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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HANNA MINA GEDEON and
SARA JANE GRIFFIN[1]

Appeal 2017-011652
Application 13/908,745
Technology Center 3600

Before CARL W. WHITEHEAD JR., JON M. JURGOVAN, and JOHN R. KENNY, *Administrative Patent Judges*.

JURGOVAN, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant seeks review under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–20. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.[2]

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[1] The Appeal Brief indicates the real party in interest is Cerner Innovation, Inc. App. Br. 3.

[2] Our Decision refers to the Specification ("Spec.") filed June 3, 2013, the Final Office Action ("Final Act.") mailed December 5, 2016, the Appeal Brief ("App. Br.") filed May 15, 2017, the Examiner's Answer ("Ans.") mailed July 19, 2017, and the Reply Brief ("Reply Br.") filed September 19, 2017.

CLAIMED INVENTION

The invention relates to detecting, presenting, and communicating an adverse event on an electronic reporting form with fields pre-populated from a patient's electronic health record (EHR). Spec. 37 (Abstract). An adverse event is a situation involving harm or potential harm to a patient or an adverse reaction of a patient to care provided. Spec. ¶ 1. Claims 1, 14, and 19 are independent and the remaining claims depend therefrom. Claim 1, reproduced below, is representative of the claimed invention:

> 1. A method in a medical information computing environment for communicating data in an electronic adverse event reporting form directly to one or more end-user receiving parties, the method comprising:
>
> monitoring by a computing device having a processor and a memory an electronic health record of a patient for specified combinations and relationships between data points indicating the occurrence of an adverse event;
>
> detecting, by the computing device, the occurrence of the adverse event based on identifying the combinations and relationships between data points indicating the occurrence of the adverse event;
>
> automatically presenting on a display device an electronic adverse event reporting form pre-populated with one or more patient data obtained from the electronic health record of the patient;
>
> receiving additional data, modifications to, or a verification of the data pre-populated in the electronic adverse event reporting form from a user; and
>
> electronically communicating, by the computing device, the data in the electronic form to the one or more end-user receiving parties, wherein the one or more end-user receiving parties comprise one or more of a government organization, a regulatory agency, a manufacturer, a non-governmental health organization, a research organization, quality control personnel, and an interested party.

App. Br. 37 (Claims Appendix).

REJECTIONS & EVIDENCE

Claims 1–20 stand rejected under 35 U.S.C. § 101 as directed to a judicial exception without significantly more. Final Act. 2–3.

Claims 1–20 stand rejected under 35 U.S.C. § 103(a) based on Mitchell (US 2009/0216555 A1, published Aug. 27, 2009), Fuerst (US 2006/0036619 A1, published Feb. 16, 2006) and Napora (US 2009/0132586 A1, published May 21, 2009). Final Act. 4–9.

ANALYSIS

§ 101 Rejection

Patent eligibility is a question of law that is reviewable *de novo*. *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1333 (Fed. Cir. 2012). Accordingly, we make our § 101 determinations concerning patent eligibility under this standard.

Patentable subject matter is defined by 35 U.S.C. § 101, as follows:

> [w]hoever 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.

In interpreting this statute, the Supreme Court emphasizes that patent protection should not preempt "the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) ("*Benson*"); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012) ("*Mayo*"); *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014)

("*Alice*"). The rationale is that patents directed to basic building blocks of technology would not "promote the [p]rogress of [s]cience" under the U.S. Constitution, Article I, Section 8, Clause 8, but instead would impede it. Accordingly, laws of nature, natural phenomena, and abstract ideas, are not patent-eligible subject matter. *Thales Visionix Inc. v. U.S.*, 850 F.3d 1343, 1346 (Fed. Cir. 2017) (citing *Alice*, 573 U.S. 208 (2014)).

The Supreme Court set forth a two-part test for subject matter eligibility in *Alice* (573 U.S. 208 (2014)). The first step is to determine whether the claim is directed to a patent-ineligible concept. *Id.* (citing *Mayo*, 566 U.S. at 76–77). If so, then the eligibility analysis proceeds to the second step of the *Alice*/*Mayo* test in which we "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. 208 (2014) (quoting *Mayo*, 566 U.S. at 72, 79). There is no need to proceed to the second step, however, if the first step of the *Alice/Mayo* test yields a determination that the claim is directed to patent eligible subject matter.

