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EXAMINER
AEDER, SEAN E

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte THOMAS SCHOLL, BRANT C. HENDRICKSON, BENJAMIN WARD, and DMITRY PRUSS

Appeal 2015-006269
Application 11/830,625[1]
Technology Center 1600

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and ERICA A. FRANKLIN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal under 35 U.S.C. § 134(a) involves claims 51–63 (Final Act.[2] 2). Examiner entered a rejection under 35 U.S.C. § 101. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify the Real Party in Interest as Myriad Genetics, Inc. (*See* App. Br. 3.)

[2] Examiner's July 17, 2014 Final Office Action.

STATEMENT OF THE CASE[3]

Appellants' disclosure "relates to human genetics, particularly to the identification of genetic polymorphic variations in the human [breast cancer susceptibility gene 1 (BRCA1)] gene" (Spec. ¶ 3; *see id.* ¶ 4). Appellants disclose that

> a method is provided for genotyping BRCA1 to determine whether an individual has a genetic variant or an amino acid variant identified in the present invention. The presence of the variants would indicate a predisposition to cancers including breast cancer and ovarian cancer. In accordance with this aspect of the invention, a sample containing genomic DNA, mRNA, or cDNA of the BRCA1 gene is obtained from the individual to be tested. The genomic DNA, mRNA, or cDNA of the BRCA1 gene in the sample should include at least the nucleotide sequence surrounding the locus of one or more of the above-described genetic variants such that the presence or absence of a particular genetic variant can be determined. Any suitable method known in the art for genotyping can be used for

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[3] This Appeal is related to Appeal 2011-000678 (Application 11/830,625), Decision entered March 29, 2011 reversing the obviousness rejection of record; Appeal 2011-000691 (Application 11/830,604), Decision entered March 23, 2011 reversing the obviousness rejections of record; Appeal 2012-003997 (Application 11/830,625), Decision entered December 18, 2013 reversing the anticipation rejection of record; Appeal 2012-004077 (Application 11/830,604), Decision entered December 18, 2013 reversing the anticipation rejection of record, expressly abandoned on March 2, 2015. We also recognize Appellants' statement that

> U.S. [P]atent [N]o. 7,250,497 (application serial no. 10/457,839) was involved in In Re: BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation[, 775 F.3d 755 (Fed. Cir. 2014)] . . . and [] the '497 patent was also the subject of a pending petition for inter partes review (Case [N]o. IPR2014-01315, petition filed August 18, 2014) [and] . . . has been dismissed.

(Reply Br. 2).

> determining the nucleotide(s) at a particular position in the BRCA1 gene.

(*Id.* ¶ 11.)

Appellants' only independent claim, claim 51, is representative and reproduced below:[4]

> 51. A method for detecting a mutation in a *BRCA1* allele comprising:
>
> analyzing a nucleic acid from a sample obtained from a human subject; and
>
> detecting a mutation in a *BRCA1* allele resulting in a *BRCA1* mRNA encoding a polypeptide comprising SEQ ID No. 92.

(App. Br. 12).

Claims 51–63 stand rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter.

ISSUE

Does the evidence of record support Examiner's finding that Appellants' claimed invention is directed to non-statutory subject matter?

ANALYSIS

Examiner finds that Appellants' claimed method is directed to non-statutory subject matter (Ans. 2–3). We agree.

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[4] Claims 52–63 depend directly or indirectly from Appellants' cancelled claim 49 (*see id.* at 12–13; *see also id.* at 4 (Appellants recognize that certain claims on Appeal depend from claim 49.)).

"Laws of nature, natural phenomena, and abstract ideas are not patentable." *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (citation omitted). The Supreme Court articulated a two-step test for patent eligibility under § 101 that "distinguish[es] 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*, 134 S. Ct. 2347, 2355 (2014) (citing *Mayo*, 132 S. Ct. at 1296–97). "First," *Alice* instructs a court to "determine whether the claims at issue are directed to one of those patent-ineligible concepts. *Id.* (citation and quotations omitted). If the claims are directed to a patent-ineligible concept then the court must proceed to the second step of the test – the "search for an inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Id.* (quotations and alterations omitted).

Turning to the first step of the *Alice*'s test, we find that the method of Appellants' claim 51 comprises: (1) analyzing a nucleic acid sample by "[a]ny suitable method known in the art for genotyping" and (2) detecting a mutation in a *BRCA1* allele that results in *BRCA1* mRNA encoding a polypeptide comprising SEQ ID No. 92 (*see* App. Br. 12; Spec. ¶ 11 (Any suitable method known in the art for genotyping can be used for determining the nucleotide(s) at a particular position in the BRCA1 gene)). Stated differently, Appellants' claimed method is directed to the "abstract mental process of 'comparing' and 'analyzing'" a nucleic acid sequence. *See In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755, 763 (Fed. Cir. 2014) (citation omitted). More specifically, the

steps of Appellants' claimed method are "directed to the patent-ineligible abstract idea of comparing BRCA sequences and determining the existence of alterations" using any known method in the art and the detection, or "identification of alterations of the gene, requir[ing] merely comparing the patient's gene with the wild-type and identifying any differences that arise." *Id.*; *see also* Spec. ¶ 11 (Any suitable method known in the art for genotyping can be used for determining the nucleotide(s) at a particular position in the BRCA1 gene).

