IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

GENETIC VETERINARY SCIENCES, INC., d/b/a Paw Prints Genetics,

Plaintiff,

v. **Civil Action No. 2:17cv108**

LABOKLIN GMBH & CO. KG & THE UNIVERSITY OF BERN,

Defendants.

OPINION & ORDER

This comes on Plaintiff, Genetic Veterinary Sciences, Inc., d/b/a Paw Print Genetics' ("Plaintiff" or "PPG") Motion for Judgment as a Matter of Law under Rule 50 of the Federal Rules of Civil Procedure ("Plaintiff's Motion for JMOL"). Doc. 140. For the reasons stated below, the Court **GRANTS** Plaintiff's Motion for Judgment as a Matter of Law.

I. BACKGROUND

This action concerns U.S. Patent No. 9,157,114 (the "'114 patent"), a patent regarding an in vitro method for genotyping Labrador Retrievers in order to discover whether the Labrador Retriever might be a genetic carrier of the disease Hereditary Nasal Parakeratosis ("HNPK"). Doc. 74 at 4; Doc. 75 at 8. HNPK is a disease that causes crusts and fissures to appear on the nose of dogs, including Labrador Retrievers. HNPK is a recessive condition that passes to a Labrador Retriever puppy when both of the dog's parents are carriers of the gene that causes HNPK. A dog's parent is considered a carrier when it only has one copy of the mutation. These carriers do not have the disease; however, when the two carriers mate, one copy of the mutation is passed to the puppy from each of them leading to the presence of HNPK. After six years of

research, one of The University of Bern's professors, Dr. Toso Leeb, discovered that the presence of HNPK in Labrador Retrievers resulted from a point mutation in the SUV39H2 gene. Once Dr. Leeb discovered this correlation, he developed a corresponding method for genotyping Labrador Retrievers, which is the subject of the '114 Patent.

Plaintiff's complaint seeks declaratory judgment that the '114 patent is invalid and therefore cannot be infringed by PPG. Doc. 1 at 6. Altogether, the '114 Patent has five (5) claims relating to the process of genotyping a Labrador Retriever for the presence of HNPK. Ex. 1 at Cols. 15-16. However, for purposes of the instant action, Plaintiff stipulated that its method is within the scope of claims one (1) through three (3), and Defendants LABOklin GmbH & Co., KG, and The University of Bern (collectively, "Defendants") agreed not to assert claims four (4) and five (5) against Plaintiff. Doc. 74 at 4; Doc. 75 at 9. According to the language of the '114 Patent, the invention recited in claims one (1) through three (3) is:

> 1. An in vitro method for genotyping a Labrador Retriever comprising:
> a) Obtaining a biological sample from the Labrador Retriever;
> b) Genotyping a SUV39H2 gene encoding the polypeptide of SEQ I NO: 1 and
> c) Detecting the presence of a replacement of a nucleotide T with a nucleotide G at position 972 of SEQ ID NO:2
>
> 2. The method according to claim 1, wherein the genotyping is achieved by PCR, real-time PCR, melting point analysis of double-stranded DNA, mass spectroscopy, direct DNA sequencing, restriction fragment length polymorphism (RFLP), single strand conformation polymorphism (SSCP), high performance liquid chromatography (HPLC), or single base primer extension.
>
> 3. The method of claim 1, wherein the genotyping utilizes a primer pair comprising of a first primer and a second primer, each compromising a contiguous span of at least 14 nucleotides of the sequence SEQ ID NO: 2 or a sequence complementary thereto, wherein:
> a) Said first primer hybridizes to a first DNA strand of the SUV39H2 gene;
> b) Said second primer hybridizes to the strand complementary to said first DNA strand of the SUV39H2 gene; and

c) The 3' ends of said first and second primers are located on regions flanking the position 972 of SEQ ID NO: 2, or of nucleotide positions complementary thereto.

Ex. 1 ("The '114 Patent") Cols. 15, 16.

II. PROCEDURAL HISTORY

On February 22, 2017, Plaintiff filed a complaint seeking declaratory judgment that the '114 patent is invalid and therefore cannot be infringed by PPG. Doc. 1 at 6. On May 8, 2017, the Court GRANTED Defendants an extension of time to respond to the Complaint. Doc. 21. Defendants filed a Motion to Dismiss on June 1, 2017. Doc. 29. The Court held a hearing on the Motion to Dismiss on October 10, 2017 and DENIED it. Doc. 67; see Doc. 68. Defendants filed an Answer and Counterclaim for Infringement on October 24, 2017. Doc. 69. By stipulation, Plaintiff agreed that for purposes of this action, its test is within the scope of claims one (1) through three (3) of the '114 patent as asserted in the counterclaim. See Doc. 63. The Parties also stipulated that Plaintiff would pay the greater of 25% of the sales price or $16 per test to Defendants if any of the three (3) claims are found valid. Doc. 78.

