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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ADITYA P. SANE, RONALD T. KURNIK, and JONATHAN M. BALDANZA

Appeal 2017-006762[1]
Application 13/688,133
Technology Center 1600

Before RICHARD M. LEBOVITZ, RICHARD J. SMITH, and DAVID COTTA, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed a "method of automatically removing a step discontinuity in data representing a Polymerase Chain Reaction (PCR) growth process," as recited in claim 1. The Examiner rejected the claims under 35 U.S.C. § 101 as subject matter ineligible for a patent and under 35 U.S.C. § 112, second paragraph, as indefinite.

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[1] The Appeal Brief ("Appeal Br.") identifies Roche Molecular Systems, Inc. as the real-party-in-interest. Appeal Brief ("App. Br.") 3.

Appellants appeal the rejections under 35 U.S.C. § 134(a). We have jurisdiction under 35 U.S.C. § 6(b). The rejections are reversed.

STATEMENT OF THE CASE

Claims 1–11 and 13–21 stand rejected by the Examiner under 35 U.S.C. § 101 because the claimed invention was found by the Examiner to be directed to patent ineligible subject matter. Examiner's Answer ("Ans.") 3; Appeal Br. 3, 10.

Claims 1–11 and 13–21 stand rejected by the Examiner under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention. Ans. 7, 30.

Independent claim 1 is representative of the claimed subject matter and is reproduced below:

> 1. A method of automatically removing a step discontinuity in data representing a Polymerase Chain Reaction (PCR) growth process, the method comprising:
>
> detecting, with a PCR system, intensity values of signals generated using a biological and/or chemical reaction sample undergoing the PCR growth process, at a plurality of growth cycles of the PCR growth process;
>
> receiving, by a computer system communicatively coupled to the PCR system, a dataset representing the PCR growth process, the dataset including a plurality of data points, each data point having a pair of coordinate values, wherein the pair of coordinate values correspond to a cycle number of the PCR growth process and an intensity value of a signal generated using the biological and/or chemical reaction sample and detected by the PCR system after a growth cycle corresponding to the cycle number;
>
> calculating, by the computer system, a first approximation

of a curve that fits the dataset by applying a first non-linear regression process to a first non-linear function to determine parameters of the first non-linear function, said parameters including a first step discontinuity parameter that represents a magnitude of the step discontinuity, the first non-linear function including the first step discontinuity parameter multiplying a step function;

calculating, by the computer system, a second approximation of a curve that fits the dataset by applying a second regression process to a second non-linear function to determine parameters of the second non-linear function, said parameters of the second non-linear function including a second step discontinuity parameter that represents the magnitude of the step discontinuity, the second non-linear function including the second step discontinuity parameter multiplying a step function, wherein the second nonlinear function is different from the first non-linear function;

determining, by the computer system, an information coefficient for each of the first and second approximations, each information coefficient indicating an accuracy of a fit of the corresponding approximation to the dataset;

selecting, by the computer system, one of the approximations based on the information coefficient, the selected approximation providing a best fit to the dataset;

determining, by the computer system, a confidence interval of the step discontinuity parameter for the selected approximation;

if the confidence interval does not include the value zero, replacing, by the computer system, a portion of the dataset with the selected approximation with the corresponding step discontinuity parameter set to zero, wherein the method is implemented in a computer system having a processor; and

determining, by the computer system, a quantity of a target molecule in the biological and/or chemical reaction sample by determining a cycle threshold (Ct) value using the dataset.

REJECTION UNDER § 101

Claim 1 is directed to a method in which the quantity of a target molecule in a sample subjected to a PCR reaction is determined ("determining, by the computer system, a quantity of a target molecule in the biological and/or chemical reaction sample by determining a cycle threshold (C_t) value using the dataset."). The determination is made by a computer system, beginning with "detecting, with a PCR system, intensity values of signals generated using a biological and/or chemical reaction sample undergoing the PCR growth process, at a plurality of growth cycles of the PCR growth process." The subsequent steps comprise calculations performed on a dataset representing the PCR growth process that culminate in determining the quantity of target molecule in the sample. We refer to these calculation steps collectively as an "algorithm."

Independent claim 13 is directed to computer-readable medium including the code for performing the same steps of claim 1. Independent claim 17 is directed to a PCR system comprising "a kinetic PCR analysis module" that performs the same steps of claim 1. The question of patent eligibility for all three independent claims turn on the same issue.

The Examiner rejected the claims under 35 U.S.C. § 101 as being directed to patent ineligible subject matter. Ans. 3. The Examiner found that the recited steps for performing PCR are conventional and that "[w]hat is left of the claims are instructions generally drawn to analysis of PCR data" which are "abstract steps" and an "abstract process." *Id.* at 4, 6. The Examiner stated:

> In the instant case, the claims are directed to only the manipulation of data as described above. The method steps themselves are considered to be an abstract idea because they do

> not purport to improve the functioning of the computer itself, there is no specific or limitation recitation of improved computer technology, nor do they effect an improvement in any other technology or technical field.

