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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/489,198	09/17/2014	Brian A. Young	920006-229539	1022

23643 7590 07/18/2018

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ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
07/18/2018	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BRIAN A. YOUNG, ESLEY M. HEIZER JR., ANGELA T. MINARD-SMITH, NANCY J. MCMILLAN, GOKHAN YAVAS, and DANIEL M. BORNMAN

Appeal 2017-007443[1]
Application 14/489,198
Technology Center 1600

Before FRANCISCO C. PRATS, JAMES A. WORTH, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims to methods involving the use of a massively parallel sequencing instrument to read the nucleotide sequences of amplified nucleic acids. The Examiner rejected the claims as being directed to subject matter ineligible for patenting.

We have jurisdiction under 35 U.S.C. § 6(b)(1).

We reverse.

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[1] Appellants state that the "real party in interest is Battelle Memorial Institute, by virtue of an assignment recorded in the Patent Office at patent record reel 034113, beginning at frame 0104." Appeal Br. 2.

STATEMENT OF THE CASE

The sole rejection before us for review is the Examiner's rejection of claims 1–10 and 12–19 as being directed to subject matter not eligible for patenting. Final Act. 4–8; Ans. 2–5.

Claims 1 and 12, the independent claims on appeal, are illustrative and reads as follows:

1. A method comprising:

amplifying one or more nucleotide sequences in a sample using a PCR amplification process to produce an amplified sample;

using a massively parallel sequencing (MPS) instrument to read the one or more nucleotide sequences of the amplified sample and generate one or more text strings based on the amplified sample;

selecting a first plurality of text strings from the one or more text strings read by the MPS instrument, wherein each of the selected first plurality of text strings represent a nucleotide sequence that-corresponds to a first target locus in the amplified sample;

comparing the selected first plurality of text strings to one another to determine an abundance count for each unique text string included in the selected first plurality of text strings;

identifying a first number of unique text strings included in the selected first plurality of text strings as representing noise responses; and

determining a method detection limit (MDL) as a function of the abundance counts for the first number of unique text strings identified as representing noise responses.

12. A method comprising:

amplifying one or more nucleotide sequences in a sample using a PCR amplification process to produce an amplified sample;

> using a massively parallel sequencing (MPS) instrument to read the one or more nucleotide sequences of the amplified sample and generate one or more text strings based on the amplified sample;
>
> selecting a first plurality of text strings from the one or more text strings read by the MPS instrument, wherein each of the selected first plurality of text strings represent a nucleotide sequence that corresponds to a first target locus in the amplified sample;
>
> comparing the selected first plurality of text strings to one another to determine an abundance count for each unique text string included in the selected first plurality of text strings; and
>
> outputting a graphical display, wherein the graphical display comprises a first plurality of graphical elements that each correspond to one of the unique text strings included in the selected first plurality of text strings and that each represent the abundance count determined for the corresponding unique text string.

Appeal Br. 10, 14.

STANDARD OF REVIEW

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

DISCUSSION

The Examiner's Prima Facie Case

In concluding that Appellants' claims are directed to subject matter ineligible for patenting, the Examiner found that the processes recited in the

rejected claims "are directed towards a judicial exception, i.e. an abstract idea." Ans. 4.

In particular, the Examiner reasoned, the claimed processes involve "obtaining sequence information and resolving the obtained sequence information in order to determine potential target sequences of interest. As such, the instant claims are drawn only to an abstract process that only manipulates data and, therefore, are not directed to statutory subject matter." *Id.*

The Examiner then addressed "[t]he second part . . . of the two step analysis [which] is to determine whether any element or combination of elements, in the claim is sufficient to ensure that the claim as a whole amounts to significantly more than the judicial exception." *Id.* at 5. As to that analysis, the Examiner determined that "[n]o additional steps are recited in the instantly claimed invention that would amount to significantly more than the judicial exception." *Id.*

In that regard, the Examiner asserted that the claims "provide[] for the additional elements of performing PCR and massive parallel sequencing of the PCR product to obtain sequence information about the sample[;] however these steps are well known and considered conventional steps of obtaining sequence information about a sample." *Id.* at 3.

Analysis

35 U.S.C. § 101 states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

The Supreme Court has "long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347, 2354 (2014).

