UNITED STATES PATENT AND TRADEMARK OFFICE

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte BHUBANESWAR MISHRA and GIUSEPPE NARZISI

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Appeal 2019-004726[1]
Application 13/139,809
Technology Center 1600

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Before ULRIKE W. JENKS, RACHEL H. TOWNSEND, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[2] appeals from the
Examiner's decision to reject claims as directed to patent ineligible subject
matter. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] A telephonic hearing was held on April 9, 2020. *See* Transcript 1.
[2] Appellant identifies New York University of New York, New York as the
real party in interest. Appeal Br. 2. We use the word "Appellant" to refer to
"applicant" as defined in 37 C.F.R. § 1.42(a).

STATEMENT OF THE CASE

According to the Specification, advances in genomic sciences have now made it possible to "generate a massive amount of short reads covering a whole genome many times." Spec. ¶ 9. These "massively large number of such non-contextual short-reads can only lend themselves to biological interpretations and biomedical applications when they can be assembled into contiguous overlapping sequences encompassing the information contained in each haplotype chromosome." *Id.* ¶ 15. It is the combination of optical mapping procedures, that use long-range information in the form of single molecule based ordered restriction maps, in conjunction with non-contextual short sequence reads, that allows for the assembly of "a genome wide personalized haplotype sequence." *Id.* ¶ 69.

Claims 74–136 are on appeal, and can be found in the Claims Appendix of the Appeal Brief. Claim 95 below is representative of the claims on appeal, and reads as follows:

> 95.   A method for assembling at least one part of at least one of at least one haplotype sequence or at least one genotype sequence of at least one genome, comprising:
>   (a) obtaining (i) a plurality of randomly located short sequence reads, and (ii) overlap information about overlaps between the randomly located short sequence reads;
>   (b) obtaining long range information for the randomly located short sequence reads, wherein the long range information includes optical map data and mate-pair data;
>   (c) automatically randomly selecting a first read from the randomly located short sequence reads;
>   (d) automatically identifying one or more overlapping second reads of the randomly located short sequence reads that overlap with the first read;

(e) automatically generating one or more scores
regarding the one or more overlapping second reads using the
overlap information and the long range information;
(f) selecting a particular read of the one or more second
overlapping reads based on the one or more scores;
(g) automatically generating a path through the plurality
of randomly located short sequence reads by repeating
procedures (e) and (f); and
(h) using a computer hardware arrangement,
automatically assembling the at least one part of the at least one
of the at least one haplotype sequence or the at least one
genotype sequence of the genome based on the path.

Appeal Br., Claims Appendix A6–A7.

Appellant requests review of Examiner's rejection of claims 74–136

under 35 U.S.C. § 101, as being directed to patent ineligible subject matter.

ANALYSIS

Examiner finds that the claims are directed to nothing more than an

abstract idea, and that the claim as a whole, considering all the claim

elements both individually and in combination, do not amount to

significantly more than the abstract idea. Ans. 3. Examiner identifies steps

(e) and (g) of the independent claims, claims 74, 95, and 116, as reciting a

mathematical concept or algorithm. Ans. 3. Examiner finds that the

additional steps in the claims are directed to analyzing and organizing

information. Ans. 3–4. Examiner finds that "[t]he claims do not describe any

specific computational steps by which the computer performs or carries out

the abstract idea, nor do they provide any details of how specific structures

of the computer are used to implement these functions." Ans. 4.

> When the claims are considered as a whole, they do not
> integrate the abstract idea into a practical application; they do
> not confine the use of the abstract idea to a particular

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> technology; they do not solve a problem rooted in or arising
> from the use of a particular technology; they do not improve a
> technology by allowing the technology to perform a function
> that it previously was not capable of performing; and they do
> not provide any limitations beyond generally linking the use of
> the abstract idea to a broad technological environment (i.e.
> computerized analysis of nucleic acid sequence data).

Ans. 6–7. Examiner finds that "[t]he step of 'generating one or more scores for the one or more reads using the overlap information and the long-rang[e] information' is a mathematical operation." Ans. 8.

