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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* GLEN DE VRIES and MICHELLE MARLBOROUGH

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Appeal 2018-008613  
Application 14/140,734  
Technology Center 3600

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Before JASON J. CHUNG, JOYCE CRAIG, and STEPHEN E. BELISLE,  
*Administrative Patent Judges.*

CRAIG, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant<sup>1</sup> appeals from the Examiner's decision to reject claims 1–4, 7, 9, 11–14, and 20–23. *See* Final Act. 1, Advisory Act. 1. We have jurisdiction under 35 U.S.C. § 6(b).

An oral hearing was held on March 10, 2020.

We affirm.

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<sup>1</sup> We use the word Appellant to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Medidata Solutions, Inc. Appeal Br. 4.

### CLAIMED SUBJECT MATTER

The claims are directed to a method and system for ensuring clinical data integrity. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A computer-implemented method for ensuring integrity of data, comprising:
  - receiving, by a computer processor, audits from an eClinical system, wherein the audits are generated as a result of transactions occurring at the eClinical system;
  - generating, using the computer processor, a data stream and a first audit stream;
  - generating, using the computer processor, a first hash number by applying a hashing algorithm to the first audit stream;
  - transmitting, using the computer processor, the data stream and first audit stream to a data provider; and
  - transmitting, using the computer processor, the first hash number to a data checker, the data provider using a second computer processor to provide to the data checker a second audit stream based on the first audit stream; and
  - the data checker using a third computer processor to generate a second hash number based on the second audit stream and comparing the first hash number to the second hash number to detect discrepancies in the data.

### REJECTION<sup>2</sup>

Claims 1–4, 7, 9, 11–14, and 20–23 stand rejected under 35 U.S.C. § 101 because the claimed invention is directed to a judicial exception without significantly more. Final Act. 15.

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<sup>2</sup> After the Final Action, Appellant cancelled claims 17–19. *See* Advisory Act, dated Nov. 16, 2017. In the Answer, the Examiner withdrew the rejections of canceled claims 17–19 and pending claims 22 and 23 under 35 U.S.C. § 112, second paragraph. The Examiner also withdrew the rejections of claims under 35 U.S.C. § 103. Ans. 3.

## ANALYSIS

Appellant argues that the Examiner’s rejection of claim 1 under 35 U.S.C. § 101 as directed to patent-ineligible subject matter is in error. Appeal Br. 9. To the extent Appellant has not advanced separate, substantive arguments for particular claims, or other issues, such arguments are waived. 37 C.F.R. § 41.37(c)(1)(iv). Appellant argues claims 1–4, 7, 9, 11–14, and 20–23 as a group. Appeal Br. 9. Given our discretion under 37 C.F.R. § 41.37(c)(1)(iv), we decide the § 101 rejection of claims 1–4, 7, 9, 11–14, and 20–23 based on representative claim 1.

### Principles of Law

“Whether a claim is drawn to patent-eligible subject matter is an issue of law that we review de novo.” *SiRF Tech., Inc. v. Int’l Trade Comm’n*, 601 F.3d 1319, 1331 (Fed. Cir. 2010).

An invention is patent-eligible if it claims a “new and useful process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101. However, the U.S. Supreme Court has long interpreted 35 U.S.C. § 101 to include implicit exceptions: “[l]aws of nature, natural phenomena, and abstract ideas” are not patentable. *E.g., Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

In determining whether a claim falls within an excluded category, we are guided by the Court’s two-part framework, described in *Mayo* and *Alice*. *Id.* at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). In accordance with that framework, we first determine what concept the claim is “directed to.” *See Alice*, 573 U.S. at 219 (“On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement

risk.”); *see also* *Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (“Claims 1 and 4 in petitioners’ application explain the basic concept of hedging, or protecting against risk.”).

