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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte STEPHEN YOUNG, MLADEN LAUDANOVIC,
and ANSON KRING

_____

Appeal 2019-004556
Application 14/565,607
Technology Center 3600

_____

Before ERIC S. FRAHM, BETH Z. SHAW, and MATTHEW J. McNEILL, *Administrative Patent Judges*.

McNEILL, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 1–17, which are all the claims pending in this application. An oral hearing was held July 29, 2020. A transcript will be entered into the record in due course. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

[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 Medidata Solutions, Inc. Appeal Br. 4.

STATEMENT OF THE CASE

Introduction

Appellant's application relates to monitoring adverse event rates for a clinical trial to detect sites that are under- or over-reporting events relative to expectation. Spec. ¶ 16. Claims 1 and 8 are illustrative of the appealed subject matter and read as follows:

> 1. A system for assessing a clinical trial site's adverse event reporting rate, comprising:
>
> an adverse event and visit count processor for receiving adverse event and subject visit data from a plurality of clinical trial sites, and calculating for each clinical trial site a total visit count and a total adverse event count; and
>
> a site adverse event rate processor for:
>
> receiving the total visit count and total adverse event count for each clinical trial site;
>
> calculating a trial-level adverse event rate for the clinical trial;
>
> calculating for each clinical trial site an expected total adverse event count based on the clinical trial site's total visit count and the trial-level adverse event rate; and
>
> comparing for each clinical trial site the expected total adverse event count to the total adverse event count to assess the probability that the clinical trial site is under-reporting or over-reporting adverse events.
>
> 8. A system for assessing a clinical trial site's adverse event reporting rate, comprising:
>
> an adverse event and visit count processor for:
>
> receiving adverse event and subject visit data from a plurality of clinical trial sites;
>
> receiving an expected visit calendar identifying distinct visits for the clinical trial; and

calculating for each clinical trial site:

a subject count and an adverse event count associated with each distinct visit; and

a total adverse event count for all subjects and all distinct visits; and

a site adverse event rate processor for:

receiving the subject count and adverse event count associated with each distinct visit;

receiving the total adverse event count;

calculating for each distinct visit a trial-level adverse event rate;

calculating for each clinical trial site:

an expected adverse event count for each distinct visit, using the trial-level adverse event rate for the same distinct visit; and

an expected total adverse event count as the sum of the expected adverse event counts for each distinct visit; and

comparing for each clinical trial site the expected total adverse event count to the total adverse event count for the clinical trial site to assess the probability that the clinical trial site is under-reporting or over-reporting adverse events.

The Examiner's Rejections

Claims 1–17 stand rejected under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter. *See* Final Act. 2–5.

Claims 1–3 stand rejected under 35 U.S.C. § 103 as unpatentable over Grundstrom (US 2014/0375650 A1; Dec. 25, 2014) and Nelson et al., *Evaluation of Signal Detection Methods for Use in Prospective Post-licensure Medical Product Safety Surveillance*, FDA-2009-N-0192 (2009) ("Nelson"). *See* Final Act. 6–10.

To the base combination, the Examiner adds Totten (US 2008/0313017 A1; Dec. 18, 2008) to reject claims 4 and 5 (*see* Final Act. 10–12); Smith (US 2008/0300902 A1; Dec. 4, 2008) to reject claims 6 and 7 (*see* Final Act. 12–14); Schultz (US 2009/0292554 A1; Nov. 26, 2009) to reject claim 8, 9, and 15 (*see* Final Act. 14–25); Schultz and Totten to reject claims 10 and 11 (*see* Final Act. 25–27); Schultz and Richman (US 6,631,384 B1; Oct. 7, 2003) to reject claim 12 (*see* Final Act. 27–30); and Schultz and Smith to reject claims 13, 14, 16, and 17 (*see* Final Act. 30–32).

ANALYSIS

Patent-Ineligible Subject Matter

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

In determining whether a claim falls within an excluded category, we are guided by the Supreme Court's two-step framework, described in *Mayo* and *Alice*. *Alice*, 573 U. S. at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). In accordance with that framework, we first determine what concept the claim is "directed to." *See Alice*, 573 U.S. at 219 ("On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement risk."); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) ("Claims 1 and 4 in petitioners' application explain the basic concept of hedging, or protecting against risk.").

