No. _____

In The
Supreme Court of the United States

HEMOPET,

Petitioner,

v.

HILL'S PET NUTRITION, INC.,

Respondent.

On Petition for Writ of Certiorari
To the United States Court of Appeals for the
Federal Circuit

PETITION FOR WRIT OF CERTIORARI

CHARLES BERMAN
938 Stanford Street
Santa Monica, CA 90403
(310) 828-4804
charlesberman@hemopet.org

ERIK S. JAFFE
(Counsel of Record)
ERIK S. JAFFE, P.C.
5101 34th Street, N.W.
Washington, D.C. 20008
(202) 237-8165
jaffe@esjpc.com

QUESTIONS PRESENTED

Section 101 of Title 35 defines patentable subject matter to include "any new and useful process * * * or any new and useful improvement thereof." Other provisions of Title 35 set forth specific conditions and requirements for the issuance of the patent itself, including that the description in the patent be sufficient "to enable any person skilled in the art to which it pertains" to make and use the invention. 35 U.S.C. § 112(a). The invention at issue in this case is a novel method for identifying, formulating, and producing pet food tailored to the genomic characteristics and gene expression of individual dogs and cats.

The Questions Presented are:

1. Is an invented method of producing a new class of products patent-eligible under § 101 where it applies a groundbreaking insight of the inventor by using techniques in a novel and previously unknown combination to produce a previously unknown result?

2. Whether the courts below erroneously conflated the patent-eligibility requirements of § 101 with the "enablement" requirements of § 112(a), thereby avoiding the more detailed analysis required under § 112 and denying overall patent eligibility on grounds not consistent with § 101 or this Court's precedents?

PARTIES TO THE PROCEEDINGS BELOW

Petitioner Hemopet was the plaintiff in the district court and the appellant in the Federal Circuit. Hemopet is a 501(c)(3) non-profit California company, founded in and operated since 1986 by Dr. W. Jean Dodds.

Respondent Hill's Pet Nutrition, Inc., was the defendant in the district court and was the appellee in the Federal Circuit.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

PETITION FOR WRIT OF CERTIORARI

Petitioner respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The Order of the District Court for the Central District of California granting summary judgment in favor of Respondent is available at 2014 U.S. Dist. LEXIS 184685 and is attached at Appendix B1-B20. The district court's final Judgment is attached at Appendix C1.

The Judgment of the Federal Circuit summarily affirming the district court is unpublished but available at 617 Fed. Appx. 997, and is attached at Appendix A1.

JURISDICTION

The Federal Circuit issued its Judgment affirming the district court on September 21, 2015. The Chief Justice granted Petitioner an extension of time to file this Petition to and including February 18, 2016. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTES INVOLVED

35 U.S.C. § 101 provides, in relevant part:

> 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, subject to the conditions and requirements of this title.

35 U.S.C. § 112 provides, in relevant part:

> (a) In general. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

STATEMENT OF THE CASE

1. This case involves the standards for determining patentable subject matter under 35 U.S.C. § 101. In particular, it involves whether a method or process patent for developing pet foods tailored to the specific genomic and nutritional needs of pets involves a patentable "useful process" or "improvement thereof" under § 101.

The courts below held that a groundbreaking and novel method for determining and formulating pet food and nutritional products tailored to the individual genome and gene expression of cats or dogs was not patent-eligible, but rather described a mere abstract idea or law of nature: that nutrition influences gene expression. That holding misconceived and narrowed this Court's precedents on the subject of patentability, failed to look at the novel combination of steps of the patented method as a whole, and threatens to constrain critical innovation in the life-sciences field and elsewhere.

2. Petitioner Hemopet is a 501(c)(3) organization that operates a greyhound rescue facility, canine blood bank, and internationally active veterinary-diagnostic facility in Garden Grove, California. Dr. W. Jean Dodds is the inventor of the Hemopet patents at issue and is a world-renowned veterinarian. She is the named inventor of more than thirty patents in the United States and abroad in the veterinary sciences. Dr. Dodds founded Hemopet in the mid-1980s and remains Hemopet's president.

3. The patents at issue in this case stem from the groundbreaking insight in 1999 by Dr. Dodds that nutrition could govern the expression of genes in the canine and feline genome. This concept is now known as "nutrigenomics." At the time of Dr. Dodds' invention, computer sequencing of the genome was just starting. Dr. Dodds recognized that computer power could be used to identify genes whose expression would be driven by nutrition. She also conceived that once the relationship between an individual animal's nutrition and gene expression was identified, computer software would allow an analysis of such relationship and the formulation and preparation of pet food and nutritional products to promote the optimal expression or regulation of genes for any given animal. Thus, the major advance of creating nutrigenomic pet foods was born. Four patents issued for this invention, and these were assigned to Hemopet. [1]

---

[1] U.S. Patent No. 7,865,343 ("the '343 Patent"), U.S. Patent No. 8,060,354 ("the '354 Patent"), U.S. Patent No. 8,234,099 ("the '099 Patent"), and U.S. Patent No. 8,224,587 ("the '587 Patent").

Each patent involves a method for tailoring pet foods and supplements to the particular genomic characteristics of animals in order to ensure optimal nutrition and gene expression. Although differing in some scientific and technical details not relevant here, the four patents each claim a method or system involving the use of (1) an electronic database of genomic data of a cat or dog, (2) an electronic database of the effect of nutrition on the genomic expression of a cat or dog, (3) a computer and software routine to determine a relationship between the two databases, and (4) developing, designing, or making a particular food product or nutritional supplement for a cat or dog to influence genomic expression in a desired direction. App. B6.

Hemopet's patented method for identifying and producing nutrigenomic pet foods tailored to individual cats or dogs is described in a variety of claims. Claim 1 of the '343 patent is representative of the method claims and discloses:

> A method of analyzing nutrition for a canine or feline animal, comprising:
>
> accessing at least one database that comprises first data relating genetic descriptor genomic data to a physiological condition, wherein the genetic descriptor genomic data is obtained from either a bodily fluid or tissue sample;
>
> accessing second data comprising the effect of nutrition on the expression of the genetic descriptor genomic data;
>
> analyzing, by use of a computer, the first and second data, relating the effect of nutrition

> on the expression of the genetic descriptor genomic data for the animal to the physiological condition, wherein the physiological condition comprises gastrointestinal function or immunological function of the animal; and
>
> formulating a nutritional diet based on the analyzed data.

App. B3 (district court opinion quoting claim). Claim 2 of the '343 patent, which depends on Claim 1 and is representative of the dependent claims at issue, adds as a further limitation "preparing a nutritional diet based on the analyzed data." App. B4 (quoting claim).[2]

---

[2] Claim 1 of the '354 patent is representative of the system claims at issue:

> 1. A system for determining a nutritional diet for a canine or feline companion animal comprising:
>
> a computer;
>
> at least one electronic database coupled to the computing system; at least one software routine executing on the computing system which is programmed to:
>
> (a) receive first data relating genomic map data to a physiological condition of the animal, and second data comprising the effect of nutrition on the expression of at least one gene in the genomic map;
>
> (b) determine a relationship between said first and second data; and
>
> (c) based on the relationship, determine a nutritional diet for the canine or feline companion animal; and formulate and prepare a nutritional diet product based on the relationship.

App. B4 (quoting claim).

In all of the claims, relevant genomic data is obtained for an animal and then compared to similar data reflecting the effect of a certain nutritional composition or diet on the genomic expression profile of that animal. After determining the relevant relationships within each data set and between the two data sets, these relationships are analyzed and, as a final step, a nutritional diet appropriate for the animal is formulated or prepared.

The patented methods for developing nutrigenomic foods and supplements represent a remarkable advance over previous techniques because they allow practitioners to identify ingredients with known effects on the expression of the genes in the genomic map that are associated with certain disease states and use those ingredients with confidence in developing food. Expert Report of Dr. Nate Sutter, June 19, 2014, at 12 [J.A. 1183]. This sort of comprehensive nutritional approach to the field of animal health diagnostics and well-being was not known in 1999 when Dr. Dodds first conceived of her invention.

