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Becker Patent Law, LLC
5424 W. Princeton Pines Ct.
Franklin, WI 53132

EXAMINER	
MORGAN, ROBERT W	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WITOLD MOSKAL

Appeal 2017-010441[1]
Application 14/079,213[2]
Technology Center 3600

Before NINA L. MEDLOCK, PHILIP J. HOFFMANN, and, CYNTHIA L. MURPHY *Administrative Patent Judges*.

MEDLOCK, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 1–13 and 15–21. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

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[1] Our decision references Appellant's Appeal Brief ("App. Br.," filed February 16, 2017) and Reply Brief ("Reply Br.," filed July 31, 2017), and the Examiner's Answer ("Ans.," mailed May 31, 2017) and Final Office Action ("Final Act.," mailed September 21, 2016).

[2] Appellant identifies Fenwal, Inc. as the real party in interest. App. Br. 1.

CLAIMED INVENTION

Appellant's claimed invention "relates generally to the storage of medical records with electronic signatures" (Spec. ¶ 1).

Claims 1, 12, and 17 are the independent claims on appeal. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A server computer for storing an electronic medical record with an electronic signature in a database, comprising:
>
> a network interface circuit configured to provide communications over a network; and
>
> a processing circuit configured to:
>
> receive an electronic medical record from a second computing device, wherein the electronic medical record comprises yield data from a procedure performed on a patient;
>
> store the electronic medical record in the database in compliance with at least one record storage criterion;
>
> after storing the electronic medical record in the database in compliance with the at least one record storage criterion, receive an electronic signature for the electronic medical record, wherein the electronic signature indicates approval of data in the electronic medical record; and
>
> store the electronic signature in association with the electronic medical record in the database.

REJECTIONS[3]

Claims 1–13, 15–17, 19, and 20 are rejected under 35 U.S.C. § 103 as unpatentable over Romans (US 7,983,930 B1, iss. July 19, 2011) and Bisbee et al. (US 2012/0086971 A1, pub. Apr. 12, 2012) ("Bisbee").

Claim 18 is rejected under 35 U.S.C. § 103 as being unpatentable over Romans, Bisbee, and Kaboff et al. (US 2010/0198608 A1, pub. Aug. 5, 2010) ("Kaboff").

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[3] The rejection of claims 1–13 and 15–21 under 35 U.S.C. § 101 has been withdrawn (Ans. 2–3).

Claim 21 is rejected under 35 U.S.C. § 103 as unpatentable over Romans, Bisbee, and Case et al. (US 2013/0190674 A1, pub. July 25, 2013) ("Case").

ANALYSIS

In addressing Appellant's arguments, we treat the claims in the order set forth in Appellant's Appeal Brief.

Dependent Claim 21

Claim 21 depends from independent claim 1, and recites that the server computer of claim 1 further comprises:

> the second computing device, wherein the second computing device is an apheresis machine configured to perform an apheresis procedure on a patient,[4] wherein the electronic medical record comprises data regarding an apheresis procedure performed on a patient, wherein the electronic medical record is unsigned and received from an embedded computing device within the second computing device,
>
> wherein the electronic signature for the electronic medical record is received from a third computing device over the network, wherein the electronic signature comprises at least one credential,
>
> wherein the third computing device is a general-purpose computing device, wherein the second computing device and third computing device are distinct computing devices each having their own housing.

Referring to claim 21, Appellant asserts that, in accordance with the claimed invention, an electronic medical record comprising yield data from a patient is stored in a database in compliance with a record storage criterion, and that

[4] Appellant explains that "[a]n apheresis device removes a patient's (e.g., donor's) blood, separates out constituents of the blood, and may return certain constituents of the blood to the patient" (App. Br. 3).

"[t]he electronic medical record is not signed when it is stored" (App. Br. 3–4; *see also id.* at 4 ("Only after the medical record with yield data is . . . stored in the database, an electronic signature for the medical record is transmitted . . . from a different computing device.")). Appellant, thus, argues that the rejection of claim 21 cannot be sustained because Bisbee's electronic record is already signed when it is stored (*id.* at 4–5).

