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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte ORHAN SOYKAN, TARA NAHEY, and JEFFREY LANDE[1]

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Appeal 2019-004078
Application 14/698,812
Technology Center 1600

_____

Before ERIC B. GRIMES, JOHN E. SCHNEIDER, and DAVID COTTA, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a diagnostic kit, which have been rejected as being directed to patent-ineligible subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

The Specification describes a study intended "to determine whether any of seven single nucleotide polymorphisms (SNP) in three genes coding

[1] Appellant identifies the Real Party in Interest as Medtronic plc. Appeal Br. 3.

for G-protein subunits were predictive of ventricular tachyarrhythmias (VT) in patients with implantable cardioverter defibrillators (ICD) without a prior history of VT." Spec. ¶ 138. "Two SNPs in the GNAS gene, C393T and C2273T, were significant univariate predictors of VT incidence." *Id*. ¶ 154. The Specification's SEQ ID NOs 1 and 2 correspond to the loci of the C393T and C2273T SNPs, respectively. *Id*. ¶ 13.

Claims 1–6, 8–12, and 21 are on appeal. Claim 1 is representative and reads as follows:

1. A diagnostic kit, comprising:

a processor; and

at least one probe for assessing the presence of one or more Single Nucleotide Polymorphisms (SNPs) associated with any one of Sudden Cardiac Arrest (SCA), Sudden Cardiac Death (SCD), Ventricular Arrhythmia (VA), or Heart Failure (HF) in a genetic sample,

wherein the SNP is contained in any one of the nucleotide sequences of SEQ ID NO.'s 1–2; and

wherein the assessment by the probe determines whether to apply treatment to SCA, SCD, VA or HF, the treatment comprising at least one of a combination CRT pacemaker having defibrillation technology (CRT-D), an Implantable Cardioverter Defibrillator (ICD), pharmacological therapy, and biological therapy; and

wherein the processor is programmed to determine whether to implant the CRT-D or ICD to treat the SCA, SCD, VA or HF based on the assessment, and

wherein the at least one probe is affixed to a substrate;

the diagnostic kit for determining an increased risk of Ventricular tachycardia (VT) and ventricular fibrillation (VF) with the treatment based on the presence of the one or more SNPs comprising at least one of a TT genotype in SEQ ID NO. 1 and a TT genotype in SEQ ID NO. 2.

The claims stand rejected as follows:

Claims 1–6, 8–12, and 21 under 35 U.S.C. § 112(b) as indefinite (Ans. 6) and

Claims 1–6, 8–12, and 21 under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter (Ans. 3).

I

The Examiner has rejected claims 1–6, 8–12, and 21 as indefinite, on the basis that claim 1 "recites run on sentences and phrases that do not make clear how the limitations structurally limit the kit being claimed. For example, it is not clear how the last phrase after . . . 'affixed to a substrate' structurally limits the claim." Ans. 7.

Appellant argues that,

> [a]s described in the Specification, patients with a TT genotype in either SEQ ID NO. 1 or SEQ ID. NO. 2 are at an increased risk of VT or VF. *See* Specification at paragraph [0164]. The diagnostic kit, by determining the presence of the recited genotypes in a patient, can be used to determine the increased risk of VT or VF, and whether or not to apply the recited treatments. *Id.*

Appeal Br. 13.

We conclude that the Examiner has not shown that the scope of the claims would have been unclear to those of ordinary skill in the art. The claim language that the Examiner points to reads: "the diagnostic kit for determining an increased risk of Ventricular tachycardia (VT) and ventricular fibrillation (VF) with the treatment based on the presence of the one or more SNPs comprising at least one of a TT genotype in SEQ ID NO. 1 and a TT genotype in SEQ ID NO. 2." Claim 1.

This limitation specifies that the "probe for assessing the presence of one or more Single Nucleotide Polymorphisms (SNPs)," previously recited in the claim, detects the presence of a TT genotype in SEQ ID NO. 1 or a TT genotype in SEQ ID NO. 2, or both. Thus, the disputed limitation structurally limits the probe that is part of the claimed kit, and does not make the claim indefinite. The rejection under 35 U.S.C. § 112(b) is reversed.