Like every method or process patent, the patents here take advantage of certain known or identifiable scientific relationships: here, between the presence of particular genes and various disease states, or between certain foods and the increased or decreased expression of certain genes. But the patents here go well beyond the mere recitation of such general principles and describe previously unknown means of applying such relationships to individual animals and the food products that will ultimately be tailored to their unique genome and gene-expression traits. Dr. Dodds had the inventive insight of leveraging new

discoveries in animal genomics towards finding real, concrete applications in pet nutrition sciences. Accordingly, every claim requires as the final physical step a specific application of the analyzed data, most commonly by formulating or preparing a diet or diet product tailored to a specific animal and based on the ordered progression of each of the preceding steps in the process. Such tangible products of the invention are the result of an analytical process that uses literally millions of data points to address a physical characteristic or condition by examining how nutrition affects the "genomic data" and "genomic map data" of a particular animal.

4. On November 2, 2012, Hemopet filed this patent infringement action against Respondent Hill's Pet Nutrition, Inc. ("Hill's") in the District Court for the Central District of California. The Complaint alleged that Hill's infringed Hemopet's four patents. Hill's responded, *inter alia*, by challenging the validity of various claims contained in the four patents as not involving patentable subject matter under § 101.[3] Hill's did not challenge whether the patents were sufficient, under § 112(a), to "enable" use of the patented methods.

5. On November 24, 2014, the district court agreed with Hill's and granted Respondent summary judgment finding that the relevant claims were invalid. Noting that the four patents at issue "disclose a method and/or system for analyzing and determining

---

[3] As relevant here, Hill's challenged claims 1 and 2 of the '343 patent, claims 1, 2, 9, and 10 of the '354 patent, claim 1 of the '099 patent, and claims 1 and 8 of the '587 patent.

a nutritional diet for cats and dogs," the court identified the "key inquiry in this case [as] whether these claims are patent eligible under 35 U.S.C. § 101, or are instead drawn to patent-ineligible abstract ideas." App. B7.

Recognizing the tension between this Court's competing statements that " '[l]aws of nature, natural phenomena, and abstract ideas are not patentable' " and that "to some extent 'all inventions * * * embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,' " the district court applied this Court's "two-step framework for distinguishing between these two types of patents." App. B9 (quoting *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014), and *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012)).

Under the first step the court asked " 'whether the claims at issue are directed to one of those patent-ineligible concepts.' " App. B9-B10 (citations omitted). The court held that Hemopet's claims were based on abstract ideas – that genes influence health and disease states and that nutrition can mediate gene expression – which are not patent-eligible under § 101. App. B10, B13.

The court relied on this Court's decision in *Mayo* and the Federal Circuit's decision in *PerkinElmer, Inc.* v. *Intema Ltd.*, 496 F. Appx 65 (2012) (unpub.), both for the proposition that Hemopet's claimed method of detailed analysis of an animal's genomically-tailored nutritional needs involved the mere recitation of abstract ideas. App. B11-B12. And while the court recognized that the "claims in Hemopet's pa-

tents go one step further; they include a final step of formulate and prepare a nutritional diet for that animal," it found such additional step of applying the data developed and analyzed in the earlier steps to be only an extension of the "abstract idea" of "determin[ing]" a pet's diet. App. B13.

The court also confused issues of patentable subject matter with issues of "enablement." In addressing the final step of the method, it asserted that the "creating or formulating processes" in the claims "are couched in the most general terms, lacking any specifics that would allow a practitioner to learn how to actually develop or produce such a diet." App. B13.[4]

The court thus ended its discussion of step one with the conclusion that "the claims at issue encompass the abstract concept of determining a nutritional diet for a dog or cat based on naturally occurring relationships." App. B13.

Turning to the second step of its analysis, the court looked 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." ' " App. B10 (quoting *Alice*, 134 S. Ct. at 2355 (alteration in original), in turn quoting *Mayo*, 132 S. Ct. at 1296-97).

The district court acknowledged Petitioner's arguments that the method " 'incorporates the notion that

---

[4] Respondent did not challenge enablement under § 112(a), and the court did not purport to analyze any evidence or arguments ordinarily used to rule on an enablement challenge under that section.

nutrition can influence gene expression' and 'applies these ideas in a practical, tangible way by transforming information and raw materials into a nutritional diet product designed to induce specific gene expression in a pet.' " App. B15. It also acknowledged the opinion of Petitioner's expert that taking the information developed in the earlier steps of the method and using it "to develop and design, or create, or determine what nutrients or caloric compositions should be used in a food product is a key part of the novelty of the invention.' " App. B15. But the court nonetheless concluded that "this step is nothing more than a general 'apply it' step that does not transform an otherwise ineligible-patent concept into a patentable invention." App. B16.

The district court sought to distinguish this Court's decision in *Diamond v. Diehr*, 450 U.S. 175 (1981), which expressly approved the patentability of processes using novel combinations of conventional methods, as involving the physical transformation of a product (uncured rubber) into a different product (cured rubber). Although seemingly acknowledging that the formulation of the final pet food product based on the initial and detailed steps and analysis in the claimed method indeed "relates to the creation of a 'different state or thing,' " it viewed the steps involved as "conventional" and "specified at a high level of generality," and thus no more than telling a practitioner to "apply" an abstract idea in general terms. App. B17.

The court similarly dismissed the substantial and specific data gathering and analysis steps as " 'well-understood, routine, conventional activity, previously

engaged in by those in the field.' " App. B18 (quoting *Mayo*, 132 S. Ct. at 1292). It gave no consideration to the fact that prior to Hemopet's disclosure of its patent claims nobody had been conducting such analysis of pet genomes, pet gene expression, and the relationship between the two, much less using such steps to formulate a pet-specific diet.

7. On January 15, 2015, the district court entered final judgment in favor of Respondent. App. C1.

8. Petitioner timely appealed to the Federal Circuit, arguing, *inter alia*, that the district court confused the inventive *application* of ideas via an ordered combination of steps viewed as a whole with the mere recitation of abstract ideas themselves. Petitioner emphasized that the guiding principle behind the exclusion of protection for abstract ideas was the concern with not preempting the further use of such ideas by others, and noted that such concern was not present in this case. Petitioner further argued that the district court had too broad a conception of what constituted an abstract idea as opposed to innovative steps taken to apply such an idea to produce concrete results, as occurred in *Diehr*.

9. While that appeal was pending, the Federal Circuit decided *Ariosa Diagnotics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), which dealt with the same legal issue of patentable subject matter under § 101. Although the inventions in *Ariosa* and this case were different, both involved novel methods in the life-sciences area and whether patents teaching a practical application of groundbreaking scientific insights were *ineligible* for patent protection as being based on such insights. The Federal Circuit, in a

widely criticized opinion, held that such methods did not present eligible subject matter under § 101 because the steps used to implement what was admittedly a groundbreaking insight regarding fetal diagnostics were accomplished via conventional or routine methods. The court relied upon language in *Mayo* that seemed to discount the use of "routine" or "conventional" activities when seeking to apply an abstract idea or law of nature to achieve a particular result. 788 F.3d at 1377-78. Indeed, it gave considerable breadth, beyond the more limited facts and circumstances of *Mayo* itself, to this Court's statements discounting conventional activities as sufficient to add inventive application to a combination of steps applying a novel idea.

Judge Linn concurred, but wrote separately to explain that he strongly disagreed with that approach to § 101, but joined the court's opinion

> only because I am bound by the sweeping language of the test set out in [*Mayo*]. In my view, the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. This case represents the consequence – perhaps unintended – of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.

788 F.3d at 1380 (Linn, J., concurring). Judge Linn viewed *Mayo* as "discount[ing], seemingly without qualification, any '[p]ost-solution activity that is purely conventional or obvious,' " and rejecting even a new *combination* of steps because the steps " '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.' " *Id.* (quoting *Mayo*, 132 S. Ct. at 1299 (original alterations omitted)). Judge Linn concluded, in language equally applicable to this case, that the invention in *Ariosa* " 'effectuate[d] a practical result and benefit not previously attained,' so its patent would traditionally have been valid." 788 F.3d at 1381. "But for the sweeping language" in this Court's *Mayo* opinion, Judge Linn saw "no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible." *Id.*

10. On Sept. 15, 2015, shortly after its June 12 *Ariosa* decision, the Federal Circuit summarily affirmed the district court judgment in the present case via unpublished order per Federal Circuit Rule 36. App. A1. Given the just-decided *Ariosa* case, that result is hardly surprising as the issues presented were largely the same and the district court decision below was generally consistent with the approach set forth in *Ariosa*.

