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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN ANDREW KELLEGREW and
MARK RAYMOND RINKER

Appeal 2019-006690
Application 13/706,529
Technology Center 3600

Before JOHN A. EVANS, JOHN P. PINKERTON, and
MICHAEL M. BARRY, *Administrative Patent Judges*.

EVANS, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's decision to reject claims 1, 4–8, 10, 11, 14–16, and 19–21, which constitute all pending claims. Appeal Br. 22–31 (Claims App.). Appellant has canceled claims 2, 3, 9, 12, 13, 17, and 18. *Id.* at 24, 25, 27, 30 (Claims App.). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.[2]

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[1] We use "Appellant" to refer to the "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Oracle International Corporation as the real party in interest. Appeal Br. 2.

[2] Rather than reiterate the arguments of Appellant and the Examiner, we refer to the Appeal Brief (filed March 25, 2019, "Appeal Br."), the Reply

STATEMENT OF THE CASE

The claims relate generally to a system for managing and reporting adverse events that may occur in a clinical trial. *See, e.g.*, Spec. ¶¶ 1, 5, 21, 26.

Invention

Claims 1, 11, and 16 are independent. Claim 1 is illustrative and is reproduced below.

> 1. A non-transitory computer-readable medium having instructions stored thereon that, when executed by a processor, cause the processor to electronically transmit data to a safety compliance management system associated with a regulatory agency in response to an adverse event of a clinical trial, the adverse event is an adverse change in health that occurs in a patient participating in the clinical trial, the electronically transmitting comprising:
>
> monitoring one or more interactions with an adverse event component by a user of an electronic data capture system, wherein the adverse event component represents the adverse event and the electronic data capture system is configured to capture data associated with clinical trials;
>
> receiving a first event in response to a first interaction with the adverse event component by the user, wherein the first event indicates a change to a data value of a safety data field and that the adverse event is to be reported to the safety compliance management system, wherein the first interaction comprises selecting a first displayable element that marks the adverse event as one to be reported to the safety compliance

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Brief (filed September 10, 2019, "Reply Br."), the Examiner's Answer (mailed July 10, 2019, "Ans."), the Advisory Action (mailed January 4, 2019, "Advisory"), the Final Office Action (mailed October 25, 2018, "Final"), and the Specification (filed December 6, 2012, "Spec.") for their respective details.

management system, and wherein the safety data field is monitored in response to the adverse event;

initiating a timer to a user-defined time interval in response to a reception in a queue of the first event;

collecting data that is stored within the electronic data capture system; and

in response to elapsing of the user-defined time interval of the timer before a second event is received in the queue, automatically electronically transmitting the collected data to the safety compliance management system, the electronically transmitting further comprising use of a user-defined safety data logical schema that defines a subset of the data within the electronic data capture system to be monitored after the data is sent, through an integration component, to the safety compliance management system, wherein the safety compliance management system is configured to manage and report safety data to a regulatory authority and the data includes one or more data fields that can be mapped to an enterprise business object that can be transmitted within an enterprise business message;

wherein the second event is in response to a second interaction with the adverse event component by the user and indicates that the adverse event is ready to be reported to the safety compliance management system, and

wherein the second interaction comprises selecting a second displayable element, different from the first displayable element, that marks the data associated with the adverse event as ready for reporting to the safety compliance management system;

wherein the adverse event is always electronically transmitted to the safety compliance management system as a result of either the elapsing of the user-defined time interval of the timer or the receiving of the second event, wherein the transmitting as a result of receiving the second event is in near real time.

Appeal Br. 22–23 (Claims App.).

References

Name	Reference	Date
Strong	US 6,167,523	Dec. 26, 2000
Trinks et al. (Trinks)	US 6,952,695 B1	Oct. 4, 2005
Klass et al. (Klass)	US 2009/0138289 A1	May 28, 2009
Goldner et al. (Goldner)	US 2009/0313170 A1	Dec. 17, 2009
Connors et al. (Connors)	US 2012/0143617 A1	June 7, 2012

Rejections

The Examiner rejected Claims 1, 4–8, 10, 11, 14–16, and 19–21 under 35 U.S.C. § 101 as directed to a judicial exception (i.e., an abstract idea) without significantly more. Final 4–21.

The Examiner rejected Claims 1, 7, 8, 10, 11, 16, and 21 under 35 U.S.C. § 103 as being unpatentable over Connors, Klass, and Trinks. *Id.* at 21–37.

The Examiner rejected Claims 4, 5, 14, 15, 19, and 20 under 35 U.S.C. § 103 as being unpatentable over Connors, Klass, Trinks, and Strong. *Id.* at 38–42.

The Examiner rejected Claim 6 under 35 U.S.C. § 103 as being unpatentable over Connors, Klass, Trinks, Strong, and Goldner. *Id.* at 42–45.

