IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENETIC TECHNOLOGIES LIMITED, Plaintiff, v. LABORATORY CORPORATION OF AMERICA HOLDINGS, LABORATORY CORPORATION OF AMERICA, and 23ANDME, INC., Defendants.	)	Civil Action No. 12-1736-LPS-CJB

REPORT AND RECOMMENDATION

Presently pending before the Court is Defendants Laboratory Corporation of America Holdings ("LabCorp Holdings"), Laboratory Corporation of America ("LabCorp America") (collectively, "LabCorp") and 23andMe, Inc.'s ("23andMe") (collectively, "Defendants") motion to dismiss for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure (the "Motion"). (D.I. 9) Defendants argue that Plaintiff Genetic Technologies Limited's ("Plaintiff") U.S. Patent No. 7,615,342 (the "'342 Patent") is directed to non-patent-eligible subject matter under 35 U.S.C. § 101 ("Section 101"). For the reasons that follow, the Court recommends that Defendants' Motion be GRANTED as to asserted claim 1 of the '342 Patent.

I. BACKGROUND

A. Factual Background

Plaintiff is an Australian corporation and is the owner of the '342 Patent by assignment. (D.I. 1 at ¶¶ 1, 10) The '342 Patent, entitled "ACTN3 Genotype Screen for Athletic

Performance," was issued on November 10, 2009. ('342 Patent at 1)[1]

The specification of the '342 Patent explains that certain genotypes are associated with physiological traits that may contribute to or reduce performance in an elite athlete. (*Id.*, col. 1:61-63) In the "Background of the Invention" section, the patent explains that the invention relates to "methods for selecting or matching a sport or sporting event to an individual . . . to increase their chances of success, optimizing the training programs of individuals, and for predicting the athletic performance of individuals[,]" based on the identification of "specific gene(s) or alterations in the gene(s) that correlate with potential athletic performance." (*Id.*, col. 1:16-23)

More specifically, the specification describes how "α-actinins play a role in thin filament organization and the interaction between the sarcomere cytoskeleton and the muscle membrane[,]" and that α-actinins further play "a role in the regulation of myofiber differentiation and/or contraction." (*Id.*, col. 2:27-38) The specification further points out the apparent functional redundancy of the α-actinin-2 gene ("ACTN2") and the α-actinin-3 gene ("ACTN3"), and asserts the hypothesis "that [ACTN2] is able to compensate for the absence of [ACTN3] in type 2 (fast) fibers in humans." (*Id.*, col. 2:54-67) Despite this apparent functional redundancy, genotype screens of elite athletes—in particular, sprinters, swimmers and cyclists—have showed "a very low frequency of homozygosity for the ACTN3 premature stop codon 577X mutation" as compared to the general Australian Caucasian population. (*Id.*, col. 3:3-10) The genotype screens also demonstrated that the frequency of the 577XX genotype was relatively higher in

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[1] The '342 Patent was attached as an exhibit to Plaintiff's Complaint. (D.I. 1, ex. A)

Caucasian elite endurance athletes. (*Id.*, col. 3:13-15) Thus, the specification explains that screening procedures for these genotypes may provide assistance in selecting young individuals with potential for elite performance in sprint-type and endurance sports. (*Id.*, col. 3:10-19)

The methods claimed in the '342 Patent embody findings that the presence of certain genes is correlated with elite sprinting, strength, or power performance. (*Id.*, col. 29:49-32:10) There are fourteen claims in the '342 Patent. (*Id.*) Claim 1, the only currently asserted claim in this matter, reads as follows:

> 1. A method to predict potential sprinting, strength, or power performance in a human comprising:
>
> a) analyzing a sample obtained from the human for the presence of one or more genetic variations in α-actinin-3 (ACTN3) gene;
>
> b) detecting the presence of two 577R alleles at the loci encoding amino acid number 577 of the α-actinin-3 (ACTN3) protein; and
>
> c) predicting the potential sprinting, strength, or power performance of the human, wherein the presence of two copies of the 577R allele is positively associated with potential sprinting, strength, or power performance.

(*Id.*, col. 29:50-61)

According to Plaintiff's Complaint, Defendants work together to provide genetic testing to the public, including ACTN3 gene testing. (D.I. 1 at ¶ 17) LabCorp, a clinical laboratory company, operates a national network of 54 primary laboratories, over 1,700 patient service centers, and nine specialized Centers of Excellence, including the National Genetics Institute. (*Id.* at ¶¶ 15, 18) Though this network, LabCorp provides a variety of testing, including advanced genomic testing such as ACTN3 gene testing. (*Id.* at ¶ 15)

Defendant 23andMe is said to market, *inter alia*, ACTN3 genomic testing and analysis services to the public, and to contract with LabCorp, which performs the actual testing of a customer's DNA. (*Id.* at ¶ 16) Upon completion of the testing, it is alleged that Defendants, "acting in concert, analyze the results; predict the sprinting, strength, or power performance of that purchaser; and report that prediction to the purchaser." (*Id.*)

