. Br. 34, 37 C.F.R. § 41.37(c)(1)(iv).

e. Claim 26

Claim 26 depends from claim 23 and additionally requires that the encounter instruction data includes an update dosage sequence step that includes "requesting that a user enter a confirmation response at the patient unit to indicate that the user has received the updated dosage for a next treatment interval." Reply Br. 16. For the same reasons discussed above with regards to claim 18, we reverse the rejection of claim 26 under 35 U.S.C. § 103 over Brown and Bossi.

ii. Obviousness of Claim 2 over Brown, Bossi, and Valk

Claim 2 depends from claim 1. Above, we have reversed the rejection of claim 1 under 35 U.S.C. § 103 over Brown and Bossi. The Examiner does not rely upon Valk to cure the deficiency of Brown and Bossi discussed above. *See* Final 16. Thus, for the same reasons discussed above, the rejection of claim 2 under 35 U.S.C. § 103 over Brown, Bossi, and Valk is reversed.

DECISION

The decision of the Examiner to reject claims 1–5, 7–16, 18–22, and 26 is reversed, and the decision to reject claims 23–25 and 27–32 is affirmed.

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-IN-PART