UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

GENETIC VETERINARY SCIENCES, INC., *doing business as* PAW PRINT GENETICS,	Civil No. 14-1598 (JRT/JJK)
Plaintiff,	**MEMORANDUM OPINION AND ORDER GRANTING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT**
v.	
CANINE EIC GENETICS, LLC,	
Defendant.	

Mark P. Walters, **LOWE GRAHAM JONES**, 701 Fifth Avenue, Suite 4800, Seattle WA 98104; and Jonathan D. Jay, **HELLMUTH & JOHNSON PLLC**, 8050 West 78th Street, Edina, MN 55439 for plaintiff.

Frank S. Farrell, Jr. and Alexander Farrell, **F S FARRELL, LLC**, 7401 Metro Boulevard, Suite 425, Edina, MN 55439, for defendant.

Canine Exercise-Induced Collapse causes dogs to lose control of their legs after strenuous exercise. Defendant Canine EIC Genetics ("Canine EIC") discovered a genetic mutation in dogs that is tied to EIC. Canine EIC subsequently secured a patent ("the '297 Patent") that identifies this mutation and lists eight claims, all of which describe slightly different methods for detecting whether a dog has the mutation and therefore has EIC. Plaintiff Genetic Veterinary Science, doing business as Paw Print Genetics ("PPG"), also tests dogs for EIC.

Anticipating patent litigation, PPG filed this action, accusing Canine EIC of telling its customers that PPG was violating Canine EIC's patent; and claiming that the

‘297 Patent is invalid because it protects a patent-ineligible natural law. PPG then filed a motion for partial summary judgment, seeking a declaratory judgment as to the invalidity of the ‘297 Patent. Because the ‘297 Patent is directed at a natural law and because it does not introduce any additional inventive concept beyond well-understood, routine, and conventional methods for determining whether the EIC mutation exists in a dog, the Court will find that the patent is invalid and will grant PPG’s motion for partial summary judgment.

BACKGROUND

I. THE PARTIES AND THE ‘297 PATENT

This case involves Canine Exercise-Induced Collapse (“EIC”), “a genetic syndrome” that causes dogs – especially Labrador Retrievers – “to lose coordination,” develop “a wobbly gait,” and eventually lose “control of the[ir] hind legs.” (First Am. Compl. ¶ 9, Jan. 17, 2014, Docket No. 9.) Dogs who suffer from EIC usually experience these effects “five to fifteen minutes after initiation of strenuous exercise.” (*Id.*) An EIC “collapse period” usually lasts five to ten minutes and the dog generally recovers fully within thirty minutes. (*Id.*)

Canine EIC is based in St. Paul, Minnesota. (Decl. of Dr. Edward Earl Patterson in Supp. of Def.’s Resp. to Pl.’s Mot. for Partial Summ. J. (“Patterson Decl.”) ¶ 2, Sept. 29, 2014, Docket No. 50.) Canine EIC co-founder Dr. Edward Earl Patterson, along with Drs. James R. Mickelson and Susan Taylor, and Katie Minor, RN, developed a genetic test to detect EIC in dogs. (*Id.* ¶ 5.) They were issued a United States patent

for that development, Patent No. 8,178,297, titled "Method of Detecting Canine Exercise-Induced Collapse." (*Id.*; Decl. of Mark P. Walters in Supp. of Mot. for Partial Summ. J. ("First Walters Decl."), Ex. A. ('297 Patent ("'297 Patent")), Aug. 29, 2014, Docket No. 44.) The '297 Patent is dated May 15, 2012. ('297 Patent.)

PPG is a Washington state company, founded in 2012 in Spokane by Dr. Lisa Shaffer. (First Am. Compl. ¶ 12.) PPG has developed numerous tests for canine genetic disorders, including for EIC. (*Id.* ¶¶ 13-14.) The company has been conducting tests for EIC since August 2013. (*Id.* ¶ 18.)

According to PPG, Canine EIC has filed two lawsuits to enforce the '297 patent, both in the District of Minnesota. (*Id.* ¶ 28.) In both cases, Canine EIC "characterized the infringing services as 'DNA testing services to detect whether a dog has or is predisposed to developing Canine [EIC].'" (*Id.* ¶ 29.) In June 2013, principals from both PPG and Canine EIC met, and Canine EIC officials offered to license PPG's EIC testing under its patent, in exchange for a 50% royalty. (*Id.* ¶¶ 31-32.) PPG did not accept the offer and consequently concluded it was under a genuine threat of being sued by Canine EIC for patent infringement. (*Id.* ¶ 33.) Indeed, PPG alleges that Canine EIC has been informing PPG customers that PPG is not legally authorized to conduct DNA testing for canine EIC. (*Id.* ¶¶ 35-37.) This litigation soon followed.

II. THE '297 PATENT

The '297 Patent essentially covers assays, or tests, for determining whether a dog has, or might develop, EIC. ('297 Patent, col. 1, l. 55-60.) This sort of genetic testing

ascertains whether the dog has mutations – also called, at least at a broad level of generality, "alleles" or "polymorphisms" – "that either cause a disease state or[, at a minimum,] are 'linked' to the mutation causing a disease state." (*Id.* col. 6, l. 60-65.)

"Genes form the basis for hereditary traits in living organisms." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* (*Myriad*), 133 S. Ct. 2107, 2111 (2013). Genes are "encoded as DNA [deoxyribonucleic acid], which takes the shape of the familiar 'double helix' . . . first described in 1953." *Id.* "Each 'cross-bar' in the DNA helix consists of two chemically joined nucleotides. The possible nucleotides are adenine (A), thymine (T), cytosine (C), and guanine (G), each of which binds naturally with another nucleotide." *Id.*

Polymorphism, a term used throughout the '297 Patent, refers "to the coexistence of more than one form of gene or portion (e.g., allelic variant) thereof. A portion of a gene of which there are at least two forms, i.e., two different nucleotide sequences, is referred to as a 'polymorphic region of a gene.'" ('297 Patent, col. 12, l. 11-15.) A polymorphic region can be a single nucleotide or several nucleotides long. (*Id.* col. 12, 1. 11-19.)

