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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* LAKSHMI SAMYUKTA KUCHIPUDI, CURTIS PARVIN, and  
JOHN YUNDT-PACHECO<sup>1</sup>

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Appeal 2019-000848  
Application 14/327,875  
Technology Center 2800

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Before MICHAEL P. COLAIANNI, CHRISTOPHER C. KENNEDY, and  
LILAN REN, *Administrative Patent Judges*.

KENNEDY, *Administrative Patent Judge*.

DECISION ON APPEAL

This case is an appeal under 35 U.S.C. § 134(a) from the Examiner’s  
decision rejecting claims 1–17. We have jurisdiction under 35 U.S.C.  
§ 6(b). We AFFIRM.

BACKGROUND

The subject matter on appeal relates to “clinical diagnostic processes,  
and more particularly to a system and method for spot-checking small out-of

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<sup>1</sup> We use the word “Appellant” to refer to “applicant” as defined in 37  
C.F.R. § 1.42. The Appellant identifies the real party in interest as Bio-Rad  
Laboratories, Inc. Appeal Br. 2.

control conditions in such processes.” Spec. ¶ 4; claim 1. Claim 1 is reproduced below from page 16 (Claims Appendix) of the Appeal Brief:

1. A method for analyzing at least one specimen in a clinical diagnostic process, the method comprising:

analyzing at least one specimen using at least one laboratory instrument;

spot-checking the results of the analysis by the at least one laboratory instrument to determine the existence of a small out-of-control condition which renders only a fraction of specimens evaluated by the at least one laboratory instrument during the existence of the condition to be unreliable;

upon receiving notification of an out-of-control condition from the at least one laboratory instrument; analyzing specimen test data from the at least one laboratory instrument using a processor to determine a scope of potential error caused by the out-of-control condition by predicting the number of unreliable patient specimen results since the last known good quality control evaluation;

identifying by the processor specimens to be re-evaluated based on the analyzing step; and

re-evaluating the identified specimens using the at least one laboratory instrument after the out-of-control condition is resolved.

#### ANALYSIS

Claims 1–17 stand rejected under 35 U.S.C. § 101 as directed to patent-ineligible subject matter. The Appellant argues the claims as a group. We address claim 1 below, and the remaining claims will stand or fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

After review of the cited evidence in the appeal record and the opposing positions of the Appellant and the Examiner, we determine that the Appellant has not identified reversible error in the Examiner’s rejection.

Accordingly, we affirm that rejection for reasons set forth below, in the Final Action, and in the Examiner’s Answer.

Determining whether a claimed invention is directed to patent-eligible subject matter is a two-step process that requires (1) evaluating whether the claim is directed toward a patent-ineligible concept, i.e., a law of nature, natural phenomenon, or abstract idea; and, if so, (2) determining whether the claim’s elements, considered both individually and as an ordered combination, transform the nature of the claim into a patent-eligible application. *See Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 217–18 (2014).

As to step (1) of *Alice*, the Examiner determines in the Final Action that claim 1 is directed to abstract ideas and identifies several claim recitations that encompass abstract ideas. *See* Final Act. 1–4. Specifically, the Examiner finds that the “spot-checking . . . to determine the existence of a small out-of-control condition” recitation, the “identifying by the processor” recitation, and the “re-evaluating the identified specimens” recitation “are similar to ‘organizing information through mathematical correlations [as in] *Digitech Image Tech., LLC v. Electronics for Imaging, Inc.* (758 F.3d 1344).” *Id.* at 2. The Examiner finds that the “analyzing” recitations and the “receiving notification of an out-of-control condition” recitation concern data collection, comparison, and analysis. *Id.* at 3.

In the Answer, the Examiner elaborates on step (1) of *Alice* and further explains that the Federal Circuit has “treated 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.” Ans. 5 (citing *Electric Power Grp., LLC v. Alstom S.A.*, 830 F.3d

1350, 1354 (Fed. Cir. 2016)). The Examiner also cites *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989), for the proposition that claims directed to testing a system to diagnose the existence of an abnormality may involve abstract ideas. Ans. 6.

As to step (2) of *Alice*, the Examiner determines that the remaining elements of claim 1, “such as a processor (computer), laboratory instrument, and not defined specimens . . . are well-understood, purely conventional or routine in the relevant field.” Final Act. 3; Ans. 7–9 (citing evidence).

Relevant to step (1) of *Alice*, the Appellant argues that claim 1 is not directed to an abstract idea because it requires “the physical processing” of an “analyte or specimen . . . through the physical interaction of those analytes with various sensors.” Appeal Br. 10. The Appellant asserts that “[s]uch testing thus implicitly requires a physical transformation and/or interaction of the analyte or specimen with various reagents and the subsequent measurement thereof.” *Id.*

Relevant to step (2) of *Alice*, the Appellant argues that claim 1 satisfies the “significantly more” criteria of *Alice*:

[T]he claims improve the technology of clinical diagnostic processes by providing for spot checking small out-of-control-conditions in a clinical diagnostic process, the claims add specific limitations providing for specific retesting of specific specimens in the event of a small out-of-control condition, and the claims directed to the detection and retesting of specimens in a clinical diagnostic process are targeted to a particular useful application.