The Patent Office has recently revised its guidance for how to apply the *Alice/Mayo* test in the *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50–57 (January 7, 2019) ("the *Revised Guidance*"). Under the Revised Guidance, we first look to whether the claim recites:

> (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, mental processes, or certain methods of organizing human activity such as a fundamental economic practice or managing personal behavior or relationships or interactions between people); and

> (2) additional elements that integrate the judicial exception into a practical application (*see* Manual of Patent Examining Procedure ("MPEP") § 2106.05(a)–(c), (e)–(h)). 84 Fed. Reg. at 51–52, 55.

A claim that integrates a judicial exception into a practical application applies, relies on, or uses the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception. 84 Fed. Reg. at 54. When the judicial exception is so integrated, then the claim is not directed to a judicial exception and is patent-eligible under § 101. 84 Fed. Reg. at 54. Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then evaluate whether the claim provides an inventive concept. 84 Fed. Reg. at 56; *Alice*, 573 U.S. 208 (2014). Evaluation of the inventive concept involves consideration of whether an additional element or combination of elements (1) adds a specific limitation or combination of limitations that are not well-understood, routine, conventional activity in the field, which is indicative that an inventive concept may be present; or (2) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, which is indicative that an inventive concept may not be present. 84 Fed. Reg. at 56.

Step 1 of the Revised Guidance

As an initial matter, we consider whether claims 1–20 fall under one of the statutory categories of invention enumerated under 35 U.S.C. §§ 100 and 101. Claims 1–13 recite "methods" which constitute "processes" under 35 U.S.C. §§ 100 and 101. Claims 14–18 recite "systems" which constitute

"machines" under 35 U.S.C. § 101. Claims 19 recites a "method" and claim 20, which is dependent from claim 19, recites a "system." Therefore, claims 19 and 20 constitute, respectively, a "process" and "machine."[3] Accordingly, each of claims 1–20 fall within one of the statutory categories of invention. The patent eligibility inquiry does not end here, however, as we must proceed to apply the *Alice/Mayo* test and *Revised Guidance* to determine whether the claims are patent eligible.

Alice/Mayo—Step 1 (Abstract Idea)
Step 2A–Prongs 1 and 2 identified in the Revised Guidance

Step 2A—Prong 1 (Does the Claim Recite a Judicial Exception?)

As an initial matter, we select claim 1 as representative of the claims and examine it to determine whether it recites a judicial exception to patentability. 37 C.F.R. § 41.37(c)(1)(iv); 84 Fed. Reg. 54.

Turning to the first step of the *Alice* inquiry (*Step 2A, Prong 1 of the Revised Guidance*), at a general level, claim 1 recites monitoring a health record of a patient for the occurrence of an adverse event and detecting an adverse event by identifying combinations and relationships between data points. Claim 1 also recites presenting an adverse event reporting form pre-populated with data from the patient's health record, adding, modifying or verifying data in the form, and communicating the form to end users. Accordingly, we determine that claim 1 recites the abstract idea of

[3] The Examiner and Appellant are advised to consider whether claim 20 is a proper dependent claim in that it recites a system but is dependent from method claim 19. *See IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377 (Fed. Cir. 2005).

monitoring a patient's health record and detecting adverse events and reporting them to an end user.

These activities are noted as carried out manually in the prior art. For example, in its background section, Mitchell (¶ 5) states "many facilities are using manual systems, voluntary reporting and limited chart review for adverse drug event capture, validation and management." Thus, as was done in the prior art noted by Mitchell, claim 1 can be carried out entirely in the human mind using pen and paper. Under these circumstances, our reviewing court has found such a claim to recite an abstract idea. *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1318 (Fed. Cir. 2016) ("[W]ith the exception of generic computer-implemented steps, there is nothing in the claims themselves that foreclose them from being performed by a human, mentally or with pen and paper."); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 ("That purely mental processes can be unpatentable, even when performed by a computer, was precisely the holding of the Supreme Court in *Gottschalk v. Benson*.").