Concepts determined to be abstract ideas, and thus patent ineligible, include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). Concepts determined to be patent eligible include physical and chemical processes, such as “molding rubber products” (*Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); “tanning, dyeing, making waterproof cloth, vulcanizing India rubber, smelting ores” (*id.* at 182 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1853))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claim at issue recited a mathematical formula, but the Court held that “a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula.” *Diehr*, 450 U.S. at 187; *see also id.* at 191 (“We view respondents’ claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula.”). Having said that, the Court also indicated that a claim “seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.” *Id.* (citation omitted) (citing *Benson* and *Flook*); *see, e.g., id.* at 187 (“It is now commonplace that

an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”).

If the claim is “directed to” an abstract idea, we turn to the second part of the *Alice* and *Mayo* framework, where “we must examine the elements of the claim to determine whether it contains an ‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.” *Alice*, 573 U.S. at 221 (quotation marks omitted). “A claim that recites an abstract idea must include ‘additional features’ to ensure ‘that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].’” *Id.* (alterations in original) (quoting *Mayo*, 566 U.S. at 77). “[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention.” *Id.*

In January 2019, the U.S. Patent and Trademark Office (USPTO) published revised guidance on the application of § 101. *See 2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (Jan. 7, 2019) (“2019 Revised Guidance”).<sup>3</sup> “All USPTO personnel are, as a matter of internal agency management, expected to follow the guidance.” *Id.* at 51; *see also* October 2019 Update at 1.

Under the 2019 Revised Guidance and the October 2019 Update, we first look to whether the claim recites:

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<sup>3</sup> In response to received public comments, the Office issued further guidance on October 17, 2019, clarifying the 2019 Revised Guidance. USPTO, *October 2019 Update: Subject Matter Eligibility* (the “October 2019 Update”) (available at [https://www.uspto.gov/sites/default/files/documents/peg\\_oct\\_2019\\_update.pdf](https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf)).

- (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human activity such as a fundamental economic practice, or mental processes) (“Step 2A, Prong One”); and
- (2) additional elements that integrate the judicial exception into a practical application (*see* MPEP §§ 2106.05(a)–(c), (e)–(h) (9th ed. Rev. 08.2017, Jan. 2018)) (“Step 2A, Prong Two”).<sup>4</sup>

2019 Revised Guidance, 84 Fed. Reg. at 52–55.

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look, under Step 2B, to whether the claim:

- (3) adds a specific limitation beyond the judicial exception that is not “well-understood, routine, conventional” in the field (*see* MPEP § 2106.05(d)); or
- (4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

2019 Revised Guidance, 84 Fed. Reg. at 52–56.

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<sup>4</sup> This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. *See* 2019 Revised Guidance - Section III(A)(2), 84 Fed. Reg. 54–55.

Step 1

Claim 1, as a method claim, falls within the process category of § 101. *See* 2019 Revised Guidance, 84 Fed. Reg. at 53–54 (citing MPEP §§ 2106.03, 2106.06).

Step 2A(i): Does the Claim Recite a Judicial Exception?

The Examiner determined that claim 1 is directed to “organizing information and performing a calculation on the information before providing the information to a sponsor of a clinical study, and then providing the result of the calculation to a regulatory agency, in order to allow the regulatory agency to detect tampering with the information when the sponsor forwards the information to the regulatory agency.” Final Act. 16. The Examiner determined this is a certain method of organizing human activity, and thus an abstract idea. *Id.* at 17. In addition, the Examiner determined that the recited generation and comparison of hash numbers is a mathematical relationship/formula. Ans. 5. The Examiner identified the following steps as part of the recited abstract idea(s):

“receiving ... audits from a clinical source,” “assembling ... the audits into a data stream and a first audit,” “generating ... a first hash number by applying a hashing algorithm to the first audit stream,” “transmitting ... the data stream and the first audit stream to a data provider [or sponsor of a clinical study],” “transmitting ... the first hash number to a data checker [or a regulatory agency],” “the data provider [or sponsor] ... provid[ing] to the data checker [or regulatory agency] a second audit stream based on the first audit stream,” and “the data checker [or regulatory agency] .... generat[ing] a second hash number based on the second audit stream and comparing the first hash number to the second hash number.”

