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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARK A. HOFFMAN,
KEVIN MATTHEW POWER, ANDREW MECKLER,
MAHCAMEH MOUSSAVI, and BONNIE LINN BATES

Appeal 2018-007651
Application 13/490,012
Technology Center 3600

Before JOHN A. JEFFERY, JUSTIN BUSCH, and
JENNIFER L. McKEOWN, *Administrative Patent Judges*.

BUSCH, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 10–12, 14–16, and 18–20, which constitute all the claims pending in this application. We have jurisdiction over the pending claims under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] 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 Cerner Innovation, Inc. Br. 3.

CLAIMED SUBJECT MATTER

Appellant's disclosure relates to "providing indications of clinical-trial criteria modifications" and, more specifically, providing suggested clinical-trial criteria modifications based on comparing aggregated patient data to the criteria that may increase the number of patients eligible for a trial. Spec. ¶ 6, Abstract. According to the Specification, the invention addresses the problem that clinical trials often lack sufficient enrollment because not enough patients are eligible to participate and the clinical-trial providers "often lack visibility to the impact of specific eligibility criteria on recruitment rates." Spec. ¶ 4. Claims 10 and 15 are independent claims, and claim 10 is reproduced below:

> 10. A computerized method for providing indications of clinical-trial criteria modifications, the method comprising:
>
> providing an indication to view one or more suggested clinical-trial criteria modifications that, if implemented, are expected to increase a number of patients eligible for a clinical trial;
>
> receiving a distribution of patient data relative to a clinical-trial criterion, wherein the distribution represents patient data that is grouped in a plurality of value ranges indicating a scope of the clinical-trial criterion;
>
> receiving, via computing device, a suggested criterion modification, wherein the suggested criterion modification includes an instruction to modify at least one of the plurality of value ranges and a new value with which to modify the at least one of the plurality of value ranges, wherein the new value modifies the scope of the clinical-trial criterion by increasing the number of patients eligible for the clinical trial, and wherein the new value of the suggested criterion modification is identified by analysis of the distribution of patient data relative to the clinical-trial criterion;
>
> receiving one or more details pertaining to an expected result if the new value of the suggested criterion modification is

> used to modify the at least one value range of the clinical-trial criterion; and
>
> concurrently displaying an indication of the distribution of patient data relative to the plurality of value ranges, an indication of the suggested criterion modification for the clinical-trial criterion, and an indication of the one or more details pertaining to the expected result that would occur if the suggested criterion modification is applied.

REJECTIONS

Claims 10–12, 14–16, and 18–20 stand rejected under 35 U.S.C. § 101 as being directed to an abstract idea. Final Act. 2–6.

Claims 15, 16, and 18–20 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Final Act. 3.

Claims 10–12, 14–16, and 18–20 stand rejected under 35 U.S.C. § 102 as anticipated by Harrison (US 2010/0088245 A1; Apr. 8, 2010). Final Act. 6–9.

ANALYSIS

We have reviewed the Examiner's rejections in light of Appellant's arguments that the Examiner erred. In reaching this decision, we have considered all evidence presented and all arguments Appellant made. Arguments Appellant could have made, but chose not to make in the Brief, are deemed waived. *See* 37 C.F.R. § 41.37(c)(1)(iv).

THE 35 U.S.C. § 101 NON-STATUTORY SUBJECT MATTER REJECTION

In addition to concluding claims 15, 16, and 18–20 are directed to an abstract idea (discussed further below), the Examiner determines these claims are directed to non-statutory subject matter because they encompass transitory computer readable storage media. Final Act. 3. Appellant does not respond to this aspect of the Examiner's rejection. Therefore, we summarily

sustain the Examiner's rejection of claims 15, 16, and 18–20 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

THE 35 U.S.C. § 101 ABSTRACT IDEA REJECTION

The Examiner concludes claims 10–12, 14–16, and 18–20 are directed to judicially excepted subject matter. Final Act. 2–6. Appellant argues the § 101 rejection of all claims as a group. *See* Br. 11 (arguing independent claim 15 and dependent claims 11, 12, 14, 16, and 18–20 are directed to eligible matter for the same reasons argued with respect to independent claim 10), 17 (arguing independent claim 15 and dependent claims 11, 12, 14, 16, and 18–20 recite an inventive concept for the same reasons argued with respect to independent claim 10). We select claim 10 as representative of the claims with respect to the rejection of claims 10–12, 14–16, and 18–20 as ineligible subject matter for being directed to no more than an abstract idea. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2016).