ANALYSIS

In making our decision, we have reviewed the rejections of claims 1, 4–8, 10, 11, 14–16, and 19–21 and considered Appellant's arguments. We have considered only those arguments Appellant actually raised in the

Briefs. Appellant has waived any argument it could have made but chose not to in the Briefs. *See* 37 C.F.R. § 41.37(c)(1)(iv). Appellant's arguments do not persuade us of Examiner error. Rather, we adopt as our own the Examiner's findings, reasoning, and conclusions, as set forth in the Final Office Action (Final 4–45), Advisory Action (Advisory 1–2), and Examiner's Answer (Ans. 4–25). For emphasis, we provide the following discussion that highlights certain parts of the record before us.

CLAIMS 1, 4–8, 10, 11, 14–16, AND 19–21: INELIGIBLE SUBJECT MATTER.

Appellant argues these claims as a group. Appeal Br. 4–11; Reply Br. 2–3. Therefore, we decide the appeal of the § 101 rejection of claims 1, 4–8, 10, 11, 14–16, and 19–21 with reference to illustrative claim 1[3] and refer to the rejected claims collectively herein as "the claims." *See* 37 C.F.R. § 41.37(c)(1)(iv); *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1162 (Fed. Cir. 2018).

We have reviewed the record *de novo*. *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1331 (Fed. Cir. 2010) ("Whether a claim is drawn to patent-eligible subject matter is an issue of law that we review de novo."). Based on our review of the record in light of recent policy guidance on patent subject matter eligibility under 35 U.S.C. § 101,[4] we sustain the § 101 rejection of claims 1, 4–8, 10, 11, 14–16, and 19–21, as discussed in greater

[3] Our § 101 analysis for claim 1 applies equally to claims 4–8, 10, 11, 14–16, and 19–21, which are not argued separately with particularity.
[4] USPTO, *2019 Revised Patent Subject Matter Eligibility Guidance*, 84(4) Fed. Reg. 50–57 (Jan. 7, 2019) ("Revised Guidance" or "Rev. Guid."); *see also* USPTO, *October 2019 Patent Eligibility Guidance Update* (Oct. 17, 2019), https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf.

detail below.

35 U.S.C. § 101

Section 101 provides that a patent may be obtained for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. The Supreme Court has long recognized, however, that § 101 implicitly excludes "[l]aws of nature, natural phenomena, and abstract ideas" from the realm of patent-eligible subject matter, as monopolization of these "basic tools of scientific and technological work" would stifle the very innovation that the patent system aims to promote. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)); *see also Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72–78 (2012); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

Under the mandatory Revised Guidance, we reconsider whether Appellant's claims recite:

1. any **judicial exceptions**, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human interactions such as a fundamental economic practice, or mental processes); and
2. **additional elements** that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)–(c), (e)–(h)).

Only if a claim, (1) recites a judicial exception, and (2) does not integrate that exception into a practical application, do we then reach the issue of 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.

A. Whether the claims recite a judicial exception.

The Revised Guidance extracts and synthesizes key concepts identified by the courts as abstract ideas to explain that the abstract-idea exception includes the following groupings of subject matter, when recited as such in a claim limitation(s) (that is, when recited on their own or *per se*): (a) mathematical concepts,[5] i.e., mathematical relationships, mathematical formulas, equations,[6] and mathematical calculations[7]; (b) certain methods of organizing human activity—fundamental economic principles or practices (including hedging, insurance, mitigating risk); commercial or legal interactions (including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business relations); managing personal behavior or relationships or interactions

[5] *Bilski v. Kappos*, 561 U.S. 593, 611 (2010) ("The concept of hedging . . . reduced to a mathematical formula . . . is an unpatentable abstract idea.").
[6] *Diehr*, 450 U.S. at 191 ("A mathematical formula as such is not accorded the protection of our patent laws"); *Parker v. Flook*, 437 U.S. 584, 594 (1978) ("[T]he discovery of [a mathematical formula] cannot support a patent unless there is some other inventive concept in its application.").
[7] *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018) (holding that claims to a "series of mathematical calculations based on selected information" are directed to abstract ideas).

between people (including social activities, teaching, and following rules or instructions)[8]; and (c) mental processes—concepts performed in the human mind (including observation, evaluation, judgment, opinion).[9]

> The preamble of independent claim 1 recites:
>
> A non-transitory computer-readable medium having instructions stored thereon that, when executed by a processor, cause the processor to electronically transmit data to a safety compliance management system associated with a regulatory agency in response to an adverse event of a clinical trial, the adverse event is an adverse change in health that occurs in a patient participating in the clinical trial, the electronically transmitting comprising:

The steps recited in the body of the claim are analyzed in Table I against the categories of abstract ideas as set forth in the Revised Guidance.

Claim 1	Revised Guidance
[a][10] monitoring one or more interactions . . . by a user . . . to capture data associated with clinical trials;	Mental processes, i.e., concepts performed in the human mind or with pen and paper (including an observation, evaluation, judgment, opinion). Rev. Guid., 84 Fed. Reg. at 52.
[b] receiving a first event in response to a first interaction . . . by the user, wherein the first event	"receiving"—Insignificant extra-solution activity, e.g., mere data-gathering. *Id.* at 55 n.31.

[8] *Alice*, 573 U.S. at 219–20 (concluding that use of a third party to mediate settlement risk is a "fundamental economic practice" and thus an abstract idea); *see* Rev. Guid., 84 Fed. Reg. at 52 n.13 for a more extensive listing of "certain methods of organizing human activity" that have been found to be abstract ideas.