Final Act. 16.

Consistent with Appellant’s description of the claims, we find that the limitations we summarize above describe commercial or legal interactions, which fall into the certain methods of organizing human activity category of abstract ideas. *See* Revised Guidance, 84 Fed. Reg. at 52; Ans. 5.

For the first time in the Reply Brief, Appellant argues that the Examiner erred in determining that the claimed invention is “method of organizing human activity” because the Examiner “did not satisfy his burden to cite ‘to an appropriate court decision that supports the identification of the subject matter recited in the claim language as an abstract idea.’” Reply Br. 9. Appellant also argues for the first time in the Reply Brief that the Examiner erred by not citing specific cases to support the determination that claim 1 recites a mathematical relationship/formula or an idea of itself. Reply Br. 10–15.

We note that the 2019 Revised Guidance “extracts and synthesizes key concepts identified by the courts as abstract ideas” (84 Fed. Reg. at 52) and does not require comparing claims to those already found to recite or be directed to an abstract idea.

Because we agree with the Examiner that the claim recites an abstract idea, we proceed to Prong Two of Step 2A to determine if the idea is integrated into a practical application, in which case the claim as a whole would not be “directed to” merely an abstract idea.

Step 2A(ii): Judicial Exception Integrated into a Practical Application?

Because we determined that claim 1 recites a patent-ineligible concept, we next determine whether the recited judicial exception is integrated into a practical application of that exception by: (a) identifying whether there are any additional elements recited in the claim beyond the

judicial exception(s); and (b) evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application.

We use the term “additional elements” for claim features, limitations, or steps that the claim recites beyond the identified judicial exception. *See* 2019 Revised Guidance, 84 Fed. Reg. at 55 n.24. In claim 1, the additional elements include the limitations “computer processor,” “second computer processor,” “third computer processor,” and “eClinical system.”

The Examiner determined that none of the additional limitations is sufficient to amount to significantly more than the judicial exception because the additional computer elements “only involve[] the use of generic computers performing generic computing functions to implement the abstract idea.” Final Act. 17.

Appellant argues that the claims are similar to claim 2 of Example 21 of the PTO’s July 2015 Update to the 2014 Interim Guidance on Subject Matter Eligibility, Appendix 1: Examples (“July 2015 Update”). Appeal Br. 9. Hypothetical claim 2 was found patent-eligible in Example 21 because, when looking at the additional elements as an ordered combination, the invention as a whole amounts to significantly more than simply organizing and comparing data. The example explains that the invention claimed in claim 2 addresses the Internet-centric challenge of alerting a subscriber with time sensitive information when the subscriber’s computer is offline. This is addressed by transmitting the alert over a wireless communication channel to activate a stock viewer application, which causes the alert to display and enables the connection of the remote subscriber computer to the data source over the Internet when the remote subscriber

computer comes online. The example explains that these are meaningful limitations that add more than generally linking the use of the abstract idea (the general concept of organizing and comparing data) to the Internet, because they solve an Internet-centric problem with a claimed solution that is necessarily rooted in computer technology, similar to the additional elements in *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014). *See* Ans. 6–8.

In *DDR*, instead of a computer network operating in its normal, expected manner by sending a website visitor to a third-party website via a clicked advertisement, the claimed invention generated and directed the visitor to a hybrid page that presented: (1) product information from the third party, and (2) the visual “look and feel” elements from the host website, thus retaining the visitor at the original website. *DDR*, 773 F.3d at 1258–59. Given this particular Internet-based solution, the court held that the claimed invention did not merely use the Internet to perform a business practice known from the pre-Internet world, but rather was necessarily rooted in computer technology to overcome a problem specifically arising in computer networks. *Id.* at 1257.