The term "allele" refers to a specific genetic sequence at a polymorphic region of a gene. (*Id.*) Alleles can have different sequence variants at different polymorphic regions. (*Id.* col. 10, l. 33-35.) When multiple alleles co-exist at a genetic locus, it is called "genetic polymorphism." (*Id.* col. 10, l. 42-44.)

In developing the invention underlying the '297 Patent, Dr. Patterson and his colleagues first searched for the genetic source of canine EIC in order to, at a minimum,

discover an allele that correlates with EIC to allow genetic testing. (*Id.* col. 8, l. 10-32.) In other words, whether or not they could discover the definitive cause of EIC, they wanted to discover a biomarker for the disease that could be identified in dogs in order to determine whether dogs have, or are susceptible to, EIC. They discovered a locus for the EIC gene on canine chromosome 9, and further discovered four positional candidate genes in that region – dynamin 1 or DNM1, PTGES2, AK1, and SLC2A8. (*Id.*) While the latter three were ruled out, "a G to T nucleotide mutation at position 767 of the DNM1 gene was identified." (*Id.*) This led to the conclusion that "EIC is . . . caused by a point mutation at nucleic acid 767" of the DNM1 gene on canine chromosome 9.[1] (*Id.* col. 26, l. 42-44; *see also id.* col. 8, l. 13.) Dr. Patterson refers to this mutation as the **T allele** of the dynamin 1 gene at location 767. (Patterson Decl. ¶ 6.) A dog is susceptible when it has two copies of the T allele and is consequently homozygous for "767T." (*Id.*)

When using the term "DNM1 allele," the '297 Patent refers to both a normal allele of the DNM1 locus and an allele "carrying a variation(s) that predispose a dog to develop EIC." ('297 Patent, col. 10, l. 35-45.) The latter allele is the one associated with EIC (i.e., the "T allele" Dr. Patterson describes in his declaration). (*Id.*)

[1] Dr. Patterson's research indicated that Canine EIC is an "autosomal recessive condition." (Patterson Decl. ¶ 7.) The gene is on an autosome, chromosome 9: a non-sex chromosome. (*Id.*) EIC appears only if the dog has received two copies of the gene, one from each parent. (*Id.*) When a dog has two copies of the gene, it is called homozygous. (*Id.* ¶ 8.) If a dog has only one copy of the gene, it is considered a carrier. (*Id.* ¶ 9.)

Given these discoveries, the patent notes that DNA testing can now "more accurately determine if a dog with clinical signs of EIC has the heritable and 'classic' form of [the] disease that can be specifically attributed to this DNM1 gene mutation." (*Id.* col. 9, l. 53-60.) Indeed, the '297 Patent describes its invention as providing "a method for detecting the presence of a biomarker associated with canine" EIC. (*Id.* col. 2, l. 49-51.) The patent notes that all the test requires is a tissue sample of the dog, followed by an "appropriate PCR and sequence analysis technology to detect the G to T single nucleotide change." (*Id.* col. 9, l. 53-60.) Nevertheless, the '297 Patent includes several embodiments, describing different ways to determine whether a single nucleotide mutation at position 767 exists. (*Id.* col. 2, l. 50-65; *id.* cols. 3-4; *see also id.* col. 22, l. 28-30 ("The present invention, therefore, provides methods and kits for determining whether a subject has or is likely to develop EIC."). Specifically, the '297 Patent includes eight claims:

> **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.
>
> **2.** The method of claim **1**, wherein prior to or in conjunction with detection, the nucleic acid sample is subject to an amplification step.
>
> **3.** The method of claim **2**, wherein dynamin 1 or a portion thereof is amplified.
>
> **4.** The method of claim **1**, wherein the detecting step is by a) allele specific hybridization; b) size analysis; c) sequencing; d) hybridization; e) 5' nuclease digestion; f) single-stranded conformation polymorphism; g) primer specific extension; and/or h) oligonucleotide ligation assay.

5. The method of claim **4**, wherein the detecting step is by size analysis, and the size analysis is preceded by a restriction enzyme digestion.

6. The method of claim **1**, wherein the detecting step is by hybridization of the nucleic acid sample from the dog to at least one oligonucleotide probe specific for the dynamin 1 (G767T) allele is immobilized on a solid surface.

7. The method of claim **1**, wherein the dog is a Labrador Retriever, Chesapeake Bay Retriever, Curly-Coated Retriever, or Border Collie.

8. A method for determining whether a dog has or is predisposed to developing an Exercise Induced Collapse (EIC), comprising:

(a) transporting a biological sample from a dog suspected of having or being predisposed to developing EIC to a diagnostic laboratory,

(b) detecting in a nucleic acid sample from the dog the allele in the dynamin 1 gene at position 767 of SEQ ID NO: 1

(c) identifying that the dog has or is predisposed to the development of EIC when the dog is homozygous for the T767 allele and

(d) providing results regarding whether the dog has the EIC associated allele.

(*Id.* cols. 99-100.)

III. THIS CASE

Following its discussions with Canine EIC regarding the '297 Patent, PPG filed suit in the Eastern District of Washington against Canine EIC. (Compl., Dec. 20, 2013, Docket No. 1.) PPG's first amended complaint, the operative complaint, seeks in Count One a declaratory judgment that all eight claims in the '297 Patent are invalid because they attempt to protect a natural law or, in the alternative, due to obviousness. (First Am. Compl. ¶¶ 45-47.) In Count Two – as to any claims that are not found invalid – PPG seeks a declaratory judgment that PPG's test does not directly infringe on those claims. (*Id.* ¶¶ 48-49.) In the remaining three counts, PPG alleges unfair competition due to

Canine EIC's statements to PPG's customers about the '297 Patent, along with trade libel and tortious interference due to the same statements. (*Id.* ¶¶ 50-55.)