B. Procedural Background

On December 20, 2012, Plaintiff commenced this action, asserting that Defendants directly and indirectly infringe one or more claims of the '342 Patent through their genotyping services. (D.I. 1 at ¶¶ 21-26) Plaintiff has subsequently confirmed that claim 1 of the '342 Patent is the only claim that is presently being asserted in this action. (D.I. 24 at 39, 41) In lieu of filing an Answer, on February 25, 2013, Defendants filed the instant Motion. (D.I. 9) The Motion was fully briefed as of March 25, 2013. (D.I. 14)

On July 15, 2013, this matter was referred to the Court by Chief Judge Leonard P. Stark to hear and resolve all pretrial matters, up to and including the resolution of case-dispositive motions. (D.I. 21) On July 30, 2013, the Court heard oral argument regarding the Motion. (D.I. 24 (hereinafter, Tr.")) Thereafter, the parties submitted several supplemental letters to apprise the Court of recent opinions—including a number of important decisions by the Supreme Court of the United States—that might impact review of the Section 101-related issues that are at play in this matter. (D.I. 16, 18, 20, 23, 25, 26, 27, 28, 29, 30) Now having the benefit of these recent decisions, the Court finds the Motion ripe for decision.

II. STANDARD OF REVIEW[2]

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a party may move to dismiss the plaintiff's complaint based on the failure to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). The sufficiency of pleadings for non-fraud cases is governed by Federal Rule of Civil Procedure 8, which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In order to survive a motion to dismiss pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true,

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[2] In a Notice of Subsequent Authority filed after briefing had closed in this case, Plaintiff alerted the Court to the United States Court of Appeals for the Federal Circuit's decision in *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335 (Fed. Cir. 2013). (D.I. 18) Plaintiff noted that in that decision, the *Ultramercial* Court addresses "four preliminary issues that ordinarily preclude Rule 12(b)(6) dismissal based upon patent ineligible subject matter." (*Id.* at 2 (citing *Ultramercial,* 722 F.3d at 1338-40)) Recently, however, in a short order that did not include discussion of the merits, the Supreme Court vacated and remanded *Ultramercial* for further consideration in light of its decision in *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). *See WildTangent, Inc. v. Ultramercial, LLC*, 134 S. Ct. 2870 (2014). At least one court has noted that this has generated uncertainty as to what impact the order and the Supreme Court's decision in *CLS Bank Int'l* would ultimately have on the rationale expressed by the Federal Circuit in *Ultramercial*. *See Data Distrib. Techs., LLC v. BRER Affiliates, Inc.*, Civil No. 12-4878 (JBS/KMW), 2014 WL 4162765, at *4 n.2 (D.N.J. Aug. 19, 2014); *cf. Diaz v. Stephens*, 731 F.3d 370, 378 (5th Cir. 2013) (noting that when the Supreme Court vacates a decision in this manner, it makes no decision on the merits of the underlying case; instead, the Supreme Court's order allows a circuit court to review its prior opinion in light of, *inter alia*, a recent Supreme Court decision in the area, in order to determine whether the prior decision is still correct or a different result is more appropriate). At a minimum, because the decision in *Ultramercial* has been vacated, it is clear that it no longer has precedential effect. *See Cnty. of L.A. v. Davis*, 440 U.S. 625, 634 n.6 (1979) ("Of necessity our decision vacating the judgment of the Court of Appeals deprives that court's opinion of precedential effect[.]") (internal quotation marks and citations omitted); *In re Joy Global, Inc.*, 381 B.R. 603, 610 (D. Del. 2007) ("[V]acating a lower court's ruling deprives that [lower] court's opinion of precedential effect.") (internal quotation marks and citations omitted). For that reason, the Court will not rely on the *Ultramercial* decision here. *See Data Distrib. Techs., LLC*, 2014 WL 4162765, at *4 n.2 (concluding that "[b]ecause there was no discussion or analysis [of *Ultramercial* in the Supreme Court's order vacating the decision], the [c]ourt will not infer any meaning and will simply avoid relying on the Federal Circuit's vacated *Ultramercial* decision").

to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks and citation omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citation omitted). In assessing the plausibility of a claim, the court must "construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citing *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).[3]

Patentability under Section 101 is a "threshold inquiry" and a question of law, *In re Bilski*, 545 F.3d 943, 950 (Fed. Cir. 2008), *aff'd*, *Bilski v. Kappos*, 561 U.S. 593 (2010), one that "may be informed by subsidiary factual issues[,]" *CyberFone Sys., LLC v. Cellco P'ship*, 885 F. Supp. 2d 710, 715 (D. Del. 2012) (citing *In re Comiskey*, 554 F.3d 967, 975 (Fed. Cir. 2009)).