11. On December 2, 2015, the Federal Circuit denied a petition for rehearing *en banc* in *Ariosa*. *Ariosa Diagnotics, Inc. v. Sequenom, Inc.*, 2015 U.S. App. LEXIS 20842 (Fed. Cir. Dec. 2, 2015). The denial was accompanied by two concurring opinions on behalf of three judges and a dissenting opinion on behalf of a fourth judge.

Judge Lourie, joined by Judge Moore, echoed the sentiments of Judge Linn's panel concurrence, viewing himself bound by the broad language of *Mayo*, but stating that in his view, "neither of the traditional preclusions of laws of nature or of abstract ideas

ought to prohibit patenting of the subject matter in this case." 2015 U.S. App. LEXIS 20842, at *6. After explaining that the application of a natural phenomenon or idea through the use of a novel combination of concrete steps to achieve a specific result ought to be patentable, Judge Lourie concluded, in terms fully applicable here, that "it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts." *Id*. at *13. Like Judge Linn, however, he agreed "that under Supreme Court precedent [the panel] had no option other than to affirm the district court." *Id*.

Judge Dyk also concurred in the denial of rehearing *en banc*, and shared

> the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena. This leads me to think that some further illumination as to the scope of *Mayo* would be beneficial in one limited aspect. At the same time I think that we are bound by the language of *Mayo*, and any further guidance must come from the Supreme Court, not this court.

Id. at *13-*14 (Dyk, J., concurring).

Finally, Judge Newman dissented, echoing the sentiment that an overly broad reading of *Mayo* was the wrong approach to § 101, but believing that *Mayo* could be distinguished on its facts. Again in language equally applicable to this case, Judge Newman observed that "the claimed method was not previously known, nor the diagnostic knowledge and benefit implemented by the method," that rather than seeking to claim a patent on a discovery or idea, the invention claimed a new "method of *using* this information," and hence the "subject matter is not ineligible under Section 101, but warrants standard legal analysis for compliance with the [other] requirements of patentability." *Id*. at *31-*32 (Newman, J., dissenting) (emphasis added).

12. Hemopet's current Petition for certiorari presents the same issues presented in *Ariosa* – issues that can only be addressed by this Court given the widely held view in the Federal Circuit that it is bound by overly broad language in this Court's *Mayo* opinion.

REASONS FOR GRANTING THE WRIT

This Court should grant the Petition for a writ of certiorari because the decision below severely constricts the scope of patent-eligible methods and processes, misconstrues this Court's guidance in cases such as *Diehr* and *Mayo*, and threatens to undermine significant scientific progress in the life-sciences and other fields.

I. The Decisions Below Severely and Incorrectly Restrict the Scope of Patent-Eligible Subject Matter under § 101.

The fundamental problem with the decisions below is that they misapply *Mayo* and *Diehr* in a manner that unduly narrows the availability of method and process patents to the great detriment of innovation in numerous fields. This case, like the Federal Circuit's decision in *Ariosa*, squarely raises these issues, involves a groundbreaking innovation that deserves the protection of the patent system, and should be taken up by this Court to set patent law back on the more balanced course seemingly intended by *Diehr* and *Mayo*.

First, although seemingly recognizing that Hemopet's various steps for formulating nutrigenomic pet food were, at worst, *applications* of ideas or laws of nature, rather than an attempt to patent the laws themselves, the court below held such applications unpatentable as no more than "extension[s]" of the abstract ideas. App. B13. But *extending* ideas into useful processes and products is precisely what inventors do, and the court's dismissive treatment of that application step is no less than disparagement of the inventive process itself. The critical focus should have been the steps taken together as an ordered whole, and whether that *combination* was inventive, not whether any individual step was inspired by a scientific fact or idea, independently inventive itself, or an extension of the prior combination of steps.

In fairness, the court's analysis was influenced by the broad and confusing language of *Mayo*, which seemed to discount the use of "conventional steps" to

apply an idea or insight and yield an eventual result. Unfortunately, *Mayo* did not explain how that statement could be reconciled with the statement in *Diehr*, which *Mayo* also expressly approved, that " 'an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.' " *Mayo*, 132 S. Ct. at 1293-94 (quoting *Diehr*, 450 U.S. at 187).

This Court in *Diehr* considered a method of curing rubber that relied on an unpatentable mathematic equation and a computer to constantly measure the temperature inside a rubber mold and re-calculate curing time. Each of these techniques was already known and practiced, but they were not practiced in combination. In terms critical for this case, the Court explained that "[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements," and that "[t]his is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Diehr*, 450 U.S. at 188.

It is the tension between the overbroad statement in *Mayo* and the inconsistent language and holding in *Diehr*, that is driving the problematic results in cases like this one and *Ariosa*, and sowing confusion in this area of patent law in general.

In this case, for example, arguing that the idea of and means to gather genomic data in general was knowable in the late 1990s misconceives the nature of the invention here. *Using* such techniques to gather data on the interaction between nutrition and gene

expression and the connection of those variables to the genomic map of an individual creature was an enormous scientific advance and an extremely valuable insight and method.

The Hemopet patents disclose a combination of steps no one was performing or would have performed absent its teaching, which is exactly the kind of thing that patent law is designed to protect and encourage inventors to disclose. That the inventor's discovery and conceptualization of a natural phenomenon *inspired* the application of a new combination of steps makes this case no different from *Diehr*, *Ariosa*, or, indeed, a broad range of the most valuable and novel inventions conceived.

While *Diehr* applied the known Arrhenius equation (*i.e.*, the abstract idea) to known steps and thereby obtained a new cured rubber product, Hemopet comparatively makes an even stronger patent claim. Dr. Dodds in 1999 applied her newly conceived understanding of a relationship between nutrition and genomic expression to propose a new combination of steps to analyze that relationship and to formulate and prepare a new pet-food product based on that analysis. This combination of multiple ordered steps is exactly the kind of ordered combination of steps that for ages has been considered a patentable process.

The novel and complex steps involved in applying Dr. Dodds' nutrigenomic insights to produce a tangible result – an individually tailored nutrigenomic diet – are far more inventive and meaningful than a mere recitation of the underlying "ideas" that genes influence health, nutrition influences gene expression, and

that a diet could be tailored to produce desired gene regulation in order to improve health. The path from idea to actual diet involves much human intervention and is a quintessential example of a novel combination of scientific ideas and methods being used to create an *inventive application* of those ideas rather than merely reciting or pointing to the underlying ideas.[5]

That the broad language in *Mayo* is being read well beyond what this Court likely intended can be seen from the more recent discussion in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), distinguishing between patenting newly discovered facts or ideas and patenting early applications of those ideas. As this Court recognized, while *Myriad* could not patent newly isolated genes themselves, "as the first party with knowledge of [them], *Myriad* was in an excellent position to claim applications of that knowledge." *Id.* at 2120. Such statement strongly suggests that the extremely narrow view of patentable subject matter now applied in the Federal Circuit likely was not this Court's intent. And while much of the Federal Circuit disagrees with that narrow approach to subject matter, the judges do not view themselves as free to correct the problem. It thus is left to this Court to restore a balanced and sensible approach to § 101.

Second, the court below also interposed a "generality" test to dismiss each individual step as being in-

---

[5] The methodology claimed Hemopet's patents is a far cry from a mere repetition of an underlying fact or idea such as "the sun rises in East; follow the rising sun to go East."

sufficient to allow a practitioner to create a nutrigenomic diet. App. B13 (objecting to claims as being in "general terms" without specifics to direct a practitioner); *see also Ariosa*, 788 F.3d at 1378 (rejecting use of conventional steps "specified at a high level of generality"). In effect, the court imported into the § 101 analysis a conclusory element of enablement that would be considered off-the-cuff and without the typically extensive evidence and analysis used when considering enablement under § 112(a). The issue is all the more troubling given that enablement under § 112(a) was neither raised by Respondent nor ruled upon by the court below.