The case was transferred from the Eastern District of Washington to the District of Minnesota on May 20, 2014. (Order re: Def.'s Mot. to Dismiss for Lack of Jurisdiction or Improper Venue, May 20, 2014, Docket No. 28.) On June 3, 2014, Canine EIC filed its answer and also counterclaimed that PPG had infringed on the '297 Patent. (Canine EIC's Answer & Countercl. to Pl.'s First Am. Compl., June 3, 2014, Docket No. 36.)

PPG filed a motion for partial summary judgment on August 29, 2014. (Pl.'s Mot. for Partial Summ. J., Aug. 29, 2014, Docket No. 42.) The motion seeks summary judgment on Counts One and Two of PPG's complaint. (*Id.*) Specifically, PPG seeks a declaratory judgment that the '297 Patent is invalid because it protects a natural law. (*Id.*)

ANALYSIS

I. STANDARD OF REVIEW

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party can demonstrate that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A fact is material if it might affect the outcome of the suit, and a dispute is genuine if the evidence is such that it could lead a reasonable jury to return a verdict for either party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A court considering a motion for summary judgment must view the facts in the light most favorable to the non-moving party and give that party the benefit of all

reasonable inferences to be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Federal courts have the authority to grant summary judgment on the issue of patent invalidity when the subject of the patent is ineligible for patent protection. *Fort Props., Inc. v. Am. Master Lease LLC*, 671 F.3d 1317, 1323-24 (Fed. Cir. 2012) (affirming the district court's decision to grant summary judgment to the plaintiffs because the patent in question "attempt[ed] to capture unpatentable abstract subject matter").

II. RELEVANT CASE LAW

Section 101 of the Patent Act governs patent eligibility, stating "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. Given the language of the claims in the '297 Patent – each one describes a "method" – this case clearly involves claims of new and useful **processes** under Section 101, which are also known as "method claims." *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1374-75 (Fed. Cir. 2011).

The Supreme Court has long recognized an exception to Section 101, however: "[L]aws of nature, natural phenomena, and abstract ideas are not patentable." *Mayo Collaborative Servs. v. Prometheus Labs.* (*Mayo*), 132 S. Ct. 1289, 1293 (2012) (internal quotation marks omitted). These exceptions are meant to avoid "tying up the future use of the[] building blocks of human ingenuity." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*

(*Alice Corp.*), 134 S. Ct. 2347, 2355 (2014) (internal quotation marks omitted). At the same time, the Supreme Court has cautioned against construing these exceptions so broadly that they "swallow all of patent law." *Id.*

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. *Id.* 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).

A. *Mayo*

Before delving into the *Mayo* test as it applies to this case, the Court will review Supreme Court and lower court case law applying and interpreting the *Mayo* principles. The *Mayo* case itself involved a summary judgment dispute over "patent claims covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high." *Mayo*, 132

S. Ct. at 1294, 1296. The patents involved research that used the concentrations of metabolites in a patient's blood to determine whether the patient was receiving too much or too little thiopurine. *Id.* at 1295. The patent claims covered a simple set of processes, whereby the drug was administered, the level of certain metabolites in the blood stream was measured, and the amount of the drug being administered was either increased or decreased. *Id.*

The Court concluded that the 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." *Id.* at 1296. That relationship alone is a natural law and, as a result, patent-ineligible. *Id.* at 1297. The key question of the case, then, was "whether the [patent] claims do significantly more than simply describe these natural relations." *Id.* The claims needed to "add **enough** to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that **apply** natural laws." *Id.*

In analyzing the steps in the process envisioned by the patent, individually and in the aggregate, the Court concluded that the claims did not add enough to garner patent protection. *Id.* The administering step in the process merely referred to the relevant audience of doctors administering thiopurine, which offered little beyond the natural law since doctors had been administering that drug long before the patent was issued. *Id.* Moreover, as the Court noted, inventors cannot get around the bar on patenting natural laws or abstract ideas by "limit[ing] the use of the formula to a particular technological environment." *Id.* (internal quotation marks omitted). The "wherein" clause of the

process simply listed the relevant natural laws. *Id.* And the determining step, which states the triggering metabolite levels in the blood, simply told doctors to test for metabolite levels using well-established monitoring methods – nothing significant enough to result in patent protection. *Id.* at 1298. Additionally, considering the steps in the aggregate did not change the Court's analysis. The Court concluded that the patent "claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id.* The Court consequently held that the patent claims at issue were invalid. *Id.* at 1305.

B. *Myriad*

The following year, the Court decided another patent-eligibility summary judgment dispute in *Myriad*. That case did not require the application of both *Mayo* steps, since the patent at issue was a composition claim, and not a process or method claim. *Myriad*, 133 S. Ct. at 2116. Neither patent **applied** the patented concept, as might be more common in a process or method claim, in a way that would trigger the two-step *Mayo* analysis. *Id.* at 2112-13, 2120 ("[T]his case does not involve patents on new **applications** of knowledge about the BRCA1 and BRCA2 genes." (emphasis added)). Nevertheless, the case is relevant because it discusses patents related to genetic testing and biomarker detection.

The inventions at issue involved the BRCA1 and BRCA2 genes. *Id.* at 2112. Mutations in those genes "can dramatically increase an individual's risk of developing breast and ovarian cancer." *Id.* Defendant patent-holder Myriad had patented two "inventions": (1) the identification, isolation, and extraction of the BRCA genes; and (2) the creation of a synthetic form of those genes. *Id.* at 2112-13. The patents, if valid, would have given Myriad the exclusive right to isolate an individual's BRCA genes and, effectively, the exclusive right to test for BRCA. *See id.* at 2113-14 ("[I]solation is necessary to conduct genetic testing.") The Court considered challenges to some, but not all, of the patents Myriad obtained. *Id.* at 2113.