Id. at 6.

The Examiner further found that no additional steps are recited in the claims "that would amount to significantly more than the judicial exception." *Id.* at 6. The Examiner stated:

> Furthermore, if a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is non-statutory. In other words, patenting abstract ideas cannot be circumvented by limiting the use of the idea to particular technological environment.

Id. at 7.

We do not agree with the Examiner's analysis and reverse the rejection.

The claims at issue in this appeal comprise steps in which mathematical calculations are performed on a dataset obtained from a PCR reaction. Steps involving mathematical calculations using algorithms are considered by the Supreme Court to be "abstract ideas" in the context of determining whether a claim is a judicial exception to 35 U.S.C. § 101. Thus, the rejected claims, as found by the Examiner involve the implementation of an "abstract idea" on a computer system. However, as held by the Federal Circuit in *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299 (2016):

> We do not assume that such claims are directed to patent ineligible subject matter because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."

> *Prometheus Labs., Inc.*, —— U.S. ——, 132 S. Ct. 1289, 1293, 182 L.Ed.2d 321 (2012) ("*Mayo*"); *see also In re TLI Commc'ns LLC Patent Litig.*, 823 F.3d 607, 611 (Fed. Cir. 2016) ("*TLI Commc'ns*"). Instead, "the claims are considered in their entirety to ascertain whether their character as a whole is directed to excluded subject matter." *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015). If the claims are not directed to an abstract idea, the inquiry ends. If the claims are "directed to" an abstract idea, then the inquiry proceeds to the second step of the *Alice* framework.
>
> In step two we consider whether the claims contain an "inventive concept" sufficient to "transform the nature of the claim into a patent-eligible application." *Alice*, 134 S. Ct. at 2355 (quotation omitted). To do so we look to both the claim as a whole and the individual claim elements to determine whether the claims contain "an element or combination of elements that is 'sufficient to more than a patent upon the [ineligible concept] itself.' " *Id.* (quoting *Mayo*, 132 S. Ct. at 1294) (alteration in original).

McRO, 837 F.3d 1299, 1311–12.

Two cases that are oft-cited in a Section 101 analysis are *Diamond v. Diehr*, 450 U.S. 175 (1981) and *Parker v. Flook*, 437 U.S. 584 (1978).

In *Diehr*, 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) ("*Application of Diehr*"; lower court decision; *Diehr* did not reproduce the claims, but *Application of Diehr* did.) 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 when cure was accomplished. *Id.*

Although the claim recited a mathematical algorithm and an abstract idea, 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 *Flook*, the claims were found to be ineligible for a patent. In *Flook*, 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 steps 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 update value. *Id.* The Court found the claim to be unpatentable under Section 101. The Court held:

> The process itself, not merely the mathematical algorithm, must be new and useful. Indeed, the novelty of the mathematical algorithm is not a determining factor at all. Whether the algorithm was in fact known or unknown at the time of the claimed invention, as one of the "basic tools of scientific and technological work," it is treated as though it were a familiar part of the prior art.

Flook, 437 at U.S., 591-92.

Further, the Court stated:

> Respondent's process is unpatentable under § 101 not because it contains a mathematical algorithm as one component, but because, once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention. 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.

Flook, 437 U.S. at 594.

In reaching this determination, the Court found that the "post-solution activity" in adjusting the alarm was insufficient to establish patent eligibility to the claim because the claim as a whole was not "an inventive application of the principle." *Id.* Rather, the Court found:

> The chemical processes involved in catalytic conversion of hydrocarbons are well known, as are the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for "automatic monitoring alarming." Respondent's application simply provides a new and presumably better method for calculating alarm limits.

Flook, 437 U.S. at 595.

The question in this appeal is whether there is an "inventive" application of the algorithms used to determine the concentration of target molecules in the sample. As in *Flook*, the claimed PCR process is well-known and conventional; accordingly, patent eligibility cannot reside in the steps of carrying it out. However, the algorithm is being used in the claimed invention to provide an improvement to the PCR process in the same way the algorithm improved rubber molding in *Diehr*. Thus, Appellant does not rely on the novelty of the algorithm, itself, to establish patent eligibility, but rather on the process as a whole in which the algorithm is used to improve

the claimed PCR process. As explained in the Specification, the application of the algorithm to PCR overcame a difficulty experienced in prior art methods:

> Embodiments of the invention remove a jump discontinuity in fluorescence of real-time polymerase chain reaction data. The presence of the discontinuity may cause incorrect result calculation and is hence recommended to be removed. Depending on the initial copy number of the target, the discontinuity in the fluorescence may be absent at high concentration levels. The confidence region of an eight parameter nonlinear model is used to accurately estimate the data. The method overcomes difficulties in prior methods for removal of the discontinuity at all concentration levels.