Concepts determined to be abstract ideas, and thus patent ineligible, include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 69 (1972)). Concepts determined to be patent eligible include physical and chemical processes, such as "molding rubber products" (*Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); "tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores" (*id.* at 183 n.7 (quoting *Corning v. Burden*, 56 U.S. (15 How.) 252, 267–68 (1854))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claim at issue recited a mathematical formula, but the Supreme Court held that "[a] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula." *Diehr*, 450 U.S. at 176; *see also id.* at 191 ("We view respondents' claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula."). Having said that, the Supreme Court also indicated that a claim "seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment." *Id.* (citation omitted) (citing *Benson* and *Flook*); *see, e.g.*, *id.* at 187 ("It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.").

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

In January 2019, the PTO published revised guidance on the application of § 101. USPTO's January 7, 2019 Memorandum, 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 ("Revised Guidance"). Under that guidance, we first look to whether the claim recites:

> (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human activity such as a fundamental economic practice, or mental processes); 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) (9th Ed. Rev. 08.2017, Jan. 2018)).

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

(3) adds a specific limitation beyond the judicial exception that is not "well-understood, routine, conventional" in the field (*see* MPEP § 2106.05(d)); or

(4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

See Revised Guidance.

Revised Guidance Step 1

Step 1 of the Revised Guidance asks whether the claimed subject matter falls within the four statutory categories of patentable subject matter identified by 35 U.S.C. § 101: process, machine, manufacture, or composition of matter. *See* Revised Guidance. Claim 1 recites an "[a] system for accessing a clinical trial site's adverse event reporting rate." Appellant does not argue the Examiner erred in concluding claim 1 falls within the four statutory categories of patentable subject matter. We agree with the Examiner's conclusion because claim 1 falls within the machine or manufacture categories.

Revised Guidance Step 2A, Prong 1

Under Step 2A, Prong 1 of the Revised Guidance, we determine whether the claims recite any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human activity such as a fundamental economic practice, or mental processes). *See* Revised Guidance.

The Examiner determines claim 1 is directed to a system for assessing a clinical trial site's adverse event reporting rate. Final Act. 2. The Examiner determines the claims are similar to collecting information, analyzing it, and

displaying certain results. *Id.* The Examiner determines the claims, therefore, recite a mental process (*see* Ans. 8–9), an "idea of itself" (*see* Final Act. 3), and mathematical relationships and formulas (*see* Final Act. 3).

Claim 1 recites "a system for assessing a clinical site's adverse event reporting rate, comprising an adverse event and visit count processor" and "a site adverse event rate processor." The "adverse event and visit count processor" performs the steps of "receiving adverse event and subject visit data from a plurality of clinical trial sites" and "calculating for each clinical trial site a total visit count and a total adverse event count." The "site adverse event rate processor" performs the steps of "receiving the total visit count and total adverse event count for each clinical trial site;" "calculating a trial-level adverse event rate for the clinical trial;" "calculating for each clinical trial site an expected total adverse event count based on the clinical trial site's total visit count and the trial-level adverse event rate;" and "comparing for each clinical trial site the expected total adverse event count to the total adverse event count to assess the probability that the clinical trial site is under-reporting or over-reporting adverse events."

We agree with the Examiner that these limitations, under their broadest reasonable interpretation, recite "assessing a clinical site's adverse event reporting rate." In particular, the "receiving adverse event and subject visit data" and "receiving the total visit count" steps characterize gathering data to be used in calculations. These data gathering steps are insignificant pre-solution activity. *See* MPEP § 2106.05(g). The three "calculating" steps and the "comparing" step are each evaluations performed on the recited data that has either been received or calculated in previous steps. We agree that this is an abstract idea under the Revised Guidance because each of these

calculations and comparisons are evaluations that may be performed in the human mind or by a human using pen and paper. Thus, claim 1 recites concepts performed in the human mind, which fall within the mental processes category of abstract ideas identified in the Revised Guidance.