Appellant contends that the claims are not directed to an abstract idea because "none of the claims recite, much less are directed to, a mathematical operation. Indeed, there is no mathematical operation recited in any of the claims of the present application." Appeal Br. 22. Appellant contends "the claimed solution of the present application is rooted in computer technology by solving the problem of genetic sequencing." *Id.* at 23. Appellant contends that the "sheer complexity of generating a haplotype or genotype sequence (e.g., based on overlapping sequence reads, scoring reads, and generating a path through the reads), []would make it impossible to be performed mentally by human." *Id.* at 24–25 (emphasis omitted). Appellant contends that the claims present an improvement "over the art due to the decreased computational space and time that result from the use of the claimed subject matter." *Id.* at 23 (citing Spec. ¶ 75).

The Supreme Court has 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." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014). The United States Patent and Trademark Office (PTO) issued the *2019*

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Revised Patent Subject Matter Eligibility Guidance ("*Guidance*"), indicating how the PTO can analyze patent eligibility under the Supreme Court's two-step framework, and the October 2019 Update to the Revised 2019 Guidance ("*Update,*" or "2019 Update Guidance, 84 Fed. Reg."), which provides further details regarding how the PTO is to analyze patent-eligibility questions under 35 U.S.C. § 101. *See* 84 Fed. Reg. 50−57; *see also* 2019 Update Guidance, 84 Fed. Reg. 55,942. Following the *Guidance*, under Revised Step 2A, we first look to whether the claim recites the following:

(1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human activity such as a fundamental economic practice, or mental processes); and

(2) additional elements that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)-(c), (e)-(h)).

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look, under Step 2B of the *Guidance*, to whether the claim:

(3) adds specific limitations beyond the judicial exception that are not "well-understood, routine, conventional" in the field (*see* MPEP § 2106.05(d)); or

(4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

See Guidance, 84 Fed. Reg.

Appellant does not argue the claims separately. We select claim 95 as representative.

STEP 1:

We first find that claim 95 is directed to "[a] method for assembling at least one part of at least one of at least one haplotype sequence or at least one genotype sequence of at least one genome." We therefore conclude that the claim is directed to a "process" for carrying out a sequence assembly and thus falls into one of the broad categories of patentable subject matter under section 101. *See* 35 U.S.C. § 100 (In "(b) [t]he term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.").

STEP 2A, Prong One:

Under the *Guidance,* in determining what concept a claim is "directed to" in step one of the Supreme Court's two-step framework, we first look to whether the claim recites any judicial exceptions to section 101, such as an abstract idea, a law of nature, or a natural phenomenon. *See Guidance*, 84 Fed. Reg. 52, 54 (Step 2A, Prong One).

In *Mayo*, the Supreme Court found "mental processes and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

Claim 95 is directed to a method of assembling a gene sequence from a collection of obtained short sequence reads. *See* Appeal Br., Claims App. A6–A7 (Claim 95 contains step "(a) obtaining (i) a plurality of randomly located short sequence reads, and (ii) overlap information about overlaps between the randomly located short sequence reads."). Claim 95 contains additional steps (b)–(h) beyond (a) obtaining the short read sequence

collection, with the end result of these steps producing a long sequence read based on the collection of short sequence comparisons. The creation of the long sequence read in claim 95 is accomplished by stitching together numerous short sequences based on their overlapping nucleotide sequence information, which just involves a comparison between two nucleic acid sequences to assess the overlap and therefore represents an abstract idea. Comparison between two gene sequences represents a mental process, i.e., an abstract idea. *See In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755, 762 (2014). We discern no distinction between comparing full-length gene sequences made up of a string of nucleic acids or short nucleic acid segments also made up of a string of nucleic acids.

We are not persuaded by Appellant's contention that that the sheer complexity of generating a sequence based on the numerous short sequence reads needed to create a long sequence is so complex that it would make it impossible to be performed mentally by a human. Appeal Br. 24–25; *see also* Reply Br. 10; and Transcript 17:11–20. The claims embrace assembling a gene sequence of any size, including small viral genomes, which could contain a small number (e.g., 100–200) of short sequence reads. Transcript 21:2–7. Moreover, just because the number of short sequences could involve a large number of short sequence reads does not mean that given enough time one of ordinary skill in the art would not be able to generate the

sequence using pencil and paper.[3] Accordingly, we are not persuaded by Appellant's contention that the claim is not drawn to an abstract idea.