Spec. ¶ 11.

The disclosed and recited steps in the algorithm are applied to PCR technology to determine the concentration of the amplified target molecule in the sample. The method, therefore, is an improvement to PCR technology because it provides for more accurately determining the quantity of the target molecule in the sample. Appeal Br. 20. An improvement to an "existing technological process" was found in *McRO* to confer patent eligibility on the claims. *McRO*, 837 F.3d at 1315. *See* also *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1336 (Fed. Cir. 2016) ("the claims at issue . . . are not directed to an abstract idea within the meaning of *Alice*. Rather, they are directed to a specific improvement to the way computers operate, embodied in the self-referential table."); Appeal Br. 22.

Specifically, in *McRO*, "the claimed improvement" was to a computer system "to produce 'accurate and realistic lip synchronization and facial expressions in animated characters' that previously could only be produced by human animators . . . [T]his computer automation is realized by

improving the prior art through "the use of rules, rather than artists, to set the morph weights and transitions between phonemes.'" *McRO*, 1313. In finding the claims patent eligible, the court stated: "The claimed process uses a combined order of specific rules that renders information into a specific format that is then used and applied to create desired results: a sequence of synchronized, animated characters." *McRO*, 1315.

Here, there is also an order of specific rules that produces an improvement to the measurement of a PCR product in a sample. As in *Diehr* where the algorithm improved the process of curing rubber, the algorithm recited in the claims improves the process of determining the target molecule in the PCR process, a physical and chemical process. There is nothing that requires a method "be tied to a machine or transform an article" to be patentable. *Bilski v. Kappos*, 561 U.S. 593, 610–11 (2010).

The concern underlying the exceptions to § 101 is pre-emption. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014). The preemption concern arises when the claims are not directed to a specific invention and instead improperly monopolize "the basic tools of scientific and technological work." *Alice*, 134 S. Ct. at 2354. However, in this case, the algorithm does not preempt other methods for determining target quantity in a PCR sample, including other methods which use the individual steps differently than how they are used in the claims. Consequently, preemption is not properly invoked.

For the foregoing reasons we reverse the Section 101 rejection of claims 1, 13, and 17, and claims 2–11 and 14–16, and 18–21, which depend from them.

REJECTION UNDER SECTION 112, SECOND PARAGRAPH

The Examiner rejected the claims as indefinite because of the recitation of "information coefficient" in the claims. The Examiner stated the term is "vague and appears incomplete because there is no definition nor detailed guidance in the present in the specification for how this value is determined to define the metes and bounds of the term." Ans. 7.

While the Examiner stated that the term "information coefficient" is indefinite, the Examiner also acknowledged the term "is generally understood in the art," imposing the indefiniteness rejection because "there is no art accepted calculation nor a single method for determining this coefficient/value." Ans. 8. A term is not indefinite merely because there is more than one way to calculate it, particularly where there is no evidence suggesting that different methods of calculation produce materially different results. The Examiner did not establish that the term is susceptible to more than one meaning, and thus ambiguous, but rather asserted it is indefinite simply because it can be calculated by different methods. The Examiner states that how the information coefficient is calculated is critical to the method, but does not provide persuasive evidence to support this assertion. The claim does not restrict how the information coefficient is calculated and thus, definitely conveys the breadth of the term to one of ordinary skill in the art. Consistently, claims 7, 16, and 19 involve specific ways of calculating the information coefficient. *See* Spec. ¶ 45 describing this embodiment.

The Examiner also stated

> Further, it is noted that the 'best fit to the dataset' is obtained using the 'information coefficient' which indicates that this value is somehow different and unique to approximations and best fit

> assessments usually used in the art since an 'information coefficient' is provided in the comparison of two non-linear function approximations.

Ans. 8.

The Examiner is referring to the following steps of claim 1:

> determining, by the computer system, an information coefficient for each of the first and second approximations, each information coefficient indicating an accuracy of a fit of the corresponding approximation to the dataset;
>
> selecting, by the computer system, one of the approximations based on the information coefficient, the selected approximation providing a best fit to the dataset;

The first recited step instructs the system to determine an information coefficient and requires the coefficient to be an indication of "an accuracy of a fit of the corresponding approximation to the dataset." The second recited step instructs the system to use the information coefficient to select an approximation providing a best fit to the dataset. The Examiner did not explain why using the information coefficient to determine a best fit to the data set renders the claim indefinite. On the face of it, the claim language clearly instructs the system to determine the best fit. We have not been directed to any evidence that the terms "information coefficient" or "best fit" are ambiguous terms. To the contrary, as admitted by the Examiner (Ans. 13) and established by Appellants (Appeal Br. 31; Reply Br. 11–12) the terms are well-known in the art and they do not introduce any lack of clarity into the claims.

The rejection of claims 1–11 and 13–21 under § 112, second paragraph is reversed.

REVERSED