Appellant argues that the claims cannot be performed in the human mind. *See* Reply Br. 5–7. In particular, Appellant argues that the amount of data involved in these calculations is "not trivial" and therefore these calculations cannot be performed in the human mind. Reply Br. 6. In support, Appellant cite examples from the Specification of clinical trials that involve hundreds, thousands, or tens of thousands of patients. *Id.* (citing Spec. ¶¶ 1, 21). Appellant argues the amount of data precludes these calculations from being performed in the human mind. *Id.*

We disagree. First, the claims do not require any particular number of adverse events, subject visits, total visits, or any other information used in the claimed calculations. Thus, under the broadest reasonable interpretation, the numbers involved in these calculations may be small and easily manageable in the human mind, as found by the Examiner. *See* Ans. 9. Appellant's argument is, therefore, not commensurate with the scope of the claims. Second, even if the examples provided in Appellant's Specification were commensurate with the scope of the claims, Appellant fails to persuade us that an ordinarily skilled artisan could not perform these calculations in their mind or with pen or paper. Our reviewing court has made it clear that mental processes remain unpatentable even when automated to reduce the burden on the user of what once could have been done with pen and paper. *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 (Fed. Cir. 2011) ("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*[, 409 U.S. 63, 67 (1972)]."). While the claimed system certainly purports to accelerate the process of assessing adverse event reporting rates, the speed increase comes from the capabilities of a general-purpose computer, rather than the patented method itself. *See 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.").

For these reasons, Appellant does not persuade us of Examiner error with respect to Step 2A, Prong 1 of the Revised Guidance. We, therefore, conclude claim 1 recites an abstract idea under the Revised Guidance.

Revised Guidance Step 2A, Prong 2

Under Step 2A, Prong 2 of the Revised Guidance, we next determine whether the claims recite additional elements that integrate the judicial exception into a practical application (*see* MPEP §§ 2106.05(a)–(c), (e)–(h)). The "additional elements" recited in claim 1 include "an adverse event and visit count processor" and "a site adverse event rate processor." These additional elements do not constitute "additional elements that integrate the judicial exception into a practical application."

Appellant argues claim 1 is directed to an improvement to another technology or technical field because the claimed system improves upon the prior art adverse event assessment technology that had calculated adverse event rate as merely the total count of adverse events divided by the total count of subjects in the clinical site or clinical trial. Appeal Br. 25. Appellant also argues claim 1 integrates any mental process into a practical application

because the claimed invention uses these calculations to determine whether a clinical site is under-reporting or over-reporting adverse events. *See* Reply Br. 8–9.

Appellant does not persuade us of Examiner error. Appellant argues the claim improves "adverse event assessment technology" by changing the manner in which the adverse event reporting rate is assessed. *Id.* However, this is an improvement to the abstract idea itself, not an improvement to any technology or technical field. The identified improvements do not "enable[] a computer . . . to do things it could not do before." *Finjan, Inc. v. Blue Coat Sys., Inc.*, 879 F.3d 1299, 1305 (Fed. Cir. 2018). Claims whose focus is "not a physical-realm improvement but an improvement in wholly abstract ideas," are not eligible for patenting. *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1168 (Fed. Cir. 2018); *see also Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1346 (Fed. Cir. 2018) ("It is well-settled that placing an abstract idea in the context of a computer does not 'improve' the computer or convert the idea into a patent-eligible application of that idea.").

As stated by our reviewing court, "[w]e often analyze software-related claims by asking whether the claims focus on a 'specific asserted improvement in computer capabilities' instead of on 'a process that qualifies as an "abstract idea" for which computers are invoked merely as a tool.'" *Ubisoft Entm't, S.A. v. Yousician Oy*, No. 2019-2399, 2020 WL 3096369, at *2 (Fed. Cir. June 11, 2020) (nonprecedential) (quoting *Finjan*, 879 F.3d at 1303).

