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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte VINAY VAIDYA and KELLY BASFIELD

Appeal 2017-005520[1]
Application 13/397,359[2]
Technology Center 3600

Before NINA L. MEDLOCK, BART A. GERSTENBLITH, and CYNTHIA L. MURPHY, *Administrative Patent Judges*.

MEDLOCK, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 1–14 and 16–63. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Our decision references Appellants' Appeal Brief ("App. Br.," filed August 4, 2016) and Reply Brief ("Reply Br.," filed February 14, 2017), and the Examiner's Answer ("Ans.," December 14, 2016) and Final Office Action ("Final Act.," mailed October 2, 2015).

[2] Appellants identify Phoenix Children's Hospital of Phoenix, Arizona as the real party in interest. App. Br. 1.

CLAIMED INVENTION

Appellants describe the claimed invention as "a prescription dosage check system and method . . . for ensuring safe and reliable prescription ordering and filling for a medication prescribed by a caregiver" (Spec. 1).

Claims 1, 16, and 62 are the independent claims on appeal. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A computer-implemented method of checking a prescription dosage when ordering a prescription using a physician order entry system having a data terminal, a central processing unit, and a central server, comprising:
>
> providing an electronic patient medical record database, containing:
>
> i) a plurality of electronic patient records each corresponding to a particular patient; and
>
> ii) historical drug ordering data;
>
> providing an electronic drug reference database, containing:
>
> i) drug dosage values or limits from drug manufacturers;
>
> ii) analyzed and assembled drug dosage data generated using the historical drug ordering data contained in the electronic patient medical record database; and
>
> iii) derived drug dosage values or limits derived using the drug dosage values or limits from the drug manufacturers stored in the electronic drug reference database along with the analyzed drug dosage data stored in the electronic drug reference database, a specificity and sensitivity of the derived drug dosage values or limits being set based on the number of physician alerts, the set of derived drug dosage values or limits being validated against the historical drug ordering data using at least in part the analysis of the historical drug ordering data;
>
> setting the specificity and sensitivity of the derived drug dosage values or limits based on the number of physician alerts;

validating the set of derived drug dosage values or limits against the historical drug ordering data using at least in part the analysis of the historical drug ordering data;

entering an order by an authorized caregiver into the data terminal, the order providing a prescribed dosage of a prescribed medication for a particular patient to receive the prescribed medication;

uploading the order to the central server;

updating an electronic patient record of the patient contained in the electronic patient medical record database with patient data in real time;

generating a dosage or dosage range using the derived drug dosage values or limits from the electronic drug reference database for the prescribed medication and at least one patient parameter obtained from the electronic patient medical record for the particular patient contained in the electronic patient medical record database;

comparing the prescribed dosage with the generated dosage or dosage range;

determining whether the prescribed dosage falls above or below the generated dosage or outside the generated dosage range; and

generating and outputting an alert if the prescribed dosage falls above or below the generated dosage or outside the generated dosage range prior to filling the prescribed medication for the particular patient.

REJECTIONS

Claims 11–14, 16, and 60–63 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that Appellants regard as the invention.

Claims 1–14 and 16–63 are rejected under 35 U.S.C. § 101 as directed to a judicial exception without significantly more.

Claims 1, 17, and 60 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol et al. (US 2002/0143580 A1, pub. Oct. 3, 2002)

("Bristol"), Mahran (US 2002/0165737 A1, pub. Nov. 7, 2002), Estes (US 2009/0275887 A1, pub. Nov. 5, 2009), and Gelston (US 2001/0050610 A1, pub. Dec. 13, 2001).

Claim 2 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Mahran, Estes, Gelston, and Velarde (US 2009/0281836 A1, pub. Nov. 12, 2009).

Claim 3 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Mahran, Estes, Gelston, and Bailey et al. (US 2002/0040282 A1, pub. Apr. 4, 2002) ("Bailey").

Claim 4 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Mahran, Estes, Gelston, and Spector et al. (US 2004/0024616 A1, pub. Feb. 5, 2004) ("Spector").

Claims 5, 6, 8, 9, 11, 12, 14, 18–28, 31, 44, and 47 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Mahran, Estes, Gelston, and Howard et al. (US 2007/0213598 A1, pub. Sept. 13, 2007) ("Howard").