The Supreme Court's two-step framework guides our analysis of patent eligibility under 35 U.S.C. § 101. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014). In addition, the United States Patent and Trademark Office recently published revised guidance for evaluating subject matter eligibility under 35 U.S.C. § 101, specifically with respect to applying the *Alice* framework. USPTO, *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (Jan. 7, 2019) ("Guidance").

If a claim falls within one of the statutory categories of patent eligibility (i.e., a process, machine, manufacture, or composition of matter), we determine whether the claim is directed to one of the judicially recognized exceptions (i.e., a law of nature, a natural phenomenon, or an abstract idea). *Alice*, 573 U.S. at 217. As part of our inquiry, we "look at the

'focus of the claimed advance over the prior art' to determine if the claim's 'character as a whole' is directed to excluded subject matter." *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016). The Guidance directs us to address this inquiry using the following two prongs of analysis: (i) does the claim recite a judicial exception (e.g., an abstract idea), and (ii) if so, is the judicial exception integrated into a practical application? 84 Fed. Reg. at 54.

Under the Guidance, if the judicial exception is integrated into a practical application, the claim is patent eligible under § 101. 84 Fed. Reg. at 54–55. If the claim is directed to a judicial exception (i.e., the claim both recites a judicial exception and fails to integrate the exception into a practical application), we next determine whether the claim provides an inventive concept, which includes determining whether any element, or combination of elements, amounts to significantly more than the judicial exception. *Alice*, 573 U.S. at 217; 84 Fed. Reg. at 56.

Here, we conclude representative claim 10 is directed to mental processes (i.e., a concept performed in the human mind, such as an observation, evaluation, judgment, and opinion), which are abstract ideas. *See* 84 Fed. Reg. at 52. Claim 10 generally is directed to suggesting modifications to clinical-trial criteria that will increase the number of patients eligible to participate in the trial.

This is consistent with how Appellant describes the claimed embodiments of the invention. Br. 8 ("The character of the claim, speaking generally, focuses on a computerized method that intelligently generates new criterion-specific values and further generates instructions to implement the new criterion-specific values in order to redefine a value range for a

particular criterion used to determine clinical trial eligibility."); Spec. ¶¶ 6 ("Embodiments of the present invention relate to providing indications of clinical-trial criteria modifications."), 22 ("Utilizing the methods and systems described herein, clinical-trial criteria associated with a particular clinical trial can be compared to corresponding patient data," "a suggested criteria modification can be determined or identified," and the "suggested criteria modification can be provided to the clinical-trial provider to assist in assessing the success of the clinical trial."), 24 ("[A]n embodiment is directed to a computerized method for providing indications of clinical-trial criteria modifications. The method includes providing an indication to view one or more suggested clinical-trial criteria modifications that, if implemented, are expected to increase a number of patients eligible for a clinical trial."), 25 (describing an embodiment that is directed to computer instructions for performing the method described in paragraph 24 of the Specification). Although not dispositive regarding the scope of the claim, we also note claim 10 explicitly recites it is a "computerized method for providing indications of clinical-trial criteria modifications." Br. 26 (Claim 10 preamble); *accord* Br. 3 ("embodiments of the invention are generally directed to intelligently formulating new values that, if implemented by a user setting participation in/eligibility [sic] parameters for each specific clinical-trial criterion, will modify the scope of in/eligibility [sic] under one or more of the clinical-trial criteria to boost patient recruitment rates").

