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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GLEN DE VRIES, ISAAC WONG, and MICHELLE MARLBOROUGH

Appeal 2017-002714
Application 14/053,405[1]
Technology Center 3600

Before BRUCE T. WIEDER, TARA L. HUTCHINGS, and ROBERT J. SILVERMAN, *Administrative Patent Judges*.

WIEDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 3–13, and 15–21. We have jurisdiction under 35 U.S.C. § 6(b). Oral arguments were presented on October 16, 2018.

We AFFIRM and enter a NEW GROUND OF REJECTION pursuant to our authority under 37 C.F.R. § 41.50(b).

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[1] According to Appellants, the real party in interest is Medidata Solutions, Inc. (Appeal Br. 3.)

CLAIMED SUBJECT MATTER

Appellants' invention relates to allowing "disparate . . . clinical data recording devices . . . to be to be assimilated into a unified clinical system." (Spec. ¶ 12.)

Claims 1, 8, 12, and 16 are the independent claims on appeal. Claim 1 is illustrative. It recites:

> 1. A method for controlling workflow using audits from disparate clinical data input functionalities, comprising:
>
> receiving, at a first component of a clinical data system, an audit from at least one clinical data input functionality;
>
> calculating, by a computer processor, whether the received audit constitutes a sufficient audit of the clinical data system, wherein the sufficiency is a configurable attribute of the clinical data system and wherein if the received audit constitutes said sufficient audit, then the received audit comprises a first sufficient audit, and if the received audit is not sufficient, transmitting the received audit to a second component of the clinical data system, generating a dependent audit at the second component, and supplementing the received audit with data contained in the dependent audit to generate the first sufficient audit;
>
> calculating, at the first component, workflow instructions in accordance with which the first sufficient audit is transmitted to a further component of the clinical data system and to an audit service;
>
> generating at the further component a second sufficient audit related to the first sufficient audit; and
>
> persisting the first sufficient audit and the second sufficient audit in a database associated with the audit service.

REJECTIONS

Claims 1, 3–13, and 15–21 are rejected under 35 U.S.C. § 101 as directed to a judicial exception without significantly more.

Claims 1, 3–11, and 15–21 are rejected under 35 U.S.C. § 112(a) as failing to comply with the enablement requirement.[2]

Claims 1, 3–13, 15, 20, and 21 are rejected under 35 U.S.C. § 112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellants regard as the invention.

Claims 1, 3–6, 8–10, 12, 13, 15, 19, and 20 are rejected under 35 U.S.C. § 103 as obvious in view of Simske (WO 2011/136781 A1, pub. Nov. 3, 2011), Ingrassia (US 2011/0225178 A1, pub. Sept. 15, 2011), and Natoli (US 2009/0080408 A1, pub. Mar. 26, 2009).

Claims 7 and 11 are rejected under 35 U.S.C. § 103 as obvious in view of Simske, Ingrassia, Natoli, and Corbett-Clark (US 2004/0177090 A1, pub. Sept. 9, 2004).

Claims 16 and 17 are rejected under 35 U.S.C. § 103 as obvious in view of Simske and Natoli.

Claim 18 is rejected under 35 U.S.C. § 103 as obvious in view of Simske, Natoli, and Corbett-Clark.

Claim 21 is rejected under 35 U.S.C. § 103 as obvious in view of Simske, Ingrassia, Natoli, and Bayliss (US 7,912,842 B1, iss. Mar. 22, 2011.)

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[2] Although the Final Action refers to the written description requirement of § 112(a) (*see* Final Action 4), as discussed *infra*, the Examiner concludes that the Specification does not meet the enablement requirement of § 112(a) (*see id.* at 7–15).

ANALYSIS

The § 101 rejection

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. Section 101, however, "contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)).

Alice applies a two-step framework, earlier set out 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*, 134 S. Ct. at 2355.