[9] *Mayo*, 566 U.S. at 71 ("'[M]ental processes[ ] and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.'" (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972))).

[10] Step designators, e.g., "[a]," are added to facilitate discussion.

indicates a change to a data value of a safety data field and that the adverse event is to be reported . . . , wherein the first interaction comprises selecting a first displayable element that marks the adverse event as one to be reported . . . , and wherein the safety data field is monitored in response to the adverse event;	"selecting" and "wherein the safety data field is monitored"—Mental processes, i.e., concepts performed in the human mind or with pen and paper (including an observation, evaluation, judgment, opinion). *Id.* at 52.
[c] initiating . . . a user-defined time interval in response to a reception in a queue of the first event;	Mental processes, i.e., concepts performed in the human mind or with pen and paper (including an observation, evaluation, judgment, opinion). *Id.*
[d] collecting data that is stored . . . ; and	Insignificant extra-solution activity, e.g., mere data-gathering. *Id.* at 55 n.31.
[e] in response to elapsing of the user-defined time interval . . . before a second event is received in the queue, . . . transmitting the collected data . . . , the . . . transmitting further comprising use of a user-defined safety data logical schema that defines a subset of the data . . . to be monitored after the data is sent . . . to manage and report safety data . . . and the data includes one or more data fields that can be mapped to an enterprise business object that can be transmitted within an enterprise business message;	"transmitting"—Insignificant extra-solution activity, e.g., mere data-gathering. *Id.* "use of a . . . schema that defines a subset of the data . . . to be monitored . . . to manage and report . . .data . . . and the data includes one or more data fields that can be mapped to an enterprise business object that can be transmitted within an enterprise business message"—Mental processes, i.e., concepts performed in the human mind or with pen and paper (including an observation, evaluation, judgment, opinion). *Id.* at 52.
[f] wherein the second event is in response to a second interaction . . . by the user and indicates that the	Insignificant extra-solution activity, e.g., mere data-gathering. *Id.* at 55 n.31.

adverse event is ready to be reported . . . , and	
[g] wherein the second interaction comprises selecting a second displayable element, different from the first displayable element, that marks the data associated with the adverse event as ready for reporting . . . ;	Mental processes, i.e., concepts performed in the human mind or with pen and paper (including an observation, evaluation, judgment, opinion). *Id.* at 52.
[h] wherein the adverse event is always . . . transmitted . . . as a result of either the elapsing of the user-defined time interval . . . or the receiving of the second event.	Insignificant extra-solution activity, e.g., post-solution activity. *Id.* at 55 n.31.

In view of Table I, these steps describe the concept of collecting information, monitoring and managing the information, and reporting certain results (adverse events), which can be performed mentally or with pen and paper. Thus, steps [a]–[h] of claim 1 recite an abstract idea in the mental processes grouping. *See* Rev. Guid., 84 Fed. Reg. at 52; *see also, e.g.*, Spec. ¶ 5 (summarizing the functionality of Appellant's invention in a similar way). As this concept relates to tracking and organizing information about patients in a clinical trial, we note that it may also be characterized as an abstract idea in the certain methods of organizing human activity grouping. *See, e.g.*, Final 6–11 (characterizing the concept of Appellant's invention similarly and determining that claim 1 recites an abstract idea in the certain methods of organizing human activity grouping). And although claim 1 recites various computing elements for performing steps [a]–[h], these are no more than generic computing elements for performing generic computing functions, as will be discussed in greater detail below. *See* discussion for *Step 2A(ii)*, *infra*. "If a claim, under its broadest reasonable interpretation,

covers performance in the mind but for the recitation of generic computer components, then it is still in the mental processes category unless the claim cannot practically be performed in the mind." Rev. Guid., 84 Fed. Reg. at 52 n.14. "Likewise, performance of a claim limitation using generic computer components does not necessarily preclude the claim limitation from being in . . . the certain methods of organizing human activity grouping, Alice, 573 U.S. at 219–20." *Id.*

We acknowledge that the claim's use of a user-defined time interval, a user-defined safety data logical schema, and data fields mapped to an enterprise business object within an enterprise business message add a degree of particularity to the claims. But the concepts embodied by these elements merely encompass the underlying abstract idea as discussed above. *See, e.g.*, *Intellectual Ventures I LLC v. Capital One Financial Corporation*, 850 F.3d 1332, 1341 (Fed. Cir. 2017). These elements are, at bottom, broadly defined rules, arrangements, or labels used for organizing, managing, and selecting data so as to report adverse events accordingly. These elements, therefore, do not alter our conclusion that the claimed invention recites an abstract idea. *See id.*

In view of the foregoing, we determine that claim 1 recites a judicial exception, *per se*.

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

If the claims recite a patent-ineligible concept, as we determine above, we proceed to *Step 2A(ii)*, where we 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.

For the following reasons, we determine that Appellant's claims do not integrate the judicial exception into a practical application. *See also* Final 11–17 (making the same determination for similar reasons); Ans. 9–16.