Claim 10 is reproduced below, with the claim limitations that recite elements of the abstract idea of suggesting modifications to clinical-trial criteria that will increase the number of patients eligible to participate in the trial emphasized in *italics*:

> 10. A computerized method for providing indications of clinical-trial criteria modifications, the method comprising:
>
> *providing an indication to view one or more suggested clinical-trial criteria modifications that, if implemented, are expected to increase a number of patients eligible for a clinical trial*;
>
> *receiving a distribution of patient data relative to a clinical-trial criterion, wherein the distribution represents patient data that is grouped in a plurality of value ranges indicating a scope of the clinical-trial criterion*;
>
> *receiving*, via computing device, *a suggested criterion modification, wherein the suggested criterion modification includes an instruction to modify at least one of the plurality of value ranges and a new value with which to modify the at least one of the plurality of value ranges, wherein the new value modifies the scope of the clinical-trial criterion by increasing the number of patients eligible for the clinical trial, and wherein the new value of the suggested criterion modification is identified by analysis of the distribution of patient data relative to the clinical-trial criterion*;
>
> *receiving one or more details pertaining to an expected result if the new value of the suggested criterion modification is used to modify the at least one value range of the clinical-trial criterion*; and
>
> *concurrently displaying an indication of the distribution of patient data relative to the plurality of value ranges, an indication of the suggested criterion modification for the clinical-trial criterion, and an indication of the one or more details pertaining to the expected result that would occur if the suggested criterion modification is applied*.

More particularly, the abstract idea of suggesting modifications to clinical-trial criteria that will increase the number of patients eligible to participate in the trial comprises (i) providing an indication to begin the process of suggesting criteria modifications to increase the number of patients eligible for a clinical trial; (ii) receiving patient data grouped into ranges relative to a clinical-trial criterion; (v) receiving a suggested criterion

modification (including an instruction to modify a value range and a new value for the value range) that (1) is identified by analyzing the received data and (2) will increase the number of eligible patients; (vi) receiving details regarding expected results if the modification is made; and (vii) displaying the patient data, an indication of the suggested modification, and an indication of the details regarding expected results. These steps that make up the concept recited in claim 10 are simply a series of observations, evaluations, and judgements for suggesting modifications to clinical-trial criteria that will increase the number of patients eligible to participate in the trial, and these steps all fall within the types of mental processes considered abstract—i.e., observations, evaluations, judgments, and opinions. *See* 84 Fed. Reg. at 52.

Consistent with our Guidance and case law, we conclude this concept is a mental process and, therefore, an abstract idea. *See* 84 Fed. Reg. at 52; *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1067 (Fed. Cir. 2011) (determining claims that recite reviewing information to determine a lower-risk immunization schedule were directed to an abstract idea because they involve only mental processes); *Digitech Image Techs., LLC v. Elecs. For Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) (concluding "taking existing information . . . and organizing this information into a new form" is an abstract idea); *SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 F. App'x 950, 954–56 (Fed. Cir. 2014) (concluding claims that analyzed provided patient information using knowledge bases to generate a ranked list of treatment regimens and advisory information for treatment regimens were directed to an abstract idea); *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018)

(concluding claims were directed to the abstract idea of "selecting certain information, analyzing it using mathematical techniques, and reporting or displaying the results of the analysis"). 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. *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."); *see Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353–54 (Fed. Cir. 2016) (concluding that "analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category" and concluding claims directed to "collecting information, analyzing it, and displaying certain results of the collection and analysis" were abstract);.

Because claim 10 recites a judicial exception, we next determine whether it integrates the judicial exception into a practical application. 84 Fed. Reg. at 54. To determine whether the judicial exception is integrated into a practical application, we identify whether there are "*any additional elements recited in the claim beyond the judicial exception(s)*" and evaluate those elements to determine whether they integrate the judicial exception into a practical application. 84 Fed. Reg. at 54–55 (emphasis added); *see also* Manual of Patent Examining Procedure ("MPEP") §§ 2106.05(a)–(c), (e)–(h) (9th ed. Rev. 08.2017, Jan. 2018).

Here, the additional limitations recited beyond the judicial exception itself fail to integrate the exception into a practical application. More particularly, claim 10 does 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 also* 84 Fed. Reg. at 55.