Appellant's argument is not persuasive at least because the Examiner relies on Romans, not Bisbee, as disclosing storage of an unsigned electronic record (*see* Ans. 3). The Examiner explains that one of test units 15A–C, as disclosed in Romans, is interpreted as the claimed "second computing device" ("substituting one of the test units 15A–C with old and well known *apheresis machine* as disclosed by Case") (*id.*). And the Examiner notes that Romans discloses that intermediate server 25 receives data from the test units, i.e., an unsigned electronic record, for holding and further processing, e.g., a diagnostician's interpretation and signature (*id.* (citing Romans, col. 4, ll. 8–67; Figs. 15A and 15B)).

We also are not persuaded of Examiner error by Appellant's argument that "[e]ven if Romans and Bisbee were combinable, the combination would not result in the recitations in Claim 21 identified by the Office Action" (App. Br. 5). Appellant notes that the Examiner takes the position in the Final Office Action that Romans teaches storing the medical record in a database, i.e., intermediate server 15 (*id.*). And Appellant argues that the signed medical record in Romans is never sent to the intermediate server, i.e., the electronic signature is not stored, in association with the electronic medical record, in the database, as called for in claim 21 (*id.*). Instead, according to Appellant, the signed medical record in Roman is sent from the diagnostician to the test unit, e.g., test unit 15A (*id.* at 5–6 (citing Romans,

col. 6, ll. 1–3; Fig. 1)). Appellant, thus, maintains that, even if Bisbee's teaching (i.e., that a trusted repository system ("TRS") server allows secure signing without relinquishing control of the document) were combined with Romans, as proposed by the Examiner, "intermediate server 25 of Romans would be the TRS server (according to the Examiner) and it would never receive any electronically signed document" (*id.* at 6). Appellant further maintains that even if Romans were modified to have intermediate server 25 receive "the electronically signed analysis of Romans" (which Appellant interprets as the diagnostician's analysis of the test data (e.g., at diagnosis center 35A in Fig. 1), rather than the test data itself), this *analysis* was not stored at intermediate server 25 before receiving the electronic signature for the analysis (*id.*).

During prosecution, the USPTO gives claims their "broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000). The Examiner proposes here to modify Romans to arrive at the claimed invention, as recited in claim 21, by (1) replacing the process of transmitting a patient record, including test data, to a diagnostician computer (elements 35A–C in Figure 1 of Romans), as disclosed in Romans, with the process of receiving an electronic signature for an electronic record while retaining the record in the database and storing the electronic signature in the database in association with the electronic record, as disclosed in Bisbee (Ans. 5–6 (citing Bisbee ¶¶ 26, 48–50)); and (2) replacing the test unit in Romans, i.e., the claimed second computing device, with an apheresis machine configured to perform an apheresis procedure on a patient, as disclosed in Case (*id.* at 7 (citing Case ¶¶ 23–27)). Although Appellant suggests otherwise, the Examiner's rejection, as we understand it, does not involve replacing Romans's intermediate server 25

with Bisbee's TRS (*see* App. Br. 6; Reply Br. 4). Instead, the Examiner proposes obtaining an electronic signature for the electronic medical record, i.e., the signature from the diagnostician, while retaining the test data in Roman's intermediate server 25.

Independent claim 1, and therefore, dependent claim 21, calls for "receiv[ing] an electronic signature for the electronic medical record, wherein the electronic signature indicates approval of data in the electronic medical record." Although we note Appellant's argument that the diagnostician can only sign off on his own analysis, and cannot sign off on test data (App. Br. 6), in our view, receiving an electronic signature from a diagnostician who interprets the electronic medical record, i.e., the test data, and prepares a diagnosis based on the electronic medical record, as disclosed in Romans, meets the claim language, i.e., the above-cited receiving step, under a broad, but reasonable, interpretation.