Claims 7, 10, 13, 29, 30, 32, 34–43, 45, 46, 48, 50, and 51 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Mahran, Estes, Gelston, Howard, and Mohapatra et al. (US 7,706,915 B2, iss. Apr. 27, 2010) ("Mohapatra").

Claim 16 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol and Estes.

Claims 33 and 49 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Mahran, Estes, Howard, Fischell et al. (US 2007/0093720 A1, pub. Apr. 26, 2007) ("Fischell"), and Kountotsis et al. (US 2012/0272713 A1, pub. Nov. 1, 2012) ("Kountotsis").

Claims 52–59 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Mahran, Estes, Gelston, Howard, Fischell, Kountotsis, and Mohapatra.

Claim 61 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Estes, and Bailey.

Claim 62 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Mahran, and Estes.

Claim 63 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bristol, Mahran, Estes, and Brummel et al. (US 2006/0106647 A1, pub. May 18, 2006) ("Brummel").

ANALYSIS

Indefiniteness

Appellants do not provide any response to the Examiner's rejection of claims 11–14, 16, and 60–63 under 35 U.S.C. § 112, second paragraph. And, although the Examiner makes no mention of the rejection in the Answer, we find no indication in the record that the rejection has been withdrawn. Therefore, we summarily sustain the rejection.

Patent-Ineligible Subject Matter

Appellants argue claims 1–14 and 16–63 as a group (App. Br. 7–10). We select independent claim 1 as representative. The remaining claims stand or fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Under 35 U.S.C. § 101, an invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. The Supreme Court, however, has long interpreted § 101 to include an implicit exception: "[l]aws of nature, natural phenomena, and

abstract ideas" are not patentable. *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014).

The Supreme Court, in *Alice*, reiterated the two-step framework previously set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp.*, 134 S. Ct. at 2355. The first step in that analysis is to "determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* If the claims are not directed to a patent-ineligible concept, e.g., an abstract idea, the inquiry ends. Otherwise, the inquiry proceeds to the second step where the elements of the claims are considered "individually and 'as an ordered combination'" to determine whether there are additional elements that "'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 566 U.S. at 79, 78).

The Court acknowledged in *Mayo*, that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. Therefore, the Federal Circuit has instructed that claims are to be considered in their entirety to determine "whether their character as a whole is directed to excluded subject matter." *McRO, Inc. v. Bandai Namco Games Am., Inc.*, 837 F.3d 1299, 1312 (Fed. Cir. 2016) (quoting *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)).

Addressing the first step of the *Mayo/Alice* framework, Appellants argue, and we agree, that an invention is not rendered ineligible for patent simply because it *involves* an abstract concept. (App. Br. 7). Instead, the

Federal Circuit has explained that "the 'directed to' inquiry applies a stage-one filter to claims, considered in light of the [S]pecification, based on whether 'their character as a whole is directed to excluded subject matter.'" *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (citing *Internet Patents Corp.*, 790 F.3d at 1346). It asks whether the focus of the claims is on a specific improvement in relevant technology or on a process that itself qualifies as an "abstract idea" for which computers are invoked merely as a tool. *See id.* at 1335–36.

Appellants criticize the Examiner's statement that the pending claims are directed to an abstract idea "because an abstract idea is recited in the claims," and charge that the rejection, at most, asserts that the claims may involve an abstract concept (App. Br. 7 (citing Final Act. 4)). Yet, Appellants cannot reasonably deny that claim 1 is directed to

> retrieving patient and medication information from databases including specificity and sensitivity pertaining to dosage values, utilizing the retrieved information to generate dosage values, creating a prescription order for the patient and updating the patient's record in real time, comparing a dosage value from the prescription order to the generated dosage values and determining whether the prescription order dosage value falls above or below the generated dosage values[,]

i.e., the abstract idea that the Examiner determined is recited in the claim (Final Act. 4).

