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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MAI WANG[1]

Appeal 2017-005768
Application 13/538,736
Technology Center 1600

Before FRANCISCO C. PRATS, JOHN G. NEW, and TAWEN CHANG, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge.*

DECISION ON APPEAL

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[1]Appellants state that the real party-in-interest is the inventor, Mai Wang. App. Br. 1.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–16 as unpatentable under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Claims 1–16 also stand rejected as unpatentable under 35 U.S.C. § 101 as being directed to nonstatutory subject matter.

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

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to a method for organizing and analyzing the distribution and/or ratio of thymine, cytosine, adenine, and guanine of a DNA sequence from a target organism. The result is then used to determine the possible impacts the target organism may have in a host such as a human body. Abstract.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and recites:

> 1. A DNA analysis method, comprising:
>
> accessing a DNA sequence input, the DNA sequence input comprising a plurality of triplets of nucleo[tide] base representation;
>
> converting the DNA sequence input into a reassembled sequence, wherein the reassembled sequence includes three layers: a first layer comprising a first element of each triplet in the DNA sequence input, a second layer comprising a second element of each triplet in the DNA sequence input, and a third layer comprising a third element of each triplet in the DNA sequence input; and

> outputting an output result based on the reassembled sequence.

App. Br. 11.

ISSUES AND ANALYSES

We agree with, and adopt, the Examiner's findings of fact and conclusions that the appealed claims are not enabled and are directed to nonstatutory subject matter. We address the arguments raised by Appellant below.

A. Rejection of the claims under 35 U.S.C. § 101

Issue 1

Appellant argues the Examiner erred because the claims are directed to statutory matter and are patent-eligible. App. Br. 7.

Analysis

The Examiner finds that Appellant's claims 1–16 are directed to an abstract idea, *viz.*, of reassembling a DNA sequence to generate nucleotide base sums as exemplified in the Specification. Final Act. 9–10. The Examiner further finds that claims 7–10 are further directed to a law of nature, *viz.*, relating a reassembled DNA sequence to a physiological effect of a target organism on a host. *Id.* at 10. The Examiner finds claim 11 is also directed to a law of nature relating a reassembled sequence to a treatment of a host. *Id.* The Examiner finds claim 12 is also directed to a law of nature relating a reassembled DNA sequence to a prevention strategy of a host. *Id.*

Appellant argues that claims 1–13 recite a novel DNA analysis method (i.e., a process) comprising six steps. App. Br. 7 (citing Spec., Fig. 7). Appellant contends claims 7–10 recite step 6 of the DNA analysis process of claim 1, further comprising: determining a physiological effect of a target organism on a host organism, the target organism embodying the input DNA sequence, to produce a determination result based on the output from the DNA analysis process, and the Imbalance Factors as illustrated in FIG. 12A, 12B, and 12C, or one or more of the theories listed in claim 8. *Id.* (citing Spec. ¶¶ 50–51, 24, 26, 28–31, Figs. 7, 12A–12C). Appellant asserts claim 11 claims step 6 of the DNA analysis process of claim 1, further comprising producing a treatment strategy based on the output from the DNA analysis process, as illustrated in 710 of Figure 7, and a Reverse Imbalance Method illustrated in Figure 13A–B. *Id.* (citing ¶¶ 36, 52). Appellant argues further that claim 12 claims step 6 of the DNA analysis process of claim 1, further comprising producing a prevention strategy based on the output from the DNA analysis process and a prevention method described. *Id.* at 8 (citing Spec. ¶¶ 37, 52).

Appellant asserts that all results disclosed in Appellant's Specification are based on the output of the DNA analysis process of claim 1 and represent solid data. App. Br. 8. Appellant therefore asserts that claims 1–16 are not directed to an abstract idea and that claims 7–12 are similarly not directed to a law of nature. *Id.*

The Examiner responds that claims 7–12 are directed to a law of nature that correlates a DNA sequence of a target organism to the effect of the target organism on a host, or with the efficacy of a treatment or prevention. Ans. 11. The Examiner finds, contrary to Appellant's argument, that it is insufficient that the claims are within one of the four

categories of invention of 35 U.S.C. § 101 because the Supreme Court has created judicial exceptions to the statute, i.e., of laws of nature, abstract ideas, and natural phenomenon exceptions to patent eligibility.