Plaintiff filed a Motion for Summary Judgment regarding validity of the '114 patent on December 22, 2017. Doc. 73. On January 18, 2018, the Parties filed a joint statement that no claim construction was necessary. Doc. 77.

On January 31, 2018, the Court heard oral argument on Plaintiff's Motion for Summary Judgment. Doc 80. On March 27, 2018 this Court entered an Order denying Plaintiff's Motion for Summary Judgment and Granting Defendants' Motion to Strike Plaintiff's Statement of Undisputed Facts in part. Doc. 93.

On March 29, 2018, Plaintiff filed a Motion for Clarification and Reconsideration of the Court's Order Denying Plaintiff's Motion for Summary Judgment and Granting Defendants'

Motion to Strike, in Part. Doc. 94. On April 4, 2018, this Court denied Plaintiff's Motion for Reconsideration. Doc. 99. The Court held a Final Pretrial Conference and entered a Final Pretrial Order on April 19, 2018. Docs. 113, 113-1. A jury trial for this matter began on April 30, 2018. Doc. 135. Plaintiff rested its case on April 30, 2018. Id. At the close of Plaintiff's evidence, Defendants moved for Judgment as a Matter of Law arguing that no reasonable juror could find claims one (1) through three (3) of the '114 Patent invalid. The Court DENIED Defendants' Motion. On May 2, 2018 Defendants rested their case and both parties filed a brief regarding the patent eligibility of Claim one (1) of the '114 Patent. Docs. 138, 139. After the close of Defendants' evidence Plaintiff filed a Motion for Judgment as a Matter of Law and moved this Court to enter judgment in Plaintiff's favor regarding the invalidity of claims one (1) through three (3) of the '114 Patent. Doc. 140. The Court GRANTED Plaintiff's Motion.

III. LEGAL STANDARDS

Under Rule 50 of the Federal Rules of Civil Procedure, before submitting the case to a jury during a jury trial and after a party is fully heard on an issue, the court may grant judgment as a matter of law if the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the nonmoving party on that issue. Fed. R. Civ. P 50. In entertaining a motion for judgment as a matter of law, the court must draw all reasonable inferences in favor of the nonmoving party. Reeves v. Sanderson Plumbing Products, Inc., 530 U.S. 133 (2000).

IV. ANALYSIS

Plaintiff seeks judgment as a matter of law that Claims one (1) through three (3) of the '114 patent are not eligible for patent protection. See generally Doc. 74. Thus, the analysis in this case follows the framework from Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347

(2014). "Whoever 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 . . . ." 35 U.S.C. § 101 (2017). The Supreme Court has "long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107, 2116 (2013) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012)) (alteration and internal quotation marks omitted). The Supreme Court created a two-step framework for assessing whether patents "in essence[] claim nothing more than abstract ideas." Synopsys, Inc. v. Mentor Graphics Corp., 839 F.3d 1138, 1146 (Fed. Cir. 2016). Courts first determine "whether the claims at issue are directed to one of those patent-ineligible concepts." Alice, 134 S. Ct. at 2355. "If so, the court then considers 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." Id. (quoting Mayo, 132 S. Ct. at 1297–98) (internal quotation marks omitted). The second step represents 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. (quoting Mayo, 132 S. Ct. at 1294). In order for that transformation to occur, the application requires "more than simply stat[ing] the law of nature while adding the words 'apply it.'" Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1377 (Fed. Cir. 2015)(quoting Mayo, 132 S. Ct. at 1294).

Claim one (1) of the '114 Patent is independent of Claims two (2) and three (3), while Claims two (2) and three (3) both depend on and recite "the method according to Claim 1."

Under Step 1 of Alice, we review Claim one (1) individually, and then as an ordered combination with Claims two (2) or three (3).

The Court **FINDS** that Claim one (1) of the '114 Patent, even in combination with Claims two (2) and three (3), is directed to patent ineligible subject matter, namely the discovery of the genetic mutation that is linked to HNPK.

In support of its Motion, Plaintiff directed this Court to the Federal Circuit's decision in Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015). In Ariosa, the Federal Circuit reviewed the validity of a patent that claimed methods of using cffDNA after a researcher discovered that the presence of cffDNA in maternal plasma and serum could lead to earlier detection of genetic mutations. Ariosa, 788 F.3d at 1373. The method for detecting set forth in Claim one (1) was comprised of two steps: 1) amplifying the cffDNA contained in a sample of the plasma or serum from a pregnant female and 2) detecting the paternally inherited cffDNA. Id. Claims two (2) and four (4) of the patent depended on claim one (1), and claimed particular methods of amplification and detection. Id. at 1374.

