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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* KEI SHIRASUNA, RYUICHIRO EBI, and SHIGEKI ABE

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Appeal 2019-003798  
Application 14/508,522  
Technology Center 1600

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Before RICHARD M. LEOVITZ, GEORGIANNA W. BRADEN, and  
DAVID COTTA, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

The claims in this appeal are directed to a cell analysis method and cell analyzer to evaluate the pathology of epithelial tissues. The Examiner rejected the claims under 35 U.S.C. § 101 as reciting patent ineligible subject matter. Pursuant to 35 U.S.C. § 134, Appellant<sup>1</sup> appeals the Examiner's determination that the claims are unpatentable. We have jurisdiction for the appeal under 35 U.S.C. § 6(b).

We AFFIRM.

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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. Appellant identifies the real party in interest as Sysmex Corporation. Appeal Br. 2 (entered Nov. 20, 2018).

## STATEMENT OF THE CASE

The Examiner determined that claims 1, 2, 4–12, 14, 16–19 and 21 are directed to a judicial exception to patent eligibility and consequently rejected the claims under 35 U.S.C. § 101. Ans. 4. The Examiner designated the rejection as a new ground of rejection based on newly citing the United States Patent & Trademark Office’s (USPTO) recently published revised guidance on the application of 35 U.S.C. § 101. USPTO’s January 7, 2019 Memorandum, *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50, 51–57 (2019) (“2019 Eligibility Guidance”).

There are two independent claims on appeal, claims 1 and 14. Claim 1 is a method claim and claim 14 is directed to an apparatus, a cell analyzer. Both claims comprise the same steps which, when accomplished, result in “an indication of the presence of cancer suspected cells in the epithelial tissues.” We select claim 1 as representative. Claim 1 reads as follows (bracketed letters [a]-[g] have been added for reference to the steps in the claim):

1. A cell analysis method comprising:

[a] receiving, by a communication interface, cell parameters of a respective sample cell collected from epithelial tissues, wherein the cell parameters include at least a first parameter representing a cell size (C) and a second parameter representing a cell nucleus size (N), wherein the sample cells are analyzed by a measurement apparatus using a cytometer to obtain the cell parameters;

[b] calculating, by a CPU, a N/C ratio of a respective sample cell based on the first and second parameters, wherein the N/C ratio represents a relative size of a nucleus in a sample cell with respect to the cell size (C) of the sample cell, and the N/C ratio becomes large when the relative size of a nucleus in a sample cell becomes large;

[c] applying, by the CPU, a first threshold (V11) to the N/C ratio of a respective sample cell to identify target cells in the sample cells having N/C ratios equal to or higher than the first threshold (V11) and non-target cells in the sample cells having N/C ratios lower than the first threshold (V11), wherein the target cells have nucleuses, relative sizes thereof being larger than relative sizes of nucleuses of the non-target cells in relation to sizes of their cytoplasm, and comprise parabasal cells in the epithelial tissues, which are more valuable for pathology of the epithelial tissues than the non-target cells;

[d] counting, by the CPU, a number (N1) of the target cells and a number (N2) of the nontarget cells;

[e] classifying, by the CPU, the target cells into at least a first group of cells and a second group of cells according to their amounts of DNA, wherein the cells in the first group each have a greater amount of DNA than the cells in the second group;

[f1] counting, by the CPU, a number (N3) of the first group of cells and a number (N4) of the second group of cells and [f2] calculating a ratio (N3/N4) of the number (N3) of the first group of cells to the number (N4) of the second group; and

[g] [g1] applying, by the CPU, a second threshold (s4) to the ratio (N3/N4) to evaluate pathology of the epithelial tissues such that an evaluation result provides an indication of the presence of cancer suspected cells in the epithelial tissues when the ratio (N3/N4) is equal to or larger than the second threshold (s4), [g2] wherein the second threshold (s4) is varied, by the CPU, according to a proportion of the target cells in the collected sample cells, wherein the proportion is calculated based on the number (N1) of the target cells and the number (N2) of the non-target cells.

## SECTION 101 REJECTION

The Examiner rejected all of the pending claims under 35 U.S.C. § 101 as directed to a judicial exception to patent eligibility. Ans. 3. The Examiner found that the claims are directed to an abstract idea and law of nature. Ans. 4–6.

### Principles of Law

Under 35 U.S.C. § 101, an invention is patent-eligible if it claims a “new and useful process, machine, manufacture, or composition of matter.” Not every discovery is eligible for patent protection, however. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). “Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas.” *Id.* The Supreme Court articulated a two-step analysis to determine whether a claim falls within an excluded category of invention. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014); *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 75–77 (2012).

