UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/918,011	05/11/2011	Patrick Shawn Beaty	BECTON 3.3-164	5249

147462 7590 03/27/2018

Botos Churchill IP Law LLP
430 Mountain Avenue
Suite 401
New Providence, NJ 07974

EXAMINER
LIN, JERRY

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
03/27/2018	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rbotos@bciplaw.com
ip.docket@bd.com
pto@bciplaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PATRICK SHAWN BEATY[1]

Appeal 2017-005815
Application 12/918,011
Technology Center 1600

Before FRANCISCO C. PRATS, JOHN G. NEW, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to methods for identifying microorganisms which have been rejected as being directed to patent ineligible subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

> Rapid and reliable detection of microorganisms in a culture, such as a blood culture, is among the most important functions of the clinical microbiology laboratory. Currently, the

---

[1] Appellant identifies the Real Party in Interest as Becton, Dickinson and Company. Appeal Br. 1.

> presence of biologically active agents such as bacteria in a patient's body fluid, and especially in blood, is determined using culture vials. A small quantity of the patient's body fluid is injected through an enclosing rubber septum into a sterile vial containing a culture medium and the vial is then incubated and monitored for microorganism growth.

Spec. 1. Culture system such as the BACTEC® systems are used to grow and detect microorganisms using a fluorescent CO_2 sensor. Spec. 1–2. The systems are programmed to detect growth using various computer algorithms. Spec. 2. "A drawback with these microorganism detection approaches is that they do not always detect microorganism type in such cultures." *Id.*

The Specification describes systems, methods, and apparatus for presumptive organism identification. *Id.*

Claims 1, 3–53, 55, and 56 are on appeal. Claim 1 is representative and reads as follows:

> 1. A method of identifying a microorganism type in a culture in a vessel, the method comprising:
>
> i) providing a vessel with a culture disposed therein, the vessel further comprising a sensor in communication with the culture;
>
> ii) obtaining a signal from the sensor, the signal being a measure of an initial biological state of the culture;
>
> iii) incubating the culture disposed in the vessel;
>
> iv) obtaining signals from the sensor, the signal being a measure of the biological state of the culture during incubation;
>
> (A) calculating a normalization relative value for each respective measurement in a plurality of measurements of a biological state of the culture in the vessel, taken at different time points between a first time point and a second time point, between (i) the respective measurement and (ii) an initial biological state of the culture taken at an initial time point, thereby forming a plurality of normalization

relative values for each of a plurality of predetermined fixed interval of time points;

(B) determining, for each respective predetermined fixed interval of time points between the first time point and the second time point, a first derivative of the normalization relative values for measurements of the biological state in the respective predetermined fixed interval of time points, thereby forming a plurality of rate transformation values, wherein the plurality of rate transformation values comprises a plurality of sets of rate transformation values, wherein each respective set of rate transformation values in the plurality of sets of rate transformation values is for a different set of contiguous time points between the first time point and the second time point;

(C) computing, for each respective set of rate transformation values in the plurality of sets of rate transformation values, an average relative transformation value as a measure of central tendency of each of the rate transformation values in the respective set of rate transformation values, thereby computing a plurality of average relative transformation values;

(D) determining a maximum metabolic rate and an extent of growth from the plurality of normalization relative values and the plurality of average relative transformation values;

(E) determining the microorganism type in the culture in the vessel from the maximum metabolic rate and the extent of growth; and

(F) outputting an identification of the microorganism type in the culture in the vessel to a user interface device, a monitor, a computer-readable storage medium, a computer-readable memory, or a local or remote computer system; or displaying an identification of the microorganism type in the culture.

The claims have been rejected under 35 U.S.C. § 101 as being directed to patent ineligible subject matter.

DISCUSSION

Issue

The issue with respect to this rejection is whether the Examiner properly concluded that the claims are directed to subject which is not eligible for patent protection.

The Examiner finds that the claims are directed to determining the microorganism type using a mathematical process involving:

> calculating a normalization relative value for a plurality of measurements, determining a first derivative of the normalization values to create a plurality of rate transformation values, computing an average relative transformation value, and determining a maximum metabolic rate and extent of growth, and determining the microorganism type in the culture form the maximum metabolic rate and extent of growth.