Thus, claim 1 recites a "mental concept" which is an abstract idea constituting a judicial exception under the *Revised Guidelines*. 84 Fed. Reg. 54.[4]

Step 2A—Prong 2 (Integration into Practical Application)

Under *Step 2A, Prong 2 of the Revised Guidance*, we consider whether claim 1 recites additional elements, or combinations thereof, that integrate the judicial exception into a practical application. *See Revised*

[4] Claim 1 could also be viewed as reciting a "method of organizing human activity" under the *Revised Guidelines*. For simplicity, we address only the "mental concept" category under the *Revised Guidelines*.

Guidance, 84 Fed. Reg. at 54–55 ("Prong Two"). The claim recites additional elements including a "*computing device having a processor and memory*," "*display device*," "*electronic health record*," and "*electronic adverse event reporting form*" that is pre-populated with patient data from the "*electronic health record*." We turn to analyze whether any of these additional elements apply the abstract idea embodied in the claims in a practical application. In this regard, the *Revised Guidance* identifies several factors to consider, which we now address.

One of the factors identified as important to determining whether additional elements of a claim apply the judicial exception to a practical application is whether they constitute an improvement to some technical area. 84 Fed. Reg. 55. In this case, the additional elements recited in claim 1 are generic computing devices that do not improve the functioning of a computer, or define an improvement to another technology or technical field. The "*computing device having a processor and memory*" and "*display device*" are, of course, generic computing devices. Also, as recited, the "*electronic health record*" and "*electronic adverse event reporting form*" are merely electronic representations of paper forms used in the prior art, as previously noted. *See* Mitchell ¶ 5. "[M]ere automation of manual processes using generic computers does not constitute a patentable improvement in computer technology." *Credit Acceptance Corp. v. Westlake Services*, 859 F.3d 1044, 1055 (Fed. Cir. 2017).

The end result of claim 1 is to communicate adverse events to an end user. However, as recited, the claim does nothing with the communicated adverse events, as the claims stop short of applying or using the judicial exception to effect a particular treatment or prophylaxis for a disease or

medical condition, and thus do not constitute a practical application under this factor of the *Revised Guidance*. 84 Fed. Reg. 55.

Claim 1 further does not recite an additional element that implements a judicial exception with, or uses a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim. *Id.* As noted, the claim recites "*computing device having a processor and memory*" and "*display device*" which are general-purpose or generic computing devices, not particular machines. The same is true of the "*electronic health record*" and "*electronic adverse event reporting form*" which are merely electronic representations of paper forms used in the prior art. No showing has been made that these additional elements provide some capability that a human could not, or that they provide some capability beyond what would normally be expected of a computer to provide. Consequently, the additional elements of claim 1 do not constitute a particular machine or attribute to which the judicial exception could be applied.

The additional elements of claim 1 do not effect a transformation or reduction of a particular article to a different state or thing. 84 Fed. Reg. 55. Rather, the additional elements operate on healthcare-related information, not on an article, and the end result is to communicate information to an end user, not to effect the state or thing of an article. The electronic forms of the claim are not recited in a manner that one would conclude they are articles that undergo transformation or are reduced to a different state or thing.

Claim 1 further does not recite any additional element that applies or uses the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment, such that the claim as a whole is more than a drafting effort

designed to monopolize the exception. 84 Fed. Reg. 55. Rather, the claim's preamble merely links the use of the judicial exception to a "*medical information computing environment*." This is insufficient to constitute a practical application of the judicial exception embodied in the claim.

In summary, the additional elements of a "*computing device having a processor and memory*," "*display device*," "*electronic health record*," and "*electronic adverse event reporting form*" are merely used as tools to perform the abstract idea of monitoring a patient's health record and detecting adverse events and reporting them to an end user similarly to the way in which paper forms were used in the prior art. *See Credit Acceptance, supra*; *see also Alice* (using a computer to create and maintain electronic records is abstract); MPEP § 2106.05. The recitation in claim 1 that certain "*end-user receiving parties*" receive the "*electronic adverse event reporting form*" is not meaningful in defining a practical application, particularly where such entity does nothing with it as the claim is recited. The additional elements of the claim merely link the judicial exception to a "*medical information computing environment*" as the technical environment or field of use in which the judicial exception is performed.