Such a drive-by treatment of enablement under § 101 is the same problem noted by several of the judges in *Ariosa*, where they observed that such issues do not properly bear upon subject-matter eligibility but should be addressed under § 112. *See, e.g., Ariosa*, 2015 U.S. App. LEXIS 20842, at *10 (Lourie, J., concurring in denial of reh'g *en banc*) (noting that objections that the "claims might be indefinite or too broad in that they do not specify how to amplify and detect, or how to separate, detect, and diagnose" do not go to whether the subject matter is patent-eligible and that "the finer filter of § 112 might be better suited to treating these as questions of patentability, rather than reviewing them under the less-defined eligibility rules"); *id.* at *32 (Newman, J., dissenting from denial of reh'g *en banc*) (noting that a new method of using scientific information "is not ineligible under Section 101, but warrants standard legal analysis for compliance with the requirements of patentability, that is, novelty, unobviousness, specificity

of written description, enablement, etc."); *see also* Maria R. Sinatra, *Do Abstract Ideas Have the Need, the Need for Speed?: An Examination of Abstract Ideas After* Alice, 84 FORDHAM L.REV. 821, 849 (2015) (raising the bar to eligibility under § 101 "by importing language traditionally reserved for § 102, § 103, and § 112" allows "judges to review information subjectively that would normally be subject to objective, clear, and convincing evidence standards").

Third, the current approach in the Federal Circuit effectively abandons the notion of undue preemption of future research and invention as being the driving force behind judicial exclusions of abstract ideas and laws of nature from § 101 coverage. Although the court below recognized that the "concern that drives these exceptions is preemption; laws of nature, natural phenomena, and abstract ideas are 'the basic tools of scientific and technological work,' " App. B9 (quoting *Alice*, 134 S. Ct. at 2354), at no point did it even suggest that Hemopet's patents would be unduly preemptive. Indeed, just as the patent in *Diehr* did "not seek to pre-empt the use of th[e] [unpatentable] equation," but "only to foreclose from others the use of that equation in conjunction with all the other steps in their claimed process," 450 U.S. at 187, so too Hemopet's patents only foreclose the particular combinations set forth therein, and leave others free to investigate and invent their own methods of achieving useful results based on the underlying "ideas" regarding genome mapping and gene expression.

The same problem of denying § 101 coverage despite the lack of preemption was present in *Ariosa*. There, the court likewise acknowledged that

"preemption is the basis for the judicial exceptions to patentability," made no effort to argue that the patent at issue had any undue preemptive effects, and concluded that application of its broadly formal reading of *Mayo* rendered any "preemption concerns * * * moot." *Ariosa*, 788 F.3d at 1379. The absence of preemption concerns was expressly noted by Judge Lourie, concurring in the denial of rehearing *en banc*, though he nonetheless felt bound by a broad reading of *Mayo* despite such incongruity. *Ariosa*, 2015 U.S. App. LEXIS 20842, at *12. All this ultimately demonstrates that the Federal Circuit's § 101 jurisprudence, whether compelled by this Court's prior statements or not, has strayed far from the fundamental justification for the judicial exceptions to § 101 and thus should be addressed by this Court.

Finally, this case is a good vehicle for addressing these issues, either alone or in combination with the soon-to-be-filed petition in *Ariosa*. This case, like *Ariosa*, involves precisely the problem of rejecting patentability for a wholly novel – indeed, groundbreaking – combination of steps to produce a unique and previously unknown result, simply because each individual step is said to involve conventional methods or the mere application of an abstract concept or law of nature. And while the present case may involve an unpublished Rule 36 order, that is only because it effectively is an application of the immediately preceding *Ariosa* decision and raises the very same issues.[6]

---

[6] At a minimum, this Court should hold this Petition for joint consideration with the *Ariosa* petition. If the Court then decides to proceed with *Ariosa* alone, this case should be held pending the outcome of that grant.

II. The Narrow Approach Below Threatens Innovation in the Life-Sciences and Other Fields.

The holding of the courts below that method patents are invalid where the individual steps of the method are conventional or apply an abstract idea or law of nature threatens to all but destroy method and process patents. In every method patent, the novelty lies not in any particular step or technique used in the method, but in the *combination* of known or knowable individual steps in a manner not previously contemplated.

In this case, for example, a groundbreaking method of improving pet nutrition is being denied patent eligibility because of confusion regarding the line between an idea and an innovative application of that idea. That scientists were already capable of analyzing a genome or measuring gene expression in animals has nothing to do with the novel insight that if you combined such analysis with manipulation of an individual pet's diet it would then become possible to formulate a pet-specific diet to optimize gene expression and health. That utterly novel result was due to the innovative and ordered combination of the steps, not any individual step.

Similarly, in *Ariosa*, a groundbreaking approach to fetal diagnostics was denied coverage under § 101 based on the same confusion between a scientific insight and its practical application. Both here and in *Ariosa*, the Federal Circuit's broad reading of *Mayo* created the "perhaps unintended" consequence of "excluding a meritorious invention from the patent protection it deserves and should be entitled to retain"

despite "no reason in policy or statue" to deny it eligibility. *Ariosa*, 788 F.3d at 1380 (Linn, J., concurring).

The consequences of the Federal Circuit's narrow approach to § 101 reach far beyond these two recent cases or a few patents at the margin. Rather, since this Court's June 2014 decision in *Alice*, 22 of 23 patent cases before the Federal Circuit dealing with § 101 have resulted in invalidation under § 101. Robert R. Sachs, *#Alicestorm: When it Rains, It Pours*, BILSKIBLOG (data as of January 22, 2016, available at http://www.bilskiblog.com/blog/2016/01/alicestorm-when-it-rains-it-pours.html) (visited February 12, 2016). District courts have invalidated claims challenged under § 101 in 128 of 185 such cases before them and the USPTO has similarly been disallowing patent applications at a very high rate when there are issues under § 101. *Id*.

The Federal Circuit's narrow view of § 101 has generated tremendous criticism from commentators, *amici*, and many Federal Circuit judges themselves. Indeed, as described above, *supra* at 12-15, no less than five judges of the Federal Circuit (Judges Linn, Lourie, Moore, Dyk and Newman) have expressed frustration and disagreement with the § 101 standard predicated on the overly broad language of this Court's *Mayo* decision. But despite such concerns, most of those judges have concluded they lack the authority to fix that jurisprudence without further guidance from this Court.

Numerous commentators likewise have found the Federal Circuit's narrow approach to § 101 subject-matter eligibility to be highly problematic. As one such commentator has observed, it is "no secret that

the Section 101 jurisprudence is a mess, as novelty and obviousness inquiries are now being analyzed under the rubric of subject matter eligibility. * * * Making matters worse, lower courts have interpreted the '101 quartet' [of *Bilski*, *Mayo*, *Myriad*, and *Alice*] more broadly than necessary, invalidating many important innovations in the process." Devlin Hartline, *Federal Circuit Should Reconsider* Ariosa v. Sequenom*: The Panel Decision Threatens Modern Innovation*, IPWATCHDOG, Aug. 20, 2015 (available at www.ipwatchdog.com/2015/08/30/federal-circuit-should-reconsider-ariosa-v-sequenom-the-panel-decision-threatens-modern-innovation/id=61171/) (visited Feb. 16, 2016); *see also, e.g.*, Sinatra, 84 FORDHAM L.REV. at 849 (Section 101 framework since *Mayo* and *Alice* "injects uncertain and subjective analysis into the subject matter patentability review by blurring the § 101 requirements with the requirements of other sections of the Patent Act").

Various *amici* also have warned of the destructive consequences that will flow from such a narrowing of eligible subject matter.

First, the Federal Circuit's narrowing of § 101 eligibility excludes many fundamental inventions from patent protection and "threatens to signal to other courts and the USPTO to expand its flawed reasoning to untold numbers of other inventions." Brief of Novartis AG as *Amicus Curiae* in Support of Rehearing *En Banc*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. Nos. 14-1139 & -1144, Doc. 181, at 4 (Aug. 27, 2015). At risk are a host of innovative technologies relating to "personalized medicine, biomarkers

and point-of-care testing." *Id.*[7] If the Federal Circuit's reasoning continues to invalidate any claim "that in some way incorporates a natural phenomenon," the "results for drug discovery and development, and for the future of medicine, could be nothing short of devastating." *Id.*[8]

---

[7] Interestingly, the individually tailored nutrigenomic diet for pets that is the end-point of Hemopet's patented method was and remains a harbinger of today's advances in personalized medicine for humans based on similar genomic analysis. Hemopet's invention, of course, occurred nearly two decades ago, though its § 101 treatment today will continue to be a harbinger for the patent treatment of analogous advances in new methods for individual genome-tailored nutritional or medical interventions for humans.