In the first step, it is determined “whether the claims at issue are directed to one of those patent-ineligible concepts.” *Alice*, 573 U.S. at 217. If it is determined that the claims are directed to an ineligible concept, then the second step of the two-part analysis is applied in which it is asked “[w]hat else is there in the claims before us?” *Id.* The Court explained that this step involves

a search for an “ ‘inventive concept’ ” – *i.e.*, an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.”

*Alice*, 573 U.S. at 217–18 (citing from *Mayo*, 566 U.S. at 75–77).

*Alice*, relying on the analysis in *Mayo* of a claim directed to a law of nature, stated that in the second part of the analysis “the elements of each claim both individually and ‘as an ordered combination’” must be considered “to determine whether the additional elements ‘transform the nature of the claim’ into a patent-eligible application.” *Alice*, 573 U.S. at 217.

The USPTO published revised guidance on the application of 35 U.S.C. § 101. USPTO’s January 7, 2019 Memorandum, 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 51–57 (2019) (“2019 Eligibility Guidance”). This guidance provides direction on how to implement the two-part analysis of *Mayo* and *Alice*.

Step 2A, Prong One, of the 2019 Guidelines, looks at the specific limitations in the claim to determine whether the claim recites a judicial exception to patent eligibility. In Step 2A, Prong Two, the claims are examined to identify whether there are additional elements in the claims that integrate the exception in a practical application, namely, is there a “meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception.” 84 Fed. Reg. 54 (2. Prong Two).

If the exception is not integrated into a practical application, then as in the *Mayo/Alice* framework, Step 2B of the 2019 Guidelines asks whether there is an inventive concept to ensure that the patent is significantly more than a patent on the ineligible concept, itself. 84 Fed. Reg. 56. In making this determination, it must be considered whether there are specific limitations or elements recited in the claim “that are not well-understood, routine, conventional activity in the field, which is indicative that an

inventive concept may be present” or whether the claim “simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, indicative that an inventive concept may not be present.” 84 Fed. Reg. 56 (footnote omitted).

With these guiding principles, we proceed to determine whether the claimed subject matter in this appeal is eligible for patent protection under 35 U.S.C. § 101. As explained in more detail below, we conclude that the claims are directed to patent-ineligible subject matter.

#### Step 2A, Prong One

In Step 2A, Prong One, of the 2019 Guidelines, the specific limitations in the claim are examined to determine whether the claim recites a judicial exception to patent eligibility, namely whether the claim recites an abstract idea, law of nature, or natural phenomenon. The 2019 Guidelines list three groupings of abstract ideas, two of which the Examiner found to be recited in claims 1 and 14 (Ans. 6): “(a) Mathematical concepts—mathematical relationships, mathematical formulas or equations, mathematical calculations” and “(c) Mental processes--concepts performed in the human mind (including an observation, evaluation, judgment, opinion).” 84 Fed. Reg. 52.

The first step of the claim, step [a], comprises “receiving” cell parameters “wherein the sample cells are analyzed by a measurement apparatus using a cytometer to obtain the cell parameters.” This step of receiving cell parameter measurements from a cytometer does not fall within any of the three groupings identified in the 2019 Guidelines as reciting an

abstract idea. It also does not recite a law of nature.

Step [b] of claim 1 calculates the ratio between nucleus size and cell size (“N/C”) based on parameters obtained from a cytometer (“calculating, by a CPU, a N/C ratio”). Because “N/C” is a mathematical formula, we find that it constitutes a mathematical concept and abstract idea under the 2019 Guidelines.

Step [c] of the claim comprises applying a threshold to the N/C ratio calculated in step [b] to determine target cells and non-target cells. The application of a threshold to a calculated ratio, a value, is act that can be performed in the human mind and therefore falls in the mental concept grouping.

In step [d], the number of target cells (N1) and non-target cells (N2) determined in step [c] are counted. Counting cells is a mental process because it can be performed in the human mind.

Step [e] of the claim comprises classifying the target cells into two groups based on their amounts of DNA. Classifying cells based on a value is a mental act that can be performed in the human mind and therefore is mental process as that grouping is described in the 2019 Guidelines.

The number of cells in each group classified in step [e] are counted in step [f1], where the first group is N3 and the second group is N4. Counting is a mental process, as found for step [d], because it can be performed in the human mind.