This characterization of the concept to which claim 1 is directed is fully consistent with the Specification, including the claim language (*see, e.g.*, claim 1; Spec. 3–4 (disclosing a method of checking a prescription dosage using a device having a data terminal, a central processing unit, a central server, an electronic patient record database, and an electronic drug reference database, comprising entering an order, comprising a prescribed

dosage of a medication for a patient, into the data terminal; uploading the order to the central server; identifying a predetermined dosage or dosage range using data from the electronic reference database and patient data contained in the electronic patient record database; comparing the prescribed dosage with the identified dosage or dosage range; determining whether the prescribed dosage falls above or below the identified dosage or the prescribed dosage falls outside of the identified dosage range; and generating and outputting an alert if the prescribed dosage is above or below the identified dosage or falls outside of the identified dosage range); *see also, e.g.*, *id.* at 27–29, 36). And, although articulated at a different level of abstraction, it also is fully consistent with Appellants' characterization of the claims as directed to "ensuring the administering of a correct dosage of a prescription medication to a patient" (*see* Reply Br. 3).[3]

Appellants assert that "[a]n 'abstract idea' refers to a quality or concept generally, having no reference to material objects or specific examples," and ostensibly maintain that the claims are not directed to an abstract idea because the claims involve physical objects, e.g., a data

[3] An abstract idea can be expressed at various levels of abstraction. *See Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1240–41 (Fed. Cir. 2016) ("An abstract idea can generally be described at different levels of abstraction. As the Board has done, the claimed abstract idea could be described as generating menus on a computer, or generating a second menu from a first menu and sending the second menu to another location. It could be described in other ways, including, as indicated in the specification, taking orders from restaurant customers on a computer."). That the Examiner articulates the abstract idea at a different level of abstraction than do Appellants is an insufficient basis for finding that the claims are not directed to an abstract idea.

terminal, a central processing unit, a central server, an electronic patient medical record database, and an electronic drug reference database (App. Br. 8). Yet, as the court noted in *In re TLI Commc'ns LLC Patent Litig.*, 823 F.3d 607 (Fed. Cir. 2016), "not every claim that recites concrete, tangible components escapes the reach of the abstract-idea inquiry." *Id.* at 611. Although claim 1 recites physical components, e.g., a data terminal, a central processing unit, and a central server, it is clear from the Specification that the recited physical components merely provide a generic environment in which to carry out the abstract idea of ensuring the administering of a correct dosage of a prescription medication to a patient, i.e., determining whether a patient prescription order dosage value falls above or below a dosage value or range of dosage values generated using patient and medication information retrieved from an electronic patient record database and an electronic drug reference database (*see* Spec. 3–4 (describing that a prescription order, comprising a prescribed dosage of a medication for a patient, is entered into the data terminal and uploaded to the central server)). The Specification's indication that the claimed invention is intended to address the need for "a user-friendly, effective system for ensuring the delivery of a safe and effective dosage of a prescribed medication" (Spec. 1), as well as its indication that the system includes dose range checking and an alert system to prevent filling of a prescription where the prescribed dosage falls outside a dosage value or range for that medication (*id.*), also underscore that the claims are directed to the abstract idea identified by the Examiner, and not to an improvement in any physical components and/or computer technology.

Appellants charge that the Examiner merely asserts that claims 1–14 and 16–63 are directed to an abstract idea and that "the rejection has not substantiated or established that the claims as a whole are directed to an abstract idea simply by stating that they are" (App. Br. 9). But, that argument is not persuasive.

The Federal Circuit acknowledged in *Amdocs* that there is no single, succinct, useful definition of "abstract idea," and the court suggested examining earlier cases of a similar or parallel nature and the way those cases were decided. *Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1294 (Fed. Cir. 2016) ("Instead of a definition [for what an 'abstract idea' encompasses], then, the decisional mechanism courts now apply is to examine earlier cases in which a similar or parallel descriptive nature can be seen—what prior cases were about, and which way they were decided."). Consistent with that guidance, the Examiner articulated the abstract idea to which the claims are directed, and also analogized the abstract idea to concepts that the courts have previously identified as abstract, i.e., comparing new and stored information (i.e., patient and medication information) and using rules to identify options (i.e., whether a prescribed dosage value exceeds or falls below a generated dosage value); processing information (i.e., patient and medication information) through a clearinghouse (i.e. a computer); and using categories (i.e., patient records versus medication information) to organize, store, and transmit information (Final Act. 5; *see al*so Ans. 3–4 (citing cases in which the courts have identified these and other similar concepts as abstract ideas)). Appellants do not contend that the Examiner's reliance on these cases is misplaced or that the cases that the Examiner identified are otherwise inapposite.