[8] *See also*, Brief of *Amici Curiae* the Wisconsin Alumni Research Foundation, *et al.* in Support of Sequenom's Petition for Rehearing *En Banc*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. Nos. 14-1139 & -1144, Doc. 178, at 10 (Aug. 25, 2015) (Federal Circuit's narrow approach to § 101 is "likely to deal a grave blow to the medical diagnostics and pharmaceutical industries and to patients whose health depends on medical innovations"); Brief of Professors Jeffrey A. Lefstin and Peter S. Menell as *Amici Curiae* in Support of Rehearing *En Banc*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. Nos. 14-1139 & -1144, Doc. 179, at 4 (Aug. 26, 2015) (Federal Circuit's narrow approach to § 101 "could significantly upend patent protection for a critical field of scientific research" and "set the patent system on a dire course"); Brief of *Amicus Curiae* Jyant Technologies, Inc. in Support of Petition for Rehearing *En Banc*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. Nos. 14-1139 & -1144, Doc. 194, at 3-4 (Aug. 27, 2015) ("the panel's reasoning threatens to abolish wide swaths of existing and future intellectual property. Almost every diagnostic test, whether medical, chemical, or agricultural, relies on some natural phenomenon" and often applies known tools, in a novel combination, "to solve a specific problem").

Second, beyond the direct exclusion of numerous important inventions, the indefiniteness and malleability of the current § 101 standards have "resulted in a level of uncertainty about the scope of patent-eligible subject matter that is unprecedented in the history of biotechnology." Brief of the Biotechnology Industry Organization (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA) as *Amici Curiae* Supporting Appellants and in Favor of *En Banc* Reconsideration, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. Nos. 14-1139 & -1144, Doc. 190, at 2-3 (Aug. 27, 2015). Such uncertainty will "impede[]" the "development and commercialization of a range of biotechnologies" and has already caused "an increasing rate of claim rejections [at the PTO], affecting a diverse range of biotechnology, including novel antibiotic molecules, industrial enzymes, diagnostic processes, and crop protection products." *Id.* at 1, 2-3.

Current jurisprudence and uncertainty that inventions can be protected thus creates a "dark cloud overshadowing thousands of issued and maintained biotechnology patents," "threatens investors' expectations," and is affecting future investment decisions." BIO and PhRMA *Amicus* Br., *supra*, at 3; *see also Amicus Curiae* Brief of the Coalition for 21st Century Medicine in Support of Sequenom, Inc.'s and Sequenom Center for Molecular Medicine, LLC's Petition for Rehearing *En Banc*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. Nos. 14-1139 & -1144, Doc. 196, at 1-2 (Aug. 27, 2015) ("The incentives to innovate provided by the patent system depend above all on predictability. * * * Recent panel decisions [by

the Federal Circuit] have improperly expanded the scope of the Supreme Court's narrow holdings in the life sciences" and "injected an element of arbitrariness into patent examination"); Brief of *Amici Curiae* Twenty-Three Law Professors in Support of Appellant's Petition for Rehearing *En Banc*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. Nos. 14-1139 & -1144, Doc. 197, at 4 (Aug. 27, 2015) (*Ariosa* standard "disincentivizes making the massive R&D investments required to create" new innovation in "genetic and other diagnostic tests"; noting "[t]his is neither hyperbole nor conjecture," citing example of Accelerate Diagnostics warning its investors of potential financial consequences of losing patent coverage for its diagnostic testing technology).

If the Federal Circuit's narrowed § 101 coverage and associated uncertain protection for innovative methods and processes is allowed to continue, "the incentives to develop them may well disappear, or move overseas, or push [companies] to rely on trade secrets, marking the death" of a patent system intended to align private interest with public good. Novartis *Amicus* Brief, *supra*, at 4; *see also* Brief of the Bioindustry Association as *Amicus Curiae* Supporting Petition for Rehearing *En Banc*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. Nos. 14-1139 & -1144, Doc. 192, at 2 (Aug. 27, 2015) (one consequence of the *Ariosa* standard "may be an exodus of investment and businesses from the US market or the life science industry in general.").[9]

---

[9] Unduly narrow eligibility standards also conflict with broader international standards, marking a "setback in long-standing efforts to harmonize patents laws." Bioindustry Ass'n

The broad and destructive implications of the Federal Circuit's current § 101 jurisprudence, and that court's own perceived impotence to correct what many of its judges recognize as troubling course, makes this case a prime candidate for Supreme Court review. Particularly in light of this Court's "repeated admonitions to interpret [its eligibility exceptions] narrowly, lest they 'eviscerate patent law,' " Novartis *Amicus* Br., *supra*, at 3 (quoting *Mayo,* 566 U.S. at 1293), reviewing the Federal Circuit's unduly narrow standards for § 101 eligibility presents "a question of exceptional importance." Brief of Intellectual Property Owners Association as *Amicus Curiae* Supporting Appellants and in Favor of Rehearing *En Banc*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. Nos. 14-1139 & -1144, Doc. 183, at 2 (Aug. 27, 2015).

The Federal Circuit's current approach "suffers from the * * * infirmity of missing the forest for the trees," that infirmity "will likely proliferate," and "is representative of the difficulties courts and the PTO are often having in properly evaluating patent eligibility since *Mayo*." *Id*. at 4, 7. With no limiting principle in sight or likely to arise from a Federal Circuit that sees itself constrained by this Court's broad language in *Mayo*, there is an "urgent need" for the Su-

---

Amicus Br., *supra*, at 2-3 (Federal Circuit decisions put "the US patentable subject matter eligibility standard at odds with those of other industrial nations."); BIO and PhRMA *Amicus* Br., *supra*, at 2-3 (our "trading partners are growing concerned about a widening U.S. departure from internationally prevailing standards for patent eligibility of at least some biotechnologies, and its effect on trade and the cross-border flow of innovation and investment.[fn omitted]").

preme Court "to readdress the contours of patent eligibility in the context of biotechnology." BIO and PhRMA *Amicus* Br., *supra*, at 8-9.

CONCLUSION

For the reasons above, this Court should grant the petition for a writ of certiorari.

Respectfully submitted,

ERIK S. JAFFE
(Counsel of Record)
ERIK S. JAFFE, P.C.
5101 34th Street, N.W.
Washington, D.C. 20008
(202) 237-8165

CHARLES BERMAN
938 Stanford Street
Santa Monica, CA 90403
(310) 828-4804
charlesberman@hemopet.org

Counsel for Petitioner

Dated: February 18, 2016

APPENDICES

APPENDIX A

617 Fed. Appx. 997; 2015 U.S. App. LEXIS 17035

Hemopet v. Hill's Pet Nutrition, Inc.

United States Court of Appeals for the Federal Circuit

September 21, 2015, Decided

2015-1218

Notice: THIS DECISION WAS ISSUED AS UNPUBLISHED OR NONPRECEDENTIAL AND MAY NOT BE CITED AS PRECEDENT. PLEASE REFER TO *FEDERAL RULES OF APPELLATE PROCEDURE RULE 32.1* GOVERNING THE CITATION TO UNPUBLISHED OPINIONS.

[*997]

JUDGMENT

This Cause having been heard and considered, it is

Ordered and Adjudged:

Per Curiam (Newman, Dyk, and Taranto, *Circuit Judges*).

AFFIRMED. ***See Fed. Cir. R. 36***.

APPENDIX B

2014 U.S. Dist. LEXIS 184685

Hemopet v. Hill's Pet Nutrition, Inc.

United States District Court for the

Central District of California

November 24, 2014, Decided; November 24, 2014, Filed

CASE NO. CV 12-01908-JLS (JPRx)

JOSEPHINE L. STATON, UNITED STATES DISTRICT JUDGE.

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT (Doc. 93)

I. INTRODUCTION

Before the Court is a Motion for Summary Judgment filed by Defendant Hill's Pet Nutrition, Inc. (Mot., Doc. 93.) Plaintiff Hemopet opposed, and Hill's replied. (Docs. 97, 105.) Having read and considered the parties' papers and heard oral argument, the Court GRANTS Defendant's Motion.