Under the two-step framework, it must first be determined if "the claims at issue are directed to a patent-ineligible concept." *Id.* If the claims are determined to be directed to a patent-ineligible concept, e.g., an abstract idea, then the second step of the framework is applied to determine if "the elements of the claim . . . contain[] an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Id.* at 2357 (citing *Mayo*, 566 U.S. at 72–73, 79).

With regard to step one of the *Alice* framework, the Examiner determines that the claims are

> directed to systems and methods . . . which merely apply the abstract idea of auditing a clinical trial (i.e. receiving an audit, calculating whether the received audit constitutes a sufficient

> audit, generating a dependent audit if the received audit is not sufficient, calculating workflow instructions, generating a second sufficient audit, and persisting the audits).

(Final Action 3.)

Appellants disagree and argue that "claim 1 is directed to a method for controlling workflow using audits from disparate clinical data input functionalities." (Appeal Br. 8.) Appellants further argue that "[a]n audit as claimed in the present invention is . . . a concrete set of information related to the specific transaction" and that "[a] 'sufficient audit' is one that includes all of the who, what, when, where, and why of the transaction." (*Id.* at 10.) Moreover, Appellants argue, "the Examiner did not identify any case that found 'auditing a clinical trial' to be abstract and he did not adequately articulate why 'auditing a clinical trial' was similar to other cases." (*Id.* at 19.)

Under step one of the *Alice* framework, we "look at the 'focus of the claimed advance over the prior art' to determine if the claim's 'character as a whole' is directed to excluded subject matter." *Affinity Labs of Texas, LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016) (quoting *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016)).

The Specification provides evidence as to what the claimed invention is directed. In this case, the Specification discloses that the invention relates to allowing "disparate . . . clinical data recording devices (also called 'clinical data input functionalities' or 'data-exporting devices' in this application) to be to be assimilated into a unified clinical system." (Spec. ¶ 12.) The Specification identifies "clinical data recording devices" or "clinical data input functionalities" as including devices such as "Fitbit Flex™, and ECG [electrocardiogram] and glucose monitors." (*Id.*) The

Specification discloses that "an audit is a record of a transaction occurring at one or more of the clinical data input functionalities or any downstream clinical system or component of clinical data system 160." (*Id.* ¶ 14.) The Specification also discloses that "an audit of the present invention may simply be constituted by the data received from a clinical data input functionality." (*Id.* ¶ 15.) And, the Specification discloses that "[t]he sufficiency of an audit, described with reference to the clinical data embodiments herein, may be a variable, configurable attribute of a clinical data system 160." (*Id.*)

The Specification also discloses:

> Workflow service 162 may provide workflow instructions by which the export data and/or audits it receives are transmitted to the downstream components of clinical data system 160. For example, workflow service 162 may receive audits 150, 152, 154 from clinical data input functionalities 110-118, parse the received audits and, based on the stored workflow instructions and the audit data, calculate specific workflow instructions regarding where to transmit or route audits 150, 152, 154 . . . .

(*Id.* ¶ 18.)

The Specification does not define the term "persisting," however, we note that the term "persistent data" includes "[d]ata that remain intact from session to session such as customer and vendor records. Although they may be updated, they are relatively permanent. Persistent data are stored in a database on disk, SSD or magnetic tape." (https://www.pcmag.com/encyclopedia/term/49122/persistent-data, last visited Oct. 26, 2018.) This is in accord with the Examiner's determination that "persisting the audit amounts to a step of storing." (*See* Answer 8.)

Like the Specification, claim 1 also provides evidence as to what the claim is directed. Claim 1 recites "receiving . . . an audit from at least one clinical data input functionality," "calculating . . . whether the received audit constitutes a sufficient audit . . . and if the received audit is not sufficient, transmitting the received audit to a second component . . . generating a dependent audit at the second component, and supplementing the received audit," "calculating workflow instructions in accordance with which the first sufficient audit is transmitted to a further component," "generating at the further component a second sufficient audit," and persisting the first sufficient audit and the second sufficient audit." In short, Appellants' claim is directed to receiving information, analyzing the information, issuing instructions in view of the analysis, generating additional information, and storing the information.