Accordingly, we determine that the additional elements of claim 1 besides the judicial exception are insufficient to amount to a practical application of the judicial exception. We conclude, therefore, that the claim is directed to a judicial exception. We thus proceed to the second step of the *Alice/Mayo* test.

Alice/Mayo—Step 2 (Inventive Concept)
Step 2B of Revised Guidance

We now examine whether claim 1 recites an inventive concept sufficient to transform the judicial exception into patent-eligible subject matter. *See Alice*, 573 U.S. 208 (2014); *Mayo*, 566 U.S. at 72, 79.

As previously stated, the monitoring, detecting, and reporting of adverse events were known in the prior art. *See* Mitchell ¶ 5. Merely computerizing this process with a "*computing device having a processor and memory*" and "*display device*" is not enough to transform a judicial exception into a patent-eligible invention. The "*electronic health record"* and "*electronic adverse event reporting form*" are computerized representations of paper records and forms used in the prior art for the same purposes.

Further, claim 1 is recited at a high level of generality and lacks details concerning the "*electronic health record"* and "*electronic adverse event reporting form*." As such, if there is any aspect of the claimed electronic record or electronic form that is different than their paper representations used in the prior art, the claim does not recite it.

Accordingly, we conclude the additional elements of claim 1 are insufficient to constitute an inventive concept that could transform the judicial exception into patent-eligible subject matter. Instead, claim 1, representative of all claims, is directed to a judicial exception, and the

additional elements of the claims do not amount to significantly more than that judicial exception. As such, the claims as recited are patent-ineligible.

Appellant's Arguments Against the Examiner's § 101 Rejection

Appellant argues the Examiner's § 101 analysis is conclusory and does not comply with the MPEP or the standard set out in the *July 2015 Update on Subject Matter Eligibility*. App. Br. 15–16. Appellant does not explain, however, why the Final Office Action fails to comply with these with these standards, and the arguments presented are unpersuasive for this reason. *See* 37 C.F.R. § 41.37(c)(1)(iv) ("The arguments shall explain *why* the examiner erred as to each ground contested by appellants." (Emphasis added.)).

Appellant also argues that the Examiner did not present any case law precedent to establish patent ineligibility of a claim reciting more than one abstract idea. App. Br. 16–19. Appellant does not explain, however, why the analysis would be any different under *Alice/Mayo* for a claim reciting multiple abstract ideas.

Appellant further contends the Examiner relied on nonprecedential decisions of *SmartGene* and *Cyberfone*, and failed to explain how the facts of the present application match the facts in *SmartGene* and *Cyberfone*. App. Br. 19–23. Rejections under § 101 are reviewable *de novo*, *see Dealertrack, supra*, and we do not rely on these cases in making our § 101 determination.

Appellant contends the Examiner errs by misapplying *Enfish* as requiring a claim to recite an improvement in the functioning of a computer in order to qualify as patent-eligible. App. Br. 23–26. Our analysis above addresses improvements as one factor to consider in the eligibility analysis.

In addition, Appellant argues the Examiner fails to analyze the claims using the abstract idea that is actually recited in the claim: "detecting and reporting adverse events." App. Br. 26. Our analysis defines the abstract idea recited in the claims in a similar manner, and applies the *Alice/Mayo* test to this abstract idea.

Appellant next contends the Examiner errs by stating that receiving and displaying data and electronically communicating forms, in general, were routine and well-understood in data management technologies, which allegedly fails to comply with the *Alice* standard. App. Br. 27–28. We do not agree with this argument. Additional elements of the claim such as the "*electronic health record*" and "*electronic adverse event reporting form*" are evaluated, for example, to determine whether they constitute an improvement that could define a practical application under Step 2A-Prong 2, or an inventive concept under Step 2B, of the *Alice/Mayo* test. The Examiner's determinations are relevant to these issues and we are not persuaded those determinations are inconsistent with judicial precedent.