In step [f2], a ratio for N3/N4 is calculated. Because “N3/N4” is a mathematical formula, we find that it constitutes a mathematical concept and abstract idea.

Step [g1] applies a second threshold to the ratio  $N3/N4$  calculated in step [f2]. As we concluded for step [c], we find the application of a threshold to a calculated ratio to be an act that can be performed in the human mind and therefore a mental concept

Step [g2] comprises “wherein the second threshold ( $s4$ ) is varied, by the CPU, according to a proportion of the target cells in the collected sample cells, wherein the proportion is calculated based on the number ( $N1$ ) of the target cells and the number ( $N2$ ) of the non-target cells.” The threshold  $s4$  is varied based on the proportion of  $N1$  and  $N2$  cells, which Appellant describes in the Appeal Brief as the  $N1/N2$  ratio. Appeal Br. 8. The limitation does not disclose a formula by which the threshold is varied. However, changing the threshold can be performed in the human mind because an evaluation is made regarding how much to adjust the threshold based on the  $N1/N2$  ratio. For example, the Specification discloses:

When the ratio  $N1/N2$  is smaller than the threshold  $s2$  (S109: YES), the CPU 301 sets  $Vsh1$  as a threshold  $s4$  (S110). When the ratio  $N1/N2$  is greater than or equal to the threshold  $s2$  (S109: NO), the CPU 301 sets as the threshold  $s4$   $Vsh2$  which is smaller than  $Vsh1$  (S111). The threshold  $s4$  is a value to be used in determination of canceration (S116) in the latter stage.

Spec. ¶ 93. Accordingly, we find that step [g2] also falls into the mental concept grouping.

In sum, we conclude the Examiner did not err in finding that claim 1 recites judicial exceptions to patent eligibility under 35 U.S.C. ¶ 101. We, thus, proceed to Step 2A, Prong Two, to determine whether these exceptions are integrated into a practical and patent-eligible application.

### Step 2A, Prong Two

Prong Two of Step 2A under the 2019 Guidance asks whether there are additional elements that integrate the exception into a practical application. As in the *Mayo/Alice* framework, we must look at the claim elements individually and “as an ordered combination” to determine whether the additional elements integrate the recited abstract idea into a practical application.

As explained above, limitations [b] through [g] of claim 1 recite judicial exceptions to patent eligibility. Specifically, each of these steps individually perform either a mathematical concept or mental process in which the cell parameters obtained from a cytometer are operated on to result in “an indication of the presence of cancer suspected cells in the epithelial tissues.” The steps calculate an N/C ratio [b], apply a threshold to the ratio to determine target and non-target cells [c], count the target and non-target cells [d], classify the target cells into two groups based on DNA [e], count the cells in each group [f1], calculate a ratio  $N3/N4$  between the two groups, apply a second threshold to the  $N3/N4$  ratio [g1], and vary the second threshold based on the  $N1/N2$  ratio [g2].<sup>2</sup> The only step in the claim

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<sup>2</sup> Clam 1 can be distinguished from Example 39 of the 2019 Subject Matter Eligibility Examples: Abstract Ideas (Jan. 7, 2019) (“2019 EE”) that use a “neural network,” a type of machine learning that is based on mathematical concepts. Although the claim in Example 39 recites a “neural network,” it does so generically without specifically reciting any steps that include mathematical concepts or mental processes. As discussed above, rejected claim 1 in this appeal recites the mental processes and mathematical concepts used to perform the claimed process, and these steps are asserted to be an improvement. Example 39, on the other hand, is not asserted to be an improvement of the neural network.

that does not recite an abstract idea is step [a] in which a cytometer is used to obtain cell parameter data, comprising cell size and nucleus size.

In order to find a practical application, the judicial exceptions must be integrated into additional elements in the claim. The only additional element recited in the claim is step [a]. Step [a] of claim 1 recites “receiving . . . cell parameters of a respective sample cell collected from epithelial tissues, . . . wherein the sample cells are analyzed by a measurement apparatus using a cytometer to obtain the cell parameters.” The cytometer therefore performs the analysis of the cells “to obtain the cell parameters.” The abstract ideas [b]–[g] recited in the claim are not integrated into the performance of the cytometer in obtaining measurements of the cell parameters, but rather are accomplished after the cytometer completes its measurement of the cell size and cell nucleus. As in *Parker v. Flook*, 437 U.S. 584 (1978), the claim is directed to the abstract ideas recited in steps [b]–[g], and not to the process of using the cell cytometer – the only additional element recited in claim 1.