"[W]e have treated collecting information, including when limited to particular content (which does not change its character as information), as within the realm of abstract ideas." *Elec. Power Grp.*, 830 F.3d at 1353. "In a similar vein, we have treated analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category." *Id.* at 1354. "And we have recognized that merely presenting the results of abstract processes of collecting and analyzing information, without more (such as identifying a particular tool for presentation), is abstract as an ancillary part of such collection and analysis." *Id.* "Here, the claims are clearly focused on the combination of those abstract-idea processes." *Id.*; *see also* Answer 8. Similarly, "creat[ing] electronic records, track[ing] multiple transactions, and issu[ing] simultaneous instructions," have been identified

by the courts as within the realm of abstract ideas. *See Alice*, 134 S. Ct. at 2359.

Although we and the Examiner describe, at different levels of abstraction, to what the claims are directed, it is recognized that "[a]n abstract idea can generally be described at different levels of abstraction." *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1240 (Fed. Cir. 2016). In this case, that does not "impact the patentability analysis." *See id.* at 1241. Moreover, here, the limitations do not recite implementation details. *See id.*

Appellants argue that the Examiner erred because "the Examiner did not identify any case that found 'auditing a clinical trial' to be an abstract idea and he did not adequately articulate why 'auditing a clinical trial' was similar to these other cases." (Appeal Br. 19.)

We do not find Appellants' argument persuasive. The law does not require identifying a case specifically determining "auditing a clinical trial" to be an abstract idea. By way of example, in *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1093–94 (Fed. Cir. 2016), claim 1 of FairWarning's patent recited "[a] method of detecting improper access of a patient's protected health information . . . comprising: generating a rule for monitoring audit log data," "applying the rule," "storing, in a memory, a hit if the event has occurred," "and providing notification." In *Electric Power*, claim 12 of Electric Power's '710 patent recited "[a] method of detecting events on an interconnected electric power grid . . . comprising: receiving a plurality of data streams," "receiving data from other power system data sources," "receiving data from . . . non-grid data sources," "detecting and analyzing events in real-time," "displaying the event analysis results and diagnoses," "displaying concurrent visualization of measurements,"

"accumulating and updating the measurements," "and deriving a composite indicator." In determining FairWarning's claims to be directed to an abstract idea, the Federal Circuit analogized those claims to the claims in *Electric Power* and noted that *Electric Power* "explained that the 'realm of abstract ideas' includes 'collecting information, including when limited to particular content'" as well as analyzing and presenting information. *See id.* Here, the Examiner has sufficiently articulated why the steps of claim 1 may be analogized to those in *Electric Power*. *See* Answer 8.

Appellants seek to analogize their claims to those in *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014), arguing that

> the pending claims . . . requir[e] numerous different technical operations, including six for claim 1 alone: calculating sufficiency of a received audit, generating a dependent audit, supplementing the received audit, calculating workflow instructions, generating a second sufficient audit, and persisting the audit. *Cf. DDR Holdings*, 773 F.3d at 1257 (describing three different operations or steps that the patent-eligible claim recites in order to "address the problem of retaining website visitors").[3]

(Appeal Br. 27.)

In *DDR Holdings*, the Federal Circuit stated that the claims "specify how interactions with the Internet are manipulated to yield a desired result – *a result that overrides the routine and conventional sequence of events ordinarily triggered by the click of a hyperlink.*" *DDR Holdings*, 773 F.3d at 1258 (emphasis added). Appellants do not persuasively argue why, e.g.,

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[3] To the extent Appellants are arguing that the number of steps in a claim is determinative of whether the claim is directed to an abstract idea, we disagree. *See, e.g., Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014) (determining an eleven-step method claim to be directed to an abstract idea).

