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 ZHENG ZHANG, DANWEI GUO, YUANDAN LOU,
ASIM SIDDIQUI, and DUMITRU BRINZA[1]

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Appeal 2016-007615
Application 13/097,677
Technology Center 1600

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Before FRANCISCO C. PRATS, RYAN H. FLAX, and
DEVON ZASTROW NEWMAN *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving
claims directed to a system and method for mapping a nucleic acid sequence
read to a reference sequence. Claims 1, 2, 5–15, 19–22, and 26–33 are on
appeal as rejected under 35 U.S.C. § 101. We have jurisdiction under 35
U.S.C. § 6(b).

We affirm.

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STATEMENT OF THE CASE

The Specification states:

in reference genome mapping, sequence reads are assembled against an existing backbone sequence (e.g., reference sequence, etc.) to build a sequence that is similar but not necessarily identical to the backbone sequence.

Once a backbone sequence is found for an organism, comparative sequencing or resequencing can be used to characterize the genetic diversity within the organism's species or between closely related species.

Spec. ¶¶ 5–6. The Specification further states, "[s]ystems, methods, software and computer-usable media for reconstructing larger continuous biomolecule-related sequences (e.g., contigs, exomes, genomes, etc.) from smaller biomolecule-related sequence reads are disclosed." *Id.* ¶ 7.

Claims 1, 15, and 22 are the independent claims. Claim 1 is representative and is reproduced below:

1. A system for mapping a nucleic acid sequence read to a reference sequence, comprising:

a first data store configured to store nucleic acid sequencing data;

a second data store configured to store reference sequence data; and

a computing device in communication with the first data store and the second data store, wherein the computing device is configured to:

obtain the nucleic acid sequence read from the first data store,

obtain a reference sequence from the second data store,

iteratively select differing lengths of a contiguous portion of the nucleic acid sequence read, wherein each iteratively

selected contiguous portion begins at a same location on the nucleic acid sequence read,

map the iteratively selected contiguous portion of the nucleic acid sequence read to the reference sequence using an approximate string mapping method that allows for a set number of mismatches with the reference sequence and produces at least one match with the reference sequence, wherein the iterative selection and mapping of the iteratively selected contiguous portion is performed until a number of matches of the iteratively selected contiguous portion to the reference sequence is less than a certain threshold number, and

map a remaining portion of the nucleic acid sequence read to the reference sequence using an ungapped local alignment method that produces an alignment of the remaining portion extending from the at least one match to map the nucleic acid sequence read to the reference sequence.

App. Br. 22–23 (Claims App'x.).

The following rejection is appealed:

Claims 1, 2, 5–15, 19–22, 26–28, and 30–33 are rejected under 35 U.S.C. § 101 as directed to patent-ineligible subject matter. Final Action 3.

DISCUSSION

Unless otherwise indicated herein, we adopt the Examiner's findings of fact, reasoning on scope and content of the claims and prior art, and conclusions set out in the Final Action and Answer. Only those arguments made by Appellants in the Appeal Brief and properly presented in the Reply Brief have been considered in this Decision. Arguments not so presented in the Briefs are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015); *see also Ex parte Borden*, 2010 WL 191083 at *2 (BPAI 2010) (informative) ("Any

bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived.").

"[T]he examiner bears the initial burden, on review of the prior art *or on any other ground*, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (emphasis added); *see also Hyatt v. Dudas*, 492 F.3d 1365, 1369–71 (Fed. Cir. 2007) (once the examiner presents a prima facie case for unpatentability, here under § 112, the burden is properly shifted to applicant).

"Phenomena of nature, though just discovered, 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)). Claims directed to *nothing more* than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible for patent protection. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); accord MPEP § 2106 (II) (discussing *Diehr*).

In analyzing patent-eligibility questions under 35 U.S.C. § 101, the Supreme Court instructs us to "first determine whether the claims at issue are directed to a patent-ineligible concept." *Alice Corp. Pty Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014). If the initial threshold is met, we then move to a second step and "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the

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additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 566 U.S. at 97).