We are not persuaded by Appellant's arguments. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), the Supreme Court established a two-step framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. The first step of the analysis is to determine whether the claims at issue are directed to one of those patent-ineligible concepts. *Mayo*, 132 S.Ct. at 1296–1297. If we determine that the claims are directed to a patent-ineligible exception to Section 101, the second step of the analysis seeks to determine whether there are additional limitations of the claim that add significantly more than the exception itself. *Id.* at 1297.

Claims 1–16 are all directed to a method of accessing, reorganizing and outputting DNA sequences, *viz.*,

> converting the DNA sequence input into a reassembled sequence, wherein the reassembled sequence includes three layers: a first layer comprising a first element of each triplet in the DNA sequence input, a second layer comprising a second element of each triplet in the DNA sequence input, and a third layer comprising a third element of each triplet in the DNA sequence input.

App. Br. 11 (claim 1). As such, the essential limitations of the claimed method constitutes a reorganization of the nucleotide base sequences into a new order, in some instances reflecting one or more guiding principles. *See, e.g.*, claims 8–10.

Appellant's claims are thus directed to a process, which is a category of patent-eligible subject matter under 35 U.S.C. § 101. However, it is well-

established in our laws that Section 101 contains important implicit exceptions: laws of nature, natural phenomena, and abstract ideas are not patentable. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116 (2013). Recognition of such exceptions have been part of this country's patent law jurisprudence for more than 150 years. *See, e.g.*, *O'Reilly v. Morse*, 15 How. 62, 112–120 (1854); *Le Roy v. Tatham*, 14 How. 156, 174–175 (1853).

The Supreme Court has held that:

> The "abstract ideas" category embodies "the longstanding rule that '[a]n idea of itself is not patentable.'" [*Gottschalk v. Benson*, 409 U.S. 63, 93 (1972)] (quoting *Rubber–Tip Pencil Co. v. Howard*, 20 Wall. 498, 507, (1874)); *see also Le Roy, supra*, at 175 ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right"). In *Benson*, for example, this Court rejected as ineligible patent claims involving an algorithm for converting binary-coded decimal numerals into pure binary form, holding that the claimed patent was "in practical effect … a patent on the algorithm itself." 409 U.S., at 71–72. And in *Parker v. Flook*, 437 U.S. 584, 594–595 (1978), we held that a mathematical formula for computing "alarm limits" in a catalytic conversion process was also a patent-ineligible abstract idea.

Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S.Ct. 2347, 2355 (2014).

Appellant's claim 1 requires accessing a DNA sequence, applying an algorithm to it to rearrange the data based upon certain principles and subsequently outputting the data. We find that, as such, Appellant's claims are directed to a rules-based reorganization of data, i.e., an abstract idea, and we therefore conclude that they are directed to a patent-ineligible exception to Section 101. *Alice*, 134 S.Ct. 2356–57; *Benson,* 409 U.S. at 93; *Parker*, 437 U.S. at 594–95.

Having concluded that the claims are directed to a judicially-created exception to Section 101, we then undertake the second step of the *Mayo* analysis to determine whether it contains an "inventive concept" sufficient to "transform" the claimed abstract idea into a patent-eligible application. 132 S.Ct. at 1294, 1298. 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.* at 1297. Transformation from an abstract idea into a patent-eligible application requires "more than simply stat[ing] the [abstract idea] while adding the words 'apply it.'" *Id.* at 1294.

We conclude that there are no such additional features sufficient to establish more than just the abstract idea itself. Claim 1 simply adds accessing the DNA sequence and outputting the results of the reorganized sequences. Claims 2–6, 9, and 13 further limit the parameters or rules of the manner by which the data is reorganized (claims 2–6), limit the organisms from which the DNA sequence is to be obtained (i.e., human, animal, or plant) (claim 9), or require that the output "includes one of a graph, chart, table, figure, photo, and outline" (claim 13).