Looking at the test outlined in Mayo and later adopted in Alice, the Federal Circuit concluded in Ariosa that under Step 1 of Alice, the methods claimed were directed to matter that is naturally occurring. Id. at 1376. The court reasoned that while the patent claimed a particular method, that method began and ended with the discovery of the existence of paternally inherited cffDNA in maternal plasma, which is a natural phenomenon. Id. It was undisputed that the existence of cffDNA in maternal blood is a natural phenomenon, and that the location of the nucleic acids existed in nature before they were found. Id. at 1376.

Similarly here, the methods claimed in the '114 patent begin and end with the discovery of a natural phenomenon. Claim 1 recites "an in vitro method for genotyping a Labrador

Retriever" for detection of this mutation. The '114 Patent, Col. 15. Both of the parties' experts explained that the scientific term "in vitro" simply means, in a glass or in a lab, and the scientific term "genotyping" simply means to look at or determine the composition of the bases or base pairs in the DNA. The fact that the research to which the patent refers is conducted in a lab does not form a basis for transforming the discovery of a law of nature into patent eligible subject matter.

Parts (a), (b), and (c) of Claim 1, which break down how the mutation is discovered, do not provide anything apart from the scientific designation of the mutation. Part (a), "obtaining a biological sample" requires someone to get a sample of DNA from a dog, which both parties' experts testified usually require obtaining a blood sample or cheek swab from the dog. Part (b), "Genotyping a SUV39H2 gene encoding the polypeptide of SEQ ID NO: 1," identifies the location of the genetic mutation; and part (c) "detecting the presence of a replacement of a nucleotide T with a nucleotide G at position 972 of SEQ ID NO:2," identifies the location of the equivalent normal gene. This was confirmed in the testimony of Dr. Leeb:

> THE COURT: Okay. Now, subparagraph (b) tells you where to find the gene that's abnormal -- what do you call it -- mutation. Step 2 -- in other words, paragraph (b) tells you where to find the mutation, which gene to go to to find it. Is that correct?
> THE WITNESS: That is correct. And, if I may add, (b) and (c) are very closely related. So (b) specifies the gene, but (c) specifies a single nucleotide within that gene.
> THE COURT: All right. So paragraph (c) explains that; the fact that some dogs have a mutation that doesn't cause it, and some dogs --
> THE WITNESS: Yes. Paragraph (c), in my example, would specify the typing error in the text.
> THE COURT: Paragraph (c) what?
> THE WITNESS: Paragraph (c) would specify the exact typing error.
> THE COURT: Typing error?
> THE WITNESS: The sequence change. So, again, the method does not claim the whole text, the whole information, it just claims the detection of that single error, the single change, single base replacement within the gene.

THE COURT: All right. So it identifies the mutation as compared with a normal gene --
THE WITNESS: Yes.
THE COURT: -- in paragraph (c).
THE WITNESS: Yes.

Dr. Leeb, also testified that the mutation of the SUV39H2 gene at position 972 in a Labrador Retriever arises through a natural process. And, Defendants' expert also testified that he believed "the mutation does occur naturally."

In response to Plaintiff's Motion for Judgement as a Matter of Law, Defendants argued that its case is analogous to those of Vanda Pharmals., Inc. v. West-Ward Pharmals. Int'l Ltd., 2018 WL 1770273 (Fed. Cir. 2018), and Rapid Litig. Mgmt., Ltd. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016). In each of those cases, the Federal Circuit held that the patent claims at issue satisfied Step 1 of Alice, and that they were not aimed at patent ineligible subject matter.

In Vanda a researcher discovered a link between persons who possessed a poor metabolizer genotype at CYP2D6 (a particular gene) and the effect of administering a particular dosage of iloperidone. See Vanda, 2018 WL 1770273 at *1. The patent claimed "a method for treating a patient" based on that discovery. Id. If the patient had a poor metabolizer genotype at CYP2D6, then the claim recited a particular dosage of treatment to be administered, and if the patient did not have a poor metabolizer genotype at CYP2D6, then it recited a different dosage. The Federal Circuit reasoned that this patent claim was distinguishable from a patent claim that was aimed at a natural phenomenon because the claim did more than simply recite how to discover the correlation between CYP2D6 and iloperidone, it additionally applied that discovery to a particular regimen of treatment.

Vanda is distinguishable from this case because the '114 Patent does not claim a method of applying the discovery—the presence a point mutation in the SUV39H2 gene—to a new

method of treating Labrador Retrievers. After many amendments of the patent, and the resulting re-drafting of its language, the patent utilizes a number of scientific terms which at first review appear difficult to understand and make the patent appear impressive on its face. However, when the language is explained, the patent simply states that the search for the mutation involves the laboratory examination of Labrador Retriever DNA, which resulted in the discovery of the mutation, which in combination with similar mutations of Labrador Retrievers who mates with a carrier results in offspring having a higher probability of inheriting the mutation. The mutation itself and the fact that it is inherited through male and female dog carriers mating are both natural phenomena.