receiving information, analyzing the information, issuing instructions in view of the analysis, generating additional information, and storing the information, is analogous to "overrid[ing] the routine and conventional sequence of events ordinarily triggered by the click of a hyperlink." *See id.*

Appellants also seek to analogize their claims to those in *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016). (Appeal Br. 27–29.) However, in *Enfish*, "the focus of the claims [was] on the specific asserted improvement in computer capabilities (i.e., the self-referential table for a computer database)." *Enfish*, 822 F.3d at 1335–36. And "the claims [were] not simply directed to any form of storing tabular data, but instead [were] specifically directed to a self-referential table for a computer database," i.e., the claims recited a "means for configuring said memory according to a logical table." *Id.* at 1336–37. Unlike *Enfish*, the claims here do "not claim a particular way of programming or designing the software . . . , but instead merely claim the resulting systems. Essentially, the claims are directed to certain functionality." *Apple, Inc.*, 842 F.3d at 1241 (citation omitted). For example, the claims do not specify how workflow instructions are calculated or how a second sufficient audit is generated. "Indeed, the claim language here provides only a result-oriented solution, with insufficient detail for how a computer accomplishes it. Our law demands more." *Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 850 F.3d 1332, 1342 (Fed. Cir. 2017).

In view of the above, we agree with the Examiner that claim 1 is directed to an abstract idea.

Step two of the *Alice* framework has been described "as a search for an ' "inventive concept" ' –*i.e.*, an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly

more than a patent upon the [ineligible concept] itself.'" *Alice*, 134 S. Ct. at 2355 (alteration in original) (citing *Mayo*, 566 U.S. at 72–73).

Appellants argue that "[t]he multiple limitations of the pending claims are plainly more specific and technical than the three limitations of the claims recited in *DDR Holdings*." (Appeal Br. 31.) Specifically, Appellants argue that "the method of claim 1 requires (1) receiving an audit, (2) calculating sufficiency of the audit, (3) transmitting the received audit, (4) generating a dependent audit, (5) supplementing the received audit, (6) calculating workflow instructions, (7) generating a second sufficient audit, and (8) persisting the audit." (*Id.* at 30.)

Nothing in Appellants' description of claim 1 requires a computer processor. This is in contrast to the claims in *DDR Holdings* where "the claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks." *DDR Holdings*, 773 F.3d at 1257. To the extent Appellants' claim 1 recites a computer processor, it is simply in the step of "calculating . . . whether the received audit constitutes a sufficient audit," i.e., it performs the routine function of analyzing information. *See Elec. Power Grp.*, 830 F.3d at 1355.

Nonetheless, in a Supplemental Brief, filed October 9, 2018, Appellants argue that "the Examiner made conclusions with respect to claim 1 that additional elements in that claim were 'well-understood, routine, and conventional.' Final Office Action at 3, 63 ('well-understood, routine, and conventional activities previously known to the pertinent industry')." (Supp. Br. 3–4.) And, Appellants further argue, these conclusions did not satisfy the Examiner's burden under *Berkheimer*. (*Id.* at 4, citing *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018).)

Berkheimer recognizes that "[t]he question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact." *Id.* at 1368. *Berkheimer* further recognizes that "[t]he mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional." *Id.* at 1369.

> Here, the Examiner finds that claim 1 recites
>
> > generic computer structure that serves to perform generic computer functions that are well-understood, routine, and conventional activities previously known to the pertinent industry (such as receiving information from electronic clinical data systems, using a computer processor to perform calculations and data processing to achieve a solution more quickly, generating and recording event log data electronically, transferring information between electronic systems, and storing data in an electronic database).

(Final Act. 3; *see also id.* at 63.) However, as discussed above, claim 1 recites a computer processor only for performing the function of analyzing information, and there can be no question that analyzing information is a routine and conventional task for a computer processor. *See, e.g.*, *Elec. Power Grp.*, 830 F.3d at 1355 (the steps of collecting, analyzing and displaying information, even if limited to a specific content, are conventional).)

