District of Minnesota Holds that Mayo, Myriad, and Alice Apply to Dog-Eat-Dog World of Canine Genetic Testing

Legal Update
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On March 31 in *Genetic Veterinary Sciences, Inc., d/b/a Paw Print Genetics v. Canine EIC Genetics, LLC*, No. 14-CV-1598 (JRT/JJK), Judge John R. Tunheim addressed the question of whether veterinarians can obtain patents for identifying genetic markers of canine disease. Not surprisingly, the court held that the Supreme Court's recent decisions regarding unpatentable subject matter (*Mayo Collaborative Servs. v. Prometheus Labs*; *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*; and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*) apply equally to all forms of medicine, even if the patient is a dog. Because the patent claims simply identified a natural law, Judge Tunheim found them invalid.

Canine EIC Genetics obtained U.S. Patent No. 8,178,297 – titled "Method of Detecting Canine Exercise-Induced Collapse" – in May 2012. As the name would suggest, Canine Exercise-Induced Collapse (EIC) is a condition that causes some dogs to collapse as a result of strenuous exercise. Shortly after obtaining its patent, Canine EIC Genetics filed two infringement suits against rival genetic testing companies in the District of Minnesota (Nos. 12-CV-1667 (DWF/AJB) and 12-CV-1668 (DWF/AJB)). Both of those cases settled within a few months of filing. Presumably feeling like the big dog in the market, Canine EIC Genetics then tried to sink its licensing teeth into Paw Print Genetics, apparently demanding a 50% royalty. Rather than running away with its tail between its legs, Paw Print Genetics stood its ground and filed a declaratory judgment action in the Eastern District of Washington. Canine EIC Genetics fought jurisdiction in Washington, and the case was transferred to its home state of Minnesota.

The Asserted Patent Claims (or How to Guarantee You Will Lose a *Mayo/Alice* Challenge)

Canine EIC Genetics' patent has a total of eight claims, all of which boil down to a veterinarian recognizing that the genetic marker for Canine EIC is "a G to T nucleotide mutation at position 767 of the DNM1 gene." For example, claim 1 is a method with only two steps:

1. A method for determining whether a dog has or is predisposed to develop Exercise Induced Collapse (EIC) comprising:

a) detecting in a nucleic acid sample the allele in the dynamin 1 gene at position 767 of SEQ ID NO: 1, and

b) identifying that the dog has or is predisposed to the development of EIC when the dog is homozygous for the T767 allele.

In other words, a veterinarian would infringe the claim by (a) detecting the mutation and (b) knowing why she had tested for that mutation. Claim 8, the only other independent claim, has two more steps: "transporting a biological sample from a dog … to a diagnostic laboratory" and "providing results regarding whether the dog has the EIC associated allele." (The claim does not specify whether the testing results are being provided by the laboratory to the vet, or by the vet to the poor animal's owner, but presumably someone wants the results of the test they paid for.) Other dependent claims added references to well-known genetic detection techniques that Canine EIC did not invent (e.g., amplification, hybridization, size analysis, sequencing, etc.).

Mayo and *Alice*'s Two-Step Analysis for Identifying Unpatentable Subject Matter Under 35 U.S.C. § 101

Before putting Canine EIC Genetics' patent claims out of their misery, Judge Tunheim summarized the Supreme Court's two-step process for identifying unpatentable subject matter under 35 U.S.C. § 101, which was originally set forth in the *Mayo* decision and further developed in *Myriad* and *Alice*. As Judge Tunheim explained,

In *Mayo*, the Supreme Court established a two-step process for distinguishing between those cases that fall within, and those that lie outside, the list of exceptions [to patentable subject matter. *Alice*, 134 S. Ct.] at 2355. **The first step** is to determine "whether the claims at issue are directed to one of those patent-ineligible concepts" (i.e., law of nature, natural phenomena, abstract idea). *Id.* In answering that question, courts look to the elements of each claim both individually and in "'an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 132 S. Ct. at 1297-98). Assuming that the claims are directed at a patent-ineligible concept, *Mayo* **step two** is "a 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.* (internal quotation marks omitted).

(Boldface, parentheticals, and second bracketed phrase by the Court; first bracketed phrase added.)

Applying the first step of the *Mayo* test, Judge Tunheim "conclude[d] that the '297 Patent is directed at a patent-ineligible natural law [because e]ach of the patent's claims serves the overarching purpose of 'determining whether a dog has or is susceptible to developing' EIC." Moving on to the second step of the *Mayo* analysis, the Court painstakingly reviewed each of the limitations added by the dependent claims and found that "[o]utside of the natural law relationship between the T767 allele and EIC, the techniques or methods identified in the claims, whether viewed individually or in the aggregate, were at the time the patent was issued 'well understood, routine, and conventional techniques that a scientist would have thought of when instructed to' test whether a certain allele exists at a specific genetic location." Judge Tunheim accordingly concluded that the claims were invalid under *Mayo* and its progeny because "[s]imply detecting a patent-ineligible concept – in this case a natural law – and then identifying the law once it is detected, is not enough to render the subject matter patentable."

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