MPEP § 2106.05(a) "Improvements to the Functioning of a Computer or to Any Other Technology or Technical Field."

"In determining patent eligibility, examiners should consider whether the claim 'purport(s) to improve the functioning of the computer itself'" or "any other technology or technical field." MPEP § 2106.05(a).

Appellant argues that the claims "are directed to an improvement to computer technology" because they "are innately tied to computers and improve the safety data reporting methodology" by, for example, "provid[ing] a true integration, where safety data can be sent from an electronic data capture system to a safety compliance management system in near real-time." Appeal Br. 6–7 (emphasis omitted). Appellant explains that "the claims . . . recite limitations that focus on addressing problems arising when integrating different systems in a clinical trial adverse event reporting system." *Id.* at 7. Appellant further explains that "a reason the present claims are subject matter eligible is the combination and integration of known disparate components to provide a technical solution for implementing the need to always report adverse events." Reply Br. 2.

In support of its position, Appellant points to the following limitations of claim 1:

> receiving a first event in response to a first interaction with the adverse event component by the user, wherein the first event indicates a change to a data value of a safety data field and that the adverse event is to be reported to the safety compliance management system;
>
> initiating a timer to a user-defined time interval in response to a reception in a queue of the first event;
>
> in response to elapsing of the user-defined time interval of the timer before a second event is received in the queue, automatically electronically transmitting the collected data to the safety compliance management system, the electronically transmitting further comprising use of a user-defined safety data logical schema that defines a subset of the data within the electronic data capture system to be monitored after the data is sent, through an integration component, to the safety compliance management system, wherein the safety compliance management system is configured to manage and report safety data to a regulatory authority and the data includes one or more data fields that can be mapped to an enterprise business object that can be transmitted within an enterprise business message; and
>
> the adverse event is always electronically transmitted to the safety compliance management system as a result of either the elapsing of the user-defined time interval of the timer or the receiving of the second event, wherein the transmitting as a result of receiving the second event is in near real time.

Appeal Br. 7–8 (tabbing added for ease of reference).

We are not persuaded by Appellant's arguments. It is true that claim 1 recites a plurality of different computing elements, including "[a] non-transitory computer-readable medium having instructions . . . executed by a processor," "an electronic data capture system," "a safety compliance management system," "an adverse event component," "a timer," and "an integration component." It is also true that the claimed invention requires certain computing elements to perform certain functions and to interact with

one or more other computing elements. But Appellant does not identify—nor do we find—any persuasive evidence in the claims or Specification that the claims provide a technical solution to a technical problem or that the recited computer or software elements (and their associated functionalities) are anything but generic. Appellant points to paragraph 15 of the Specification, which discloses that "embodiments of the invention can provide a true integration, where safety data can be sent from an electronic data capture system to a safety compliance management system in near real-time." *See* Appeal Br. 6–7 (citing Spec. ¶ 15) (emphasis omitted). But the Specification describes an example of claim 1's "integration component" as merely a communication channel from which predefined data is sent or received. Spec. ¶ 38. In other words, an "integration component" could just be a network including a communication channel, such as a wired or wireless link that integrates two computing systems or devices by allowing for the connection and sharing of data between them. "That a computer receives and sends the information over a network—with no further specification—is not even arguably inventive." *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014). Similarly, "[t]he computers in *Alice* were receiving and sending information over networks connecting the intermediary to the other institutions involved, and the Court found the claimed role of the computers insufficient" to render the claims non-abstract. *Id.* And although certain embodiments describe the computing elements as corresponding to Oracle Corporation commercial software products,[11]

[11] *See, e.g.*, Spec. ¶¶ 19, 21, 25, 29, 37–39, 46, 47, Figs. 2, 4 (for example, the "integration component" may correspond to Oracle's "integration endpoint" software).

Appellant does not describe the features of these products or their functionalities with any specificity, much less require their use to perform Appellant's invention. In addition, the mere fact that data is sent "in near real time" does not change our analysis because "relying on a computer to perform routine tasks more quickly or more accurately is insufficient to render a claim patent eligible." *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015).[12]

Appellant also argues that, similar to the Board's finding in *Ex Parte Smith*,[13] "the Specification provided further context to conclude that the use of the claimed timing mechanisms and the associated temporary restraints on execution of trades provided a specific technological improvement over prior derivatives trading systems," "the present specification discloses how the novel integration functionality recited in the claims provide technical improvements over prior clinical trial systems." Appeal Br. 8–9. We do not agree. First, as discussed above, although the Specification discloses that "embodiments of the invention can provide a true integration" between systems, the Specification does not describe with specificity how such integration is achieved beyond the use of generic computer networking

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[12] *See also Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266, 1278 (Fed. Cir. 2012) ("[T]he fact that the required calculations could be performed more efficiently via a computer does not materially alter the patent eligibility of the claimed subject matter."); *Alice*, 573 U.S. at 224 (concluding that "the use of a computer to create electronic records, track multiple transactions, and issue simultaneous instructions" was not an inventive concept).