In *Flook*, a claim reciting a mathematical concept was found to be ineligible for patent, despite providing “a new and presumably better method for calculating alarm limit values.” *Flook*, 437 U.S. at X. The claim was directed to a “method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons.” *Flook*, 437 U.S. at 596–97 (Appendix to Opinion). The recited steps in the *Flook* claim comprised determining a new alarm base using a mathematical algorithm, using the alarm base to update an alarm limit, and then adjusting the alarm limit to the updated value. *Id.* The Court found the claim to be a judicial exception to subject matter ineligibility, holding that “[t]he process itself, not merely the

mathematical algorithm, must be new and useful.” *Id.* at 591.

In this case, the improvement described by Appellant is in the abstract idea recited in [b]–[f] of claim 1, and not an improvement to the cytometer recited in [a] of the claims. While we recognize that the “indication of the presence of cancer suspected cells in the epithelial tissues” is improved, the solution to this problem of detecting cancers is asserted by Appellant to the mathematical operations and mental processes utilized to discern whether a cell is cancerous, which are judicial exceptions to patent eligibility.

The claims in this appeal are distinguishable from the claims in *Diamond v. Diehr*, 450 U.S. 175 (1981), in which the claims were directed to a method of operating a rubber-molding press to mold a compound by curing it in a mold cavity. *Application of Diehr*, 602 F.2d 982, 983–84 (CCPA 1979). The temperature in the mold during the rubber-molding process was constantly determined and provided to a digital computer. *Id.* The computer calculated the Arrhenius equation for the reaction time during the cure to determine when the compound was cured and to automatically open the press. *Id.* Although the claim recited a mathematical algorithm, the Arrhenius equation, the Court held that the claim was eligible for a patent.

[W]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.

*Diehr*, 450 U.S. at 192–93.

In this case, while the steps in the rejected claim instruct how to determine an indication of cancer, the abstract idea embodied in these steps does not change how the cytometer operates. This is in contrast to *Diehr*, where the mathematical formula recited in the claim informed when to open the mold to obtain the cured product.

The claims in this appeal are also different from those in *Thales Visionix, Inc. v. U.S.*, 850 F.3d 1343 (Fed. Cir. 2017). In *Thales*, the improvement was found to be in the “combination of sensor placement and calculation based on a different reference frame.” *Id.* at 1348. Although the claims used mathematical equations to determine the position of a moving object relative to a moving reference frame, the court found that the claims were eligible for a patent under § 101 because they were “directed to systems and methods that use inertial sensors in a non-conventional manner to reduce errors in measuring the relative position and orientation of a moving object on a moving reference frame.” *Id.* at 1348–1349. In this appeal, Appellant has not provided evidence that the manner in which the cytometer is used enables the subsequent steps to provide an indication of cancer. Rather, it is the abstract idea as whole embodied in claims [b]–[g] which accomplishes this objective from the measurements initially obtained from a cytometer.

Appellants argue that claim 1 in this appeal is like *Thales* because *Thales* held that “the computer functionality . . . which qualifies to be patent-eligible, includes not only the functionality that computers are meant to perform, such as memory access, but also the functionality that computers are programmed to perform, such as the functionality of location sensors for calculating the location and orientation of an object.” Appeal Br. 22. We do

not agree because *Thales*, as discussed above, specifically held the eligibility to reside in the “combination” of the sensors and the mathematical concepts. *Thales*, 850 F.3d at 1348 (“this combination of sensor placement and calculation based on a different reference frame mitigates errors by eliminating inertial calculations with respect to the earth”).

We are also not persuaded by Appellant’s argument that *Finjan, Inc. v. Blue Coat Sys.*, 879 F.3d 1299 (Fed. Cir. 2018), would lead to a different decision. In *Finjan*, the court drew an analogy to the self-referential table in *Enfish, LLC v. Microsoft Corporation*, 822 F.3d 1327 (Fed. Cir. 2016), finding that the claims were not be directed to an abstract idea, *inter alia*, because “the method of claim 1 employs a new kind of file that enables a computer security system to do things it could not do before.” *Id.* at 1305. Here, rejected claim 1 does not employ computer functionality to achieve a result as in *Finjan* and *Enfish*. None of steps [b]–[g] involve computer functionality, e.g., virus-scanning in *Finjan*. The steps are performed on a generic computer, using the computer as computing device without affecting its functionality. Likewise, Appellant’s argument that *Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356 (Fed. Cir. 2018) “changed the landscape of the 101 analysis again and taught that an improvement to the qualifying computer functionality” may be patent-eligible (Appeal Br. 23) is inapplicable because an improvement to computer functionality is not recited in claim 23.