Appellants argue, for the first time in the Supplemental Brief, that "the Examiner did not refer to the other independent claims (8, 12, and 16, which were described by Appellant separately, *see* App. Br. at 12-13.)" (Supp. Br. 4; *see also* Appeal Br. 30–31 (also describing claims 1 and 8, but not presenting separate arguments).) Although claims 8, 12, and 16 are "described" in the Appeal Brief at pages 12–13, Appellants did not

separately argue these claims in the Appeal Brief. Appellants also argue, for the first time in the Supplemental Brief, that "the Examiner did not cite to anything in dependent claims 3-7, 9-11, 13, 15, and 17-21 that is 'well-understood, routine, and conventional.'" (*Id.*) But these dependent claims were also not separately argued in the Appeal Brief, e.g., Appellants did not argue that the Examiner failed to make a determination that particular limitations of these dependent claims were well-understood, routine and conventional. "[T]he failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately." 37 C.F.R. § 41.37(c)(1)(iv).

Appellants seek to analogize claim 1 to Example 35, claim 2, in the December 2016 "Subject Matter Eligibility Examples: Business Methods" ("Eligibility Examples") supplement to the 2014 Interim Guidance on Subject Matter Eligibility (2014 IEG).[4] (Reply Br. 12–13.) We disagree.

In discussing Example 35, claim 2, the Eligibility Examples explains that "the claimed combination of additional elements presents a specific, discrete implementation of the abstract idea." (Eligibility Examples 10.) As discussed above, here the claims do "not claim a particular way of programming or designing the software . . . , but instead merely claim the resulting systems. Essentially, the claims are directed to certain functionality." *Apple, Inc.*, 842 F.3d at 1241 (citation omitted).

Taking the claim steps separately, the function performed at each step is purely conventional. Receiving information, analyzing the information,

[4] Available at https://www.uspto.gov/sites/default/files/documents/ieg-bus-meth-exs-dec2016.pdf.

issuing instructions in view of the analysis, generating additional information, and storing the information are basic computer functions. *See, e.g.*, *Elec. Power Grp.*, 830 F.3d at 1355–56. Appellants argue, however, that the claims "are still patent eligible because the ***combination*** of the steps . . . 'operates in a non-conventional and non-generic way to ensure that' disparate clinical data input functionalities may interoperate within a clinical data system, which did not occur before." (Reply Br. 13.) We do not find this argument persuasive because although claim 1 recites "disparate clinical data input functionalities" in its preamble, only a single clinical data input functionality is required by the claim ("at least one clinical data input functionality"). Thus, Appellants' argument is not commensurate with the scope of the claim. Moreover, "[i]t has been clear since *Alice* that a claimed invention's use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention 'significantly more' than that ineligible concept." *BSG Tech LLC v. BuySeasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018); *see also FairWarning*, 839 F.3d at 1096–97 ("FairWarning contends that its system allowed for the compilation and combination of . . . disparate information sources and that the patented method 'made it possible to generate a full picture of a user's activity, identity, frequency of activity, and the like in a computer environment.' . . . As we have explained, 'merely selecting information, by content or source, for collection, analysis, and [announcement] does nothing significant to differentiate a process from ordinary mental processes, whose implicit exclusion from § 101 undergirds the information-based category of abstract ideas.' *Elec. Power*, 830 F.3d at 1355." (internal citation omitted).)

Appellants also seek to analogize the present claims to those in *Amdocs (Israel) Limited v. Openet Telecom, Inc.*, 841 F.3d 1288 (Fed. Cir. 2016). (Reply Br. 14–15.) Specifically, Appellants argue that "Appellant's [sic] claims include receiving and supplementing steps that are similar to the receiving and correlating steps in the claim in *Amdocs*." (*Id.* at 15.)