That is not the case here. Unlike in *DDR* or claim 2 of Example 21, Appellant’s “method for ensuring integrity of data” is not claimed as solving or otherwise addressing a problem specifically arising in computer networks. Claim 1. For example, Appellant’s claimed invention recites no language that pertains to “alerting a subscriber with time sensitive information when the subscriber’s computer is offline” by a transmission of an alert to an application that “cause[d] the alert to display and enable[d] the connection of the remote subscriber computer to the data source over the Internet when the

remote subscriber computer comes online,” as in claim 2 of Example 21. Nor does claim 1 recite improving the three recited computer processors, as recited in claim 1, or any (unclaimed) computer or network.

We note that, although the Federal Circuit in *DDR* held claims “necessarily rooted in computer technology” to be patent eligible, the court issued a relevant warning:

[W]e caution, however, that not all claims purporting to address Internet-centric challenges are eligible for patent. For example, in our recently-decided *Ultramercial* opinion, the patentee argued that its claims were “directed to a specific method of advertising and content distribution that was previously unknown and never employed on the Internet before.” But this alone could not render its claims patent-eligible. In particular, we found the claims to merely recite the abstract idea of “offering media content in exchange for viewing an advertisement,” along with “routine additional steps such as updating an activity log, requiring a request from the consumer to view the ad, restrictions on public access, and use of the Internet.”

*DDR Holdings*, 773 F.3d at 1258 (citations omitted).

Considering claim 1 as a whole, then, Appellant’s invention lacks a technical solution to a technical problem like the claims in *DDR* and claim 2 of Example 21. Claim 1 as a whole merely uses instructions to implement the abstract idea on a computer or, alternatively, merely uses a computer as a tool to perform the abstract idea. Here, the additional limitation(s) do not integrate the judicial exception into a practical application. More particularly, the claims do not recite (i) an improvement to the functionality of a computer or other technology or technical field (*see* MPEP § 2106.05(a)); (ii) a “particular machine” to apply or use the judicial exception (*see* MPEP § 2106.05(b)); (iii) a particular transformation of an

article to a different thing or state (*see* MPEP § 2106.05(c)); or (iv) any other meaningful limitation (*see* MPEP § 2106.05(e)). *See* 2019 Revised Guidance, 84 Fed. Reg. at 55. Rather, claim 1 recites an abstract idea as identified in Step 2A(i), *supra*, and none of the limitations integrates the judicial exception into a practical application.

Therefore, because the abstract idea is not integrated into a practical application, we conclude that the claim is directed to the judicial exception.

Step 2B — “Inventive Concept” or “Significantly More”

If the claims are directed to a patent-ineligible concept, as we conclude above, we proceed to the “inventive concept” step. For Step 2B we must “look with more specificity at what the claim elements add, in order to determine ‘whether they identify an “inventive concept” in the application of the ineligible subject matter’ to which the claim is directed.” *Affinity Labs of Texas, LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1258 (Fed. Cir. 2016) (quoting *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016)). We look to see whether there are any “additional features” in the claims that constitute an “inventive concept,” thereby rendering the claims eligible for patenting even if they are directed to an abstract idea. *Alice*, 573 U.S. at 221. Those “additional features” must be more than “well-understood, routine, conventional activity.” *Mayo*, 566 U.S. at 79.

The Examiner determined that the additional elements in claim 1 merely involve a processor performing the conventional computer functions of providing data to the data provider and a hash number to the data checker, and the data provider forwarding the data to the data checker. The data checker then performs a calculation on the received data and compares the result to the received hash. Ans. 7–8.

We agree with the Examiner that claim 1 does not recite any additional elements that are not well-understood, routine, and conventional.

Appellant argues for the first time in the Reply Brief that the Examiner proffered no factual evidence to support that the additional elements are well-understood, routine, and conventional. *See* Reply Br. 7 (citing *Berkheimer v. HP, Inc.*, 881 F.3d 1360 (Fed. Cir. Feb. 8, 2018)).