The Examiner determined:

> The process of claims 15 and 19-21 is directed to a judicial exception of aligning query nucleotide sequences that are iteratively selected from differing lengths of a contiguous portion of a nucleic acid sequence that begin at a same location on the nucleic acid sequence data using approximate string mapping followed by ungapped local alignment, and scoring alignments by a mathematical algorithm, which is similar to the abstract idea of comparing information regarding a sample or test subject to a control or target data at issue in Univ. of Utah research Found. v. Ambry Genetics Corp., 774 F.3d 755, 113 USPQ2d 1241 (Fed. Cir. 2014)).

Answer 2–3 (referring to *In re BRCA1– and BRCA2–Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755 (Fed. Cir. 2014)). Having determined under *Alice* step one that the claims are directed to the above-identified abstract idea, the Examiner moved to *Alice* step two and determined that "[t]he additional element in independent claims 1, 15, and 22 is stored sequence data that is retrieved by a computer," and identified that the Lancaster and Shendure references taught that using a computer for such sequencing is conventional. Answer 3–4.

The Federal Circuit has "recognize[d] that defining the precise abstract idea of patent claims in many cases is far from a 'straightforward' exercise. *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1150 (Fed. Cir. 2016) (quoting *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1257 (Fed. Cir. 2014)). In *In re BRCA1*, the Federal Circuit held that a claimed method for screening a germline of a human subject for an alteration of the BRCA1 gene by comparing a sample BRCA1 gene

sequence with a reference, wild-type germline sequence of BRCA1 gene was directed to an abstract idea — a "mental process of 'comparing' and 'analyzing' two gene sequences." *In re BRCA1*, 774 F.3d at 763–64 ("allowing a patent on the comparison step could impede a great swath of research relating to the BRCA genes, and it is antithetical to the patent laws to allow these basic building blocks of scientific research to be monopolized."). Because, in identifying the abstract idea to which the claims are directed, the Examiner compares the appealed claims to those found patent-ineligible in *In re BRCA1*, we conclude the Examiner determined that the claims are directed to the abstract idea of manipulating data (akin to a mental process), that data being in the form of genetic/nucleotide information, and also to making comparisons of the data using a mathematical algorithm. Here, as a part of this abstract idea of manipulating and comparing data, the Examiner further found that the claims were directed to the concept of iteratively selecting different lengths of a contiguous portion of nucleic acid sequence beginning at the same location on the nucleic acid sequence. Answer 2–3.

"[W]e continue to 'treat[ ] analyzing information by steps people [could] go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category.'" *Synopsys*, 839 F.3d at 1146–47 (quoting *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016) (citations omitted); *see also Electric Power Group*, 830 F.3d at 1353 ("collecting information, analyzing it, and displaying certain results of the collection and analysis" "fall[s] into a familiar class of claims 'directed to' a patent-ineligible

concept," that of the abstract idea). The Federal Circuit has recognized that "a claim for a *new* abstract idea is still an abstract idea." *Synopsys*, 839 F.3d at 1151.

Having found the claims to be directed to an abstract idea, the Examiner proceeded to determine under *Alice* step two that, "[t]he claims have additional elements that constitute conventional steps appended to the judicial exception. The additional element in independent claims 1, 15, and 22 is stored sequence data that is retrieved by a computer." Answer 3. Claim elements to which the Examiner necessarily referred, briefly summarized, include, e.g., "a first data store . . . ," "a second data store . . . ," "a computing device . . . configured to: . . . iteratively select . . . [and] map . . . ." *See* App. Br. 22 (Claim App'x). The Examiner pointed to the Lancaster[2] and Shendure[3] references as support that using a computer programmed to perform nucleic acid sequence mapping was known, routine, and conventional. Answer 3–4. For example, Lancaster discloses using computers and software tools, e.g., BLAST, for comparing query sequence data to genomic data of a biosequence database using "word matching" with "w-mers," "ungapped extension," and "gapped extension" steps, including a "threshold comparator" for deciding whether to keep or discard a w-mer. *See, e.g.*, Lancaster 281–86. Moreover, Lancaster, particularly at the pages cited, is predominantly a review article, which details the customary and

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[2] Joseph Lancaster et al., *Acceleration of ungapped extension in Mercury BLAST*, 33 MICROPROCESSORS AND MICROSYSTEMS 281–89 (2009) ("Lancaster").
[3] Jay Shendure & Hanlee Ji, *Next-generation DNA sequencing*, 26 NAT. BIOTECH. 1135–45 (2008) ("Shendure").

well-known techniques, e.g., BLAST, for examining DNA sequence data. The Examiner determined that "[t]he additional [claim] elements do not comprise an inventive concept that transforms the claimed judicial exception into a patent-eligible application of the judicial exception." Answer 4.