"This is not a situation where the claims 'are directed to a specific improvement to the way computers operate' and therefore not directed to an abstract idea, as in cases such as *Enfish, LLC v. Microsoft Corp.*, 822 F.3d

1327, 1336 (Fed. Cir. 2016). . . . To the contrary, the claims are written at a distinctly high level of generality." *Solutran, Inc. v. Elavon, Inc.*, 931 F.3d 1161, 1167 (Fed. Cir. 2019). The focus of the claims is on the practice of assessing adverse event rates, "and the recited generic computer elements 'are invoked merely as a tool.'" *Credit Acceptance Corp. v. Westlake Svcs.*, 859 F.3d 1044, 1055 (Fed. Cir. 2017) (citing *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335–36 (Fed. Cir. 2016)); *see also Versata Dev. Grp., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1334 (Fed. Cir. 2015) (collecting cases).

Appellant's argument that the claims integrate the mental process into a practical application because the claimed invention is used to determine whether a clinical site is under-reporting or over-reporting adverse events is also unpersuasive. To integrate the exception into a practical application, the additional claim elements must, for example, improve the functioning of a computer or any other technology or technical field (*see* MPEP § 2106.05(a)), apply the judicial exception with a particular machine (*see* MPEP § 2106.05(b)), affect a transformation or reduction of a particular article to a different state or thing (*see* MPEP § 2106.05(c)), or apply or use the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment (*see* MPEP § 2106.05(e)). *See* Revised Guidance.

Appellant does not persuade us that the claims integrate the abstract idea into a practical application for any of these reasons. To the extent Appellant contends that the recited limitations, including those detailed above in connection with Prong 1, integrate the abstract idea into a practical application (*see* Reply Br. 8–9), these limitations are not *additional* elements *beyond* the abstract idea, but rather are directed to the abstract idea as noted

previously. *See* 2019 Revised Guidance, 84 Fed. Reg. at 54 (instructing that *additional* recited elements should be evaluated to determine whether the claim integrates the exception into a practical application of the exception; *see also* 2019 Revised Guidance, 84 Fed. Reg. at 55 n.24 ("USPTO guidance uses the term 'additional elements' to refer to claim features, limitations, and/or steps that are recited in the claim *beyond the identified judicial exception*." (Emphasis added)).

Thus, Appellant does not persuade us of Examiner error with respect to Step 2A, Prong 2 of the Revised Guidance. We, therefore, conclude the judicial exception is not integrated into a practical application under the Revised Guidance.

Revised Guidance Step 2B

Under Step 2B of the Revised Guidance, we next determine whether the claims recite an "inventive concept" that "must be significantly more than the abstract idea itself, and cannot simply be an instruction to implement or apply the abstract idea on a computer." *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1349 (Fed. Cir. 2016). There must be more than "computer functions [that] are 'well-understood, routine, conventional activit[ies]' previously known to the industry." *Alice*, 573 U.S. at 225 (second alteration in original) (quoting *Mayo*, 566 U.S. at 73).

As discussed above, Appellant argues claim 1 is directed to a technological improvement. As explained above, Appellant's argument that the claims recite an improvement to computer technology is unpersuasive because claim 1 recites an improvement to a mental process, not an improvement to computer technology. Appellant does not persuasively

identify any "inventive concept" sufficient to transform the claims from an abstract idea to a patent-eligible application. For these reasons, we agree with the Examiner (*see* Ans. 11–12) that the claims do not recite an "inventive concept" sufficient to transform the claims from an abstract idea to a patent-eligible application. We, therefore, sustain the patent-ineligible subject matter rejection of claim 1. We also sustain the rejection of independent claims 8 and 15, which Appellant argues are patent eligible for the same reasons. *See* Appeal Br. 9–27; Reply Br. 4–11.

Dependent Claims

Appellant argues the Examiner erred in concluding dependent claims 2–7, 9–14, 16, and 17 are directed to patent-ineligible subject matter because the Examiner's findings are conclusory and ignore claim limitations. *See* Appeal Br. 27–28.

Appellant does not persuade us of Examiner error. The dependent claims recite further detail regarding system for assessing a clinical site's adverse event reporting rate, but do not recite limitations that change the nature of the recited abstract idea or that change the claims into something significantly more than the abstract idea. For example, claim 2 recites "wherein the calculating a trial-level adverse event rate for the clinical trial comprises dividing the sum of the total adverse event counts for all sites by the sum of the total visit counts for all sites." In other words, claim 2 recites further detail regarding the method of performing a "calculating" step recited in claim 1. This additional detail does not materially affect the abstract idea analysis and does not add additional elements to the claim.