As to the first invention, the Court noted that Myriad "did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes." *Id.* at 2116. Indeed, the "location and order of the nucleotides existed in nature before Myriad found them." *Id.* Moreover, Myriad also did not "create or alter the genetic structure of [the] DNA." *Id.* The Court characterized Myriad's principal contribution as "uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13." *Id.* The Court noted that while the company had found a very important gene, discovering it and separating it from its surrounding genetic material "is not an act of invention." *Id.* at 2117. As a result, the first invention did not merit patent protection. *Id.* Creating the synthetic gene (called "cDNA"), something entirely new, on the other hand, did qualify for patent protection. *Id.* at 2119.

In its concluding paragraphs, the Court noted that while Myriad might have also sought to bring a method or process claim – which would more likely trigger the *Mayo*

two-step analysis – such a claim might fail as well. *Id.* The Court noted that "the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents." *Id.* They were "well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach." *Id.* at 2119-20 (internal quotation marks omitted).

C. *Alice Corp.*

The Supreme Court next decided *Alice Corp.* That case involved the "abstract idea" exception, and not a natural law exception.[2] The claims at issue covered a computerized scheme that mitigated "settlement risk" between contracting parties. *Alice Corp.*, 134 S. Ct. at 2352. At *Mayo* step one, the Court concluded that the patent's claims revolved around an abstract idea – the concept of intermediated settlement (i.e., using a third party to reduce settlement risk). *Id.* at 2356. That concept is "a fundamental economic practice long prevalent in our system of commerce." *Id.* (internal quotation marks omitted).

The Court proceeded to *Mayo* step two, looking for some inventive concept beyond the abstract idea. *Id.* at 2357. The Court noted that this step requires more than an abstract idea, with the words "apply it" added on. *Id.* at 2358. Here, the additional element beyond the abstract idea was the computer program which applied that abstract

[2] The *Mayo* two-step analysis is essentially the same, whether the patent is directed at a law of nature or an abstract idea. *See Alice Corp.*, 134 S. Ct. at 2357 (applying the *Mayo* analysis, which involved a patent directed at a law of nature, to a patent directed at an abstract idea).

idea. But the Court noted that "wholly generic computer implementation is not generally the sort of additional feature that provides any practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself." *Id.* (internal quotation marks omitted). Analyzing the steps covered by the patent, the Court concluded that the computer application involved nothing more than "well-understood, routine, conventional activities previously known to the industry." *Id.* at 2359 (internal quotation marks and alterations omitted). And the Court reached the same conclusion when it analyzed the patent's steps as an ordered combination. *Id.* ("Viewed as a whole, petitioner's method claims simply recite the concept of intermediated settlement as performed by a generic computer."). Thus, under *Mayo*, the patent was invalid because it covered an abstract idea. The Court affirmed the Federal Circuit, which had affirmed the district court's grant of summary judgment, concluding that the subject matter of the patent was ineligible under 35 U.S.C. § 101. *Id.* at 2353, 2360.

D. *BRCA*

In *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation* (*BRCA*), 774 F.3d 755 (Fed. Cir. 2014), the Federal Circuit considered an appeal of a denial of a preliminary injunction, which arose from additional litigation related to the BRCA patents at issue in the Supreme Court's *Myriad* decision. *Id.* at 758. Relevant here, the court considered challenges to two claims of the BRCA patents that involved patented methods. Specifically, "[t]he methods, directed to identification of alternations

of the gene, require[d] merely comparing the patient's gene with [a wild-type gene] and identifying any differences that arise." *Id.* at 763.

One party argued these methods claims were ineligible under *Mayo*, because they "simply identify a law of nature (the precise sequence of the BRCA genes, and comparisons of the wild-type BRCA sequences with certain mutations of those gene sequences found in the test subject) and apply conventional techniques." *Id.* at 762. The court opted not to decide whether *Mayo* was directly on point, however, because the method claims at issue "suffer[ed] from a separate infirmity: they recite abstract ideas." *Id.* at 762-63 ("Laws of nature are not the only implicit exception to patentable subject matter by 35 U.S.C. § 101. Natural phenomena and abstract ideas are also not patentable."). The comparison of wild-type BRCA sequences with mutations of those sequences was an abstract idea that the court found corresponded with *Mayo* step one. *Id.* at 763-64.

After concluding the two claims were directed at a patent-ineligible concept – an abstract idea, *id.* at 764 – the court moved on to *Mayo* step two, asking "whether the remaining elements, either in isolation or combination with the other non-patent-ineligible elements, are sufficient to transform the nature of the claim into a patent-eligible application." *Id.* at 763 (internal quotation marks omitted). For that step, the court looked to the remainder of the patent claims, specifically "the techniques to be used in making the comparisons" between the wild-type sequences and mutations. *Id.* The court then concluded that the claims did not "add enough to make" themselves patent eligible. *Id.* at 764. Indeed, the patent holder, Myriad, did "not challenge the . . . finding

that the claims contain no otherwise new process for designing or using probes, primers, or arrays beyond the use of BRCA1 and BRCA2 sequences in those processes." *Id.* (internal quotation marks omitted). The court concluded that the claims did "nothing more than spell out what practitioners already knew – how to compare gene sequences using routine, ordinary techniques." *Id.* Indeed, these were exactly the "well-understood, routine, and conventional techniques that a scientist would have thought of when instructed to compare two gene sequences." *Id.*