In sum, the recited steps do not improve computer functionality and the cytometer of claim 1 does not “play a significant part in permitting the claimed method to be performed” and, therefore, does not “impose a

meaningful limit on the scope of a claim.” *Versata Development Group v. SAP America*, 793 F.3d 1306, 1335 (Fed. Cir. 2015).

### Step 2B

Because we determined that the judicial exception is not integrated into a practical application, we proceed to Step 2B of the 2019 Guidelines, which asks, as in the *Mayo/Alice* framework, whether there is an inventive concept. The claim as a whole must be examined to determine whether it “also contain[s] other elements or a combination of elements, sometimes referred to as an ‘inventive concept,’ sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.” *See Mayo*, 566 U.S. at 72–73.

In this step, we also consider whether the elements recited in the claim constitute “well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality.” 84 Fed. Reg. 56.

Appellant provides argument regarding the presence of an inventive concept recited in the claims, referencing the following limitation recited in the claim ([g]):

applying, by the CPU, a second threshold (s4) to the ratio (N3/N4) to evaluate pathology of the epithelial tissues such that an evaluation result provides an indication of the presence of cancer suspected cells in the epithelial tissues . . .

wherein the second threshold (s4) is varied, by the CPU, according to a proportion of the target cells in the collected sample cells, wherein the proportion is calculated based on the number (N1) of the target cells and the number (N2) of the non-target cells.

Appellant argues that “[t]he important feature of the present invention is that the threshold value S4 [sic, “s4”] is variable and changed depending on the ratio (N1/N2), i.e., the ratio between the number (N1) of target cells included in the region A3 and the number (N2) of non-target cells included in the region A4” (with reference to Fig. 11A reproduced in the Appeal Brief). Appeal Br. 8.

Appellant explains that the inventors found “that a variation of the amount of the target cells still affects the (N3/N4) ratio derived from the target cells, or more precisely, a variation of the (N1/N2) ratio affects the (N3/N4) ratio.” *Id.* Appellant states that the “the use of a single threshold to evaluate the ratio (N3/N4) could lead to inaccurate results in cancer screening tests and that the ratio (N3/N4) needs to be evaluated with different threshold values depending on the ratio (N1/N2).” *Id.* at 9.

Appellant shows that, by following the steps in the claimed method, a lab technician would have visually screened fewer samples than compared to the prior art. *Id.* at 10. Thus, Appellant states:

[C]laims 1 and 14 recite an unconventional solution to evaluation of cancer risk level, i.e., a threshold applied to the (N3/N4) which is variable depending on the . . . [N1/N2] ratio. The prior art applied a fixed threshold to the (N3/N4) ratio which can result in inaccurate evaluation of cancer risk level. The claimed unconventional solution improves the accuracy of evaluation of cancer risk level. This unconventional method and resulting improvement highlight that claims 1 and 14 provide something more than merely an abstract idea.

Appeal Br. 25.

The Examiner acknowledges this solution to the problem of cancer cell detection, but responded as follows:

The claimed subject matter appears to merely describe an alternative way of analyzing input data relating to cell parameters, i.e., cell size (C) and nucleus size (N). As cited above, the claimed method recites use of a CPU to perform well known, routine and conventional tasks that could be executed by any CPU with normal functionality.

Ans. 11–12.

The “inventive concept” identified by Appellant is an abstract idea, itself, and is part of a series of steps in the claim which we have found also to be abstract ideas. Appellant’s explanation of the improvement to cancer screening expressly points to making the s4 threshold adjustable, which we determined to be a mental process. Appeal Br. 9–10. As explained in *Parker v. Flook*, 437 U.S. 584, 594 (1978):

Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.

In this case, Appellant may have discovered that varying the threshold s4 depending on the N1/N2 ratio improves the accuracy of evaluation of cancer risk level, but the phenomenon is an abstract idea and cannot confer eligibility on the claims.

For the foregoing reasons, we affirm the Examiner’s determination that claim 1 is ineligible for a patent under § 101. Separate arguments were not provided for claims 2–6 and 13–26 and therefore these claims fall with claim 1. 37 C.F.R. 41.37(c)(1)(iv).

CONCLUSION

In summary:

<b>Claims Rejected</b>	<b>Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
1-6 and 13-26	§ 101	1-6 and 13-26	
<b>Overall Outcome</b>		1-6 and 13-26	

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