Appellants charge in the Reply Brief that the Examiner has not properly established that the claims are directed to an abstract idea, and that the Examiner improperly considers the claim as a listing of a series of unrelated, disjointed and overgeneralized concepts (Reply Br. 1–2 (citing Ans. 3–4)). But, we cannot agree with Appellants that the Examiner has overgeneralized the claimed invention as directed to

> retrieving patient and medication information from databases including specificity and sensitivity pertaining to dosage values, utilizing the retrieved information to generate dosage values, creating a prescription order for the patient and updating the patient's record in real time, comparing a dosage value from the prescription order to the generated dosage values and determining whether the prescription order dosage value falls above or below the generated dosage values[,]

or that the Examiner has, otherwise, failed to consider the claims as a whole (*id.*).

In rejecting the claims under § 101, the Examiner analyzed the claims using the *Mayo/Alice* two-step framework, in accordance with the guidance set forth in the USPTO's "2014 Interim Guidance on Patent Subject Matter Eligibility," 79 Fed. Reg. 74618 (Dec. 16, 2014), in effect at the time the Final Office Action was mailed (Final Act. 4–6). And, as described above, the Examiner's identification of the concept to which the claims are directed is fully consistent with the Specification, including the claim language.

Appellants charge, as described above, that the Examiner has not properly established that the claims are directed to an abstract idea (*see* Reply Br. 1–3). And Appellants ostensibly maintain that the Examiner's analogies are improperly drawn and/or unsupported (*see id.*). Yet, we fail to see how or why, and Appellants do not adequately explain how or why, the method, as recited in claim 1, for example, involves more than collecting

information (i.e., patient and medication information); analyzing the information (i.e., to derive dosage values and limits); and displaying the results of the collection and analysis (i.e., alerts), without any particular inventive technology — which the Federal Circuit has repeatedly held is within the realm of abstract ideas. *See, e.g.*, *Elec. Power Grp. LLC v. Alstom, S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016) (holding that claims focused on collecting information, analyzing it, and displaying certain results of the collection and analysis were directed to an abstract idea because "[t]he advance they purport to make is a process of gathering and analyzing information of a specified content, then displaying the results, and not any particular assertedly inventive technology for performing those functions.").

Appellants further argue that the Examiner failed to consider the claims individually, as required by USPTO guidelines, and that Examiner "improperly judged all of claims 1–14 and 16–63 to fall together as a group" (App. Br. 9). Yet, we decline to find error in the Examiner's approach, as claims 1–14 and 16–63 are all directed to the same abstract idea. *See Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1348 (Fed. Cir. 2014) (explaining that when all claims are directed to the same abstract idea, "addressing each claim of the asserted patents [is] unnecessary"). Here, the Examiner explicitly noted that "[t]he abstract idea for Claims 16 and 61 is similar to the abstract idea for the Claims 1–14 and 17–60 except that Claims 16 and 61 do not require storing a specificity and sensitivity in a database, or updating the patient record in real-time" and that "[t]he abstract idea for **Claims 62–63** is similar to the abstract idea for . . . **Claims 1–14 and 17–60** except that **Claims 62–63** do

not require updating the patient record in real-time" (Final Act. 4–5). It also is telling here that, aside from asserting that the Examiner failed to consider the limitations of claims 1–14 and 16–63 individually, Appellants offer no separate arguments for the patent-eligibility of these claims but instead argue the claims as a group.

We also are not persuaded by Appellants' argument that the rejection "confuses the concept of abstractness under 35 USC 101, with the concept of novelty under 35 USC 102" (App. Br. 10). Contrary to Appellants' suggestion, the Examiner did not determine that the claims, as a whole, are directed to an abstract idea because "the 'additional limitations' represent 'generic computer structure' that performs functions 'that are well-understood, routine, and conventional activities known to the pertinent industry'" (*id.*). Nor did the Examiner refer to generic computer structure in the context of a discussion of novelty. Instead, the Examiner determined that the claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the additional elements or combination of elements in the claims, other than the abstract idea, amount to no more than a recitation of "A) generic computer structure that serves to perform generic computer functions that serve to merely link the abstract idea to a particular technological environment (**i.e.**[,] **a computer**)" and "B) functions that are well-understood, routine, and conventional activities previously known to the pertinent industry (i.e. storing, processing (**i.e. setting, validating, generating/computing), receiving, and transmitting data**)" (Final Act. 5–6) — a determination fully consistent with the controlling precedent. *See DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1256 (Fed. Cir. 2014) ("And after *Alice*,

there can remain no doubt: recitation of generic computer limitations does not make an otherwise ineligible claim patent-eligible.").