Similarly, claim 4 recites:

wherein the total visit count for each clinical trial site is

calculated as a weighted count by:

receiving subject visit data from a plurality of clinical trial sites; and

calculating for each clinical trial site and for each reported visit a weighted visit count, wherein the weighted count contribution represents an estimated proportion of all required visit data that have been already reported for the subject for the given reported visit.

Appellant argues the "weighted count" and "weighted visit count" limitations integrate the abstract idea into a practical application. We disagree for the same reasons discussed above with respect to claim 1. That is, the identified limitations are not "additional elements," nor does Appellant persuasively explain how these limitations improve the functioning of a computer or any other technology or technical field (*see* MPEP § 2106.05(a)), apply the judicial exception with a particular machine (*see* MPEP § 2106.05(b)), affect a transformation or reduction of a particular article to a different state or thing (*see* MPEP § 2106.05(c)), or apply or use the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment (*see* MPEP § 2106.05(e)). *See* Revised Guidance.

Appellant's arguments regarding the remaining dependent claims are unpersuasive for the same reasons. We, therefore, sustain the patent-ineligible subject matter rejection of claims 2–7, 9–14, 16, and 17.

Obviousness

Independent claim 1

We have reviewed the Examiner's obviousness rejection of claim 1 in light of Appellant's contentions that the Examiner has erred. We disagree with Appellant's contentions. Except as noted below, we adopt as our own:

(1) the findings and reasons set forth by the Examiner with respect to the obviousness rejection of claim 1 in the action from which this appeal is taken and (2) the reasons set forth by the Examiner in the Examiner's Answer with respect to the obviousness rejection of claim 1 in response to Appellant's Appeal Brief. We concur with the conclusions reached by the Examiner. We highlight the following additional points.

Appellant argues the Examiner erred in rejecting claim 1 as unpatentable over Grundstrom and Nelson. *See* Appeal Br. 30–34; Reply Br. 11–16. In particular, Appellant argues the Examiner erred in finding the combination of references teaches or suggests a "system for assessing a clinical trial site's adverse event reporting rate," "calculating for each clinical trial site an expected total adverse event count based on the clinical trial site's total visit count and the trial-level adverse event rate," and "comparing for each clinical trial site the expected total adverse event count to the total adverse event count to assess the probability that the clinical trial site is under-reporting or over-reporting adverse events." *See* Appeal Br. 30–34; Reply Br. 11–16.

Appellant argues the Examiner erred because the claims focus on calculating an adverse event *reporting* rate and Grundstrom's teachings focus on identifying adverse event rates that differ from trial averages. *See* Appeal Br. 30–31. Appellant argues the Examiner acknowledges that Grundstrom does not disclose adverse event counts based on subject visits, but states without support that it would be a simple substitution to use such a count. *See id.* at 31. According to Appellant, this substitution is not "simple" and is based on unfounded inferences. *See* Reply Br. 14–15.

The Examiner finds Grundstrom teaches comparing a rate of study indicators for each site with a mean rate across an entire trial. Ans. 14; *see also* Grundstrom ¶ 38. The Examiner finds Grundstrom teaches evaluating this adverse event data for each patient at each site. Ans. 14 (citing Grundstrom ¶¶ 39–42). The Examiner finds Grundstrom does not expressly disclose that the adverse event rate calculation uses the number of patient visits, but Grundstrom teaches evaluating protocol deviations compared to the total number of patient visits. *Id.* (citing Grundstrom ¶ 108). The Examiner finds calculating adverse event rates compared to the number of patient visits would have been an obvious, simple substitution of one known element for another to obtain predictable results. Ans. 14–15.