Final Act. 2–3. The Examiner finds that the mathematical process is an abstract idea and is directed to a judicial exception. *Id.*

The Examiner also finds that the claims do not include additional elements that amount to significantly more than the judicial exception. *Id.* The Examiner finds that the additional elements of "providing a vessel with a culture and sensor, obtaining a signal from the sensor, incubating the culture in the vessel, and obtaining signals from the sensor as a measure of the biological state of the culture" are "well-known, conventional and routine data-gathering steps." *Id.*

Appellant contends that a proper application of the *Alice/Mayo* test demonstrates that the claims are directed to patentable subject matter. Appeal Br. 8. With respect to the first step of the *Alice/Mayo* test, Appellant contends that the claims are not directed to an abstract idea but are directed

to "a specific implementation of a solution to a problem in the field of culture testing (i.e., automatically determining the type of microorganism in a culture)." Appeal Br. 11. Appellant also contends that the claims do not tie up "the use of normalization relative values, rate transformation values, or average relative transformation values." *Id.*

With respect to the second part of the *Alice/Mayo* test, Appellant contends that the claims recite elements that amount to significantly more that the judicial exception. Appeal Br. 16. Appellant contends that the invention offers an improvement to technical field of microorganism identification. Appeal Br. 17–18. Appellant also argues that the additional elements include unconventional steps that confine the claims to the identification of microorganisms. Appeal Br. 18–20. Appellant argues that the claims do not append well-understood routine and conventional activities known in the industry. Appeal Br. 20–22. Finally, Appellant argues that the instant claims are similar to those in *SiRF Technology, Inc. v. ITC,* 601 F.3d 1319 (Fed Cir. 2010), where our reviewing court found the claims to present patentable subject matter. Appeal Br. 22–23.

Analysis

Under § 101, "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" may be eligible for a patent, subject to the conditions and requirements of the Patent Act. 35 U.S.C. § 101. But, under Supreme Court precedent, "'[L]aws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo Collaborative Services* v. *Prometheus Labs., Inc.,* 132 S. Ct. 1289, 1293 (2012) (citation omitted). "Groundbreaking, innovative, or even brilliant

discovery does not by itself satisfy the § 101 inquiry." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S. Ct. 2107, 2117 (2013).

The Supreme Court articulated a two-step test for patent eligibility under § 101 that "distinguish[es] patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp. Pty. Ltd.* v. *CLS Bank Int* 7, 134 S. Ct. 2347, 2355 (2014) (citing *Mayo,* 132 S. Ct. at 1296–97) ("the *Alice/Mayo* test"). "First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, what else is there in the claims before us?" *Id.* (citation and quotations omitted). Second, we "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." *Id.* (quotations and alterations omitted).

We agree with the Examiner that claim 1 is directed to ineligible subject matter. The present claims are directed to mathematical manipulation of data to determine if a naturally occurring feature of a microorganism is present. As such the claims are directed to an abstract idea and a natural phenomenon and are not eligible for patent protection.

Appellant contends that the claims are not directed to an abstract idea in that the claims are directed to a specific implementation of a solution to a problem in the field of microbiology. Appeal Br. 10–11. Appellant cites to *Enfish, LLC v. Microsoft Corp.,* 822 F.3d 1327 (Fed. Cir. 2016) and *McRO, Inc. v. Bandai Namco Games Am. Inc.* 837 F.3d 1299(Fed. Cir. 2016) in support of his position.

Appellant's argument is unpersuasive. In *Enfish*, the claims were focused on an improvement to computer functionality itself. *Enfish,* 822 F.3d at 1336. Specifically the invention was directed to a novel computer database which improved the way computers operate. *Id.* In contrast, the present claims merely take data and apply well known mathematical operations to determine if a natural characteristic is present. *See, Digitech Image Techs. v. Electronics for Imaging, Inc.,* 758 F.3d 1344, 1351 (Fed. Cir. 2014). ("Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible.")

Similarly, Appellant's reliance on *McRO* is also unpersuasive. In *McRO*, the invention was directed to application of a specific set of rules to improve lip-sync animation. *McRO*, 837 F.3d at 1314. Here the invention uses known, general mathematic operations to manipulate data which is obtained by conventional means.