We are not persuaded, on the present record, that the Examiner erred in rejecting independent claim 1 under 35 U.S.C. § 101. Therefore, we sustain the Examiner's rejection of claim 1, and claims 2–14 and 16–63, which fall with claim 1.

Obviousness

Independent Claim 1 and Dependent Claims 17 and 60

We are persuaded by Appellants' argument that the Examiner erred in rejecting independent claim 1 under 35 U.S.C. § 103(a) at least because none of the cited references, individually or in combination, discloses or suggests "setting the specificity and sensitivity of the derived drug dosage values or limits based on the number of physician alerts," as recited in claim 1 (App. Br. 11–13). The Examiner cites Estes as disclosing the argued limitation (Final Act. 11 (citing Estes ¶¶ 81–83)). But we agree with Appellants that there is nothing in the cited portions of Estes that discloses or suggests setting the specificity and sensitivity of drug dosage values or limits based on the number of physician alerts, as called for in claim 1.

Estes discloses an infusion pump system 10, with reference to Figures 1 and 2, comprising a glucose monitoring device 50 in communication with an infusion pump assembly 60 configured to supply insulin or other medication to a user via an infusion set 70 (Estes ¶ 27); pump assembly 60 includes a pump device 100 that dispenses medicine from a medicine cartridge 120 through a flexible tube 72 of the infusion set 70 to a cannula housing 74 where the dispensed medicine enters through the user's skin via a cannula 76 attached to the underside of cannula housing 74 (*id.*

¶ 31). Estes discloses that in some embodiments, the infusion pump system is configured to alert the user when an occlusion, e.g., a kink in the flexible tube, is detected, so as to remedy the possible interruption of medicine delivery to the user (*id.* ¶ 80). And Estes further discloses that, in certain situations (e.g., when transient kinks occur that self-correct, i.e., without user intervention, after a short period of time), it may be advantageous to detect a pattern of high pressure signals in the medicine cartridge (indicative of a kink) before communicating the alert to the user (*id.*).

Estes, thus, discloses in paragraphs 81–83, cited by the Examiner, that the system can include an occlusion detection system with an adjustable sensitivity value, e.g., the sensitivity value can be set such that an alert is not issued, i.e., an occlusion is not determined to exist, until after a predetermined time has elapsed or after a pressure sensor (sampling the pressure in the medicine cartridge) outputs a predetermined number of consecutive high pressure signals. However, we fail to see how, and the Examiner does not adequately explain how Estes, by its disclosure of an occlusion detection system, i.e., detecting an interruption in the delivery of medicine caused by a kink in a flexible tube and issuing an alert, alone or in combination with Bristol and Mahran, discloses or suggests setting the specificity and sensitivity of derived drug dosage values or limits based on a number of physician alerts, as called for in claim 1.

Therefore, we do not sustain the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a). For the same reason, we also do not sustain the rejection of dependent claims 17 and 60. *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").

Independent Claims 16 and 62

Independent claims 16 and 62 include language substantially similar to the language of claim 1, and stand rejected based on the same rationale with respect to Estes applied to claim 1 (*see* Final Act. 41–42, 52–53). Therefore, we do not sustain the Examiner's rejections of claims 16 and 62 for the same reason set forth above with respect to claim 1.

Dependent Claims 2–14, 17–61, and 63

The rejections of dependent claims 2–14, 17–61, and 63 do not cure the deficiency in the rejections of independent claims 1, 16, and 62. Therefore, we do not sustain the Examiner's rejections under 35 U.S.C. § 103(a) of these dependent claims for the same reason set forth above with respect to the independent claims.

DECISION

The Examiner's rejection of claims 11–14, 16, and 60–63 under 35 U.S.C. § 112, second paragraph, is affirmed.

The Examiner's rejection of claims 1–14 and 16–63 under 35 U.S.C. § 101 is affirmed.

The Examiner's rejections of claims 1–14 and 16–63 under 35 U.S.C. § 103(a) 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