II

The Examiner has rejected claims 1–6, 8–12, and 21 under 35 U.S.C. § 101. The Examiner finds that "[t]he claims are directed to multiple judicial exceptions. With regard to the processor, the claim describes the abstract idea of making a treatment determination." Ans. 4. The Examiner notes that the claims include the additional elements of "a 'diagnostic' kit, as well as nucleic acid probes," but "packaging processors and probes in kit format was well understood, routine, and conventional in the field as was the use of probes, including those affixed to substrates, for genetic analysis. The polymorphisms in the claims are not new, and genetic tests already existed prior to the effective filing date." *Id*. at 5.

The Examiner concludes that these "additional elements alone, and in combination, do not add significantly more to the abstract idea since they do not structurally or functionally change the processor and are directed to routine and conventional activity." *Id*. The Examiner also concludes that "[t]he additional recitation of 'wherein the at least one probe . . . for determining an increased risk of . . . VT . . . with the treatment based on the presence of the one or more SNPs', is itself merely describing a natural

correlation between the alleles of the SNP, increased risk of VT and VF, and treatment outcome which is also a judicial exception." *Id*. at 6.

Appellant argues that "Claim 1 recites a processor that makes a treatment decision . . . [which is] the application of human actions to treat a patient, which is in no way a law of nature." Appeal Br. 11. Appellant also argues that "[p]rior to the invention, it was neither routine nor conventional to make any treatment decisions based on the TT genotypes for a patient." *Id*. at 8–9. Finally, Appellant argues that "Claim 1 is confined to a specific embodiment of a diagnostic kit, and does not seek to preempt any other use of the correlation between the recited genotypes and an increased risk of VT or VF." *Id*. at 11.

An invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. However, the Supreme Court has concluded that "[l]aws of nature, natural phenomena, and abstract ideas" are not patentable under 35 U.S.C. § 101. *See, e.g.*, *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014).

To determine if a claim falls into an excluded category, we apply a two-step framework, described in *Mayo* and *Alice*. *Id.* at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). We first determine what the claim is "directed to." *See Alice*, 573 U.S. at 219 ("On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement risk."); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) ("Claims 1 and 4 in petitioners' application explain the basic concept of hedging.").

Patent-ineligible abstract ideas include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611), mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)), and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 69 (1972)). In contrast, patent-eligible inventions include physical and chemical processes, such as "molding rubber products" (*Diamond v. Diehr*, 450 U.S. 175, 192 (1981)); "tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores" (*id.* at 182 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1854))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claimed method employed a mathematical formula, but the Supreme Court held that "[a] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula." *Diehr*, 450 U.S. at 176; *see also id.* at 191 ("We view respondents' claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula."). The Supreme Court noted, however, that a claim "seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment." *Id.* (citing *Benson* and *Flook*); *see, e.g.*, *id.* at 187 ("It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.").

If the claim is "directed to" an abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, and "examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Alice*, 573 U.S. at 221 (quotation marks omitted). "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.* (quoting *Mayo*, 566 U.S. at 77 (alterations in original)). "[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention." *Id.*

The PTO recently published revised guidance on the application of § 101. *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (January 7, 2019) ("Revised Guidance"). Under that guidance, we first determine whether the claim recites:

> (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)).

See 84 Fed. Reg. at 54–55. Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then determine whether the claim:

> (3) adds a specific limitation beyond the judicial exception that is not a "well-understood, routine, conventional activity" 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 84 Fed. Reg. at 56.

Revised Guidance Step 2(A), Prong 1

Following the Revised Guidance, we first consider whether the claims recite a judicial exception. Claim 1 recites, among other elements, "the processor is programmed to determine whether to implant the CRT-D or ICD to treat the SCA, SCD, VA or HF based on the assessment"; i.e., "the assessment by the probe [that] determines whether to apply treatment." We agree with the Examiner that this claim language "describes the abstract idea of making a treatment determination." Ans. 4. This determination can be performed mentally, for example by a person observing whether a probe specific to a TT genotype in SEQ ID NO: 1 or SEQ ID NO: 2 hybridizes to DNA in a genetic sample.

In addition, we agree with the Examiner that claim 1 "describ[es] a natural correlation between the alleles of the SNP, increased risk of VT and VF, and treatment outcome which is also a judicial exception." Ans. 6. The Specification states that "[t]he two SNPs were associated with an increased risk of VT." Spec. ¶ 183. The Specification also states that "[t]he GNAS SNPs described herein (e.g., SEQ ID No.'s 1 and 2) can affect the expression level of the GNAS protein, which in turn can affect the efficacy

of cardiac resynchronization therapy (CRT), generally. . . . [T]he SNPs described herein may be predictors of the efficacy of CRT and/or ICD therapy." *Id*. ¶ 158.