The court compared the patents at issue to a different BRCA patent from a related case ("claim 21 of the '441 patent" or "claim 21"), which a Federal Circuit judge had suggested was patent eligible. *Id.* at 764-65. That patent also involved a comparison between wild-type BRCA genes and mutations in a patient's genes. *Id.* Assuming, without deciding, that claim 21 was patent eligible, the court noted that that patent was different than the patents at issue. *Id.* Claim 21 was more limited and narrow. It was "limited to the particular mutations the inventors discovered: detecting ten specific mutations from the wild-type, identified as predisposing mutations, for the specific purpose of identifying increased susceptibility to specific cancers." *Id.* at 765 (internal quotation marks and alterations omitted). The court noted that the claims it was reviewing were "significantly broader and more abstract, as they claim[ed] all comparisons between the patient's BRCA genes and the wild-type BRCA genes." *Id.* The court ultimately affirmed the district court's denial of the preliminary injunction to Myriad, holding that all "claims on appeal are directed to ineligible subject matter in violation of 35 U.S.C. § 101." *Id.*

III. *MAYO* STEP ONE: DIRECTED AT PATENT-INELIGIBLE CONCEPT

The first step is to "determine whether the claims at issue are directed to a patent-ineligible concept." *Alice Corp.*, 134 S. Ct. at 2355. At the hearing, Canine EIC clarified that it believes its patent is **not** directed toward a natural law. Canine EIC compares this case with *BRCA*. Noting that that case involved broad and abstract patents, which "claim[ed] all comparisons between the patient's BRCA genes and the wild-type BRCA genes," *BRCA*, 774 F.3d at 765, Canine EIC argues that its patent claims are much more narrowly drawn, patenting only one test that identifies one mutation that is tied to one disease.

Although this argument may be relevant to the inquiry at *Mayo* step two, it does not alter the Court's step one analysis. Whether a claim is narrowly drawn, or more broadly attempts to capture every facet of a law of nature, is a debate that is relevant at *Mayo* step two, when a court determines to what extent a patent that is directed toward a patent-ineligible subject features a patentable inventive concept. *See, e.g.*, *Mayo*, 132 S. Ct. at 1301-02 (analyzing the breadth and abstractness of a patent in the second stage of the *Mayo* analysis); *Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings*, No. 12-1736, 2014 WL 4379587, at *14 (D. Del. Sept. 3, 2014) (same).

Here, the Court concludes that the '279 Patent is directed at a patent-ineligible natural law.[3] Each of the of patent's claims serves the overarching purpose of

[3] Canine EIC also briefly argues that this Court should not render a decision on patent ineligibility before engaging in a formal claim construction or allowing for discovery. However,

(Footnote continued on next page.)

"determining whether a dog has or is susceptible to developing" EIC. ('297 Patent, col. 1, l. 57-59.) The patent's methods reach that EIC determination by identifying the naturally occurring source of EIC – a "point mutation at nucleic acid 767" – and testing dogs for that mutation. (*Id.* col. 26, l. 40-45; *see also id.* col. 2, l. 49-51 ("The present invention provides a method for detecting the presence of a biomarker associated with canine [EIC]").) Indeed, the only two independent claims (i.e., that do not merely modify and refer back to a prior claim) are claims one and eight, and both of them state as their central purpose the discovery of whether an individual dog's genetic code displays evidence of a mutation that correlates with EIC. (*Id.* col. 99, l. 24-26 ("A method for determining whether a dog has or is predisposed to develop [EIC]."); *id.* col. 100, l. 30-33 (same).) The '297 Patent's claims, just like those in *Myriad*, for example, are directed at identifying and observing a natural law – a genetic mutation that is tied to a disease in a living organism. *Myriad*, 133 S. Ct. at 2116-19 (discussing the identification and isolation of genes that, when they experience mutations, can lead to a higher risk of breast and ovarian cancer).

(Footnote continued.)

the parties do not present any factual disputes, or competing claim constructions, that warrant a delay. As other courts have noted, a Court may proceed with a Section 101 analysis at the summary judgment stage, even if there has not been factual discovery or formal claim construction. *See, e.g.*, *Cyberfone Sys., LLC v. CNN Interactive Grp., Inc.*, 558 Fed. App'x 988, 991 n.1 (Fed. Cir. 2014) ("[The plaintiff] argues that claim construction must precede the § 101 analysis, but does not explain which terms require construction or how the analysis would change. . . . There is no requirement that the district court engage in claim construction before deciding § 101 eligibility."); *Genetic Techs. Ltd.*, 2014 WL 4379587, at * 5-*6.

Even if, as Canine EIC argues, some of the '297 Patent claims involve non-natural processes or materials, those claims are still directed at identifying a genetic biomarker that exists in nature. *See Mayo*, 132 S. Ct. at 1297 ("While it takes human action . . . to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action."); *Genetic Techs. Ltd.*, 2014 WL 4379587, at *10 (recommending that the district court grant the defendants' motion to dismiss due to patent ineligibility, and concluding, at *Mayo* step one, that a patent that "sets out the correlation between a particular genetic variation and sprinting, strength or power performance," is directed at "a natural process, [and is] an eternal truth that exists in principle apart from any human action" (internal quotation marks omitted)). Unlike the cDNA patent in *Myriad*, the patent claims at issue here are not directed at creating entirely new, non-natural genetic material. *Myriad*, 133 S. Ct. at 2119. Instead, the '297 Patent uses non-natural processes to serve its purpose of identifying a natural law. Consequently, the Court concludes that the '297 Patent is directed at natural law, and moves next to *Mayo* step two.[4]

[4] To the extent that Canine EIC attempts to distinguish this case from some of those cited by PPG because those cases involve patents that relate to human – and not canine – treatments, testing, or genetics, the Court finds no authority that gives any weight to this distinction. The question of whether a test, or set of tests, for discovering a genetic mutation is protected by the patent laws is analyzed the same way, irrespective of whether that test is used on humans or dogs.