II. BACKGROUND

On November 2, 2012, Hemopet filed a Complaint in this Court against Hill's for patent infringement. (Doc. 1.) On January 16, 2013, Hemopet filed a First Amended Complaint ("FAC"). (Doc. 19.) Hemopet asserts that Hill's has infringed and continues to in-

fringe four patents that Hemopet was assigned and owns. (Id.) After the parties' filed their briefs regarding claim construction, this Court issued **[*2]** its Order on Claim Construction on May 13, 2014. (Order on Claim Construction, Doc. 76.)

On September 18, 2014, Hill's filed a Motion for Summary Judgment. (Doc. 93.) Hill's argues that Hemopet's infringement claims fail as a matter of law because (1) claims 1 and 2 of U.S. Patent No. 7,865,343, claims 1, 2, 9, and 10 of U.S. Patent No. 8,060,354, claim 1 of U.S. Patent 8,234,099, and claims 1 and 8 of U.S. Patent No. 8,224,587 are invalid under 35 U.S.C. § 101; (2) claims 1, 2, 9, and 10 of the '354 patent, claim 1 of the '099 patent, and claims 1 and 8 of the '587 patent are invalid under 35 U.S.C. § 102; (3) claims 1 and 2 of the '343 patent, claims 1, 2, 9, and 10 of the '354 patent, claim 1 of the '099 patent, and claims 1 and 8 of the '587 patent are not infringed; and (4) Hill's acts of using, selling, or offering for sale pet food products, the process that Hill's uses to manufacture pet food products, and Hill's identification of any ingredients prior to the issuance of Hemopet's patents do not infringe claims 1 or 2 of the '343 patent, claims 1, 2, 9, or 10 of the '354 patent, claim 1 of the '099 patent, or claims 1 or 8 of the '587 patent. (Id. at 2.)

The patents at issue all disclose in a similar manner "a method, apparatus and system of obtaining, analyzing and reporting laboratory test data in relation to the health assessment data of an animal together with the genetic data related to that same animal." '343 patent, col. 2:6-2:9. **[*3]** According to the claims largely shared by the patents, the invention

allows the user to "formulate and prepare a nutritional diet product based on the relationship" between "first data relating genomic map data to a physiological condition of the animal" and "second data comprising the effect of nutrition on the expression of at least one gene in the genomic map." '354 patent, col. 25:3-25:12.

Claim 1 of the '343 patent, entitled "Method of Analyzing Nutrition for a Canine or Feline Animal," reads:

> A method of analyzing nutrition for a canine or feline animal, comprising: accessing at least one database that comprises first data relating genetic descriptor genomic data to a physiological condition, wherein the genetic descriptor genomic data is obtained from either a bodily fluid or tissue sample;
>
> accessing second data comprising the effect of nutrition on the expression of the genetic descriptor genomic data;
>
> analyzing, by use of a computer, the first and second data, relating the effect of nutrition on the expression of the genetic descriptor genomic data for the animal to the physiological condition, wherein the physiological condition comprises gastrointestinal function or immunological function of the **[*4]** animal; and formulating a nutritional diet based on the analyzed data.

'343 patent, col. 23:41-24:4.

Claim 2 of the '343 patent reads:

> The method of claim 1 further comprising preparing a nutritional diet based on the analyzed data.

Id., col. 24:5-24:6.

Claim 1 of the '354 patent, entitled "System and Method for Determining a Nutritional Diet for a Canine or Feline Animal," reads:

> A system for determining a nutritional diet for a canine or feline companion animal comprising:
>
> a computer;
>
> at least one electronic database coupled to the computing system;
>
> at least one software routine executing on the computing system which is programmed to:
>
> (a) receive first data relating genomic map data to a physiological condition of the animal, and second data comprising the effect of nutrition on the expression of at least one gene in the genomic map;
>
> (b) determine a relationship between said first and second data; and
>
> (c) based on the relationship, determine a nutritional diet for the canine or feline companion animal; and formulate and prepare a nutritional diet product based on the relationship.

'354 patent, col. 24:63-25:11.

Claims 2, 9, and 10 of the '354 patent, though slightly different in structure, disclose the same system and/or method as claim 1 for "determining **[*5]** a nutritional diet for a canine or feline companion animal." Id., col. 25:13-25:31; Id. col. 25:58-26:4; Id. col. 26:5-26:18.

Claim 1 of the '099 patent, entitled "Computer Program for Determining a Nutritional Diet Product for a Canine or Feline Animal," reads:

> A non-transitory computer-readable medium for determining a nutritional diet for a canine or feline companion animal stored thereon instructions for a computer to execute the medium comprising:
>
> at least one electronic database; and
>
> at least one software routine comprising instruction for:
>
> (a) receiving first data relating genomic map data to a physiological condition of a canine or feline companion animal, and second data comprising the effect of nutrition on the expression of genes in the genomic map data;
>
> (b) determining a relationship between said first and second data; and preparing a nutritional diet for the canine or feline companion animal based on the relationship.

'099 patent, col. 24:66-25:11.

Claim 1 of the '587 patent, entitled "Method and System for Determining a Nutritional Diet for a Canine or Feline Animal," reads:

> A method for determining a nutritional diet for a canine or feline companion animal comprising the steps of:
>
> (a) receiving first data relating **[*6]** the expression of at least one gene from a genomic map of the animal to a physiological condition of the animal,
>
> (b) receiving second data comprising an effect of nutrition on the expression of least one gene from the genomic map;
>
> (c) determining a relationship between the first and second data using a suitably programmed computer, and
>
> (d) determining a nutritional diet for the animal based on the relationship of said first and second data.

'587 patent, col. 25:46-26:1.

Finally, claim 8 of the '587 patent essentially combines the language of claim 1 of the '354 patent and claim 1 of the '587 patent. Id. col. 26:28-26:42.

In sum, the patents in suit claim (1) an electronic database consisting of data regarding the map of part of the DNA sequence of a cat or dog, (2) an electronic database consisting of the effect of nutrition on the expression of at least one gene from the map of part of the DNA sequence of a cat or dog, (3) utilizing a computer and software routine to determine a relationship between these two databases, and (4) developing, designing, or making a particular nutrient or caloric composition for a cat or dog. (*See generally* Order on Claim Construction.) All of the claims are

implemented using a computer and software **[*7]** routine.

The four patents at issue therefore disclose a method and/or system for analyzing and determining a nutritional diet for cats and dogs. The key inquiry in this case is whether these claims are patent eligible under 35 U.S.C. § 101, or are instead drawn to patent-ineligible abstract ideas. Hill's argues that these patents are also invalid under 35 U.S.C. § 102 and that Defendant has not infringed the patents. (*See* Mot.) However, because the Court finds that all four patents are invalid under 35 U.S.C. § 101, we need not address Defendant's § 102 and non-infringement arguments.

III. LEGAL STANDARD

In deciding a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-moving party and draw all justifiable inferences in that party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). Summary judgment is proper "if the [moving party] shows that there is no genuine dispute as to any material fact and the [moving party] is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. A factual issue is "genuine" when there is sufficient evidence such that a reasonable trier of fact could resolve the issue in the non-movant's favor, and an issue is "material" when its resolution might affect the outcome of the suit under the governing law. *Anderson*, 477 U.S. at 248.

The moving **[*8]** party bears the initial burden of demonstrating the absence of a genuine issue of fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct.

2548, 91 L. Ed. 2d 265 (1986). "When the party moving for summary judgment would bear the burden of proof at trial, it must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial." *C.A.R. Transp. Brokerage Co. v. Darden Rests., Inc.*, 213 F.3d 474, 480 (9th Cir. 2000) (citation and quotation marks omitted). The burden then shifts to the non-moving party to "cit[e] to particular parts of materials in the record" supporting its assertion that a fact is "genuinely disputed." Fed. R. Civ. P. 56(c)(1); *see also In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387 (9th Cir. 2010) ("non-moving party must come forth with evidence from which a jury could reasonably render a verdict in the non-moving party's favor").

The burden of establishing patent invalidity or any claim thereof rests with the party asserting such invalidity. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242, 180 L. Ed. 2d 131 (2011). An invalidity defense must therefore be proved by clear and convincing evidence. *Id.*

IV. DISCUSSION

As noted above, Hill's argues that Hemopet's infringement claims fail as a matter of law because the four patents at issue are invalid under 35 U.S.C. § 101 for claiming ineligible subject matter.