In *Mayo*, the Court held that "Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." 566 U.S. at 77. Similarly here, the recitation in claim 1 of "determining an increased risk of Ventricular tachycardia (VT) and ventricular fibrillation (VF) with the treatment based on the presence of the one or more SNPs comprising at least one of a TT genotype in SEQ ID NO. 1 and a TT genotype in SEQ ID NO. 2" sets forth a law of nature—the natural correlation between the recited SNPs and an increased risk of VT or VF.

In summary, we agree with the Examiner that claim 1 recites an abstract idea—the mental step of "determin[ing] whether to implant the CRT-D or ICD to treat the SCA, SCD, VA or HF based on [a probe's] assessment"—as well as a law of nature—the correlation between a TT genotype in SEQ ID NO: 1 or SEQ ID NO: 2 and an increased likelihood of ventricular arrhythmia. *See* 84 Fed. Reg. at 52.

Revised Guidance Step 2(A), Prong 2

Although claim 1 recites an abstract idea, it would still be patent-eligible if "the claim as a whole integrates the recited judicial exception into a practical application of the exception"; i.e., if the claim "appl[ies], rel[ies] on, or use[s] the judicial exception in a manner that imposes a meaningful limit on the judicial exception." 84 Fed. Reg. at 54. The analysis of

determining whether the claim integrates the judicial exception into a practical application includes "[i]dentifying whether there are any additional elements recited in the claim beyond the judicial exception(s)" and "evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application." *Id.* at 54–55.

The "examples in which a judicial exception has not been integrated into a practical application" include "[a]n additional element . . . [that] merely includes instructions to implement an abstract idea on a computer, or merely uses a computer as a tool to perform an abstract idea" and "an additional element [that] adds insignificant extra-solution activity," such as mere data-gathering, to the judicial exception. *Id.* at 55.

Here, claim 1 does not integrate the recited abstract idea and law of nature into a practical application, because the claimed kit consists of only two components: a processor and a probe affixed to a substrate. The claim itself does not specify any hardware or software configuration that is required for the processor to carry out the recited function. Consistent with claim language, the Specification broadly defines the term "processor," Spec. ¶ 89, and does not provide any more specific description of a processor as recited in claim 1. "[T]he mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention." *Alice*, 573 U.S. at 223.

Claim 1 also does not require any specific structure for the immobilized probe recited in the claims. Rather, the claims require only a "probe for assessing the presence of one or more Single Nucleotide

Polymorphisms (SNPs)," "wherein the SNP is contained in any one of the nucleotide sequences of SEQ ID NO.'s 1–2," and "the one or more SNPs compris[e] at least one of a TT genotype in SEQ ID NO. 1 and a TT genotype in SEQ ID NO. 2."

That is, claim 1 simply requires any probe that determines the presence or absence of one of the SNPs that correlates with an increased risk of VT or VF. The probe is therefore required in order to carry out the data-gathering needed to apply the natural law recited in the claim: the natural correlation between the recited SNPs and an increased risk of VT or VF.

The upshot is that the probe recited in claim 1 simply allows the kit to be used to gather data from which to draw an inference in light of the correlation between the SNPs and the risk of VT or VF. *Cf. Mayo*, 566 U.S. at 79 ("The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations.").

In summary, claim 1 recites an abstract idea and a law of nature and does not integrate them into a practical application. It is therefore directed to a judicial exception to patentability.

Revised Guidance Step 2(B)

Finally, the Revised Guidance directs us to consider whether claim 1 includes "additional elements . . . [that] provide[] 'significantly more' than the recited judicial exception." 84 Fed. Reg. at 56. The Revised Guidance states that an additional element that "simply appends well-understood, routine, conventional activities previously known in the industry, specified at a high level of generality, to the judicial exception, . . . is indicative that an inventive concept may not be present." *Id*.

Here, the only elements recited in claim 1, other than the abstract idea and law of nature themselves, are a generic processor and a probe. As discussed above, claim 1 does not recite, and the Specification does not describe, any unconventional hardware or software as being needed for the processor to carry out the recited function, and "the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention." *Alice*, 573 U.S. at 223.

With regard to the immobilized probe, the Specification provides evidence that using immobilized probes to determine the presence of a specific nucleic acid sequence in a sample is conventional in the art. For example, the Specification states that

> [n]umerous forms of diagnostic kits employing arrays of nucleotides are known in the art. They can be fabricated by any number of known methods. . . . The DNA microarrays generally have probes that are supported by a substrate so that a target sample is bound or hybridized with the probes. . . . The hybridized targets and probes can also be detected by voltage, current, or electronic means known in the art.