IV. *MAYO* STEP TWO: INVENTIVE CONCEPT

At *Mayo* step two, the Court "must examine the elements of the claim[s at issue] to determine whether [they] contain[] an inventive concept sufficient to transform the claimed" natural law "into a patent-eligible application." *Alice Corp.*, 134 S. Ct. at 2357. The Court asks whether the claims "add enough to their statements of the [correlation between certain mutations and Canine EIC] to allow the processes they describe to qualify as patent-eligible processes that apply natural laws." *Mayo*, 132 S. Ct. at 1297. The steps in the patent, beyond the law of nature, must be more than "well-understood, routine, conventional activity already engaged in by the scientific community." *Id.* at 1298.

In light of these principles, the Court concludes that none of the eight claims of the '297 Patent includes any inventive concept. Outside 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. *BRCA*, 774 F.3d at 764. Indeed, that is why the Patent Examiner, in examining what distinguished the subject of this patent from the prior art in the field, focused only on the natural law. (First Walters Decl., Ex. B at 4-5 ("The prior art fails to provide the link between dynamin-1 and EIC.").) The examiner did not highlight anything unique about the methods and processes used in the '297 Patent to identify the "link between dynamin-1 and EIC." (*Id.*)

An analysis of the various claims at issue supports this conclusion. Claim one simply states the natural law at the heart of the '297 Patent (i.e., the biomarker – the T767 allele – that is tied to EIC), and then describes detecting that biomarker through "a nucleic acid sample" and, if that nucleic acid sample shows that the dog is homozygous for the T767 allele, then identifying the dog as having or being predisposed to EIC. ('297 Patent, col. 99, l. 24-32.) Simply 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. *See, e.g., Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 949-50 (N.D. Cal. 2013) (noting that the methods used to detect DNA sequences under the patent claims at issue were "well-understood, routine, and conventional"); *Genetic Techs. Ltd.*, 2014 WL 4379587, at *12 ("[T]he [patent's] 'detecting' step fares no better [under the *Mayo* step two analysis]. It simply tells users of the process to detect the presence of two 577R alleles in the sample, again without specifying any particular method for doing so.").

Claims two and three offer nothing more, beyond routine and conventional processes. Both reference claim one, and both use an amplification process: claim two involves the amplification of the nucleic acid sample and claim three involves the dynamin 1 gene being amplified. ('297 Patent, col. 99, l. 33-37.) Amplification is also a routine, well-known, and conventional step for detecting a biomarker. The court in *Ariosa Diagnostics, Inc.*, for example, concluded that a patent that used amplification as a method to detect cell-free fetal DNA ("cffDNA") in serum or plasma samples from a pregnant female, did not feature an inventive concept that was sufficient to warrant patent

eligibility. 19 F. Supp. 3d at 941-42, 948-49 (citing expert testimony that "the amplification and detection of DNA sequences in plasma or serum was well known by 1997"). Indeed, as PPG points out, even the '297 Patent itself labels amplification as a well-known and widely used technique for genetic detection. (*See* '297 Patent, col. 4, l. 7-13 ("'Amplifying' utilizes methods such as the polymerase chain reaction (PCR), ligation amplification (or ligase chain reaction, LCR), strand displacement amplification, nucleic acid sequence-based amplification, and amplification methods based on the use of Q-beta replicase. **These methods are well known and widely practiced in the art**." (emphasis added)).)

Claim four cites to claim one and includes eight different types of detection methods, each of which is a routine, conventional, and well-known approach to genetic detection. ('297 Patent, col. 99, l. 37-43 (listing the following eight detection methods: "a) allele specific hybridization; b) size analysis; c) sequencing; d) hybridization; e) 5' nuclease digestion; f) single-stranded conformation polymorphism; g) primer specific extension; and/or h) oligonucleotide ligation assay").) Two of the eight techniques involve hybridization, a widely utilized genetic technique. *BRCA*, 774 F.3d at 764-65 (noting that the patent claims at issue involved hybridization and concluding that the techniques employed were clearly "well-understood, routine, and conventional"); *see also* '297 Patent, col. 4, l. 4-13 ("In one embodiment of the present invention, the method also involves contacting the sample with at least one oligonucleotide probe to form a hybridized nucleic acid and amplifying the hybridized nucleic acid. . . . These methods

are well known and widely practiced in the art.”))[5] The same is true of size analysis, (First Walters Decl., Ex. C at 6 (discussing a type of size analysis in a technical article from 1989 on the amplification of a specific genetic locus)); sequencing, (‘297 Patent,

[5] In a decision by the Federal Circuit that was later affirmed in part and reversed in part by the Supreme Court in *Myriad*, Judge Bryson concurred in part and dissented in part regarding Myriad’s BRCA patents. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1348-49 (Bryson, J., concurring in part and dissenting in part), *aff’d in part, rev’d in part sub nom. Myriad*, 133 S. Ct. at 2120. In discussing Myriad’s attempt to patent a natural law, Judge Bryson noted that while the company could not patent a law of nature, it could “patent **applications** of its discovery.” *Id.* at 1349 (emphasis added). Judge Bryson elaborated: “As the first party with knowledge of the [BRCA] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.” *Id.* Judge Bryson used as an example of one of these valid applications of natural law claim 21 of the ‘441 patent, which involved the detection of a germlike alteration in a BRCA1 gene by hybridizing a BRCA1 gene probe. *Id.* (citing U.S. Patent No. 5753441 (filed May 19, 1998)). In *Myriad*, the Supreme Court cited favorably Judge Bryson’s statement regarding Myriad’s ability to claim application of that knowledge, since it was the company that discovered the BRCA1 and BRCA2 sequences. *See Myriad*, 133 S. Ct. at 2120.