Rather, the additional elements simply use computers as tools to implement the abstract idea requiring no more than generic computer elements to perform generic computer functions or add insignificant extra-solution activity. The only additional element recited in claim 10 is the "computing device" via which the suggested modification is received. The computing device is a generic computer element recited at a high level of generality. The Specification and claims provide only generic high-level descriptions of the computing device, without providing detail indicating these elements include any improvement to existing computers or technology. *Cf. Berkheimer Memo*[2] *§ III.A.1*; *see* Spec. ¶¶ 28 (explaining "[t]he present invention may be operational with numerous other general

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[2] "Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*)" at 3 (Apr. 19, 2018), available at https://www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.PDF (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).

purpose or special purpose computing system environments or configurations" and listing various generic types of computing systems or devices, such as "personal computers, server computers, hand-held or laptop devices"), 30–31 (describing generic computing elements within a "control server" implemented on "a general purpose computing device").

Although the recited steps of "providing an indication to view one or more suggest clinical-trial criteria modifications" and "concurrently displaying" indications of the patient data, suggested modification, and expected result details are part of the recited abstract idea, for purposes of this Decision, we alternatively evaluate these steps as additional elements. These steps, however, are the type of insignificant extra-solution activity the courts have determined insufficient to transform judicially excepted subject matter into a patent-eligible application. *See* 84 Fed. Reg. at 55, 55 n.31; MPEP § 2106.05(g); *Parker v. Flook*, 437 U.S. 584, 590 (1978) (determining that adjusting an alarm limit is insignificant extra-solution activity and explaining "[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance"); *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Can.*, 771 F. Supp. 2d 1054, 1065 (E.D. Mo. 2011) *aff'd*, 687 F.3d 1266 (Fed. Cir. 2012) (explaining that "providing data . . . [is] insignificant post-solution activity"); *Bilski v. Kappos*, 561 U.S. 593, 612 (2010) (holding the use of well-known techniques to establish inputs to the abstract idea as extra-solution activity that fails to make the underlying concept patent eligible); *Elec. Power*, 830 F.3d at 1354 (recognizing "that merely presenting the results of abstract processes of collecting and analyzing information, without more (such as

identifying a particular tool for presentation), is abstract as an ancillary part of such collection and analysis").

Appellant asserts representative claim 10 is not directed to an abstract idea because the claimed method "intelligently generates new criterion-specific values and further generates instructions to implement the new criterion-specific values in order to redefine a value range for a particular criterion used to determine eligibility." Br. 7–10. Appellant also contends claim 10 is not directed to an abstract idea because improves on the prior art by reciting "concrete elements that" solve two problems with existing solutions—a lack of "information transparency or visibility" because users or clinicians were unable to see which criterion and value ranges were negatively affecting patient eligibility and the need to use guessing or trial-and-error techniques to determine which criteria and values to modify. Br. 8–9.

Appellant paraphrases claim 10's limitations and asserts that "[a]ccordingly, claim 10 provides much more than . . . simply collecting and comparing known information (*Classen*) and collecting information, analyzing it, and displaying certain results of the collection and analysis (*Electric Power Group*)." Br. 9–10. Appellant concludes by asserting that "the character of independent claim 10, viewed as a whole in light of the Specification, addresses the lack of electronic information transparency and the piecemeal 'guess-timation' that was required in the prior systems and methods" and, therefore, "claim 10 is not directed to an abstract idea." Br. 10.

Notably, Appellant neither claims nor describes any claimed *technological* improvement tied to the invention recited in claim 10. Rather,

Appellant merely claims a general use of a computing device to aid in analyzing data to determine a suggested modification to achieve a goal of enlarging a pool of patients eligible to participate in a clinical trial. As broadly recited, claim 10 encompasses (1) receiving a distribution of patient data relative to the criterion, an indication to view a suggested modification, and details regarding a result expected if the modification is made; (2) providing any suggestion to modify any clinical-trial criterion as long as the suggestion (i) is derived by analyzing the patient data, (ii) includes both an instruction to modify the criterion and a new value with which to modify the range, and (iii) increases the number of patients eligible to participate in the trial; and (3) displaying any indications of the patient data, suggested modification, and the expected result details.