Appellant contends the claims recite additional elements directed to inventive concepts that are distinct from abstract ideas. App. Br. 29–30. We addressed this issue at length in our analysis above, and we do not agree Appellant has shown any additional elements are directed to inventive concepts.

Appellant argues the claims recite additional features which are not "routine and conventional" in the context of the claimed invention. App. Br. 30–31. Appellant contends each of the claims describes a particular arrangement of elements that is a technical improvement over prior art ways of populating and communicating electronic adverse event reporting forms.

Id. As discussed previously, however, Appellant does not explain how particularly the claims capture a technical improvement, or what capability beyond things a computer would normally be expected to provide, is achieved by the recited computerized features that paper health records and adverse event forms could not provide. In this regard, we note that lawyer's arguments and conclusory statements, which are unsupported by factual evidence, are entitled to little probative value. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997). We also note that the Examiner finds the claims involve receiving, processing, and storing data and electronic record keeping (Final Act. 3), which have been held to be well-understood, routine and conventional functions of a computer. *July 2015 Update: Subject Matter Eligibility*, https://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf (last viewed 9/6/2019); *Alice*, 573 U.S. at 225 (electronic record keeping is one of the most basic functions of a computer, as is obtaining data, adjusting account balances, and issuing automated instructions); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 706, 716 (updating an activity log is a routine step).

Appellant provides several additional arguments in the Reply Brief. Specifically, Appellant argues the § 101 rejection (1) is arbitrary and capricious (Reply Br. 3–5); (2) relies on non-precedential cases (Reply Br. 5–6); (3) lacks consistency in justifying the rejection (Reply Br. 6–8); (4) improperly relies on *Fairwarning* (Reply Br. 8–10); (5) fails to consider the claims more analogous to *McRo* than *FairWarning* (Reply Br. 10–12); (6) improperly relies on *Electric Power Group* (Reply Br. 12–14); (7) misapplies *Enfish* (Reply Br. 14–14); (8) would invalidate claims shown to

be patent eligible in judicial precedent (Reply Br. 15–17); and (9) misapplies the concept of "routine and conventional" (Reply Br. 17–20).

Many of these arguments we addressed previously. To the extent we have not, it is because Appellant presents new arguments raised for the first time in the Reply Brief, which the Examiner has not had an opportunity to consider. Such arguments are not considered by the Board in rendering a decision absent a showing of good cause for their late submission, which has not been presented here. *See* 37 C.F.R. § 41.41(b)(2).

In summary, we have considered Appellant's arguments but are not persuaded that claims 1–20 are directed to patent-eligible subject matter under § 101 for the stated reasons.

§ 103(a) Rejections

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007) ("*KSR*"). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Claim 1

The Examiner finds the claimed "*electronic adverse event reporting form*" is disclosed by Mitchell. Final Act. 4–5 (citing Mitchell ¶ 26);

Ans. 6–7 (citing Mitchell ¶ 48). Specifically, the Examiner finds Mitchell's list of suspected adverse drug events discloses the claimed feature. *See* Mitchell ¶ 48.

Appellant does not agree with the Examiner, and argues that the combination of Mitchell, Fuerst, and Napora fails to disclose the claimed feature. App. Br. 31–35. Specifically, Appellant argues the term "*adverse event reporting form*" is given a clear and precise meaning in the Specification and that graphical representations of adverse event reporting forms are provided in Figures 9–13 and described in paragraphs 69 and 70 thereof. *Id.* at 32. Aside from pointing to these parts of the Specification, however, Appellant provides no explicit definition for the claimed term. In any case, Appellant contends the "*adverse event reporting form*" set forth in the Specification and claims is not disclosed by the prior art combination.

At the outset, we note that claim terms are given their broadest reasonable interpretation consistent with the specification. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1369 (Fed. Cir. 2004). The Specification broadly describes the claimed electronic form. For example, the Specification describes that "[t]he electronic form may be of any format or style and have any desired features." Spec. ¶ 48. The Specification also mentions embodiments of an electronic form may have "a format and data entry points." *Id.* These characteristics of an "*adverse event reporting form*" are consistent with Mitchell's list of suspected drug events which "may be provided in an electronic format that allows the medication safety specialist to categorize, reorder and review suspected drug events" and to provide an indication of confirmed adverse drug events. Mitchell ¶¶ 48, 51,

Fig. 6. Accordingly, we are not persuaded by Appellant's argument that the claimed term is distinguishable from the prior art.