Section 101 of the Patent Act defines the subject matter that is eligible for patent protection: "Whoever invents or discovers any new and useful **[*9]** process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." 35 U.S.C. § 101. This sec-

tion, however, contains important implicit exceptions. "Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354, 189 L. Ed. 2d 296 (2014) (quoting *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116, 186 L. Ed. 2d 124 (2013)). The concern that drives these exceptions is preemption; laws of nature, natural phenomena, and abstract ideas are "the basic tools of scientific and technological work" and granting patents based on these exceptions might impede innovation more than it would promote it. Yet, to some extent "all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Alice*, 134 S. Ct. at 2354 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293, 182 L. Ed. 2d 321 (2012)). "Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept." *Alice*, 134 S. Ct. at 2354 (citing *Diamond v. Diehr*, 450 U.S. 175, 187, 101 S. Ct. 1048, 67 L. Ed. 2d 155 (1981)).

The Supreme Court has analyzed § 101 by distinguishing "between patents that claim the building blocks of human ingenuity and those that integrate the building blocks into something more, thereby transforming them into a patent-eligible invention." *Alice*, 134 S. Ct. at 2354 (internal quotations and citations omitted). The Supreme Court, in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 182 L. Ed. 2d 321 (2012), set **[*10]** forth a two-step framework for distinguishing between these two types of patents. "First, we determine whether the claims at issue are directed to one

of those patent-ineligible concepts. If so, we then ask, [w]hat else is there in the claims before us?" *Alice*, 134 S. Ct. at 2355 (alteration in original) (quoting *Mayo*, 132 S. Ct. at 1296-97). The second step is essentially "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.'" *Alice*, 134 S. Ct. at 2355 (alteration in original) (quoting *Mayo*, 132 S. Ct. at 1294). The elements of each claim must therefore be considered both individually and "as an ordered combination." *Mayo*, 132 S. Ct. at 1298 (2012).

A. Patent-Ineligible Concept

We must first determine whether the claims at issue in Hemopet's four patents are directed to patent-ineligible concepts.

Hill's argues that the claims at issue simply reflect naturally occurring phenomena. Specifically, Hill's argues that the claims "are directed to the abstract concept of determining a nutritional diet for a canine or feline based on naturally occurring relationships between physiological conditions and genomic data and the effect of nutrition on genomic data." **[*11]** (Mot. at 7-8, Doc. 93.) Therefore, Hill's contends the claims simply recite abstract concepts followed by an "apply the law" step. (Mot. at 9.)

Hemopet responds that the claims at issue "are directed to a new way of developing a dog or cat food, not an abstract concept." (Opp'n. at 4, Doc. 97.) Hemopet relies on the opinions of expert Dr. Nate Sutter in arguing that a novel and tangible creation results from the patent claims: "[T]he Asserted Pa-

tents disclose obtaining robust genomic-level data through the use of sophisticated, high throughput techniques, comparing that first data to second data of similar scale reflecting changes as a result of nutrition, and then leveraging the results of that analysis into formulating and preparing a canine or feline nutritional diet or product." (Id.; Opp'n, Ex. 2, 07/17/14 Sutter Report P 103.) Hemopet further contends that the relationship between nutrition and gene expression is induced through human intervention and used to develop a novel nutritional diet or product. (Opp'n at 5.)

However, Supreme Court and Federal Circuit precedent is clear that patents which set forth laws of nature or relationships "that exist in principle apart from any human **[*12]** interaction" are not patentable without more. *Mayo*, 132 S. Ct. at 1297. For example, in *Mayo*, the Supreme Court considered whether claims that covered a process that helped doctors who use thiopurine drugs treat patients with autoimmune diseases by determining whether a given dosage level is too high or too low encompassed unpatentable natural laws or patent-eligible applications of those laws. *Id.* at 1294. The court found that "[w]hile it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action." *Id.* at 1297. As a result, the Supreme Court held that the patent in *Mayo* was invalid because "the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets

forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law." *Id.* at 1299.

Further, in *PerkinElmer, Inc.* v. *Intema Ltd.*, the Federal Circuit addressed a patent that disclosed specific screening methods for estimating the risk of fetal Down's syndrome. 496 F. App'x 65 (2012). One of the representative claims disclosed **[*13]** the method through the following steps: "[1] measuring the level of at least one screening marker from a first trimester of pregnancy . . . [2] measuring the level of at least one second screening marker from a second trimester of pregnancy...[3] and determining the risk of Down's syndrome by comparing the measured levels of both...with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies." *Id.* at 67. The *PerkinElmer* Court found that "an increased risk of fetal Down's syndrome produces certain analytical results is a natural process" and thus the "measuring" and "determining" steps were "insufficient to make the claim patent-eligible because it is well-understood, conventional information." *Id.* at 71. The Federal Circuit therefore affirmed the district court's holding that "physical data-gathering steps, which may cover patent-eligible subject matter, are insufficient to make claims reciting abstract ideas patent-eligible applications of the ineligible concepts." *Id.* at 72.

Hemopet's four patents encompass claims similar to those found in *Mayo* and *PerkinElmer*. The claims at issue here tell practitioners to: (1) measure and use data relating **[*14]** the map of part of the DNA

sequence of the animal to a physiological condition of the animal, (2) measure and use data comprising the effect of nutrition on the expression of at least one gene from the map of part of the DNA sequence of the animal, (3) compare the two sets of data to determine a relationship, and (4) determine, formulate, and prepare a nutritional diet for that animal. (*See generally* Order on Claim Construction.) Though different terminology may be used, a similar claim structure is present here as it was in *Mayo* and *PerkinElmer*. The main addition here that was not present in the claims addressed in *Mayo* and *PerkinElmer* is that the claims in Hemopet's patents go one step further; they include a final step of formulate and prepare a nutritional diet for that animal. Nevertheless, the formulation and preparation of pet food is nothing more than an extension of the abstract idea of "determine" a dog or cat's diet. The creating or formulating processes directed in the claims are couched in the most general terms, lacking any specifics that would allow a practitioner to learn how to actually develop or produce such a diet. *See Alice*, 134 S. Ct. at 2359-2360 (explaining that the claims at issue were **[*15]** not patent-eligible because the "system and media claims add nothing of substance to the underlying abstract idea"). Therefore, all of the claims are squarely within the realm of "abstract ideas" as defined by the Supreme Court.

The Court therefore agrees with Hill's that the claims at issue encompass the abstract concept of determining a nutritional diet for a dog or cat based on naturally occurring relationships. We therefore turn to the second step of *Mayo*'s framework to determine

whether directing in general terms the development and design of a particular nutrient or caloric composition for a dog or cat transforms the abstract idea into something patent-eligible. (*See* Order on Claim Construction at 14-15.)

B. Inventive Concept

The second step of *Mayo*'s framework involves examining "the elements of the claim to determine whether it contain[s] an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application. *Alice*, 134 S. Ct. at 2357 (quoting *Mayo*, 132 S. Ct. at 1298). Claims "are not patentable unless they have additional features that provide practical assurance that the processes are genuine applications of those laws rather than drafting efforts designed to monopolize the correlations." *Mayo*, 132 S. Ct. at 1291. "[T]o **[*16]** transform an unpatentable law of nature into a patent-eligible application of such a law, a patent must do more than simply state the law of nature while adding the words 'apply it.'" *Mayo*, 132 S. Ct. at 1290 (citing *Gottschalk v. Benson*, 409 U.S. 63, 93 S. Ct. 253, 34 L. Ed. 2d 273 (1972)). "The introduction of a computer into the claims does not alter the analysis at *Mayo* step two." *Alice*, 134 S. Ct. at 2357.

Hill's argues that the patent claims at issue simply describe naturally occurring phenomena or recite abstract ideas "with no detail or explanation of how to determine the relationship, determine the content or formulate the diet." (Mot. at 9.) For example, Hill's contends that Claim 2 of the '354 patent, representative of all four of Hemopet's patents, is simply comprised of two steps (a) and (b), which are directed to

receiving two sets of data that are naturally occurring, step (c), which is directed to determining a relationship between the two sets of data, and step (d), which is a general direction to determine and formulate a nutritional diet without any detail concerning how to perform this final step. (Mot. at 11-12.) Hill's argues that the computer, electronic databases, and software routines described in the claims are "purely functional and generic" and do not provide "a meaningful limitation beyond generally linking the use of the method to a particular technological environment." (Mot. at 14.) **[*17]**

Hemopet argues in opposition that "the claimed invention incorporates the notion that nutrition can influence gene expression" and "applies these ideas in a practical, tangible way by transforming information and raw materials into a nutritional diet product designed to induce specific gene expression in a pet." (Opp'n at 6.) Hemopet once again relies on the opinion of Dr. Sutter to contend that the last step "of taking the resulting information from the analysis performed on the data sets and using it to develop and design, or create, or determine what nutrients or caloric compositions should be used in a food product is a key part of the novelty of the invention." (Id.; Opp'n, Ex. 2 at P 112.)

The Court agrees with Hemopet that this final step in the claims, creating a nutritional product for dogs or cats, is an additional step not found in previous claims the Supreme Court has addressed. *See Alice*, 134 S. Ct. 2347, 189 L. Ed. 2d 296; *Mayo*, 132 S. Ct. 1289, 182 L. Ed. 2d 321; *PerkinElmer*, 496 F. App'x 65. However, the Court finds Hill's to be correct

that this step is nothing more than a general "apply it" step that does not transform an otherwise ineligible-patent concept into a patentable invention. For that reason, Hemopet's reliance on *Diehr* misses the mark.

In *Diehr*, the Supreme Court **[*18]** addressed a claimed process for molding raw, uncured synthetic rubber into cured precision products. *Diehr*, 450 U.S. at 177. The claims described a process where a mold is used "for precisely shaping the uncured material under heat and pressure[,]" whereby synthetic rubber is then created by curing it in the mold so that the product would "retain its shape and be functionally operative after the molding is completed." *Id.* The Court found that the specifically claimed physical and chemical process for molding precision synthetic rubber products satisfied § 101 as possibly patentable subject matter because the claims "involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing." *Id.* at 184. Because the "claims describe in detail a step-by-step method for accomplishing such, beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure," the *Diehr* Court found that the patent set forth an industrial process of the type that has historically been protected by our patent laws. *Id.*

However, here, claim 1 of the representative '354 patent recites "measuring" and "determining" steps that the Supreme **[*19]** Court and Federal Circuit have found to be patent ineligible. *See Alice*, 134 S. Ct. 2347, 189 L. Ed. 2d 296; *Mayo*, 132 S. Ct. 1289,

182 L. Ed. 2d 321; *PerkinElmer*, 496 F. App'x 65. Only the final step, "determine a nutritional diet for the canine or feline companion animal; and formulate and prepare a nutritional diet product based on the relationship," relates to the creation of a "different state or thing." However, whether considered individually or in combination with the other steps, the claims do nothing more than instruct the practitioner to implement the abstract ideas of the first few unpatentable steps in the final step. "[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable...." *Mayo*, 132 S. Ct. at 1292 (2012). This is nothing more than telling the practitioner to "apply it" in general terms. Hemopet's claims do not describe in detail a step-by-step method for developing a nutritional diet product. *Diehr* therefore does not control here.

Hemopet also relies on the opinion of Dr. Sutter to argue that the necessary "inventive concept" is included in the claims through the use of computers, databases, and software: "The inventive concept here pertains to the integration of this data into **[*20]** something more—the collection and storage of raw data in a computer using databases that identify the relationships within the two data sets of the invention.... Using databases to parse and organize the raw data into these sets allows the practitioner to eventually, as described in the next step, integrate the sets even further to identify new relationships with a level of scientific and statistical reliability previously unachievable using other systems." (Opp'n at 6;

Opp'n, Ex. 2 at P 106.) However, the functions performed by the computer, database, or software routine at each step of Hemopet's process are "well-understood, routine, conventional activity, previously engaged in by those in the field." *Mayo*, 132 S. Ct. at 1292; *see Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d 1266, 1278 (Fed. Cir. 2012) ("To salvage an otherwise patent-ineligible process, a computer must be integral to the claimed invention, facilitating the process in a way that a person making calculations or computations could not."); *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1333 (Fed.Cir.2010) ("In order for the addition of a machine to impose a meaningful limit on the scope of a claim, it must play a significant part in permitting the claimed method to be performed, rather than function solely as an obvious mechanism for permitting a solution to be achieved more **[*21]** quickly, i.e., through the utilization of a computer for performing calculations."). Dr. Sutter may be correct that "[a]nalyzing the relationships as disclosed in the invention is not merely a matter of comparing column A with column B in a simple 10 row spreadsheet," but measuring, storing, parsing, organizing, and analyzing the relationships of data are basic functions of a computer and database-related software. (Opp'n, Ex. 2 at P 107.); *see Alice, 134 S. Ct. at 2358* ("mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention"); *Bancorp, 687 F.3d at 1278* ("The computer required by some of Bancorp's claims is employed only for its most basic function, the performance of repetitive calculations, and as such does not impose meaningful limits on the scope of those claims."). "In

other words, the complexity of the implementing software or the level of detail in the specification does not transform a claim reciting only an abstract concept into a patent-eligible system or method." *Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1345 (Fed. Cir. 2013). Hemopet's collection and storage of raw data in a computer using databases that identify the relationships between the two data sets therefore does not transform patent-ineligible claims into something **[*22]** valid under § 101. (*See* Mot., Ex. 18, 4/12/12 Giger Decl. at P 14.) ("The analysis, selection, design and development is not complex, once the datasets are processed, which would likely have been quite straightforward for data analysts.") Even when viewed as an "ordered combination," the claims simply recite the abstract concept of determining a nutritional diet for a dog or cat based on naturally occurring relationships and fail to include any express language to define how the nutritional diet is actually formulated, developed, or produced.

Hemopet finally contends that the claims are limited to formulating or preparing a nutritional diet product or diet and therefore the preemption concerns inherent in § 101 are not at issue in this case. (Opp'n at 9-11.) However, "the prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity.'" *Bilski v. Kappos,* 561 U.S. 593, 610-11, 130 S. Ct. 3218, 177 L. Ed. 2d 792 (2010) (quoting *Diamond v. Diehr*, 450 U.S. 175, 191-192, 101 S. Ct. 1048, 67 L. Ed. 2d 155 (1981)). Therefore,

the last step of the claims directing the practitioner to create, develop, or formulate a nutritional diet for a cat or dog based on previous electronic data collection and analysis does not change **[*23]** the Court's conclusion that the patents are invalid under § 101. *See Bancorp*, 687 F.3d at 1280 (explaining that "*Flook* established that limiting an abstract idea to one field of use or adding token post-solution components did not make the concept patentable") (quoting *Bilski*, 130 S. Ct. at 3231). Under Supreme Court precedent, this "limitation" is simply not enough to transform the abstract idea inherent in the claims into a patent-eligible invention.

For these reasons, the Court finds that the claims at issue are drawn to a patent-ineligible abstract idea. Summary judgment is therefore GRANTED because claims 1 and 2 of U.S. Patent No. 7,865,343, claims 1, 2, 9, and 10 of U.S. Patent No. 8,060,354, claim 1 of U.S. Patent 8,234,099, and claims 1 and 8 of U.S. Patent No. 8,224,587 are invalid under 35 U.S.C. § 101.

IV. CONCLUSION

For the foregoing reasons, Defendant's Motion is GRANTED. Defendant is directed to submit a proposed judgment forthwith.

DATED: November 24, 2014

JOSEPHINE L. STATON

UNITED STATES DISTRICT JUDGE

APPENDIX C

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

HEMOPET, Plaintiff,	Case No.: SACV 12-01908-JLS (JPRx)
v.	**JUDGMENT**
HILL'S PET NUTRITION, INC., Defendant.	Honorable Josephine L . Staton

The Court, having considered Defendant Hill's Pet Nutrition, Inc. Motion for Summary Judgment (Doc. 93), the arguments and evidence presented in the moving, opposition and reply papers and at oral argument, and a decision granting Defendant's Motion for Summary Judgment having been duly rendered on November 24, 2014 (Doc. 119), deciding that claims 1 and 2 of U.S. Patent No. 7,865,343, claims 1, 2, 9, and 10 of U.S. Patent No. 8,060,354, claim 1 of U.S. Patent 8,234,099, and claims 1 and 8 of U.S. Patent No. 8,224,587 are invalid under 35 U.S.C. § 101:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that Judgment is entered in favor of Defendant Hill's Pet Nutrition, Inc.

Dated: January 15, 2015 **SO ORDERED:**

s/ Josephine Staton

Honorable Josephine L. Staton
United States District Judge