Defendants' reliance on CellzDirect is also misplaced. In CellzDirect the Federal Circuit held that a claim was not directed to natural law when it claimed a "new and useful laboratory technique for preserving hepatocytes." CellzDirect, 827 F.3d at 1048. The Federal Circuit was careful to distinguish its ruling from other cases where claims amounted to nothing more than "observing or identifying the ineligible concept itself." Id(citing Genetic Techs., Ltd. v. Merial L.L.C., 818 F.3d 1369, 1373-74 (Fed. Cir. 2016)(rejecting claim where it recited methods for detecting a coding region of DNA based on its relationship to non-coding regions) and Ariosa, 788 F.3d at 1373-74(rejecting claims that recited methods for detecting paternally inherited cffDNA in the blood or serum of a pregnant female)). Unlike CellzDirect, Claim 1 of the '114 Patent is not a new and useful laboratory technique. To the contrary, Claim 1 amounts to nothing more than "observing or identifying" the natural phenomenon of a mutation in the SUV39H2 gene, which has been rejected by the Federal Circuit as a basis for satisfying Step 1 of Alice.

Plaintiff's expert, Dr. Shaffer, and Defendants' expert, Dr. Friedenberg, agreed on the key issues. Although Dr. Friedenberg's testimony was sometimes inconsistent and his demeanor was quite defensive, Dr. Friedenberg agreed with Dr. Shaffer that the mutation itself was a natural phenomenon. The Court **FINDS** based on this undisputed evidence that the mutation is a natural phenomenon. Dr. Friedenberg described Claim 1 as being a method and stated that it was the method of discovery claimed to be patentable. However, the evidence does not support Dr. Friedenberg's opinion that paragraphs (a), (b), and (c) of Claim 1 constitutes a method. As referenced earlier, in the Court's questions to Dr. Leeb, the inventor, he indicated that paragraph (b) simply identifies the location of the mutation, and paragraph (c) identifies the mutation as compared to a normal gene.

The Court **FINDS** that paragraphs (a) through (c) merely provide the supplying of Labrador DNA in part (a), point to the location of the mutation in dog's DNA in (b), and in (c) describe and locate the point mutation. These three paragraphs constitute a discovery of a natural phenomenon, not a method.

Under Step 2 of Alice, the Ariosa court examined the remaining elements of the claim to determine whether the claim contained any inventive concept sufficient to transform the claimed naturally occurring phenomenon into a patent-eligible application. Ariosa, 788 F.3d at 1376. The Federal Circuit concluded that nothing in the remaining claims so transformed the claim. Id. at 1377. Instead, the evidence showed that the remaining methods claimed were already well-known in the art, well-understood, routine, and conventional at the time the patent was issued. Id.

Claims 2 and 3 of the '114 Patent only contain a number of alternative methods to locate the mutation, all of the methods are well known and have been around for decades. Defendants' expert, Dr. Friedenberg, testified:

> "What we're talking about in claim 2...we're talking about techniques. These are techniques, many of which I've done, many of which—all of which some researcher has done and has been around for years. What's new here is the method of genotyping that particular gene and that particular change in a Labrador Retriever dog, because no one had done it before..."

Claim 3 simply recites one of several means of locating the mutation. Again, this is a technique that has been well-known in the scientific community for decades. In regard to Claim three (3), Defendants' expert, Dr. Friedenberg, testified on cross-examination:

> Q. And then claim 3, that talks about using a primer pair, correct?
> A. Uh-huh.
> Q. Have you ever used primer pairs in PCR?
> A. Sure, but never to genotype base pair position 972 in the SUV39H2 gene.
> Q. But would you agree with me that the primer pair technique that's being used to genotype this particular gene is a technique that's been around for a while?
> A. It's just like boiling or baking, a technique.
> Q. And it's decades old before this patent, correct?
> A. Decades old.

Accordingly, after translating the complex scientific jargon used in the patent, the result is that it contains a valuable scientific discovery of a natural phenomenon without any inventive concept which transforms it from patent ineligible subject matter to patent eligible subject matter.

V. CONCLUSION

The discovery of the mutation required years and many hours of well conducted research. However, the utility of and expertise utilized in the discovery do not transform it into patentable subject matter, nor do Claims 2 and 3 add any inventive concept to the natural phenomenon.

Accordingly, and for the reasons stated, this Court **GRANTS** Plaintiff's Motion for a Judgment of invalidity as a Matter of Law.

The Clerk is **REQUESTED** to send a copy of this Opinion & Order to all counsel of record.

It is so **ORDERED**.

/s/
Henry Coke Morgan, Jr.
Senior United States District Judge

HENRY COKE MORGAN, JR.
SENIOR UNITED STATES DISTRICT JUDGE

Norfolk, Virginia
May 11, 2018