Spec. ¶ 118. The Specification also states that "[v]arious techniques can be employed for affixing an oligonucleotide for use in a microarray. In situ synthesis of oligonucleotide or polynucleotide probes on a substrate is performed in accordance with well-known chemical processes." *Id*. ¶ 120. "Immobilization of probes or oligonucleotides on a substrate or surface may be accomplished by well-known techniques." *Id*. ¶ 121.

The Specification does not disclose any unconventional aspects of the "probe . . . affixed to a substrate" that is recited in claim 1. The only thing about the recited probe that is specific to the claimed invention is that it is designed to indicate the presence of a SNP comprising a TT genotype in

SEQ ID NO: 1 or SEQ ID NO: 2. That aspect of the recited probe, however, merely requires that it be capable of determining the natural correlation to which the claim is directed.

Therefore, claim 1 requires only a generic processor and an immobilized probe, both of which are used in a routine and conventional way to carry out the data-gathering needed to determine the natural correlation to which the claimed kit is directed. The combination of elements recited in the method of claim 1 does not amount to significantly more than the judicial exception itself, and under 35 U.S.C. § 101 the claimed kit is ineligible for patenting.

Appellant's Arguments

Appellant argues that

> Claim 1 recites a processor that makes a treatment decision based on the genotype of a patient. The treatment decision is not the correlation between the SNPs and an increased risk of VT or VF, the alleged law of nature. Instead the treatment decision is the application of human actions to treat a patient, which is in no way a law of nature.

Appeal Br. 11.

This argument is unpersuasive. Claim 1 is directed to a kit, not a method of treating a patient. The claimed kit supplies information to a clinician, who then decides what, if any, action to take with respect to a patient. The information supplied by the claimed kit is whether implantation of a CRT-D or ICD is indicated because the kit's probe detects the presence of a SNP comprising a TT genotype in SEQ ID NO: 1 or SEQ ID NO: 2, and therefore the patient is at an increased risk of ventricular tachycardia or ventricular fibrillation. Thus, the claimed kit does no more than supply

information regarding the natural correlation between a SNP and the risk of VT/VF.

Appellant also argues that "[p]rior to the invention, it was neither routine nor conventional to make any treatment decisions based on the TT genotypes for a patient or to determine an increased risk of VT or VF based on the TT genotypes recited." Appeal Br. 8–9. Appellant argues that, "[g]iven that no examples in the prior art have been cited showing that a processor making a treatment determination based on homozygosity for the T alleles in the recited sequences . . . , the Examiner has failed to show that the limitations of Claim 1 are 'routine, well-understood, or conventional.'" *Id*. at 9, citing *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018).

This argument is unpersuasive. The relevant question is not whether the natural correlation, to which the claim is directed, was routine or conventional—i.e., known—at the time the invention was made. The question is whether the claim includes *additional* elements that are not well-understood, routine, and conventional, and that transform the claim into a patent-eligible application of the natural correlation. *See Alice*, 573 U.S. at 217 (If "the claims at issue are directed to one of th[e] patent-ineligible concepts . . . we consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application.").

Here, while it is true that "whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact," *Berkheimer*, 881 F.3d at 1368, Appellant's Specification itself provides sufficient evidence (as discussed

above) to support a finding that both the processor and immobilized probe recited in claim 1 were routine and conventional in the art as of the instant application's filing date.

Finally, Appellant argues that "Claim 1 does not seek to tie up any method of detecting an increased risk of VT or VF. . . . Claim 1 is confined to a specific embodiment of a diagnostic kit, and does not seek to preempt any other use of the correlation between the recited genotypes and an increased risk of VT or VF." Appeal Br. 11.

This argument is also unpersuasive. "While preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F3d 1371, 1379 (Fed. Cir. 2015). Where "claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, . . . preemption concerns are fully addressed and made moot." *Id.* Here, for the reasons discussed above, we conclude that the claims on appeal are directed only to patent-ineligible subject matter under the *Mayo* framework. Preemption concerns in this case are fully addressed by that conclusion.

Claims 2–6, 8–12, and 21 were not argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
1–6, 8–12, 21	§ 112(b)		1–6, 8–12, 21
1–6, 8–12, 21	§ 101	1–6, 8–12, 21	
Overall Outcome		1–6, 8–12, 21	

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