Claims 14–16 add "input modules" or "output modules" for accessing the initial DNA sequence and outputting the results of the data reorganization and a processor for performing the data reorganization. Appellant's Specification discloses that such modules and processor can be part of an ordinary or generic computer using software well known in the art. *See, e.g.*, Spec. ¶¶ 57–58. These, too, are insufficient to raise the claims above the judicial-exception barrier. Wholly generic computer implementation is not generally the sort of "additional featur[e]" that provides any "practical assurance that the process is more than a drafting

effort designed to monopolize the [abstract idea] itself." *Alice*, 134 S.Ct. at 2350–51 (quoting *Mayo*, 132 S.Ct. at 1297). Similarly, Appellant's claim 16, which recites: "A tangible non-transitory computer-readable storage medium that stores computer instructions which, when executed by a computer, cause the computer to perform operations comprising the DNA analysis method of Claim 1," is directed to a generic computer storage medium that performs the abstract algorithm function of claim 1 and fails to add a significant inventive concept to the claim to allow it to rise above the judicial exception.

Finally, Appellant points to claims 7–12, which recite various treatment strategies based upon the output of the recited algorithm and certain principles of traditional Chines medicine. We agree with the Examiner that applying the recited principles of treatment to an already existing phenomenon of nature also falls within the judicial exceptions to Section 101. In this respect, the facts of the appeal are similar to those of *Mayo*, in which physicians were required to determine a course of treatment based upon administering a thiopurine drug, determining the results of a previously known assay, and determining a course of treatment. *See Mayo*, 132 S.Ct. at 1295. In this instance, Appellant's claims require determining the relationship between the derived DNA sequences of a certain organism and the nature of the disease or condition caused by the organism (a phenomenon of nature, existing prior to Appellant's discovery) and applying a known principle of treatment to that disease condition. As such, and by the same reasoning set forth by the Supreme Court in *Mayo*, we conclude that these claims also fall within the judicially-created exception to Section 101 barring claims that recite a phenomenon of nature without also adding a

significant inventive concept. We consequently affirm the Examiner's rejection of the claims on this ground.

B. Rejection of the claims under 35 U.S.C. § 112, first paragraph

Issue

Appellant argues the Examiner erred in finding that the claims are not enabled by the disclosures of Appellant's Specification.

Analysis

The Examiner finds that Appellant's claims recite subject matter that was not described in Appellant's Specification in such a way as to enable a person of ordinary skill in the appropriate art to make and/or use the invention. Final Act. 4. In reaching this conclusion, the Examiner applies the analysis set forth by our reviewing court in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1998) to Appellant's claims. *Id.* at 5.

Applying the *Wands* factors, the Examiner finds, specifically, that: (a) there would be an unpredictable amount of experimentation required to use the claimed subject matter, because: (b) Appellant's Specification does not disclose how a starting point for a given polynucleotide sequence is determined, nor does it provide guidance for how to choose a nucleotide sequence from the entire genome of a target organism, which for bacterial target organisms is on the order of 1-5 million nucleotides in length; (c) the DNA sequences analyzed in Figure 8C shows a dengue fever virus sequence, but without suggesting how the initial nucleotide sequence is determined, as explained in (b); (d) the nature of the invention, i.e., determining the effect of a sequence of an organism on a host, is complex; (e) the prior art does not disclose the claimed subject matter and teaches that

there is no rational basis for the contention in the specification that reassembled sequences can be used to discern effects of polynucleotides in different layers of an organism; (f) The skill of those in the art of medicine is high; (g) because the prior art does not show the claimed subject matter and provides no rational basis for using the claimed subject matter, the prior art suggests that the predictability of success in practicing the claimed subject matter is low; and (h) the claims are broad because using the claimed subject matter requires correctly identifying the effect of a target organism on a host by analysis of a reassembled sequence that has no rational relationship to the action of the polynucleotide sequence from which the reassembled sequence was derived. Final Act. 5–9.