Appellant (1) reproduces or paraphrases the various claim limitations, which recite receiving and/or providing various types of information (i.e., patient data, suggested criterion modifications that include an instruction and a value range, and presenting portions of the information), (2) argues the claims solve the two-fold problem of prior systems and methods, and (3) states that the claim language is different from, and more than, what was recited in *Electric Power* and *Classen*. Br. 8–11. However, Appellant does not persuasively explain *why* or *how* the claims differ from claims the Federal Circuit previously found ineligible. We agree with the Examiner that the identified "two-fold problem" is a business problem, not a technical problem, and Appellant's claimed solution, which captures, analyzes, and displays information to provide suggested modifications to clinical-trial criteria, provides a business solution without improving a computer, technology, or other technical field. *See* Ans. 3. Analyzing data to provide

suggested modifications to increase the number of patients eligible for a trial broadly claims a solution rooted in data collection and analysis, not a solution rooted in technology.

Moreover, Appellant does not identify particular limitations in claim 10, let alone limitations *in addition to* the abstract idea, that allegedly differentiate the claims over those found ineligible in *Electric Power* and *Classen*. Instead, Appellant vaguely alleges claim 10 recites "concrete elements" and an ordered combination that solve the identified business problems associated with increasing a desired number of patients to participate in a clinical trial. These arguments are insufficient to demonstrate Appellant's claims are directed to something other than mental processes to perform the abstract idea of suggesting modifications to clinical-trial criteria that will increase the number of patients eligible to participate in the trial.

For these reasons, we determine claim 10 recites an abstract idea comprised of mental steps and fails to integrate the judicial exception into a practical application. Therefore, claim 10 is directed to an abstract idea, and we analyze the claims under step two of *Alice* to determine whether there are additional limitations that individually, or as an ordered combination, ensure the claims amount to "significantly more" than the abstract idea. *Alice*, 573 U.S. at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72–73, 77–79 (2012)).

As stated in the Guidance, many of the considerations to determine whether the claims amount to "significantly more" under step two of the *Alice* framework are already considered as part of determining whether the judicial exception has been integrated into a practical application. 84 Fed. Reg. at 56. Thus, at this point of our analysis, we determine if claim 10 adds

a specific limitation, or combination of limitations, that is not well-understood, routine, conventional activity in the field, or simply appends well-understood, routine, conventional activities at a high level of generality. 84 Fed. Reg. at 56.

Appellant argues claim 10 recites elements that, considered as an ordered combination, provide an inventive concept because claim 10 solves the two problems in prior art systems and methods (i.e., lack of information transparency and requiring trial-and-error modifications). Br. 13–15. Appellant argues there is no evidence in the record that claim 10's elements were well-understood, routine, and conventional and the fact that claim 10's ordered combination of elements is not present "in prior computerized clinical trial referral systems" demonstrates the ordered combination was not well-understood, routine, and conventional. Br. 13, 15. Appellant further asserts claim 10's ordered combination "confines the claim to a particular useful application, via a computerized clinical trial referral engine." Br. 13.

An inventive concept "cannot be furnished by the unpatentable law of nature (or natural phenomenon or abstract idea) itself." *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016); *see also* 84 Fed. Reg. at 56; *Alice*, 573 U.S. at 217 (explaining that, after determining a claim is directed to a judicial exception, "we then ask, '*[w]hat else* is there in the claims before us?'" (emphasis added, brackets in original) (quoting *Mayo*, 566 U.S. at 78)). Instead, an "inventive concept" is furnished by an element or combination of elements that is recited in the claim *in addition to* the judicial exception and sufficient to ensure the claim as a whole amounts to significantly more than the judicial exception itself. *Alice*, 573 U.S. at 218–19 (citing *Mayo*, 566 U.S. at 72–73); *see BSG Tech LLC v. BuySeasons, Inc.*,

899 F.3d 1281, 1290 (Fed. Cir. 2018) (explaining that the Supreme Court in *Alice* "only assessed whether the claim limitations *other than the invention's use of the ineligible concept* to which it was directed were well-understood, routine and conventional," (emphasis added)).