[13] *Ex Parte Eileen C. Smith, Anthony Montesano, Edward T. Tilly, Mark A. Esposito, Stuart J. Kipnes, & Anthony J. Carone*, Appeal No. 2018-000064, 2019 WL 764497 (PTAB 2019).

elements and functionality. Second, the claimed timing mechanisms here are not technical in nature and do not provide any technical solution to a technical problem. Rather, they are part of the underlying abstract idea and relate to confirming whether an adverse event exists by allotting an additional period of time to further evaluate or treat the patient's condition.

Appellant further argues that, similar to the claims identified as patent-eligible in *Ex Parte Lu*,[14] "the present claims are directed to an improvement in integrating an electronic data capture system with a safety compliance management system so that adverse events are always sent to a regulatory agency." Reply Br. 3. We are not persuaded by Appellant's argument. The claims in *Lu* focused specifically on computer software technology—in particular, on "'software endpoint applications [integrated] with a single transaction facility to enable transactions between a first endpoint and a second endpoint' and [electronic data interchange (EDI)] messages which are received and generated relative that first endpoint." *Lu*, at *4. There, the Board explained that "the advance over the prior art is a mechanism ('utility') for 'forward[ing] an EDI request from a sending party to applications that may act as either a payer or provider,'" which "solves the problem of integration between these two parties by providing the developer with an application that is capable of automatically generating an Electronic Data Interchange (EDI) response message to a request." *Id.* at *5 (citing U.S. Patent Application No. 12/185,178, Spec. ¶ 4).

[14] *Ex Parte Anh Q. Lu, Gautham Pamu, & David Y. Yu*, Appeal No. 2017-007127, 2018 WL 5631453 (PTAB 2018).

By contrast, the focus of claim 1 as currently recited is not on an improvement to computer technology, but on an algorithm for collecting, managing, monitoring, and reporting patient information relating to a clinical trial. And as discussed above, although the claim recites various computing elements, these elements are recited generically without the level of specificity needed to characterize the claim as being directed to an improvement in computer or software technology. Likewise, the Specification describes embodiments of these elements and functions in no more than generic terms. *See, e.g.*, Spec. ¶¶ 14, 16–20, 46, Fig. 1.

MPEP § 2106.05(b) Particular Machine.

The *Bilski*[15] machine-or-transformation test is only applicable to method (process) claims on appeal in the present application. Although method claims 11, 14, and 15 are computer-implemented using a plurality of computing elements, these claims do not recite a particular machine. Rather, the Specification describes embodiments that use such computing elements in no more than generic terms as a tool for performing the recited processes. *See, e.g.*, Spec. ¶¶ 14, 16–20, 46, Fig. 1. "[A]dditional elements that invoke computers or other machinery merely as a tool to perform an existing process will generally not amount to significantly more than a judicial exception." MPEP 2106.05(b)(II) (citing *Versata Development Group v. SAP America*, 793 F.3d 1306, 1335 (Fed. Cir. 2015)).

MPEP § 2106.05(c) Particular Transformation.

This section of the MPEP guides: "Another consideration when determining whether a claim recites significantly more is whether the claim

[15] *Bilski v. Kappos*, 561 U.S. 593 (2010).

effects a transformation or reduction of a particular article to a different state or thing." "'[T]ransformation and reduction of an article to a different state or thing is *the clue* to the patentability of a process claim that does not include particular machines.'" *Bilski*, 561 U.S. at 658 (quoting *Benson*, 409 U.S. at 70) (emphasis added and internal quotation marks omitted).

Appellant's claims, which recite monitoring, receiving, selecting, initiating, collecting, transmitting, managing, reporting, mapping, and marking operations—do not effect a "transformation or reduction of an article into a different state or thing constituting patent-eligible subject matter," but instead merely create, receive, transmit, store, evaluate, manipulate or reorganize data. *See In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008) (en banc), *aff'd sub nom. Bilski*, 561 U.S. at 593; *see also CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 (Fed. Cir. 2011) ("The mere manipulation or reorganization of data . . . does not satisfy the transformation prong."). Applying this guidance here, we determine Appellant's claims fail to satisfy the transformation prong of the *Bilski* machine-or-transformation test.

> MPEP § 2106.05(e) Other Meaningful Limitations.
>
> This section of the MPEP guides:
>
> > For a claim that is directed to a judicial exception to be patent-eligible, it must include additional features to ensure that the claim describes a process or product that applies the exception in a meaningful way, such that it is more than a drafting effort designed to monopolize the exception. The claim should add meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment to transform the judicial exception into patent-eligible subject matter.
>
> MPEP § 2106.05(e).

"*Diamond v. Diehr* provides an example of a claim that recited meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment" by reciting "additional elements such as the steps of installing rubber in a press, closing the mold, constantly measuring the temperature in the mold, and automatically opening the press at the proper time," which "sufficiently limited the use of the mathematical equation to the practical application of molding rubber products." *Id.* (citing *Diehr*, 450 U.S. at 177–78, 184, 187). "In contrast, the claims in *Alice Corp. v. CLS Bank International* did not meaningfully limit the abstract idea of mitigating settlement risk" because "the additional elements such as the data processing system and communications controllers . . . merely linked the use of the abstract idea to a particular technological environment (i.e., 'implementation via computers') or were well-understood, routine, conventional activity." *Id.* (citing *Alice*, 573 U.S. at 226).