*Id.* at 13.

*Legal Framework*

In determining whether a claim falls within a category excluded from eligible subject matter, our inquiry focuses on the Supreme Court’s two-step framework described in *Mayo* and *Alice*, set forth above. *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. Concepts determined to be abstract ideas, and thus patent ineligible, include, e.g., mathematical concepts, e.g., *Parker v. Flook*, 437 U.S. 584, 594–95 (1978), and mental processes, e.g., *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 182 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1854)); and manufacturing flour, *Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876)).

Not every claim that recites a mathematical concept is patent ineligible. 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.” 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.”). 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.* (citing *Flook and Gottschalk v. Benson*, 409 U.S. 63 (1972)); *see also, 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.* (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.*

The USPTO published revised guidance on the application of § 101. *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (Jan. 7, 2019) (“Guidance”). Under the 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* MPEP § 2106.05(a)–(c), (e)–(h) (9th ed. 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* Guidance 52, 55–56.

*Judicial Exception (Guidance step (1))*

Consistent with the Examiner’s analysis, claim 1 recites steps of (1) obtaining data by “analyzing” generically recited “specimen[s]” using generically recited “laboratory instrument[s],” (2) “spot-checking” the data to “determine the existence of” abnormalities (“out-of-control condition”), (3) “analyzing” the data to “determine a scope of potential error” caused by the abnormality, (4) “identifying” specimens to be re-evaluated, and (5) “re-evaluating” the specimens after fixing the abnormality. *See* Appeal Br. 16 (claim 1). As set forth above, the claim recites steps of evaluating data to identify abnormalities, and then evaluating data to identify samples that were affected by the abnormality and that therefore need to be retested after the abnormality is fixed. Claim 1 concerns error identification and correction. We agree with the Examiner that, under the broadest reasonable interpretation of the claim, the “spot-checking,” “analyzing . . . to determine a scope of potential error,” and “identifying” recitations could be carried out in the human mind as a mental process.

We also agree with the Examiner that *In re Grams* is instructive. In *Grams*, the claim at issue concerned “[a] method of diagnosing an abnormal

condition in an individual” and recited, *inter alia*, steps of (1) “performing . . . clinical laboratory tests on [an] individual,” (2) comparing measured values to reference values to “produc[e] . . . a first quantity representative of the condition of the individual,” (3) “comparing” data “to determine whether the individual’s condition is abnormal,” and (4) upon identifying an abnormal condition, running “successive[] testing.” *Grams*, 888 F.2d at 836–37. The Federal Circuit determined that the recited steps “are in essence a mathematical algorithm.” *Id.* at 837. We agree with the Examiner that the subject matter of claim 1 is sufficiently similar to that of the claims at issue in *Grams* to determine that the subject matter of claim 1 encompasses mathematical algorithms or concepts. *Cf.* Spec. ¶ 21 (“Application module 20 may execute any sequence of diagnostic steps or one or more diagnostic algorithms in conjunction with implementing any clinical diagnostic process . . .”).

The Appellant does not persuasively contend otherwise. The Appellant does not address *Grams*. In accordance with the Guidance, step (1), we determine that claim 1 recites both mathematical concepts and mental processes, and thus recites an abstract idea.

*Integration into a Practical Application (Guidance step (2))*

Turning to step (2) of the Guidance, we determine that claim 1, as a whole, does not integrate the judicial exception into a practical application. Integration into a practical application requires an additional element or a combination of additional elements in the claim to “apply, rely on, or use 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.” Guidance 53–54; *see also id.* at 55

(setting forth exemplary considerations indicative that an additional element or combination of elements may have integrated the judicial exception into a practical application).

As noted above, the Appellant does not persuasively assert that claim 1 does not recite abstract ideas; rather, the Appellant argues that claim 1 is not “directed to” to those abstract ideas because of the physical elements of the claim such as the “specimen” and the “laboratory instrument.” Appeal Br. 9–12.

That argument is not persuasive because the presence of physical elements in a claim is not dispositive of whether a claim is directed to abstract ideas. *See, e.g., Grams*, 888 F.2d at 836–37 (holding ineligible a claim that recited performing laboratory tests on an individual (i.e., a specimen) despite acknowledging that the claim includes a “physical process step” of “performing clinical tests on individuals”). As noted above, the Appellant does not address *Grams*, which also included physical elements.

The Appellant also argues that the claims “improve the technology of clinical diagnostic processes by providing for spot checking small out-of-control conditions in a clinical diagnostic process.” Appeal Br. 13. That argument is not persuasive because it does not persuasively identify an actual improvement to a process or technology. On the contrary, it appears that claim 1 essentially takes the concept of error identification (by spot-checking) and correction in the context of a clinical diagnostic laboratory and performs certain aspects of the process on a computer. *See Alice*, 573 U.S. at 222 (“[T]he mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention.”).