Appellant next argues the combination of Mitchell, Fuerst, and Napora fails to disclose an "*adverse event reporting form*" that is "*pre-populated*" with patient data. App. Br. 32–33. Appellant contends the Examiner concedes that Mitchell does not disclose a "*pre-populated*" form. *Id*. We do not agree that the Examiner conceded this point, because the Examiner does rely on Mitchell to disclose a pre-populated form. *See* Final Act. 4. Specifically, Mitchell states the warehouse processor creates a list of suspected adverse drug events to be distributed to a medication safety specialist to categorize, reorder and review suspected drug events. Mitchell ¶ 48. Mitchell further states "[i]n addition to creating the list of suspected adverse drug events, according to one embodiment, *data corresponding to the patients in association with which a suspected adverse drug event occurred may be compiled and used* to update a Medical Safety Scorecard, an example of which is shown in FIG. 6." *Id.* Emphasis added. This statement at least suggests Mitchell's list in electronic format may be pre-populated with patient data before the medication safety specialist provides an indication of confirmed adverse drug events. Mitchell ¶ 51. Thus, we are not persuaded the Examiner errs in finding that Mitchell discloses the claimed features. We also noted that the term "*pre-populated*" is not set out affirmatively in the claim as a method step. Consequently, Appellant argues for patentability on the basis of a step that is not actually recited and thus Appellant's argument is not commensurate with the scope of the claims.

Limitations not appearing in the claims cannot be relied upon for patentability. *In re Self*, 671 F.2d 1344, 1348 (CCPA 1982).

For the claimed feature of allowing a user to perform data input, change or verification to the "*adverse event reporting form*," we agree with the Examiner that Napora discloses this feature. Specifically, Napora states "the user interacts with the Online Form by entering new data and/or editing the data that has been automatically populated into the form." Napora ¶ 98. Thus, Napora establishes it was known to enter and edit data, and to automatically populate online forms, in the healthcare industry.

Appellant further argues that the Examiner errs by ascribing two different meanings to the claim term "*adverse event reporting form*." App. Br. 34. Appellant appears to be arguing that, if the Examiner uses the list of adverse drug events of Mitchell to disclose the "*adverse event reporting form*" then Fuerst and Napora must also disclose that same list in order to be properly combinable with Mitchell. This type of rigid approach to the obviousness analysis has been rejected by the Supreme Court. *See KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007). In any event, the Examiner set forth reasons why one of ordinary skill in the art would have combined the prior art references. Final Act. 5. Appellant does not address or refute the Examiner's reasons to combine.

Appellant further argues that Fuerst "fails to teach at least *an electronic adverse event reporting form formatted according to a standard form provided by one or more regulatory bodies*." App. Br. 34. The Examiner contends this argument pertains to language added to the claims in a response after Final Office Action dated February 16, 2017, which the Examiner refused to enter. Ans. 7; Advisory Action dated March 1, 2017.

The claim amendments are thus not part of the record on appeal. As a result, Appellant's argument is not supported by corresponding language in the claims. *See Self, supra*. In addition, Appellant has not shown why making an electronic form the same as a standard form provided by a regulatory body would have been nonobvious.

In the Reply Brief, Appellant argues (1) contrary to the Examiner's assertion, the Appeal Brief does show a difference between the claimed invention and Mitchell; and (2) the Appeal Brief describes differing ways that the "adverse event reporting form" is interpreted in the rejection. We addressed these arguments previously and do not revisit them here.

Remaining Claims

Appellant presents the same arguments for the remaining claims, which are unpersuasive for the stated reasons. Accordingly, the remaining claims fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

DECISION

We affirm the Examiner's rejection of claims 1–20 under 35 U.S.C. § 101 as directed to patent-ineligible subject matter.

We affirm the Examiner's rejection of claims 1–20 under 35 U.S.C. § 103(a).

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