Appellant does not identify which elements are elements *in addition to* the abstract idea, let alone which additional elements or combination of elements allegedly are not well-understood, routine, and conventional. Rather, Appellant generally asserts "the elements of independent claim 10, when considered as an ordered combination, are not well-understood, routine, or conventional." Br. 15. As already noted, the majority of claim 10 recites mental processes that are part of the abstract idea.

Claim 10 fails to recite specific additional limitations (or a combination of limitations) that are not well-understood, routine, and conventional. Rather, the only additional elements (i.e., the "computing device" and the two steps we previously noted we alternatively consider an additional element for purposes of this Decision—"providing an indication to view one or more suggest clinical-trial criteria modifications" and "concurrently displaying" indications of the patient data, suggested modification, and expected result details) are generic computer components recited at a high level of generality or extra-solution activity, which do not recite limitations beyond what was well-understood, routine, and conventional in the field. *See Berkheimer Memo* § III.A.1; Spec. ¶¶ 28, 30–31.

To the extent Appellant argues claim 10 is similar to the claims held eligible in *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016), we disagree. *See* Appeal Br. 12–14.

In *BASCOM*, the court found "the patent describes how its particular arrangement of elements is a technical improvement" and, when construed in favor of BASCOM,[3] the claims may be read to improve an existing technological process. *BASCOM*, 827 F.3d at 1350. As discussed above, claim 10 does not improve an existing technological process, but rather receives and analyzes data using a generic "computing device" to meet a desired functional goal (increasing the number of patients eligible for a trial). Additionally, unlike the arrangement of elements (i.e., installation of a filtering tool at a specific location) in *BASCOM*, 827 F.3d at 1349–50, claim 10 does not recite a non-conventional and non-routine arrangement of known elements because the only component recited in the method is the "computing device," which is only used in claim 10 for "receiving, via the computing device, a suggested criterion modification." Using a computing device to receive data, one of the most basic functions of any computing device, does not even arguably constitute an unconventional or non-routine arrangement or use of the generic "computing device."

Finally, Appellant asserts, without further explanation, that claim 10 does not preempt "using different steps or system arrangements" to generate similar outcomes. Br. 16. We disagree that the lack of complete pre-emption demonstrates patent eligibility in this case. Claim 10 limits the performance of the recited mental processes only by providing an indication to view a suggested modification, using a "computing device" for "receiving . . . a suggested criterion," and displaying patient data, the suggested modification, and the expected results of the modification. Such limitations either

[3] In *BASCOM*, BASCOM appealed the district court's granting of a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *BASCOM*, 827 F.3d at 1341

constitute details that limit the data used in mental processes or, for the reasons discussed above, are well-understood, routine and conventional elements insufficient to integrate the abstract idea into a practical application.

Moreover, although "preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. . . . Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015); *see also OIP Techs. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362–63 (Fed. Cir. 2015) ("And [the fact] that the claims do not preempt all price optimization or may be limited to price optimization in the e-commerce setting do[es] not make them any less abstract.").

For the above reasons, Appellant has not persuaded us of Examiner error, and we sustain the Examiner's rejection of claims 10–12, 14–16, and 18–20 under 35 U.S.C. § 101 as being directed to ineligible subject matter.

THE 35 U.S.C. § 102 REJECTION

The Examiner finds Harrison discloses every limitation recited in claims 10–12, 14–16, and 18–20. Final Act. 6–9. Of particular relevance to the dispositive issue with respect to this Appeal, the Examiner finds Harrison discloses "receiving . . . a suggested criterion modification" including "a new value with which to modify the at least one of the plurality of value ranges," as recited in claim 10. Final Act. 7 (citing Harrison ¶¶ 90, 142–151; Fig. 24). The Examiner provides no explanation regarding how Harrison's cited portions disclose this limitation. In the Answer, the

Examiner cites a different paragraph of Harrison. Ans. 9 (citing Harrison ¶ 141). The entire explanation the Examiner provides in the Answer states:

> Harrison teaches analyzing each protocol criteria and displaying the top ten greatest impacts on patient eligibility. Harrison further teaches that analysis of the criteria allows suggestions of potential modifications to enhance study size, increase patient enrollment, etc. (para. 141). Examiner states that the Harrison's teaching of suggestion for potential modifications includes the instructions on how to modify the criterion and adjust protocol criteria.