Appellant next argues that the present claims do not tie up a judicial exception. This argument is also unpersuasive. Our reviewing court has expressly rejected similar contentions regarding preemption, stating that a patentee's "attempt to limit the breadth of the claims by showing alternative uses . . . outside of the scope of the claims does not change the conclusion that the claims are directed to patent ineligible subject matter." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015). The court explained that, "[w]hile 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 . . . preemption concerns are fully addressed and made moot." *Id.*

We, therefore, agree with the Examiner that, as to part one of the Supreme Court's test, Appellant's claims are expressly directed an abstract idea.

As to part two of the test, the remaining elements are directed to equipment and steps that are well known in the art. This is best demonstrated by Appellant's own statement that by "using the novel systems, methods, and apparatus of the present invention, an incubating system, such as the BACTEC® blood culture system, **can be programmed** to determine the microorganism type in a culture before manual tests, such as a Gram stain or a subculture, are performed." Spec. 2 (emphasis added). Thus the present invention involves programming for known blood culture systems. The presence of a generic blood culture system, including all of its elements, is not unlike using a generis computer to implement software and does not constitute something significantly more than the judicial exception. *See, Alice,* 134 S.Ct. at 2357.

Appellant contends that the claims recite an improvement to a technical filed, specifically determination of a microorganism type. Appeal Br. 17–18, Reply Br. 7–8. We are unpersauded. As the Examiner points out, there is no evidence of record that shown that the claimed method offers an improvement over the prior art. Ans. 4.

In support of his argument, Appellant argues that the present method "may 'obviate any need to perform a Gram test or subculture in order to identify the microorganism type that is infecting the culture.'" Appeal Br.

18, Reply Br. 7. We find this unpersuasive. As stated in the background of the invention, "A drawback with [prior art] microorganism detection approaches is that they do not always detect microorganism type in such cultures." Spec. 2. This does not appear to be any different from the claimed system which may avoid the need for further procedures.

Moreover, all inventions can be said to be an improvement over what was known before. However, not every improvement constitutes patentable subject matter. *See, Intellectual Ventures I LLC v. Capital One Bank (USA),* 792 F.3d 1363, 1367 (Fed. Cir. 2015) (claims to improved speed of efficiency did not render claims patentable).

Appellant next argues that the invention includes unconventional steps that confine the claim to a particular useful application. Appeal Br. 19. Appellant point to the fact that the claims are directed to more than just mathematical concepts but are tied to "a vessel with a culture disposed therein to automatically determine the type of microorganism in the culture." *Id.*

We find this argument unpersuasive. As noted above, lack of preemption alone does not support a finding that the claims are directed to patent eligible subject matter. In addition, the use of a vessel to grow the microorganism as well as acquiring data as the microorganism grows, are conventional steps. Only the application of various mathematical concepts to that data is different.

Appellant argues that the "invention does not simply append well-understood, routine and conventional activities known to the industry, specified at a high level of generality to a judicial exception." (emphasis

and title caps omitted) Appeal Br. 20. We remain unpersuaded. The instant invention is one that can be accomplished by programming the recited mathematical concepts or steps into an existing blood culture machine. Spec. 2, Appeal Br. 18, Reply Br. 6. Thus the invention appears to be nothing more than using an existing blood culture machine to obtain data about the culture and then using various mathematical concepts to manipulate the data. This is an application of a judicial exception to a well-known and conventional activity.

Finally, Appellant argues that the present claims are similar to those in *SiRF* where our reviewing court found the claims to be patentable. Appeal Br. 22. Appellant contends that like the system in *SiRF*, the claimed method requires the use of specific components, namely a sensor that gathers information about the conditions in the culture vessel over time or a culture vessel. Appeal Br. 22–23.

We have considered Appellant's argument and are unpersuaded. As our reviewing court noted in *SiRF*, "[i]n order for the addition of a machine to impose a meaningful limit of the scope of a claim, it must play a significant part in permitting the claimed method to be performed, rather than function solely as an obvious mechanism for permitting a solution to be achieved more quickly." *SiRF*, 601 F.3d at 1333. In *SiRF*, a GPS receiver was found to be essential to performing the claimed method. *Id* at 1332. In the present case, as the Examiner has found, the claimed sensor and culture vessel are not essential to the performance of the claimed mathematical calculations. Ans. 7.

We, therefore, agree with the Examiner that, under the Supreme Court's two-part test, claim 1 recites subject matter ineligible for patenting under § 101.

SUMMARY

We affirm the rejection of claims 1, 3–53, 55, and 56 under 35 U.S.C. § 101.

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).

AFFIRMED