We determine that claim 1 does not add "other meaningful limitations" at least because the additional elements discussed above are nothing more than generic components performing generic functions, which do not amount to a meaningful limitation that is significantly more than an abstract idea.

MPEP § 2106.05(f) Mere Instructions to Apply an Exception.

In view of the foregoing, we find no evidence that the claims do anything more than invoke generic computer components as a tool in which computer software instructions apply the judicial exception.

MPEP § 2106.05(g) Insignificant Extra-Solution Activity.

The claims receive, collect, transmit, and send data, which are classic examples of insignificant extra-solution activity. Rev. Guid., 84 Fed. Reg.

55, 55 n.31; *see also, e.g.*, *Bilski*, 545 F.3d at 963.

MPEP § 2106.05(h) Field of Use and Technological Environment.

"[T]he Supreme Court has stated that, even if a claim does not wholly pre-empt an abstract idea, it still will not be limited meaningfully if it contains only insignificant or token pre- or post-solution activity—such as identifying a relevant audience, a category of use, field of use, or technological environment." *See Alice*, 134 S.Ct. at 2356. Here, even though the limitations of claim 1 may be "narrowly drawn" to certain instances and arrangements of information about a patient participating in a clinical trial, limiting an abstract idea to a particular field of use in this manner does not convert an otherwise ineligible concept into an inventive one. *See* Rev. Guid., 84 Fed. Reg. at 55, *id.* nn. 31–32. Nor does the claim's implementation using the recited computing elements do more than generally link the use of a judicial exception to a particular technological environment. *See id.* at 55. Appellant does not present any persuasive evidence otherwise.

In view of the foregoing, we determine the claims are "directed to" a judicial exception.

Step 2B: Does the Claim Provide an Inventive Concept?

Because the claim has been determined to be directed to a judicial exception under revised *Step 2A*, we now evaluate the additional elements individually and in combination under *Step 2B* to determine whether they provide an inventive concept (i.e., whether the additional elements amount to significantly more than the exception itself). Rev. Guid., 84 Fed. Reg. at 56. It is indicative of the absence of an inventive concept where the claims simply append well-understood, routine, conventional activities previously

known to the industry, specified at a high level of generality, to the judicial exception. *Id.*

Here, the Examiner determines that "[w]hen the additional elements in claim 1 are considered as an ordered combination, they amount to a generic technological platform on which commercially available software is executed to carry out well-understood, routine, and conventional functions pursuant to compliance with regulatory obligations." Final 15, *see also id.* at 13–17; *see* Ans. 9–10 (citing Spec. ¶¶ 16–17 as evidence that the claims do not recite a particular computer). In particular, the Examiner explains that "[t]he safety compliance management system, electronic data capture system, and integration component are apparently built upon the computer recited as generic components, where the individual labels or titles for each of these additional elements describes the function rather than structure and as such does not amount to any particular computer." Final 13. The Examiner further explains that these additional elements are recited at a high level of generality, correspond to commercially available products, and, therefore, are well-understood, routine, and conventional in the field. *Id.* at 14; Ans. 17–18. The Examiner additionally explains how the functions performed by these additional elements are well-understood, routine, and conventional. Final 14–15; Ans. 17–18.

We agree with the Examiner. Appellant's disclosure describes the claimed computer system consistent with its being well-understood, routine, and conventional, at a high level of generality. *See, e.g.*, Spec. ¶¶ 14, 16–20, 46, Fig. 1. For example, the Specification discloses that:

> Processor 22 may be any type of general or specific purpose processor. . . . Memory 14 can be comprised of any combination of random access memory ("RAM"), read only

> memory ("ROM"), static storage such as a magnetic or optical disk, or any other type of machine or computer-readable medium. System 10 further includes a communication device 20, such as a network interface card or other communications interface, to provide access to a network. As a result, a user may interface with system 10 directly, or remotely through a network or any other method. A computer-readable medium may be any available medium that can be accessed by processor 22. A computer-readable medium may include both a volatile and nonvolatile medium, a removable and non-removable medium, a communication medium, and a storage medium. A communication medium may include computer readable instructions, data structures, program modules or other data in a modulated data signal such as a carrier wave or other transport mechanism, and may include any other form of information delivery medium known in the art. A storage medium may include RAM, flash memory, ROM, erasable programmable read-only memory ("EPROM"), electrically erasable programmable read-only memory ("EEPROM"), registers, hard disk, a removable disk, a compact disk read-only memory ("CD-ROM"), or any other form of storage medium known in the art. . . . Database 34 can be an operational database, an analytical database, a data warehouse, a distributed database, an end-user database, an external database, a navigational database, an in-memory database, a document-oriented database, a real-time database, a relational database, an object-oriented database, or any other database known in the art. . . . [E]ach functionality may be performed by hardware (e.g., through the use of an application specific integrated circuit ("ASIC"), a programmable gate array ("PGA"), a field programmable gate array ("FPGA"), etc.), or any combination of hardware and software.