We are also not persuaded by Appellant's contention that the claims do not include a mathematical formula and thereby do not embrace an abstract idea. *See* Appeal Br. 22 ("[T]here is no mathematical operation recited in any of the claims of the present application."). Just because the claim does not contain a mathematical formula in the form of equations does not mean that an algorithm is not required to achieve the step of creating a score, i.e. creating more data. We look to the Specification to determine what is encompassed by "generating one or more scores regarding the one or more overlapping second reads." We understand this step to be what is described in the Specification as the score function. *See, e.g.*, Spec. ¶¶ 16, 72, 73,102–112. The Specification provides an exemplary score function as follows:

> If (Overlap(A,B) && Overlap(B,C)) {Score(A, B, C) =[Score(A,B) + Score(B,C)]+ [Overlap(A,C)? Score(A,C): O]}

Spec. ¶ 103.

A score-function according to the Specification "can be used to guide the manner in which the short-sequence reads are arranged and further combined into haplotype sequence information (either in its entirety or in parts in terms of contigs)." *Id.* ¶ 79. Based on these disclosures in the Specification, we agree with Examiner that "[t]he step of 'generating one or more scores for the one or more reads using the overlap information and the

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[3] *See CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1372–73 (Fed. Cir. 2011) (Holding that a claim whose "steps can be performed in the human mind, or by a human using a pen and paper" is directed to an "unpatentable mental process[].").

long-range information' is a mathematical operation." Ans. 8; *see also*
Transcript 23:3–21.

We, therefore, agree with Examiner that the claim recites an abstract
idea because in addition to the underlying algorithm needed to create scores
that are used for the assembly of the gene sequence, the assembly of a gene
sequence (the final step of the process) itself is a process that can be
achieved in the human mind with the help of pencil and paper, but for the
recitation of "using a computer hardware arrangement." *Versata Dev. Grp.,
Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1335 (Fed. Cir. 2015) ("Courts have
examined claims that required the use of a computer and still found that the
underlying, patent-ineligible invention could be performed via pen and paper
or in a person's mind."); *see also* Guidance 84 Fed. Reg. at 52 n.14 ("If a
claim, under its broadest reasonable interpretation, covers performance in
the mind but for the recitation of generic computer components, then it is
still in the mental processes category unless the claim cannot practically be
performed in the mind."). Accordingly, we determine that the claim recites
an abstract idea.

STEP 2A, Prong Two:

Having made the determination that claim 95 recites an abstract idea,
under the *Guidance*, we next examine whether there are additional elements
beyond the abstract idea that integrate the judicial exception into a practical
application. Under the *Guidance*, this is referred to as the "Prong Two"
inquiry under "Step 2A." *Guidance*, 84 Fed. Reg. 54–55. Under the Prong
Two analysis, we look to whether the claim as a whole "appl[ies], rel[ies]
on, or use[s] the judicial exception in a manner that imposes a meaningful
limit on the judicial exception." *Id.*

Appellant contends that "the claimed solution of the present application is rooted in computer technology by solving the problem of genetic sequencing." Appeal Br. 23 (citing Spec. ¶¶ 4–31). We are not persuaded because claim 95 uses a computer only for its most basic functions to perform repetitive calculations to form alignments in order to implement the abstract idea of determining scores in order to string together multiple short sequences to arrive at a full-length gene sequence. We agree with Examiner that, contrary to Appellant's assertion, the problem is not rooted in computer technology but instead is rooted in the problem of meaningfully organizing collected information in genetic sequencing. *See* Ans. 10.

Appellant contends that the claim integrates the judicial exception into a practical application. *See* Appeal Br. 25–26. We are not persuaded.

In making a determination under Step 2A, Prong Two we look to see if the claims recite additional elements such as improvements to computer functioning or another technological field, applying the judicial exception by use of particular machine, transformational reduction of a particular article to different state or thing, or using the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment. *See* MPEP 2106.05 (9th ed., rev. 08.2017 (Jan. 2018)); *Guidance,* 84 Fed. Reg. 54–55.