The Appellant also asserts, without significant explanation, that *In re Abele*, 684 F.2d 902 (CCPA 1982), supports a conclusion that the claims are directed to patent-eligible subject matter. Appeal Br. 14.

We are not persuaded that *Abele* supports the Appellant's position. In *Grams*, the Federal Circuit stated, “[i]n *Abele* . . . the algorithm served to improve the CAT-scan process.” *Grams*, 888 F.2d at 835 (emphasis added). In *In re Bilski*, 545 F.3d 943, 962–63 (Fed. Cir. 2008), *aff'd sub nom. Bilski v. Kappos*, 561 U.S. 593 (2010), the Federal Circuit also discussed *Abele* and explained that “the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible” (emphasis added). Thus, the claims at issue in *Abele* were eligible because they recited an improvement to a technical process and because they transformed raw data into a visual depiction of a physical object.

The Appellant does not persuasively identify any such technical improvement or transformation that claim 1 implicates, *see Grams*, 888 F.2d at 835; *Bilski*, 545 F.3d at 963, sufficient to integrate the judicial exception into a practical application. We are not persuaded that laboratory testing of a specimen using a laboratory instrument, *see Appeal Br. 10–12*, is the type of “transformation” that supports patent eligibility under *Abele/Bilski*. *See Grams*, 888 F.2d at 836–37 (holding claims ineligible despite recitation of “clinical laboratory tests which measure the levels of chemical and biological constituents of the individual”).

On this record, we are not persuaded that claim 1 integrates the judicial exception into a practical application. Thus, claim 1 is directed to the recited abstract ideas.

*Inventive Concept (Guidance steps (3) and (4))*

Turning to steps (3) and (4) of the Guidance, the Appellants have not shown error in the Examiner’s determination that the limitations of claim 1 beyond the abstract idea itself are well understood, routine, and conventional. The Appellant does not attempt to specifically identify any claim element that is not well understood, routine, and conventional.

The Appellant, however, argues that “the claims add specific limitations providing for specific retesting of specific specimens in the event of a small out-of-control condition.” Appeal Br. 13. That argument is unpersuasive because the Appellant does not adequately explain, with citation to applicable case law, how the “re-evaluating” step renders the claims patent eligible, or how it amounts to anything more than routine postsolution activity. *See Mayo*, 566 U.S. at 79 (citing *Bilski* and *Diehr* for the proposition that “the prohibition against patenting abstract ideas ‘cannot be circumvented by’ . . . adding ‘insignificant post-solution activity.’”). Similar to the re-evaluating step at issue in this case, the claim at issue in *Grams*, discussed above, included a “successive[] testing” step after an abnormal condition was identified from the first testing step, but was nevertheless held to be ineligible. *Grams*, 888 F.2d at 836–37. We also observe that, to the extent that the claim is directed to an abstract algorithm (a series of steps to achieve error identification and correction), the “re-evaluating” step appears to simply be part of the algorithm. *See id.* at 837 (identifying the “successive[] testing” step as part of a mathematical algorithm). The Appellant does not address *Grams* or otherwise persuasively explain how the re-evaluating step prevents the claim from being “directed to” the abstract ideas encompassed by the claims; nor does

the Appellant persuasively explain how or why that step should be considered an “improvement” to any existing process. *Cf. BSG Tech LLC v. BuySeasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018) (“It has been clear since *Alice* that a claimed invention’s use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention ‘significantly more’ than that ineligible concept.”).

The Appellant also argues that “the claims directed to the detection and retesting of specimens in a clinical diagnostic process are targeted to a particular useful application.” Appeal Br. 13. We, however, do not discern how claim 1 is “targeted” to a limited application. As set forth above, claim 1 generically recites analyzing a “specimen” using a “laboratory instrument,” and using a generic “processor” to determine the scope of error and to identify specimens to be re-evaluated. The “spot-checking” recitation appears to be broad and generic. On this record, we are not persuaded that the claim 1 is “targeted to a particular useful application” in a way that would render it patent eligible. Appeal Br. 13.

On this record, having considered the limitations individually and in combination, we are not persuaded that any step of claim 1 beyond those encompassing the abstract idea itself recites subject matter that is not well understood, routine, and conventional, or that claim 1 otherwise amounts to “significantly more” than the abstract ideas to which it is directed.

We have carefully considered the Appellants’ arguments but are not persuaded of reversible error in the Examiner’s rejection of claim 1 under § 101.

CONCLUSION

In summary:

| <b>Claims Rejected</b> | <b>35 U.S.C. §</b> | <b>Basis</b> | <b>Affirmed</b> | <b>Reversed</b> |
|------------------------|--------------------|--------------|-----------------|-----------------|
| 1-17                   | 101                | Eligibility  | 1-17            |                 |

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

AFFIRMED