Spec. ¶¶ 16, 17, 20, 46.

And, as the Examiner explains, the Specification's disclosure that certain computing elements may correspond to certain Oracle software products appears to indicate that these products were commercially available at the time of invention, which likewise appears to indicate that these

elements were well-understood, routine, and conventional in accordance with *Berkheimer*[16] and the *Berkheimer* memo.[17] *See* Ans. 17–18.

We also note that Appellant's § 101 arguments include assertions that certain claim elements are novel. *See, e.g.*, Appeal Br. 9; Reply Br. 2–3. But "'novelty' . . . is of no relevance in determining . . . patentable subject matter." *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1315 (Fed. Cir. 2016) (emphasis omitted) (quoting *Diehr*, 450 U.S. at 188–89).[18]

In view of the foregoing, we sustain the rejection of claims 1, 4–8, 10, 11, 14–16, and 19–21 under 35 U.S.C. § 101.

CLAIMS 1, 4–8, 10, 11, 14–16, and 19–21: OBVIOUSNESS.

In an obviousness analysis, the cited references must be considered for the entirety of what they teach and suggest to one skilled in the art. *See, e.g.*, *In re Hedges*, 783 F.2d 1038, 1039 (Fed. Cir. 1986) (citing *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965)). Further, each reference cited by the Examiner must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). The relevant inquiry is "what the *combined teachings* of th[os]e references would have suggested to those of ordinary

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[16] *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018).
[17] Robert W. Bahr, *Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (Berkheimer v. HP, Inc.)*, USPTO 3 (2018) ("*Berkheimer* Memo").
[18] *See also Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1340 (Fed. Cir. 2017) ("[e]ligibility and novelty are separate inquiries"); *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151 (Fed. Cir. 2016) ("The search for a § 101 inventive concept is . . . distinct from demonstrating § 102 novelty.").

skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (emphasis added). Here, in rejecting claim 1 as obvious, the Examiner relies on the combined teachings of Connors, Klass, and Trinks. Final 21–34; *see also* Advisory Act. 1–2; Ans. 19–25.

Appellant argues claims 1, 4–8, 10, 11, 14–16, and 19–21 together as a group. *See* Appeal Br. 14–20; Reply Br. 3–4. Appellant's arguments in the Appeal Brief rest on the following two assertions:

(1) Connors's mobile communications devices 110 and documentation server 138 fail to disclose the "electronic data capture system" and "safety compliance management system", respectively, along with certain associated functionalities, as recited in claim 1 (Appeal Br. 14–19; and (2)

(2) Klass merely discloses a waiting period before *maybe* sending an alert, whereas the claim requires "always" sending an alert (*id.* at 19–20) (emphasis omitted).

For the foregoing reasons, Appellant's arguments do not persuade us of Examiner error.

In particular, Appellant argues that Connors's mobile communications devices 110 fail to disclose "user-defined safety data logical schema that defines a subset of the data within the electronic data capture system to be monitored after the data is sent." Appeal Br. 17–18. Appellant also argues that Klass does not disclose this limitation because "there is **NO DISCLOSURE** of the monitoring the data by the **SENDERS** of the data in Klass, as would be required by the claims." *Id.* at 19. These arguments do not persuade us of error.

As an initial matter, Appellant is incorrect in asserting that claim 1 requires "monitoring the data by the **SENDERS** of the data." *Id.* Rather, the claim language at issue recites "a subset of the data . . . to be monitored after the data is sent," which does not specify the entity performing the monitoring, nor does it even require that monitoring actually occur. Therefore, applying the broadest reasonable interpretation of the claim language, the Examiner finds, and we agree, that Klass teaches the disputed limitation with its disclosure of an adverse drug events (ADE) monitoring system that uses predefined ADE rules to see if the data corresponds to a patient's lab and pharmacy data received over a network from laboratory and pharmacy information systems. Final 29 (citing Klass ¶¶ 42–43, 52–54, 66, Figs. 3, 6, 7). Because the Examiner has shown that Klass teaches the disputed limitation, we need not address whether Connors does as well. *Keller*, 642 F.2d at 425.

Appellant also argues, without further explanation, that Connors's mobile communications devices 110 fail to disclose several other limitations of claim 1. Appeal Br. 17. These arguments are not persuasive because Appellant failed to present *substantive* arguments and supporting *evidence* persuasive of Examiner error regarding the aforementioned disputed limitations. *See In re Lovin*, 652 F.3d 1349, 1357 (Fed. Cir. 2011) ("[W]e hold that the Board reasonably interpreted Rule 41.37 to require more substantive arguments in an appeal brief than a mere recitation of the claim elements and a naked assertion that the corresponding elements were not found in the prior art."). Moreover, Appellant's argument is not persuasive because it attacks Connors individually, whereas the Examiner relies on the combined teachings of Connors, Klass, and Trinks for teaching or

suggesting the disputed limitations. *Keller*, 642 F.2d at 425.