We disagree. In relevant part, claim 1 of *Amdocs* recites "computer code for using the accounting information with which the first network accounting record is correlated to *enhance* the first network accounting record." *Amdocs*, 841 F.3d at 1299 (emphasis added). In an earlier opinion, *Amdocs (Israel) Limited v. Openet Telecom, Inc.*, 761 F.3d 1329 (Fed. Cir. 2014) ("*Amdocs I*"), the court had "construed 'enhance' as meaning 'to apply a number of field enhancements in a distributed fashion.' [*Amdocs I*] at 1340. We took care to note how the district court explained that '[i]n this context, "distributed" means that the network usage records are processed close to their sources before being transmitted to a centralized manager.' [*Amdocs I*] at 1338." *Amdocs*, 841 F.3d at 1300.

In view of the above claim interpretation of the term "enhance," we do not find Appellants' argument persuasive. Specifically, Appellants do not explain what limitation(s) in claim 1 correspond to the claim element "to enhance the first network accounting record," when the term "enhance" is properly construed.

Appellants also argue that the claims "do not tie up or preempt any abstract idea" and that "recent Federal Circuit cases have held that claims that do not preempt an abstract idea are patent eligible." (Reply Br. 13, citing *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016).) We disagree.

"Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015). In other words, "preemption may signal patent ineligible subject matter, [but] the absence of complete preemption does not demonstrate patent eligibility." *Id.*

In view of the above, we agree with the Examiner that claim 1 seeks to claim patent-ineligible subject matter. Independent claims 8, 12, and 16, and dependent claims 3–7, 9–11, 13, 15, and 17–21 are not separately argued in the Appeal or Reply Briefs and fall with representative claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

The § 112(a) rejection

> With regard to claim 1, the Examiner concludes that
>
> > the recited steps of "generating a dependent audit at the second component, and supplementing the received audit with data contained in the dependent audit to generate the first sufficient audit," is not described in the specification that one skilled in the art would know how to program the disclosed computer to perform the necessary steps as claimed. The specification does not describe the algorithm (e.g. the necessary steps and/or flowcharts) that perform [sic] the claimed function in sufficient detail.
> >
> > . . . .
> >
> > One skilled in the art would not know how to program a computer to perform these steps without knowing how these steps are actually performed.

(Final Action 4–6.) Applying the same reasoning, the Examiner reaches a similar conclusion with regard to the claim 1 steps "calculating, at the first

component, workflow instructions in accordance with which the first sufficient audit is transmitted to a further component of the clinical data system and to an audit service" (*id.* at 6), and "generating at the further component, a second sufficient audit related to the first sufficient audit" (*id.* at 7). In other words, the Examiner concludes that the Specification does not meet the enablement requirement of § 112(a).

The test for compliance with the enablement requirement is whether the Specification, as filed, is sufficiently complete to enable any person skilled in the art to make and use the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). When rejecting a claim for lack of enablement, "the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." *In re Wright*, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993).

> Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d at 737. The Examiner does not address the *Wands* factors.

With regard to the Examiner's determination that "[t]he specification does not describe the algorithm (e.g. the necessary steps and/or flowcharts) that perform [sic] the claimed function" (Final Action 5), we note that

"normally, writing code for . . . software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed." *Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1549 (Fed. Cir. 1997). "Thus, flow charts or source code listings are not a requirement for adequately disclosing the functions of software." *Id.* Here, the Examiner does not sufficiently explain *why* a person skilled in the art would have to engage in undue experimentation to practice the claimed invention. Therefore, we will reverse the rejection of claim 1 under § 112(a).

The Examiner relies on similar reasoning in rejecting claims 3–11 and 15–21 under § 112(a). (*See* Final Action 8–15.) And for similar reasons, we will reverse the rejection of those claims under § 112(a).

The § 112(b) rejection

With regard to claim 1, the Examiner concludes that the claim is indefinite because "[t]he term 'sufficient' is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." (Final Action 16.) And, in view of the definition of "audit" in paragraph 14 of the Specification ("an audit is a record of a transaction occurring at one or more of the clinical data input functionalities or any downstream clinical system or component of clinical data system 160"), "it is particularly difficult to know what may be meant by a 'sufficient audit.'" (*Id.*) Independent claims 8 and 12 contain similar language.