Therefore, we sustain the Examiner's rejection of dependent claim 21 under 35 U.S.C. § 103.

Independent Claim 1 and Dependent Claims 2–7

Appellant argues that the Examiner erred in rejecting claims 1–7 by reference to Appellant's arguments with respect to claim 21, which we found unpersuasive. Therefore, we sustain the Examiner's rejection of claims 1–7 under 35 U.S.C. § 103.

Dependent Claim 8

Claim 8 depends from independent claim 1, which recites that "the electronic medical record comprises yield data from a procedure performed on a patient." Claim 8 further requires that "the electronic medical record comprises data regarding an apheresis procedure performed on a patient."

We are not persuaded that the Examiner erred in rejecting claim 8 under 35 U.S.C. § 103 at least because the feature that Appellant maintains is not disclosed or suggested by the cited references, i.e., that the electronic medical record comprises data regarding "an apheresis procedure" performed on a patient, does not alter or in any way affect the manner in which the claimed method is performed. As such, it constitutes nonfunctional descriptive material that may not be relied on to distinguish over the prior art for purposes of patentability.

The Federal Circuit has long held that where a limitation claims printed matter that is not functionally or structurally related to its physical substrate, the printed matter may not be relied on to distinguish over the prior art for purposes of patentability. *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability). In applying the printed matter doctrine, the first step is to determine whether the limitation is, in fact, directed to printed matter, i.e., whether the limitation claims the content of information. *See In re Distefano*, 808 F.3d 845, 848 (Fed. Cir. 2015). If so, "one must then determine if the matter is functionally or structurally related to the associated physical substrate, and only if the answer is 'no' is the printed matter owed no patentable weight." *Id.* at 851. *See also King Pharms Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1278–79 (Fed. Cir. 2010) (applying the "printed matter" reasoning to method claims).

Here, claim 8 claims the informational content of the electronic medical record, and as such, is directed to printed matter. The relevant inquiry then is whether the recitation that the electronic medical record comprises "data regarding an apheresis procedure performed on a patient"

has a "new and unobvious functional relationship" with the method. *Id.* at 1279. In other words, we look to whether the medical-procedure-specific content of "the data from a procedure performed on a patient" changes the way the steps of independent claim 1 are performed.

There is no objective evidence of record that the fact that the electronic medical record comprises data regarding an apheresis procedure performed on a patient, as opposed to another medical procedure performed on the patient, affects the function of the claimed method in any way. Regardless of the medical-procedure-specific nature of the data in the electronic medical record, the steps of the claimed method (e.g., the receiving and storing steps) are still performed the same way, and the underlying method is the same. As such, the argued limitation, i.e., that the electronic medical record comprises data regarding "an apheresis procedure" performed on a patient, constitutes non-functional descriptive material that may not be relied on for patentability. *See In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004).

Therefore, we sustain the Examiner's rejection of dependent claim 8 under 35 U.S.C. § 103.

Dependent Claim 9

Claim 9 depends from independent claim 1, and recites that "the electronic medical record is received from an embedded processor of a medical device, wherein the medical device is configured to perform a medical procedure on a patient." Appellant's argument with respect to claim 9 is substantially similar to Appellant's argument with respect to claim 21, and is similarly unpersuasive. Therefore, we sustain the Examiner's rejection of dependent claim 9 under 35 U.S.C. § 103.

Dependent Claim 10

Claim 10 depends from independent claim 1, and recites that "the processing circuit is configured to receive medical records from at least two different care areas within an environment." We agree with the Examiner that Romans meets the claim language (Final Act. 12 (citing Romans, col. 3, ll. 35–67)). To the extent that Appellant argues that Romans does not disclose that medical records are received from care areas such as "an intensive care unit, a primary care unit, a clinic, etc.," as described in paragraph 18 of Appellant's Specification (App. Br. 9), we note that limitations appearing in the specification are not read into the claim. *See E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003).