Some courts have discussed whether Judge Bryson’s language – specifically his use of claim 21 of the ‘441 patent as an example, and the Supreme Court’s implicit adoption of some of his language, implies that using hybridization techniques is a specific application of a natural law that is patent eligible. *See Ariosa Diagnostics, Inc.*, 19 F. Supp. 3d at 952 n.8. The *Ariosa* court rejected that implication, noting that the parties in its case had not shown that hybridization was conventional at the time of the patent that Judge Bryson was discussing. *Id.* In other words, the *Ariosa* court declined to read too much into Judge Bryson’s language, because it was not clear whether hybridization was conventional or new at the time and, as a result, it was unknown what exactly had led Judge Bryson to read claim 21 and its hybridization method as patent-eligible.

This Court concludes that hybridization is routine and conventional, given the evidence presented by PPG. And the Court does not read Judge Bryson’s language as requiring it to uphold the validity of a patent that uses a hybridization method. Indeed, since *Ariosa*, the Federal Circuit in *BRCA* has clarified that – assuming Judge Bryson was correct about claim 21 of the ‘441 patent – what made that claim valid was not its use of hybridization, but its narrowness. *BRCA*, 774 F.3d at 765 (“Claim 21 claims a method of detecting alterations in which the alterations being detected are expressly identified in the specification by tables 11 and 12. . . . Thus, the detection in claim 21 is limited to the particular mutations the inventors discovered: detecting ten specific mutations from the wild-type. . . .”) The Court will therefore not read more into Judge Bryson’s language than the Federal Circuit did. The Court will address separately below the argument that Judge Bryson’s language, and the language in *BRCA*, show that this case involves a narrower application of a natural law – which is therefore patent eligible – than the broad patents at issue in *Ariosa* and *BRCA*.

col. 27, l. 8-10 ("Detection of point mutations may be accomplished by molecular cloning of the DNM1 allele(s) and sequencing the allele(s) using techniques well known in the art.")); 5' nuclease digestion, (First Walters Decl., Ex. D at 2 (describing, in a 1999 article, a 5' nuclease assay as an "attractive" option for screening for polymorphisms)); single-stranded conformation polymorphism, ('297 Patent, col. 27, l. 15-17 ("There are six well known methods for a more complete, yet still indirect, test for confirming the presence of a mutant allele: 1) single stranded conformation analysis . . . .")); primer specific extension, (First Walters Decl., Ex. F at 5 (discussing, in a 1990 article, primer specific extension as a tool for detecting a nucleotide at a variable site of target DNA)); and oligonucleotide ligation assay, (*Id.*, Ex. G at 6 ("Both ligation and binding of the . . . oligonucleotides are efficient and rapid steps that should permit quantitative detection of target molecules.").)

Claim five references claim four, and clarifies that the detecting step "is by size analysis, and the size analysis is preceded by a restriction enzyme digestion." ('297 Patent, col. 99, l. 42-45.) A 1986 article provided by PPG shows that this technique was also well-known at the time the '297 Patent was issued. (First Walters Decl., Ex. H at 3-4 ("Mapping [of restriction sites surrounding a polymorphic site] was performed by standard procedures with single and double **restriction enzyme digests**." (emphasis added)).) Similarly, claim six, which references claim one and has a detection step that involves "hybridization of the nucleic acid sample from the dog to at least one oligonucleotide probe specific for the dynamin 1 (G767T) allele" and immobilization "on a solid surface," ('297 Patent, col. 100, l. 23-27), involves well-known probing and

detection techniques. (*Id.* col. 30, l. 26-28 ("The DNA (or nucleic acid) sample may be contacted with the oligonucleotide probe in any suitable manner known to those skilled in the art.").)

Claims seven offers nothing beyond claim one; it simply references the detection method in the first claim and specifies that the dog in question is one of four canine breeds. (*Id.*, col. 100, l. 27-30.) Finally, claim eight, the only other independent claim, aside from claim one, which references no other claim, suffers from the same infirmities as claim one. Like claim one, claim eight specifies as its purpose determining "whether a dog has or is predisposed to developing" EIC. (*Id.* col. 100, l. 31-33.) Then the claim essentially provides the same steps as in claim one: detection and identification. (*Id.*, l. 37-41.) The only difference is that the claim also includes two added steps: transporting a sample from the dog to a laboratory prior to detection and identification and, afterward, providing the results of detection and identification. (*Id.*, l. 33-36, 42-45.) Claim eight contains no patent-eligible inventive concept. Moreover, considering each claim, and the steps involved in each, in "ordered combination" does not change the analysis; no set of steps in any of the claims, viewed as a whole, provides an inventive concept that renders the claims patent eligible. *Mayo*, 132 S. Ct. at 1298.

The broad principles in *Mayo* and *Alice Corp.* also support the Court's conclusion. Like the patent claims at issue in *Mayo*, the key claims at issue in the '297 Patent – claims one and eight – involve generalized steps that essentially tell experts about the natural law; the claims simply tell someone treating a canine to detect whether the natural law – the specific allele tied to EIC – exists or is implicated in the dog being treated.

Mayo, 132 S. Ct. at 1297-98 (concluding that the patent's three steps (labeled the administering, determining, and wherein steps) were insufficient to transform the claim into a patent-eligible one, and noting that case law supports "the view that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws . . . patentable"); *see also Alice Corp.*, 134 S. Ct. at 2360 (rejecting as patent ineligible a method claim that involved an "abstract idea implemented on a generic computer" and noting that "the function performed by the computer at each step of the process [was] purely conventional" (internal quotation marks and alterations omitted)).