We recognize that Appellants' claimed method specifically requires the detection of a *BRACA1* mRNA that encodes a specific polypeptide, a polypeptide comprising SEQ ID No. 92 (*see* App. Br. 12).[5] We find, however, that this requirement of Appellants' claimed method simply limits the genus of naturally occurring mutations that may be detected by the use of well-understood, routine, convention techniques to a naturally occurring mutation that results in a *BRCA1* mRNA encoding a polypeptide comprising SEQ ID No. 92. Even if, a mutation in *BRCA1* mRNA that results in the production of polypeptide comprising SEQ ID No. 92 was "a newly discovered fact about human biology . . . [it] involves no creation or alteration of DNA sequences," and its detection, as claimed by Appellants, "does not purport to identify novel detection techniques." *See Genetic*

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[5] Appellants disclose that the polypeptide comprising SEQ ID No. 92 "correspond[s] to codon sequences in mutant mRNAs created by the direct splicing of exon 13 to exon 21 – mutant mRNAs that are transcribed from mutant alleles of the BRCA1 gene bearing [such a mutation] – and [] contain[s] certain amino acid residues encoded by codons representing both exons" (Spec. ¶ 72).

Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369, 1376 (Fed. Cir. 2016). As Examiner explains:

> While the natural existence of nucleic acids comprising a particular BRCA1 mutation resulting in BRCA1 mRNA encoding a polypeptide comprising SEQ ID NO:92 has not been described in the prior art, the recited active steps of the claims encompass known, routine and conventional methods to detect just any BRCA1 mutation comprising sequencing full-length BRCA1 nucleic acids. The rejected claims are only differentiated from routine, conventional, and well-known methods by recitation of a result that a particular mutation naturally exists and disclosure that the presence of said mutation naturally indicates an increased predisposition to cancer.

(Ans. 3; *see also id.* at 3–4; *cf.* App. Br. 7; Reply Br. 3.) Thus, when Appellants' claim 51 is considered as a whole, we find that it is directed to the use of an abstract mental process to detect natural phenomena and is, therefore, directed to a patent-ineligible concept.

Turning to the second step of *Alice*'s test, the "search for an inventive concept," as discussed above, we find that although Appellants' claimed invention may involve the use of a newly identified natural phenomena, i.e., a BRCA1 mRNA that encodes a polypeptide having SEQ ID No. 92, Appellants' claimed method otherwise uses well-understood, routine, conventional activity to perform the analysis required by Appellants' claimed method. "[A] claim directed to a newly discovered law of nature . . . cannot rely on the novelty of that discovery for the inventive concept necessary for patent eligibility; instead, the application must provide something inventive, beyond mere well-understood, routine, conventional activity." *Genetic Techs.*, 818 F.3d at 1376. Thus, the well-understood, routine, convention techniques admittedly involved in Appellants' analysis

does not provide the requisite inventive concept required to render Appellants' claimed method patent eligible. *See id.* at 1376–1377; *see also* Ans. 5 ("Such limitations are not meaningful limitations and are not enough to qualify the claimed method as reciting something 'significantly more' than the judicial exception(s)").

Therefore, when Appellants' claimed method is considered as a whole, we find no error in Examiner's finding that Appellants' claimed method "is directed to judicial exception(s) (i.e., a law of nature, a natural phenomenon, and/or an abstract idea) without significantly more" (Ans. 2).

Subject matter eligibility under 35 U.S.C. § 101 was not before this Board in Appellants' prior Appeals; therefore, we are not persuaded by Appellants' contentions regarding their prior Appeals (*see* App. Br. 6–8). For the same reason and emphasizing the different statutory ground of rejection currently before this Panel, as opposed to the grounds of rejection in Appellants' prior Appeals, we are not persuaded by Appellants' contention that their "claims are eligible for patenting in this [A]ppeal under the same reasoning as they were novel and non-obvious in the previous two appeals" (App. Br. 7–8 (footnote omitted)).

For the reasons set forth above, we are not persuaded by Appellants' contention that

> [i]t is still true under § 102 that nothing in the art taught actual detection of the recited BRCA1 mutation. It is also true under § 101 that detecting such a mutation (not simply looking for it) was not routine and conventional in the art at the time of Appellants' filing.

(App. Br. 8.)

For the reasons set forth above, we are not persuaded by Appellants' contention that "claims to a natural principle itself are ineligible while

[Appellants'] claims to a [] method of detecting that principle are eligible" (App. Br. 8; *see also id.* at 9). Here, as in *Mayo*, Appellants' claims "literally . . . just take a process that was well-understood, routine and convention and add '**statements** . . .' to 'inform a relevant audience about certain laws of nature," e.g., the presence of a naturally occurring BRCA1 mutation in an individuals' nucleic acid sample (*see* App. Br. 9; *see id.* (Mayo's "'wherein' clauses . . . are statements that merely describe (or inform an audience about) a pre-existing but newly 'discovered' fact about the process rather than any new or even modified step or element of the process" and, thus, "they are not truly a part of the process and do no 'meaningfully limit' the claim (of even limit it at all)"); *see* Reply Br. 6–7).

For the foregoing reasons, we are not persuaded by Appellants' contention that "[u]nlike in Mayo, . . . [n]o one had ever analyzed a patient specimen and then detected a mutation in a *BRCA1* allele resulting in a *BRCA1* mRNA encoding a polypeptide comprising SEQ ID No. 92," thus, Appellants' method steps are not "routine and conventional at the time of Applicants' filing because they had never been practiced" (App. Br. 10; *see also id.* at 10–13; Reply Br. 3–6).

CONCLUSION OF LAW

The evidence of record supports Examiner's finding that Appellants' claimed invention is directed to non-statutory subject matter.

The rejection of claim 51 under 35 U.S.C. § 101, as directed to non-statutory subject matter is affirmed. Claims 52–63 are not separately argued and fall with claim 51.

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