We are not persuaded by Appellant’s argument that the Examiner erred. The Specification describes that “[t]he present invention is not intended to be limited to any particular operating system, software application, or market,” and “any examples of particular software applications or markets used herein are included for illustration purposes and are not intended to be limiting.” Spec. ¶ 9. In addition, the Specification describes that “[t]he blocks shown in FIGS. 1–3 are examples of modules that may comprise systems 100, 200, and 300, and do not limit the blocks or modules that may be part of or connected to or associated with these systems.” Spec. ¶ 24. Moreover, the Specification describes that “[a]spects of the present invention may be embodied in the form of a system, a computer program product, or a method. Similarly, aspects of the present invention may be embodied as hardware, software or a combination of both.” Spec. ¶ 35.

Because the Specification describes the additional elements in general terms, without describing the particulars, we conclude the claim limitations may be broadly but reasonably construed as reciting conventional computer components and techniques, particularly in light of Appellant’s

Specification, as cited above. *See Berkheimer Memo*<sup>5</sup> § III.A.1; Spec. ¶¶ 9, 24, 35. Moreover, courts have recognized that receiving or transmitting data over a network, in a manner similar to that recited in the claims, is well-understood, routine, and conventional. *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015) (sending messages over a network); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014) (computer receives and sends information over a network).

We conclude claim 1 does not have an inventive concept because the claim, in essence, merely recites various computer-based elements along with no more than mere instructions to implement the identified abstract idea using the computer-based elements.

Appellant does not direct our attention to anything in the Specification that indicates the computer components perform anything other than well-understood, routine, and conventional functions. *See buySAFE*, 765 F.3d at 1355 (“That a computer receives and sends the information over a network—with no further specification—is not even arguably inventive”); *In re TLI Commc’ns LLC Patent Litig.*, 823 F.3d 607, 614 (Fed. Cir. 2016) (server that receives data, extracts classification information from the received data, and stores the digital images insufficient to add an inventive

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<sup>5</sup> “Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*)” at 3 (Apr. 19, 2018) (explaining that a specification that describes additional elements “in a manner that indicates that the additional elements are sufficiently well-known that the specification does not need to describe the particulars of such additional elements to satisfy 35 U.S.C. § 112(a)” can show that the elements are well understood, routine, and conventional).

concept); *Alice*, 573 U.S. at 225–26 (receiving, storing, sending information over networks insufficient to add an inventive concept).

Instead, Appellant argues that, because the Examiner has withdrawn the rejection under 35 U.S.C. § 103, the Examiner has determined that the claims include allowable subject matter over the prior art and, by definition, the claims are not “well-understood, routine, and conventional in the field.” Reply Br. 6.

Appellant’s argument is unavailing. The novelty of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter. *Diamond v. Diehr*, 450 U.S. 175, 188–89 (1981). Our reviewing court further guides that “[e]ligibility and novelty are separate inquiries.” *Two-Way Media Ltd. v. Comcast Cable Commc’ns, LLC*, 874 F.3d 1329, 1340 (Fed. Cir. 2017); *see also Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1263 (Fed. Cir. 2016) (holding that “[e]ven assuming” that a particular claimed feature was novel does not “avoid the problem of abstractness”).

Appellant also argues that the Examiner erred by not providing a written analysis of the dependent claims. Reply Br. 8. We disagree with Appellant that the Examiner did not provide written analysis of the dependent claims. In the Final Action, the Examiner determined that all claims recite an abstract idea (Final Act. 16), determined that “method claims 1–4, 7, 9, 20, and 21 recite that the method steps are performed using computer processors and claims 22 and 23 recite that functions are performed using a processor and a memory” (*id.* at 17), and also addressed the additional elements of the dependent claims (*id.* at 18).

Because the claims are directed to an abstract idea and lack an inventive concept, we sustain the Examiner's § 101 rejection of independent claim 1 and grouped claims 2–4, 7, 9, 11–14, and 20–23, not argued separately with particularity.

#### DECISION

We affirm the Examiner's decision rejecting claims 1–4, 7, 9, 11–14, and 20–23.

#### DECISION SUMMARY

<b>Claims Rejected</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
1–4, 7, 9, 11–14, 20–23	101	Eligibility	1–4, 7, 9, 11–14, 20–23	

#### TIME PERIOD FOR RESPONSE

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