Canine EIC contrasts this case with *Mayo*, arguing that certain claims in the '297 Patent – specifically claims two through six – involve more detailed processes than the steps in *Mayo*, which operated at a "high level of generality," *Mayo*, 132 S. Ct. at 1300. The decisions in *BRCA*, *Ariosa*, and *Genetic Technologies Ltd.*, however, show that this Court's decision to find that all eight claims in the '297 Patent are patent-ineligible best comports with the Supreme Court's precedent. In *BRCA*, for example, the claims at issue involved detailed and specific hybridization and amplification techniques for comparing a person's genes with the wild-type and identifying differences. *BRCA*, 774 F.3d at 761-72. The court concluded that the claims involved an abstract idea, versus a natural law, *id.* at 762, but the analysis at *Mayo* step two is the same for natural laws and abstract ideas, *id.* at 764-65 (quoting *Mayo* and *Alice Corp.* in its *Mayo* step two analysis). The *BRCA* court acknowledged that the claims offered more than just the patent-ineligible abstract idea: it noted that the claims included complex hybridization and amplification

processes. *Id.* at 764. But it concluded nonetheless that these techniques provided no new inventive concept. *Id.* Instead, just like the detection techniques outlined in all eight claims in this case, the *BRCA* court found that the claims at issue did "nothing more than spell out what practitioners already knew – how to compare gene sequences using routine, ordinary techniques."[6] *Id.* The court in *Ariosa* reached the same conclusion about patents that provided detailed steps for detecting cffDNA from maternal serums or plasma. *Ariosa Diagnostics, Inc.*, 19 F. Supp. 3d at 941-42, 949-50; *see also Genetic Techs. Ltd.*, 2014 WL 4379587, at *2, *11-*14.

Even if the '297 Patent is not saved by the detailed processes recounted in all eight claims, Canine EIC also notes that the patent is sufficiently limited and narrow in that it only patents the connection between one mutation and one disease, without controlling the ties between that mutation and other diseases, or even patenting any detection of a dog that is heterozygous, as opposed to homozygous, for the 767T allele. In other words, the '297 Patent is more akin to claim 21 of the '441 patent in *BRCA*, which was limited to particular genetic alterations tied to specific cancers. 774 F.3d at 765. And the '297 Patent is not so broad as to "preempt" entirely the use of the natural law at issue. *Mayo*, 132 S. Ct. at 1294; *see also Ariosa*, 19 F. Supp. 3d at 953. But analogizing to the complicated relationship between mutations in the BRCA genes and cancer – a complex and multi-faceted disease with many iterations – is only so helpful in analyzing a simpler

[6] To the extent Canine EIC relies on *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1249, 1258-59 (Fed. Cir. 2014), which involves an online marketing patent, the Court concludes that *BRCA* is more relevant and on point, since it involves a genetic patent similar to the one at issue in this case.

case. The '297 Patent identifies the relationship between a specific mutation and a unique disease in dogs. By delineating a long list of conventional, routine, and well-known processes for identifying the mutation associated with the disease, the patent seeks to tie up and control any detection and research related to that biomarker and EIC. Indeed, the patent's language is written in broad strokes, making clear that its purpose is to control that connection. (*See, e.g.*, '297 Patent, cols. 1, l. 57-60; *id.* col. 2, l. 49-51.) Canine EIC provides no evidence that other biomarkers may be associated with EIC, or that the biomarker at issue may be associated with other iterations of EIC or similar diseases. It has not shown that the '297 Patent is doing nothing more than narrowly wading into a deep ocean of research and innovation around dogs, genetics, and EIC. Instead, the '297 Patent broadly seeks to control all the ties between the 767T allele and EIC, which renders it ineligible for patent protection.[7]

Finally, to the extent Canine EIC argues that the processes in its '297 Patent are non-natural, or that the novelty or lack thereof of the processes and methods are not at

[7] Canine EIC also relies on the decision in *Genetic Technologies, Ltd. v. Agilent Technologies, Inc.* (*Agilent*), 24 F. Supp. 3d 922, 928-29 (N.D. Cal. 2014), which concluded that a patent that covered "the correlation between [genomic] variations in non-coding and coding DNA regions" was an unpatentable law of nature, but then found that it was eligible for patent protection because it offered an additional inventive concept. This case is distinguishable in large part because the court in *Agilent* was considering a motion to dismiss and was restricted to the complaint at issue. *Id.* at 925, 933. More importantly, the court in *Agilent* relied on a rigid application of the Federal Circuit's decision in *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335 (Fed. Cir. 2013), a case the Supreme Court has since vacated, *WildTangent, Inc. v. Ultramercial, LLC*, 134 S. Ct. 2870 (2014). Indeed, on remand the Federal Circuit did not follow the same reasoning process as in its vacated *Ultramercial* decision; specifically, it did not so rigidly apply the four factors Canine EIC applies in its brief. *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715-16 (2014). As a result, the Court finds that cases like *BRCA* and *Ariosa* are more relevant to this case.

issue, it ignores the clear guidance from the Supreme Court and the Federal Circuit in *Mayo* and its progeny on how to analyze Section 101 cases. The question is not whether any aspect of the patent involves non-natural processes; it is what the patent is directed to and – if the patent is directed to a patent-ineligible concept – whether the non-natural processes provide an additional inventive concept of enough heft to make the patent valid. *Mayo*, 132 S. Ct. at 1296-98. As a result, the novelty of the processes included in the patent – whether they are truly new and innovative, or whether they are routine, well-known, and conventional – is absolutely central to the Section 101 analysis. *Id.* Here, the Court concludes that no inventive concept saves the '297 Patent from its focus on a patent-ineligible natural law. Because all that it adds to the natural law are well-known genetic detection methods, the Court finds the patent's eight claims to be invalid and will grant PPG's motion for partial summary judgment.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Genetic Veterinary Sciences, Inc.'s Motion for Partial Summary Judgment [Docket No. 42] is **GRANTED**.

DATED: March 31, 2015
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge