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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT SPOKANE

GENETIC VETERINARY SCIENCES, INC., d/b/a PAW PRINT GENETICS

Plaintiff,

v.

VETGEN, LLC

Defendant.

CV-13-415-TOR

COMPLAINT FOR DECLARATORY JUDGMENT

JURY TRIAL DEMANDED

Plaintiff GENETIC VETERINARY SCIENCES, INC., d/b/a PAW PRINT GENETICS ("PPG") for its complaint against VETGEN, LLC ("VetGen") hereby alleges as follows:

NATURE OF THE ACTION

1. This action arises under 28 U.S.C. § 1331, 2201, and 2202 and the United States Patent Act, 35 U.S.C. § 1 et. seq.

2. PPG brings this action for a declaration that no activities relating to its genetic test for von Willebrand's disease ("vWD") in dogs directly or indirectly infringe (either literally or under the doctrine of equivalents) any valid claim of U.S. Patent Nos. 6,040,143 ("the '143 Patent"), 6,074,832 ("the '832 Patent"), 6,767,707 ("the '707 Patent"), 6,780,583 ("the '583Patent"), and 6,410,237 ('237 Patent) (collectively "the patents-in-suit").

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PARTIES

3. PPG is a Washington corporation with a principal place of business at 850 E. Spokane Falls Blvd., Suite 200, Spokane, Washington, 99202.

4. VetGen is a Delaware limited liability company with a principal place of business at 3728 Plaza Dr., Suite One, Ann Abor, Michigan 48101.

JURISDICTION AND VENUE

5. This court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a) and (b) because this is a civil action arising under the Patent Act, 35 U.S.C. § 1 et. seq. This court also has jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201 and 2202 because an immediate and substantial controversy exists between PPG and VetGen whether the PPG tests for vWD infringe any valid claim of the patents-in-suit.

6. Venue is appropriate in this judicial district pursuant to 28 U.S.C. §§ 1400(b), 1391(b), and 1391(c) because this is a patent case and a substantial part of the events giving rise to the claim occurred in this judicial district and VetGen is subject to personal jurisdiction within this judicial district. Specifically, VetGen sells vWD tests covered by one or more claims of the patents-in-suit in direct competition with PPG to residents of Washington State. These competitive sales by VetGen are made from its interactive website. In addition to these sales, VetGen has entered into a number of arrangements with Washington State University ("WSU") permitting VetGen to develop a market for vWD testing in direct competition with PPG here in Washington State.

7. PPG is informed and believes and on that basis alleges that VetGen currently sells a panel test for Doberman Pinchers "[i]n cooperation with Dr Kathryn Meurs, Washington State University (WSU) and the Veterinary Cardiac Genetics Lab." This test includes a result for vWD that is covered by one or more claims of the patents-in-suit.

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8. PPG is informed and believes and on that basis alleges that VetGen has entered into agreements with WSU authorizing use for certain clinical studies conducted in this judicial district vWD testing covered by one or more claims of the patents-in-suit.

FACTS

Background Facts Relevant to von Willebrand's Disease

9. von Willebrand's disease in both dogs and humans is a bleeding disorder of variable severity that results from a quantitative or qualitative defect in von Willebrand Factor "(vWF"). There are three types of vWD. Type I vWD is most common. It can cause serious bleeding problems, but in most patients it is generally the least severe form of vWD. Type I vWD is inherited in a dominant, incompletely penetrate fashion. Bleeding in patients with Type I vWD is mostly due to a reduced level of vWF instead of any qualitative defect in vWF.

10. In Type II vWD, patients have essentially normal levels of vWF, but the factor in these patients is abnormal and they develop bleeding complications. Type II vWD is inherited in an autosomal recessive fashion in dogs but is primarily inherited in an autosomal dominant fashion in humans; affected patients make an abnormal variant of vWF in their blood that does not function properly.

11. Type III is the most serious form of vWD, which can require transfusions of blood or other extreme interventions. In this type of vWD, the trait is inherited in an autosomal recessive fashion and affected patients have no detectable vWF in their blood.

12. Professor Erik von Willebrand of Helsinki, Finland first described this bleeding disorder in humans in 1926. The human vWF gene was subsequently identified in 1985 (Ginsburg et al. and Lynch et al.) and the cDNA sequence of the gene was first reported in 1986 (Bonthron et al.). The identification of the vWF gene eventually led to the identification of mutations within the gene which cause the various subtypes of human vWD. Mutations causing

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human vWD Type III, II, and I were identified in 1988 (Ngo et al. (Type III)), 1989 (Ginsburg et al. (Type II)), and 1996 (Eikenboom et al. (Type I)).

13. By 1988, vWD was recognized as one of the most prevalent bleeding disorders in dogs and had been identified in many different breeds, including examples of all three subtypes (Dodds 1988, Johnson et al. 1988, Brooks et al. 1992). Because of the known relationship between vWF plasma levels and vWD, plasma vWF antigen (vWF:Ag) concentration was being measured in dogs by clinicians as a marker for vWD in the 1980's (as discussed by Brooks et al. 1992).

14. Based on publications disclosing vWF as the causative gene, the location of this gene and mutations that cause all three forms of vWD in humans, and the known relationship between vWF plasma levels and vWD in dogs, it would have been obvious for a person having ordinary skill in the art working in the field at the time of the earliest priority date claimed by any VetGen patent to look for similar vWF abnormalities in the canine genome.

PPG's Business and Development of its vWD Test for Dogs

15. PPG was founded in 2012 in Spokane, Washington by Dr. Lisa Shaffer. Dr. Shaffer is a geneticist and successful entrepreneur. She has authored over 300 scholarly articles, almost two dozen book chapters, and four books in various aspects of clinical genetics. She serves on a number of professional, academic, and community boards and has won several industry awards, including the honor of being named one of the top 10 women CEOs by *Inc. Magazine*. The company she co-founded in 2003, Signature Genomics Laboratories, grew rapidly and was sold to PerkinElmer, Inc., in 2010.

16. PPG's laboratory developed, validated, and launched seventy tests for various genetic disorders for canines in May 2013 and launched an additional forty-five tests in July 2013.

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17. PPG's tests for all types of vWD were developed by Dr. Blake Ballif, PPG's Laboratory and Scientific Director, along with PPG's Senior Manager of Development and Laboratory Operations, Kyle Sundin. Dr. Ballif and Mr. Sundin also worked with a genetic counselor, Abigail Hata, who was responsible for identifying in the public literature the location of each mutation giving rise to each form of vWD in dogs.

18. Once PPG knew from public literature the location of each mutation giving rise to all known forms of vWD in dogs, PPG developed a genotyping technique to screen genomic DNA in a particular sample to determine whether a particular dog has a mutation known to be responsible for causing vWD.

19. According to PPG's test for vWD, DNA is isolated from cheek cells collected by PPG's customers who, after taking the sample with three separate swabs per dog, enclose each swab in a sterile test tube affixed with a label to identify the dog. After genomic DNA is harvested, quantified, and checked for quality, it is screened for its vWD genotype through multiple polymerase chain reactions ("PCR") at sequence areas including regions above and below the known locations for the vWD mutations.

20. According to PPG's test for vWD, two independent tests are performed simultaneously for the vWF gene for the various types of disease and known mutations using routine methods known to those of ordinary skill in the art.

21. PPG has made significant financial investments in the development of its tests, including the test for vWD. PPG has been conducting tests for vWD Type III (in the Kooikerhandje breed) since May 2013 and for vWD Type II (in the Collie, German Shorthaired Pointer, and German Wirehaired Pointer breeds) and Type III (in the Shetland Sheepdog breed) since July 2013 and will continue to develop and conduct tests for vWD in the future.

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Recent Changes to Patent Law Concerning Patent Eligibility

22. On March 20, 2012, the U.S. Supreme Court decided the case *Mayo v. Prometheus*, 566 U.S. ___, 132 S. Ct. 1289 (2012). This case considered patent claims for a method of giving a drug to a patient, where the patented method included measuring metabolites of the drug in the patient's blood with a known threshold in mind. According to the patented method, if metabolites were over the threshold, the patient had been given a sufficient dose of the drug. And if metabolites were below the threshold, this indicated that the patient should be given a larger dose.

23. The Court in *Prometheus* held that the claim under consideration was invalid because the level of metabolites in a patient's blood and its correlation to a certain condition in the body (i.e., whether a drug was dosed appropriately) is a natural law for which patent protection is unavailable. *Id.* at 1305.

24. According to the Court in *Prometheus*, only *application*s of a natural law are eligible for patent protection, but those "applications" must be genuine and not those which result from drafting efforts designed to monopolize the natural correlations. For example, the claim at issue in *Prometheus* was technically an "application" of the natural law because it instructed doctors to make a determination regarding appropriate dosing, but this was not a "genuine application" that could transform the natural law into something eligible for patent protection. *Id.* at 1299-1300.

25. The Court reasoned in *Prometheus*, that instructions for making such determinations were well known in the art. And because "[t]hese instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field," it was not a sufficient application of the natural law to transform the claim into one that is eligible for patent protection. *Id.*

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26. On June 13, 2013, the U.S. Supreme Court decided the case *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. ___, 133 S. Ct. 2107 (2013). This case considered whether claims to DNA isolated from a human cell were eligible for patent protection.

27. For decades leading up to this decision, the United States Patent Office (USPTO) had allowed claims to isolated DNA sequences on a theory that those sequences, once isolated from a cell and found to have a certain use, e.g., for determining a particular disease state or disease risk factor, were eligible for patent protection as "compositions of matter." The Court in *Myriad* rejected traditional USPTO rationale for allowing claims to isolated DNA, holding in relevant part that "genes and the information they encode are not patent eligible under [35 U.S.C.] § 101 simply because they have been isolated from surrounding genetic material." 133 S. Ct. at 2120.

28. In view of the recent changes in the law with respect to patent eligibility for diagnostic testing methods and isolated DNA, several claims in thousands of U.S. patents are no longer valid.

VetGen's Patents

29. The '143 Patent is entitled "DNA Encoding Von Willebrand Factor and Methods of Use." The '143 Patent lists March 21, 2000 as the date of issue. A true and correct copy of the '143 Patent is attached as **Exhibit A**.

30. PPG is informed and believes, and thereon alleges, that VetGen is the exclusive licensee of the '143 Patent.

31. The '832 Patent is entitled "DNA Encoding Canine Von Willebrand Factor and Methods of Use." The '832 Patent lists June 13, 2000 as the date of issue. A true and correct copy of the '832 Patent is attached as **Exhibit B**.

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32. PPG is informed and believes, and thereon alleges, that VetGen is the exclusive licensee of the '832 Patent.

33. The '583 Patent is entitled "DNA Encoding Canine Von Willebrand Factor and Methods of Use." The '583 Patent lists August 24, 2004 as the date of issue. A true and correct copy of the '583 Patent is attached as **Exhibit C**.

34. PPG is informed and believes, and thereon alleges, that VetGen is the exclusive licensee of the '583 Patent.

35. The '707 Patent is entitled "DNA Encoding Canine Von Willebrand Factor and Methods of Use." The '707 Patent lists July 27, 2004 as the date of issue. A true and correct copy of the '707 Patent is attached as **Exhibit D**.

36. PPG is informed and believes, and thereon alleges, that VetGen is the exclusive licensee of the '707 Patent.

37. The '237 Patent is entitled "DNA Encoding Von Willebrand Factor and Methods of Use." The '237 Patent lists June 25, 2002 as the date of issue. A true and correct copy of the '237 Patent is attached as **Exhibit E**.

38. PPG is informed and believes, and thereon alleges, that VetGen is the exclusive licensee of the '237 Patent.

VetGen's Statements Concerning Infringement of the Patents-in-suit

39. VetGen has taken the position that the patents-in-suit cover methods of testing whether a canine carries the vWD mutation.

40. Specifically, on May 15, 2012, VetGen sued Medical Diagnostic Laboratories, LLC and Vetnostic Laboratories (hereinafter "The MDL-Vetnostic Litigation"), alleging that

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"[t]his is an action for patent infringement arising under the Patent Laws of the United States, 25 U.S.C. § 1 et. seq., alleging infringement of United States Patent Nos. 6,040,143 ("the '143 patent"), 6,074,832 ("the '832 patent"), 6,410,237 ('237 patent), 6,767,707 ("the '707 patent") and 6,780,583 ("the '583 patent")." *VetGen LLC v. Medical Diagnostic Lab. LLC*, No. 2:12-cv-12171 (E.D. Mich.).

41. In the MDL-Vetnostic Litigation, VetGen took the position that Claim 17 of the '143 patent is "representative" of other claims in the patents-in-suit drawn to methods for detecting the gene for vWF and whether the mutations that give rise to vWD existed in that gene. *See id.* Docket No. 1 ¶ 23.