Appellants argue that "[a] 'sufficient audit' for a transaction is one that includes all of the who, what, when, where, and why of that

transaction." (Appeal Br. 39.[5]) Appellants also argue that "Specification ¶ 0026 describes in detail when audits are insufficient and what needs to make them sufficient (or standardized)." (*Id.* at 40.)

> Thus, an audit may be insufficient if it does not include correlatable data such as "identifiers of the protocol by which the clinical data in the audit are received, the clinical study, site(s), subject(s), and time, dependency or causality stamps" and the system will supply such data in order to make the audit sufficient or standardized.

(*Id.* at 41, quoting Spec. ¶ 26.)

Paragraph 26 of the Specification discloses, in relevant part:

> In some embodiments of the present invention, the clinical data input functionalities, such as EDC [electronic data capture] 110 or activity tracker 112, may not transmit sufficient data to constitute an audit for use by clinical data system 160. Instead, the insufficient data, once received by a component of clinical data system 160, may be viewed as programmatically supplemented by one or more subsequent, dependent (described further with regard to FIGS. 4 and 5 herein) audits, which dependent audits contain data which is required to constitute an audit and which is correlatable to the insufficient, received data. Correlatable data may include identifiers of the protocol by which the clinical data in the audit are received, the clinical study, site(s), subject(s), and time, dependency or causality stamps.

(Spec. ¶ 26.)

Paragraph 26 of the Specification refers to "[c]orrelatable data [which] may include identifiers of the protocol by which the clinical data in the audit are received, the clinical study, site(s), subject(s), and time, dependency or causality stamps." But it does not disclose that this data, no

[5] Appellants provide no citation to the record in direct support of this proffered definition of the term "sufficient audit." (*See* Appeal Br. 10.)

more and/or no less, constitutes a "sufficient audit." It does not disclose that "[a] 'sufficient audit' . . . is one that includes all of the who, what, when, where, and why of that transaction," as argued by Appellants. (*See* Appeal Br. 39.)

> The Federal Circuit has stated that
>
> > when the USPTO has initially issued a well-grounded rejection that identifies ways in which language in a claim is ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention, and thereafter the applicant fails to provide a satisfactory response, the USPTO can properly reject the claim as failing to meet the statutory requirements of § 112(b).

In re Packard, 751 F.3d 1307, 1311 (Fed. Cir. 2014). In this case, the Examiner presents a well-grounded rejection identifying why the term "sufficient audit" is unclear in this context. Appellants' arguments do not overcome the rejection.

New ground of rejection: § 112(b) rejection of claim 19

Claim 19 depends from independent claim 16. Claim 19 recites, in relevant part, "wherein the computer processor further calculates the sufficiency of an audit . . . and, if the received audit does not constitute a sufficient audit, transmits the received audit to a second component . . . ."

For the reasons discussed above, we find, as with claim 1, that the term "sufficient audit" is unclear in the context of the claim. Therefore, we will enter a new ground of rejection of claim 19 under § 112(b).

The § 103 rejections

The Examiner finds that Simske discloses "calculating, at the first component, workflow instructions in accordance with which the first sufficient audit is transmitted (See page 21, first complete paragraph, page 15, first complete paragraph, workflows updated based on updates to database, downstream workflows affected, also see page 12, first complete paragraph[])] . . . ." (Final Action 19–20.) Appellants disagree and argue that Simske does not disclose "generat[ing] workflow instructions that direct where the first sufficient audit is transmitted." (*See* Appeal Br. 47–48.)