We sustain the Examiner's rejection of dependent claim 10 under 35 U.S.C. § 103.

Dependent Claim 11

Claim 11 depends from independent claim 1, and recites that "processing circuit is configured to, after storing the electronic medical record in the database in compliance with the at least one record storage criterion, transmit a notification that causes a remote computing device to request credentials for the electronic signature." The Examiner cites Romans at column 4, lines 45–67 and column 5, lines 50–67, as disclosing the claim limitation (Final Act. 12). There, Romans discloses that the intermediate computer transmits the electronic record containing the test data to a diagnosis center for interpretation/analysis by a diagnostician. Romans further discloses, as the Examiner notes with respect to claim 21, that the diagnosticians are provided with computers that are equipped with signature recorders that are capable of biometric recognition.

In our view, Romans meets the claim language under a broad, but reasonable, interpretation. Therefore, we sustain the Examiner's rejection of dependent claim 11 under 35 U.S.C. § 103.

Independent Claim 12 and Dependent Claims 13, 15, and 16

Appellant's arguments with respect to claims 12, 13, 15, and 16 are substantially similar to Appellant's arguments with respect to claim 21, which we found unpersuasive. Therefore, we sustain the Examiner's rejection of claims 12, 13, 15, and 16 under 35 U.S.C. § 103.

Independent Claim 17 and Dependent Claims 18 and 20

Independent claim 17 is directed to a server computer for storing an electronic medical record with an electronic signature in a database and recites that the server computer comprises a processing circuit configured to, *inter alia*, "generate a user interface screen configured to receive an electronic signature for the medical record" and "transmit the user interface screen to the medical device over the network." The Examiner acknowledges that Romans does not specifically disclose this limitation, and the Examiner cites Bisbee to cure the deficiency of Romans (Final Act. 18). The Examiner reasons that "Bisbee teaches it is old and well known [to] *transmit the user interface screen to the medical device over the network; receive an electronic signature entered using the user interface screen*" (*id.* (citing Bisbee ¶¶ 38–45)). And the Examiner concludes that it would have been obvious to a person of ordinary skill in the art at the time of Appellant's invention to modify Romans to include transmitting the user interface screen to the medical device over the network and receiving an electronic signature entered using the user interface screen because "it will allow securely signing stored electronic original information objects without

the trusted repository system (TRS) ever relinquishing control of the authoritative copy of the electronic original information object or document" and further because "merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination" (*id.* at 18–19).

Appellant maintains that neither Romans nor Bisbee, alone or in combination, discloses or suggests modifying a medical device to receive a user interface screen from a server computer for receiving an electronic signature (App. Br. 11). Appellant, thus, observes if the sphygmomanometer, i.e., a medical device, of Romans were modified to receive an electronic signature user interface, the interface would be at the practitioner's location 15A (*see* Romans, Fig. 1), not at the diagnostician's location 35A, i.e., where the analysis is signed (*id.*).

Appellant's argument is persuasive. Accordingly, we do not sustain the Examiner's rejection under 35 U.S.C. § 103 of independent claim 17. For the same reason, we also do not sustain the rejection of claims 18 and 20, which depend therefrom. *Cf. In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("dependent claims are nonobvious if the independent claims from which they depend are nonobvious").

Dependent Claim 19

Claim 19 depends from independent claim 17, and recites that "the processing circuit is configured to transmit the user interface screen to an apheresis machine." We do not sustain the Examiner's rejection under 35 U.S.C. § 103 of independent claim 17; therefore, we also do not sustain the rejection of dependent claim 19. *Cf. In re Fritch*, 972 F.2d at 1266.

DECISION

The Examiner's rejections of claims 1–13, 15, 16, and 21 under 35 U.S.C. § 103 are affirmed.

The Examiner's rejections of claims 17–20 under 35 U.S.C. § 103 are reversed.

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).

AFFIRMED-IN-PART