We conclude the Examiner's determinations are reasonable and discern no error therein. Here, the determined abstract idea to which the claims are directed is data manipulation (that data being in the form of genetic/nucleotide information) and making routine computer-aided comparisons of that data using a mathematical algorithm. Simply adjusting the way that that data is manipulated and using a computer system programmed to do so, something that is evidenced to be routine and customary, does not transform the abstract idea into a patent-eligible invention.

Appellants argue the Examiner's rejection only generally states that the claims include merely routine and conventional elements beyond the abstract idea and that this lack of specificity (i.e., failure to do an element-by-element analysis) warrants reversal of the rejection. App. Br. 10–11. Further to this point, Appellants argue that the Examiner stated "that Lancaster and Li fail to disclose at least 'iteratively selecting differing lengths of a contiguous portion of the nucleic acid sequence read,' wherein each iteratively selected contiguous portion begins at a same location on the nucleic acid sequence read,' as recited in claim 1," but concluded that it amounted to conventional steps. *Id.* at 11 (citing Final Action 11). Appellants argue the Examiner's rejection lacks factual support (where Lancaster and Li fall short) that claim elements were well-understood,

routine, and conventional. App. Br. 12; *see also* Reply Br. 11–12 (similarly discussing Lancaster and Shendure).

Because of the way the Examiner has reasonably identified and framed the abstract idea to which the claims are directed, we are not persuaded by these arguments. The Examiner pointed to Lancaster and Li in the Final Action and then to Lancaster and Shendure in the Answer as factually evidencing that using computer systems programmed to map genetic sequences was routine and conventional. *See* Final Action 5 and Answer 3–4. Our review of these references, as discussed above, shows that the Examiner's determination was not erroneous. Where, as here, the claims are directed to the abstract idea of manipulating and comparing (even genetic) data, doing so with a programmed computer using mathematical algorithms is not patent eligible.

Appellants argue they have "provided an explanation as to why the pending claims recite an improvement to the technological process of nucleic acid sequencing and an improvement to the functioning of a computer." App. Br. 16. Appellants assert that the claims are directed to "an improvement to an existing technological process," i.e., nucleic acid sequencing, because, as the Specification explains, "[a]n iterative application (multi-anchor mapping) of approximate string mapping to different anchor regions of a sequence read can prevent SNPs and repetitive regions of the reference sequence from seriously affecting the performance of the anchor-extension mapping method." App. Br. 17 (citing Spec. ¶ 87).

Again, because of the way the Examiner has reasonably identified and framed the abstract idea to which the claims are directed, we are not

persuaded by these arguments. Here, the argued-improvement is to the abstract idea itself (i.e., iteratively manipulating data), rather than to an existing technological process. There is no evidence that a computer is improved by the claimed invention. Differently manipulating data is still manipulating data, which is not patent-eligible.

We find the facts here to be analogous to those of *Intellectual Ventures I LLC v. Capital One Financial Corporation*, 850 F.3d 1332 (2017), where the claims were held to be directed to a computer programmed to edit XML documents, which the Federal Circuit "conclude[ed] [were] . . . at their core, directed to the abstract idea of collecting, displaying, and manipulating data." *Id.* at 1339–40. Even though the patent at issue in *Intellectual Ventures I* indicated its invention provided a concrete solution to a particular problem in computer programming, it "at best, . . . limits the invention to a technological environment for which to apply the underlying abstract concept," which does "not render an otherwise abstract concept any less abstract." *Id.* at 1340 (citing *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1259 (Fed. Cir. 2016)). Under step two of the *Alice* analysis, the *Intellectual Ventures I* court held that claims reciting generic computer components or elements and identifying their functions, e.g., organizing, mapping, identifying, defining, detecting, and modifying, "merely describe the functions of the abstract idea itself" and are not sufficient to supply significantly more than the abstract idea so as to confer patent-eligibility. *Id.* at 1341. This is analogous to the facts here because the appealed claims are directed to the abstract idea of manipulating data, even if in an arguably distinct way, and using generic computer

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components and elements in their customary ways. Therefore, the result

here must be the same as the result in *Intellectual Ventures I*.