Simske discloses an information tracking system that "may assist in creating an accurate provenance record (i.e., history) of a product and/or document." (Simske 2–3.) By way of example, Simske, in the first complete paragraph on page 21, discloses that its system

> may be used for validation of missing reads in an existing track-and-trace/provenance through noncontradictory sensor information. In this example, the information input at subscribers A, B and D is obtained for the provenance, but there is a missed read at subscriber C. Non-subscriber sensor network information may be used to provide a read at Subscriber C. For example, data may be retrieved from a news website which posted surveillance footage of rats in a warehouse of Subscriber C, and product at issue is shown in the footage. This information credibly located the product at Subscriber C at the timing between leaving Subscriber B and arriving at Subscriber D. The data aggregation thus creates a fully-explicit provenance (i.e., a complete time stamp) for the product.

(*Id.* at 21.) Thus, this paragraph, cited by the Examiner, discloses creating a complete provenance for a product. But even if we consider this complete provenance to be similar to a sufficient audit, the Examiner does not sufficiently explain how this discloses "calculating . . . workflow

instructions in accordance with which the first sufficient audit is transmitted to a further component," as recited in claim 1.

Simske defines the term "workflow" as referring "to an automated process during which products, documents, information, or tasks are passed from one participant to another for action or informative purpose, according to a set of procedural rules." (*Id.* at 3.) And in the first complete paragraph on page 15, Simske discloses that when its registry database

> is updated, it is to be understood that these updates may also affect one or more workflows upstream, downstream, and or at the point at which the database . . . is updated (e.g., at the node where the request entry was submitted, or the triggering event occurred, or the audit was initiated).

(*Id.* at 15.) But, again, the Examiner does not sufficiently explain how this discloses "calculating . . . workflow instructions in accordance with which the first sufficient audit is transmitted to a further component," as recited in claim 1.

The first complete paragraph on page 12 of Simske discloses:

> All of the collected sensor data is transmitted to the computing device 16, which alone or in conjunction with the anonymity/obfuscation engine 30 and/or the filter 32 is configured to process the data and generate output that is directly transmitted to an originator of a request and/or is used to update the database 20. In particular, the generated output may be used to change and/or update one or more fields in the database 20, thereby altering a workflow currently in the system 18. The computing device 16 is configured to generate analytics (e.g., which process raw data and generate logical data representations of the raw data) after performing one or more analyses on the raw data. The analysis performed will depend, at least in part, upon the query, triggering event, or external condition that initiated the data search. The analysis performed may also depend upon the reputation, reliability, ranking, etc. of the data producer (e.g.,

> subscriber or nonsubscriber), especially in instances where there is conflicting data.

(*Id.* at 12.) This paragraph discloses transmitting all of the collected sensor data, i.e., an audit from the sensor(s), to the computing device 16, i.e., a computer processor, and transmitting some output to an originator of a request. However, the Examiner does not sufficiently explain how this discloses "calculating . . . workflow instructions in accordance with which the first sufficient audit [i.e., *the audit itself*,] is transmitted to a further component."

Independent claims 8, 12, and 16 include similar language and the Examiner relies on the above disclosures in Simske in rejecting these claims under § 103(a). (*See* Final Action 29–30, 38, 50.) In view of the above, we will reverse the rejection of independent claims 1, 8, 12, and 16 and dependent claims 3–7, 9–11, 13, 15, and 17–21 under § 103(a).

DECISION

The Examiner's rejection of claims 1, 3–13, and 15–21 under 35 U.S.C. § 101 is affirmed.

The Examiner's rejection of claims 1, 3–11, and 15–21 under 35 U.S.C. § 112(a) is reversed.

The Examiner's rejection of claims 1, 3–13, 15, 20, and 21 under 35 U.S.C. § 112(b) is affirmed.

The Examiner's rejections of claims 1, 3–13, and 15–21 under 35 U.S.C. § 103 are reversed.

We enter a new ground of rejection of claim 19 under 35 U.S.C. § 112(b).

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides that, "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." Section 41.50(b) further provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THIS DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner.

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record.

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; 37 C.F.R. § 41.50(b)