Appellant further argues that "Klass fails to disclose any components that can be considered the recited 'electronic data capture system' and 'safety compliance management system associated with a regulatory agency.'" Appeal Br. 18. This argument attacks Klass, but the Examiner relies on Connors for teaching the disputed elements. *See* Final Act. 23–24; *Keller*, 642 F.2d at 425. Moreover, the Examiner finds, and we agree, that Connors teaches an electronic data capture system and safety compliance management system with its disclosures of a mobile communications device and a documentation server (that can report SAE results to the FDA), respectively. Final 23–24 (citing, e.g., Connors ¶¶ 24, 40, 54–55); *see also* Connors ¶ 35.

Claim 1 further recites "wherein the adverse event is always electronically transmitted to the safety compliance management system as a result of either the elapsing of the user-defined time interval of the timer or the receiving of the second event." Appellant argues Klass does not disclose this limitation because "in Klass the alert is being sent back to the healthcare provide[r] FROM WHICH THE DATA WAS RECEIVED," whereas "the claims require the adverse event to be sent from where the event was generated (i.e., the electronic data capture system) to the 'safety compliance management system' upon expiration of the timer." Appeal Br. 19–20.

But the Examiner relies not only on Klass, but on the combined teachings of Connors and Klass for rendering the disputed limitation obvious. Final Act. 30–32; Ans. 22–24. More specifically, the Examiner finds Connors's reporting of an SAE to the documentation server immediately upon receipt from the participant teaches this limitation except

for the adverse event being sent as a result of "the elapsing of the user-defined time interval of the timer." Final Act. 27–28 (citing Connors ¶¶ 54, 60) (emphasis omitted). The Examiner cites Klass merely "as evidence that it was known in the art to condition the transmission of an alert regarding an adverse event on the expiration of a timeframe or user-defined time period." Ans. 22 (citing Klass ¶¶ 9, 61, 74, 78, 107); *see also* Final Act. 30–32. In other words, according to the Examiner, "the origin and destination of the adverse event alert or report is taught in cited portions of Connors (Action, pp. 27–28), and Klass is relied upon only to teach that the transmitting of the alert or report is in response to user-defined time interval expiring as shown by the italicized portion of the limitation in the office action (Action, p. 30)." Ans. 24.

We find no error in the Examiner's findings at least because Klass discloses generating and sending an alert about a potential ADE ("adverse event is . . . electronically transmitted") after a defined waiting period has ended ("elapsing of the user-defined time interval") without proper or appropriate action being taken. *See, e.g.*, Klass ¶¶ 73–74. We also find reasonable the Examiner's explanation that combining the cited teachings of Connors with those of Klass to arrive at the disputed limitation "is merely a combination of prior art elements according to known techniques to produce predictable results." Final Act. 33, *see also id.* at 32–33. And using Klass's waiting period allows for additional evaluation or treatment of the patient to ensure that a potential ADE does exist (*see, e.g.*, Klass ¶ 73), which may well yield an improvement in the accuracy and reliability of ADE reporting in systems such as Connors's. Appellant's arguments do not persuasively rebut the Examiner's findings and explanations.

For similar reasons, we are not persuaded by Appellant's argument that the Examiner erred because in Klass, an alert may not "always" be sent, for example, if appropriate action is taken during the waiting period. *See* Appeal Br. 19–20. The Examiner relies on Connors, not Klass, for teaching the concept of "always" electronically transmitting an alert. Final Act. 27–28 (citing Connors ¶¶ 54, 60). And nevertheless, Klass also teaches this feature because an alert is generated and sent *every* time proper or appropriate action has *not* been taken with respect to a potential ADE during the defined waiting period. *See* Ans. 23.

Appellant's argument that the ADE in Klass is not the same as the claimed "adverse event" (Reply Br. 3–4) fares no better. This argument attacks the teachings of Klass individually, but the Examiner's rejection is based on the combined teachings of Connors and Klass, which include the unrebutted finding that Connors teaches an adverse event with its disclosure of a serious adverse event related to a clinical trial. *See, e.g.*, Final Act. 22–23 (citing Connors ¶¶ 11–13, 24). That there may be minor contextual differences between Klass's ADE and the claimed "adverse event" is of no moment. While Appellant may have shown that the references have differences, this alone is insufficient to rebut a *prima facie* case of obviousness. *See In re Beattie*, 974 F.2d 1309, 1312–13 (Fed. Cir. 1992).

For the foregoing reasons, we sustain the Examiner's rejection of claims 1, 4–8, 10, 11, 14–16, and 19–21 under 35 U.SC. § 103.

CONCLUSION

We AFFIRM the rejection of claims 1, 4–8, 10, 11, 14–16, and 19–21 under 35 U.S.C. § 101.

We AFFIRM the rejection of claims 1, 4–8, 10, 11, 14–16, and 19–21 under 35 U.S.C. § 103.

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 4–8, 10, 11, 14–16, 19–21	101	Eligibility	1, 4–8, 10, 11, 14–16, 19–21	
1, 4–8, 10, 11, 14–16, 19–21	103	Connors, Klass, Trinks, Strong, Goldner	1, 4–8, 10, 11, 14–16, 19–21	
Overall Outcome			1, 4–8, 10, 11, 14–16, 19–21	

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