Ans. 9.

Appellant argues the § 102 rejection of all claims as a group. *See* Br. 23 (arguing "independent claim 15 recites similar elements to the elements discussed with regard to independent claim 10" and, therefore, independent claim 15 and dependent claims 11, 12, 14, 16, and 18–20 are not anticipated by Harrison for the same reasons presented with respect to claim 10). We select claim 10 as representative of the claims with respect to the rejection of claims 10–12, 14–16, and 18–20 as anticipated by Harrison under 35 U.S.C. § 102. *See* 37 C.F.R. § 41.37 (c)(1)(iv) (2016).

Appellant acknowledges that Harrison discloses analyzing a group of patients eligible for a trial, referred to as a "patient cohort," using multiple criteria, presenting "a list that ranks the multiple clinical trial protocol criteria by their respective impact on clinical trial eligibility within the patient cohort," and allowing a user to select and change different sets of criteria to "'work through various scenarios, determining the impact of patient and physician eligibility based on various combinations.'" Br. 20–21 (citing Harrison ¶¶ 142–145, 149–151). Appellant argues, among other things, that Harrison's ranked list, however, does not include a "new suggested value for modifying one of the ranked criteria" and "merely

allowing a user to manually select different sets of multiple protocol criteria" and work though different scenarios fails to disclose receiving a suggested modification that includes a new suggested value, as required by claim 10. Br. 21.

Harrison discloses that "[a]nalyzing each clinical trial criteria individually [in relationship to the patient population] allows the system 100 to *suggest potential modifications to enhance study size*." Harrison ¶ 141 (emphasis added). Harrison, therefore, discloses subject matter similar to what is recited in claim 10's disputed limitation, and Harrison achieves the same goal recited in claim 10's receiving step, which recites receiving a suggested modification that includes "a new value with which to modify the at least one of the plurality of value ranges . . . [and] wherein the new value modifies the scope of the clinical-trial criterion by increasing the number of patients eligible for the clinical trial." Br. 27 (claim 10).

Harrison then discloses "they system 100 allows the sponsor to make real-time modifications to the protocol criteria and see how each change might influence the overall patient pool, predicted enrollment rates or eligible physicians." Harrison ¶ 141. This disclosure also describes similar features to those recited in claim 10 in that Harrison discloses providing information to a user regarding clinical-trial criteria and how modifications to those criteria may affect the number of eligible patients.

We see nothing in Harrison's cited portions that disclose providing a suggestion that includes "a new value with which to modify the at least one of the plurality of value ranges," let alone a finding by the Examiner that Harrison discloses this "new value." We agree with the Examiner that Harrison discloses (1) analyzing criteria, (2) displaying a ranked list of the

criteria having the greatest impact on patient eligibility, and (3) suggesting potential modifications that will enhance a study size. However, the Examiner never identifies anything in particular in Harrison that discloses the recited "new value."

Whether these disclosures may suggest to a person of ordinary skill in the art that Harrison provides "a new value" with which to modify value ranges for one of the criteria is not before us because the Examiner does not reject the claims as obvious in view of Harrison's teachings. Given the anticipation rejection before us, the Examiner's findings are problematic. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). As stated, we see nothing in Harrison's cited portions that explicitly discloses a suggestion including a new value. Furthermore, to rely upon inherency, the Examiner must show the inherent feature *necessarily* exists; the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

We are constrained by this record, for the reasons discussed above, to reverse the Examiner's rejection of representative claim 10 and independent claim 15, which recites commensurate limitations. For the same reasons, we reverse the Examiner's rejection of dependent claims 11, 12, 14, 16, and 18–20, which ultimately depend from one of claims 10 and 15 and incorporate the limitations of the claims from which they depend.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
10–12, 14–16, 18–20	§ 101	10–12, 14–16, 18–20	
10–12, 14–16, 18–20	§ 102 Harrison		10–12, 14–16, 18–20
Overall Outcome		10–12, 14–16, 18–20	

AFFIRMED