42. Claim 17 of the '143 Patent reads as follows:

> A method of detecting canine von Willebrand Factor gene in a sample comprising the steps of:
>
> (a) contacting the sample with an oligonucleotide comprising contiguous nucleotides of the nucleic acid sequence of SEQ ID NO. 1 and capable of specifically hybridizing with the canine von Willebrand Factor gene, under conditions favorable for hybridization of the oligonucleotide to any complementary sequences of nucleic acid in the sample; and
>
> (b) detecting hybridization, thereby detecting a canine von Willebrand Factor gene.

43. In the MDL-Vetnostic Litigation, VetGen alleged that Defendants' "tests (upon information and belief) must utilize probes which bind to the mutation site on the vWD-causing gene, and therefore must infringe the asserted patents." *Id.* ¶ 25.

Evidence of a Definite and Concrete Dispute Between VetGen and PPG

44. On October 9, 2013, Dr. Shaffer received a letter as Founder and CEO of PPG from Ramon Royal, President of VetGen (hereinafter, "the VetGen Letter"). Identifying the '143 and the '832 patent, the VetGen Letter states that its purpose is "to make you [i.e., PPG] aware of the above referenced U.S. patents" and that VetGen "holds the rights to these patents under an

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exclusive license agreement with the Regents of the University of Michigan and Michigan State University." A true and correct copy of the VetGen Letter is attached to this complaint as **Exhibit F**.

45. Implicit in the VetGen Letter is the threat of a future infringement lawsuit. This is the only communication VetGen has ever sent to PPG. The two companies are direct competitors in the market for vWD testing services. The only reason VetGen has "to make [PPG] aware" of the '143 and the '832 patents is to preserve its right to allege in a later infringement lawsuit that PPG "willfully" infringed these patents.

46. While the '237, the '707, and the '583 patents were not specifically mentioned in the VetGen Letter, they are substantially related to the '143 and the '832 patents. All patents claim methods for detecting vWD in canines and VetGen has alleged in connection with the MDL-Vetnostic Litigation that claim 17 of the '143 patent is "representative" of other method claims in all patents-in-suit. The patents-in-suit also share the same four inventors, Patrick J. Venta, George J. Brewer, Vilma Yuzbasiyan-Gurkan, and William D. Schall, with the only exception being that the '832 lists an additional inventor, John Duffendeck.

47. The patents-in-suit are further related by the fact that the '237, the '707, and the '583 patents all claim priority to the '143 patent's filing date. Moreover, the specification, claims, drawings, and figures of the '237, the '707, and the '583 patents are substantially the same to those found in the '143 and the '832 patents.

48. Given the fact that the '237, the '707, and the '583 patents are closely related to the '143 and the '832 patents, and further given VetGen's litigation history and in particular, its history of asserting the '143, the '832, the '237, the '707, and the '583 patents in a single lawsuit, the VetGen Letter creates an actual controversy between the parties regarding all patents-in-suit.

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CLAIM FOR RELIEF

COUNT ONE—DECLARATORY JUDGEMENT OF NON INFRINGEMENT

49. PPG re-alleges and incorporates by references all allegations contain in paragraphs 1-48 above.

50. PPG seeks a declaration from this Court that no activities relating to its tests for vWD directly infringe (either literally or under the doctrine of equivalents), contribute to infringement, or induce infringement of any valid claim of the ’143, the ’832, the ’237, the ’707, or the ’583 patents.

COUNT TWO—DECLARATORY JUDGEMENT OF INVALIDITY

51. PPG re-alleges and incorporates by references all allegations contain in paragraphs 1-48 above.

52. PPG seeks a declaration from this Court that certain claims of the ’143, the ’832, the ’237, the ’707, or the ’583 patents are invalid for failing to meet one or more requirements for patentability found in the Patent Act, 35 U.S.C. § 101, 102, 103, or 112.

PRAYER FOR RELIEF

Wherefore, PPG prays for the following relief from this Court.

A. Judgment in its favor on all claims for relief;

B. A declaration that no activities relating to PPG’s test for vWD directly or indirectly infringe any valid claim (either literally or under the doctrine of equivalents) of the ’143, the ’832, the ’237, the ’707, or the ’583 patents.

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C. A declaration that certain claims of the '143, the '832, the '237, the '707, or the '583 patents are invalid for failing to meet one or more requirements for patentability found in the Patent Act, 35 U.S.C. § 101, 102, 103, or 112.

D. An award to PPG of its costs and reasonable expenses to the fullest extent permitted by law;

E. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and award of attorney's fees and costs; and

F. Such other and further relief as the court may deem just and proper.

DATED this 13th day of December, 2013.

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