Our reviewing court has summarized the Supreme Court's two-part test for distinguishing between claims to patent-ineligible exceptions, and claims to patent-eligible applications of those exceptions, as follows:

> Step one asks whether the claim is "directed to one of [the] patent-ineligible concepts." [*Alice*, 134 S. Ct. at 2354]. If the answer is no, the inquiry is over: the claim falls within the ambit of § 101. If the answer is yes, the inquiry moves to step two, which asks whether, considered both individually and as an ordered combination, "the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo* [*Collaborative Services v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1297 (2012)]).
>
> Step two is described "as a search for an 'inventive concept.'" *Id.* (quoting *Mayo*, 132 S. Ct. at 1294). At step two, more is required than "well-understood, routine, conventional activity already engaged in by the scientific community," which fails to transform the claim into "significantly more than a patent upon the" ineligible concept itself. *Mayo*, 132 S. Ct. at 1298, 1294.

Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (paragraphing added).

In the present case, Appellants persuade us that the preponderance of the evidence does not support the Examiner's conclusion that the rejected claims recite subject matter ineligible for patenting. In particular, even if we were to agree with the Examiner that the rejected claims are directed to the abstract idea of obtaining and manipulating nucleic acid sequence data, Appellants persuade us (*see* Appeal Br. 7–8; Reply Br. 3) that the Examiner

has not shown sufficiently that the additional features recited in the claims constitute well-understood, routine, conventional activity already engaged in by skilled artisans in the field in which this application is involved.

As seen above, in addition to the claimed "comparing," "identifying," and "determining" steps identified by the Examiner as constituting data manipulation (Ans. 3), both independent claims on appeal recite the steps of "using a massively parallel sequencing (MPS) instrument to read the one or more nucleotide sequences of the amplified sample and generat[ing] one or more text strings based on the amplified sample[, and] selecting a first plurality of text strings from the one or more text strings read by the MPS instrument." Appeal Br. 10, 14 (claims 1 and 12).

In setting out the rejection, however, the Examiner did not identify any specific evidence, in the Specification or otherwise, to support the assertion (Ans. 3) that the use of an MPS instrument in the manner required by claims 1 and 12 was merely a well-understood conventional element routinely employed by skilled artisans for analyzing sequence data, and therefore added nothing to the elements of the claims alleged as being directed to a judicial exception.

In that regard, we note the following assertion by the Examiner, suggesting that Appellants' Specification provides such evidence:

> The specification provides guidance that PCR can produce copies that contain errors, however this is known by the skilled artisan and it would be understood that variations in a set of compiled sequences would have to be verified back to the starting sample or that the few random differences obtained from Massive Parallel Sequencing (MPS) represent these PCR variant sequences.

Id. at 7.

The Examiner however, does not cite to any particular portion of the Specification, or evidence elsewhere in the record, to demonstrate that the use of an MPS instrument in the manner required by claims 1 and 12 was merely a well-understood conventional element routinely employed by skilled artisans for analyzing sequence data. Indeed, Appellants' Specification supports a contrary finding, suggesting that at the time this application was filed, MPS analysis was not yet conventional or routine:

> Forensic DNA analysis ***is about to cross*** a threshold where DNA samples ***will begin to be analyzed routinely*** by MPS (also sometimes referred to in the art as "next-generation" or "current-generation" sequencing). The advent of routine MPS for forensic DNA analysis ***will create*** large quantities of nucleotide sequence data that may enable richer exploitation of DNA in forensic applications.

Spec. ¶ 5 (emphasis added).

Thus, even if we were to agree with the Examiner that the rejected claims involve an abstract idea, i.e., manipulation of nucleic acid sequence data, we are not persuaded that the preponderance of the evidence on this record supports a factual finding that other features of the claims, MPS in particular, were well-understood, routine, conventional activities already engaged in by skilled artisans in the field, given the absence of evidence cited by the Examiner to support such a finding, and given the above-quoted disclosures in Appellants' Specification. *See Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018) ("Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination.").

Accordingly, because the Examiner has not shown by a preponderance of the evidence that the combination of features set forth in

Appellants' claims is merely a recitation of an abstract idea alongside nothing more than well-understood, routine, and conventional elements already engaged in by skilled artisans in the field, we must reverse the Examiner's rejection.

SUMMARY

For the reasons discussed, we reverse the Examiner's rejection of claims 1–10 and 12–19, as being directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more.

REVERSED