Examiner finds that "[t]here is no practical element [integration] in either the assembly or the sequence." Ans. 12. We agree with Examiner that the judicial exceptions are not linked to the process of obtaining the short sequence reads. *See* Spec. ¶ 9; *see also* Ans. 6 (citing multiple references), *id.* at 14. The judicial exceptions are also not integrated into the data

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gathering of the optical map data or mate-pair data as these function the same way regardless of the additional algorithm. *See* Transcript 27:6–8 ("the fact that you performed these additional specific algorithm steps doesn't affect the way that the optical map is obtained in the first place."), 25:24– 26:4; *see* Ans. 13 ("computerizing a sequence assembly algorithm as claimed was a practice that was well-understood, routine and conventional in the art prior to the time of invention."); *see also* Spec. ¶¶ 9, 23. We also agree with Examiner that the claim does not integrate the judicial exception into a particular computer or processing system. *See* Ans. 13 ("[T]he Specification expressly states that the invention was implemented using a 'typical personal computer[,]' which indicates that computerizing a sequence assembly algorithm as claimed was a practice that was well-understood, routine and conventional in the art prior to the time of invention."); *see also* Spec. ¶ 126.

Furthermore, the steps of obtaining (a and b), selecting (c), and identifying (d) are data gathering steps that themselves do not apply the abstract score function step, and while the selection step (f) is based on applying the score function, neither that step nor the generating step (g) applies the abstract assembling step, they are simply more data gathering for the abstract idea that is the assembly of the sequence step based on the collected and organized data. *See e.g.*, MPEP § 2106.05(g); *see also CyberSource*, 654 F.3d at 1370 ("We have held that mere '[data-gathering] step[s] cannot make an otherwise nonstatutory claim statutory.'" (alterations in original)). Thus, even if one abstract idea can be considered to be integrated because it is applied in further steps to create the assembled sequence, the assembling step is not integrated into a practical application.

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Because the judicial exception is not integrated into a practical application, we conclude that claim 95 is directed to an abstract idea.

STEP 2B:

Step 2B requires that we look to whether the claim "adds a specific limitation beyond the judicial exception that [is] not 'well-understood, routine, conventional' in the field." *See* MPEP § 2106.05(d).

Appellant contends that "the improvement in the claims of the present application is system/method/computer-accessible medium that can quickly and accurately assemble a haplotype or genotype sequence, and reduces time and complexity as compared to previous systems." Appeal. Br. 28 (citing *Thales Visionix, Inc. v. US*, 850 F. 3d 1343 (Fed. Cir. 2017)).

Here, the claimed method takes in two streams of information, the overlap information from step (a) and the optical map data and mate-pair data from step (b), and based on these two input streams the claim then determines a score in step (e), based on this score the method prunes the overlap reads in step (f), and by using the combination of the score and pruned overlap reads the method generates a path in step (g) from which to ultimately assemble the gene sequence in step (h). *See generally* Specification; *see also* Transcript 24:9–13, 27:25–28:3. Thus, the claimed process incorporates the algorithms to generate scores that improve the accuracy of assembling short nucleic acids sequences into a long contiguous string of nucleic acids. *See* Spec. ¶¶ 75, 115, 123 (Scoring-and-Unfolding Trimmed Tree Assembler (SUTTA) "outperforms the assemblies from both TIGR and Arachne in terms of, e.g., assembly quality."), 125 and Figs. 3−11; *see also* Transcript 19:19–20:2.

As the *Guidance* indicates, unconventional data gathering in combination with a specifically recited application can render a claim patent eligible under section 101 despite the fact that the judicial exception is not considered to be integrated into a practical application. *Id.* at 56 and n.39 (citing *Exergen Corp. v. Kaz USA, Inc.*, 725 F. App'x 959, 966 (Fed. Cir. 2018).). Here, claim 95 recites the collection of data in the form of short sequence reads, created using standard protocols, as well as gathering more data in the form of optical map data and mate-pair data, both of which are also known protocols, and applying mathematical equations in order to combine these two data streams to arrive at a full-length gene sequence. *See* Spec. ¶¶ 9, 10. Although each data gathering steps is conventional, what is unconventional is using both data streams at the same time to feed into the scoring step (e) and pruning step (f) in order to achieve higher accuracy in the long continuous sequence. When the process steps of the claim are considered as an ordered combination, we find that the scoring step adds an inventive concept and thus amounts to significantly more than the judicial exception.

Thus, we reverse the Examiner's rejection of claims 74–136 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
74–136	101	Eligibility		74–136

REVERSED