In their Reply Brief, Appellants argue:

> Similar to *Enf[ish]* and *Rapid Litigation Management*, the improvement to nucleic acid sequencing recited in the pending claims renders them patent eligible. In particular, Appellant's Specification discusses the advantage to exemplary embodiments of the claimed mapping technique. "An iterative application (multi-anchor mapping) of approximate string mapping to different anchor regions of a sequence read can prevent SNPs and repetitive regions of the reference sequence from seriously affecting the performance of the anchor-extension mapping method." Specification at ¶ [0087]. Accordingly, the iterative selection recited in claims 1, 15, and 22 provide an **improvement to the technological process** of nucleic acid sequencing at least because the claimed system can achieve greater efficiencies with less error.

Reply Br. 6 (discussing *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed.

Cir. 2016) and *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827

F.3d 1042 (Fed. Cir. 2016)). Appellants further cite *Bascom Global Internet

Services, Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016) in

support of their contention that their "claims recite subject matter that is not

routine or conventional in the field of nucleic acid sequencing and subject

matter that improves an existing technological process." *See* Reply Br. 8.

The inventions claimed in *Enfish* and *CellzDirect* and *Bascom* are

distinguishable from the appealed claims. The claims here are unlike the

claims in *Enfish*, where the Federal Circuit relied on the distinction made in

Alice between computer functionality improvements and uses of existing

computers as tools in aid of processes focused on "abstract ideas." *See

Enfish*, 822 F.3d at 1335–36; *see also Alice*, 134 S.Ct. at 2358–59. Such a

distinction has common-sense force even if it presents challenges in application due to the programmable nature of ordinary existing computers.

In *Enfish*, the Federal Circuit applied this distinction to reject a patent-eligibility challenge because the claims there were not focused on advances in uses to which existing computer capabilities could be put, but were focused instead on a specific improvement—a particular database technique—in how computers could basically function in storing and retrieving data. *Enfish*, 822 F.3d at 1335–36; *see also Bascom*, 827 F.3d at 1348–49. In *Bascom*, the Federal Circuit (construing the facts in favor of *Bascom*), found that the invention was directed to the abstract idea of "filtering content," but recognized that software inventions could be patent eligible as could improvement to database systems, as in *Enfish*, and urged "an analysis of whether there are arguably concrete improvements in the recited computer technology," ultimately concluding that, when taken individually the recited generic computer network and components were not inventive, but when considered as a whole, including the locating of the filter system, the claims did not merely recite the abstract idea and generic computer components. *Bascom*, 827 F.3d at 1349–50. In *CellzDirect*, the Federal Circuit found that the claims were not directed to the natural phenomenon that hepatocytes could survive being frozen multiple times, but to a way to make a cell preparation using such knowledge. *CellzDirect* 827 F.3d at 1048.

The present case is different: the focus of the claims is not on an improvement in computers as tools or upon an innovative way to use computers or their elements, or on taking advantage of a natural

phenomenon to achieve an improved lab technique, but is focused on an independently abstract idea that uses computers as tools; that abstract idea being the manipulation and comparison of stored (genetic) data. As noted above, data manipulation has long been held to be an abstract idea. Here the arguably innovative technique of the appealed claims is inextricably a part of the abstract idea of manipulating data itself. Moreover, the invention on appeal does not relate to a new or improved way of collecting a genetic sequence sample or data or to new or improved computer hardware or functioning. Nothing in the claims, understood in light of the Specification, requires anything other than off-the-shelf, conventional computer, network, and display technology for gathering, sending, comparing, and presenting information about genetic sequences.

For the reasons set forth above, we are compelled to affirm the rejection.

SUMMARY

The rejection of the claims as directed to patent-ineligible subject matter is affirmed.

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