Appellant does not persuade us of Examiner error. As found by the Examiner, Grundstrom teaches calculating a mean number of adverse events for each patient at each clinical trial site. Grundstrom ¶ 38. Grundstrom teaches that after these values are calculated, "the mean for each site is compared against the study mean." *Id.* If the mean varies from the study mean by more than a threshold amount, "indicators" are generated to identify the site to the clinical trial managers. *Id.* ¶¶ 37–38. We agree with the Examiner that Grundstrom does not explicitly teach performing the claimed "calculating" and "comparing" steps because Grundstrom's calculations and comparisons are based on average adverse event rates at clinical sites, rather than total adverse event counts. *See* Ans. 14–15. However, Grundstrom's teachings would have at least suggested to an ordinarily skilled artisan that total counts are compared at least because average adverse event rates are merely total adverse event counts divided by the number of patients at a clinical site. Grundstrom ¶ 38. This is further

supported by the visualization tools taught by Grundstrom to display this information, including Figure 6 which depicts adverse event rate per site and further depicts total adverse events and total subjects screened in the same visualization tool. *See* Grundstrom Fig. 6, ¶¶ 38–42. We agree with the Examiner that this finding is further supported by Grundstrom's teachings that total patient visit counts are used in calculations such as protocol deviation calculations. *See* Ans. 14 (citing Grundstrom ¶ 108). Appellant's arguments to the contrary do not persuasively identify error in the Examiner's findings.

Accordingly, we sustain the obviousness rejection of claim 1. We also sustain the obviousness rejection of dependent claims 2–7, for which Appellant relies on the same arguments. *See* Appeal Br. 37.

Independent Claims 8 and 15

The Examiner finds the combination of Grundstrom, Nelson, and Schultz teaches or suggests "receiving an expected visit calendar identifying distinct visits for the clinical trial," as recited in claim 8. *See* Final Act. 18 (citing Schultz ¶ 117); Ans. 16–17. In particular, the Examiner finds Grundstrom teaches aspects pertaining to patient visits, but is deficient with respect to "distinct" patient visits. *See* Ans. 16–17 (citing Grundstrom ¶¶ 108, 15–17, 32, 33, 38, 39–42). The Examiner finds Schultz teaches "distinct visits." *See id.* at 17 (citing Schultz ¶ 117).

Appellant argues the Examiner erred in rejecting claims 8 and 15 because the cited combination does not teach or suggest the "receiving" step. *See* Appeal Br. 34–37; Reply Br. 17–18. In particular, Appellant argues neither Grundstrom nor Schultz teaches "distinct visits" in reference to patient visits and, even if that were taught, neither reference nor the

combination teaches "receiving an expected visit calendar" as claimed. *See id.*

Appellant persuades us of Examiner error with respect to these claims. Schultz teaches an "expected CRA monitoring visit schedule for each site." Schultz ¶ 117. CRAs are clinical research assistants (*id.* ¶ 38) that monitor sites for various reasons (*id.* ¶ 98). Schultz's teaching of a "schedule" for expected CRA monitoring visits does not relate to patient visits to clinical sites, and the Examiner fails to explain or sufficiently establish how this teaching, in combination with Grundstrom and Nelson, teaches or suggests "receiving an expected visit calendar" as claimed. We, therefore, do not sustain the obviousness rejection of claim 8. We also do not sustain the obviousness rejection of independent claim 15, which recites commensurate limitations. We also do not sustain the obviousness rejection of claims 9–14, 16, and 17, which depend from independent claims 8 and 15.

DECISION SUMMARY

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
1–17	101	Eligibility	1–17	
1–3	103	Grundstrom, Nelson	1–3	
4, 5	103	Grundstrom, Nelson, Totten	4, 5	
6, 7	103	Grundstrom, Nelson, Smith	6, 7	
8, 9, 15	103	Grundstrom, Nelson, Schultz		8, 9, 15
10, 11	103	Grundstrom, Nelson, Schultz, Totten		10, 11

12	103	Grundstrom, Nelson, Schultz, Richman		12
13, 14, 16, 17	103	Grundstrom, Nelson, Schultz, Smith		13, 14, 16, 17
Overall Outcome			1–17	

CONCLUSION

Because we sustain at least one ground of rejection with respect to each claim on appeal, we affirm the decision of the Examiner rejecting claims 1–17. *See* 37 C.F.R. § 41.50(a)(1) (2018).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 41.50(f).

AFFIRMED