Appellant points to paragraph [0044] of the Specification, which discloses: "The starting point of the DNA sequence is predetermined before entering the DNA analysis system." App. Br. 5. Appellant therefore asserts that defining the starting point of the sequence is not part of the invention and the Examiner's statements are therefore irrelevant to the invention. *Id.*

Appellant also contends that the invention is enabled because over 120 pathogen genome sequences provided by NCBI have been analyzed by Appellant using the methods claimed, and the results are allegedly consistent with high accuracy. App. Br. 5–6. Appellant argues that Figure 7 of the Specification provides flow charts of the process, and Figure 5 depicts an illustration of how the input digital genome data are converted to the output (i.e., the "HUE Structure"). *Id.* at 6. According to Appellant, a skilled person in the art, which Appellant defines as someone with basic computer programming training, can make the same system following the steps depicted in Figures 5, 7, 9, and 10. *Id.*

Appellant asserts that, to apply the tool in the medical field, researchers and doctors will read the HUE Charts (i.e., the output generated from the process) and a list of preset rules, such as the information provided in Figures 12A–C and 13A–B, to determine the physiologic impacts on the target organism, and the corresponding treatment and prevention plans. App. Br. 6.

The Examiner responds that the data presented with respect to the NCBI sequences were not persuasive of enablement, because evidence was not provided showing how the choice of preliminary sequence was enabled at the time of filing.[2] Ans. 10. The Examiner finds that, contrary to Appellant's arguments, the basis of the Examiner's rejection is not that the tables cannot be generated given a starting sequence, but rather that the combination of the prior art and the specification does not enable the critical choice of what initial sequence to analyze and further does not enable useful results. *Id.* at 10–11.

We are not persuaded by Appellant's arguments. Paragraph [0044] recites, in relevant part:

> Flowchart 700 of FIG. 7 illustrates a method, to be performed by, for example, a DNA analysis system, configured according to an embodiment of the invention. At 702, a DNA sequence input is received at, for example, an input module. This input may include a digital sequence with nucleobase representations, such as a "ready-made" DNA sequence in GENBANK or FAST A format. Alternatively, actual DNA may be obtained by, for example, extraction from the target organism, after which a DNA sequence is produced by a sequencer. *The*

[2] The Examiner further observes that the NCBI sequences cited by Appellant, and their analyses, are not of record in the prosecution of this application. Ans. 10 (citing Appendix to Appl. Ser. No. 12/391,866).

> *starting point of the DNA sequence is predetermined before entering the DNA analysis system*

(emphasis added). Although the Specification discloses that the "starting point of the DNA sequence is predetermined," Appellant's Specification does not specify how such a predetermination is made or by which rules or procedures it may be determined, nor does it disclose examples of prior art teaching how such a predetermination may be made.

Furthermore, the claims recite simply "a DNA sequence," without further limitation, and the Specification discloses no clear guidance as to how such a sequence may be selected. Given the fact that a reading frame difference of a single nucleotide in a given DNA sequence would provide significantly different results when Appellant's method is applied, the lack of guidance as to how a person of ordinary skill would choose an initial sequence of DNA at which to begin the method recited in Appellant's claims renders the claims non-enabled. The conclusory statement in the Specification that the "starting point of the DNA sequence is predetermined before entering the DNA analysis system" is, absent further clarification in the Specification or in the prior art, in itself insufficient to show that a person of ordinary skill in the art would understand how to use Appellant's invention. We consequently agree with the Examiner's conclusion that the claims are not enabled, and we affirm the rejection of the claims on this ground.

DECISION

The Examiner's rejection of claims 1–16 as unpatentable under 35 U.S.C. § 101 is affirmed.

The Examiner's rejection of claims 1–16 as unpatentable under 35 U.S.C. § 112, first paragraph, for lack of enablement is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

AFFIRMED