III. DISCUSSION

Defendants move to dismiss Plaintiff's Complaint, without leave to amend, on the basis that the '342 Patent is drawn to non-patent-eligible subject matter under Section 101. Defendants assert dismissal is warranted because Plaintiff's claims are directed to the discovery of a natural law—that is, that individuals with a particular genetic variation are better sprinters than those without it. (D.I. 9, 14) The Court will first set out the general framework for Section 101

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[3] If Rule 12(b)(6) is used to assert an affirmative defense, as here, dismissal is permitted only if the well-pleaded factual allegations in the complaint, construed in the light most favorable to the plaintiff, suffice to establish the defense. *See Jones v. Bock*, 549 U.S. 199, 215 (2007); *see also Kabbaj v. Google, Inc.*, Civ. No. 13-1522-RGA, 2014 WL 1369864, at *2 n.2 (D. Del. Apr. 7, 2014) (explaining that an affirmative defense apparent on the face of a complaint can provide the basis of a dismissal pursuant to Rule 12(b)(6)).

analyses, and will then turn to application of the relevant principles to asserted claim 1 of the '342 Patent.[4]

A. Patentable Subject Matter

Patent-eligible subject matter is defined in Section 101 of the Patent Act:

> 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. § 101. In choosing such expansive terms "modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

Yet while the scope of Section 101 is broad, there is an "important implicit exception [to it]: [l]aws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (internal quotation marks and citation omitted); *see also Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293

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[4] Before doing so, the Court addresses a preliminary issue. Although the parties touched on certain other claims of the '342 Patent in their briefing and at oral argument, the lion's share of their focus was on claim 1 of the patent. Additionally, Plaintiff and Defendants agree that Plaintiff is currently asserting that Defendants infringe only claim 1 (the parties dispute whether there is an existing case or controversy over the remaining claims of the patent-in-suit). (D.I. 1 at ¶¶ 13, 22, 25; D.I. 9 at 1; D.I. 13 at 8-9; D.I. 14 at 4-5; Tr. at 39-41, 53) Under the circumstances here, the Court finds it appropriate to address the eligibility of claim 1 only, and to recommend that if the District Court ultimately affirms the Court's recommendation on the Motion as to that claim, that it order Plaintiff to provide notice as to whether any other claims will be asserted against Defendants in this case, or whether the case should be closed. *Cf. BuySAFE, Inc. v. Google Inc.*, 964 F. Supp. 2d 331, 334, 337 (D. Del. 2013) (granting motion for judgment on the pleadings on the grounds that four claims of the patent-in-suit were not patent eligible pursuant to Section 101, as those were the only asserted claims in the action and were the four claims that the defendant had focused on in its motion), *aff'd*, — F.3d — (Fed. Cir. Sept. 3, 2014).

(2012). "'Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, [because] they are the basic tools of scientific and technological work.'" *Prometheus*, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)); *see also Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) ("He who discovers a hitherto [law of nature] has no claim to a monopoly of it which the law recognizes."). This is true even if the discovery of the particular natural law at issue is considered groundbreaking, innovative, or even brilliant. *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013). Thus, the Supreme Court has written that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are manifestations of . . . nature, free to all men and reserved exclusively to none." *Prometheus*, 132 S. Ct. at 1293 (internal quotation marks and citations omitted).

The Supreme Court, however, has also recognized that too broad an interpretation of this exclusionary principle could eviscerate patent law. *Id.*; *see also CLS Bank Int'l*, 134 S. Ct. at 2354. This is because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Prometheus*, 132 S. Ct. at 1293; *see also CLS Bank Int'l*, 134 S. Ct. at 2354. To that end, it has explained that "'an *application* of a law of nature . . . to a known structure or process may well be deserving of patent protection.'" *Prometheus*, 132 S. Ct. at 1293-94 (emphasis in original) (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)); *see also Funk Bros.*, 333 U.S. at 130 ("If there is to be invention from [a

discovery of a law of nature], it must come from the application of the law of nature to a new and useful end.").

In terms of the process used to analyze patent eligibility under Section 101, the United States Court of Appeals for the Federal Circuit has identified a two-step approach. *See, e.g.*, *Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1341 (Fed. Cir. 2013); *Comcast IP Holdings I, LLC v. Sprint Commc'ns Co. L.P.*, — F. Supp. 2d —, 2014 WL 3542055, at *2 (D. Del. July 16, 2014). First, a court should identify whether the claimed invention fits within one of the four statutory classes set out in Section 101. *Accenture Global Servs.*, 728 F.3d at 1341; *Comcast IP Holdings I, LLC*, 2014 WL 3542055, at *2. Second, it must assess whether any of the judicially recognizable exceptions to subject-matter eligibility apply, including whether the claims are to patent-ineligible laws of nature. *Accenture Global Servs.*, 728 F.3d at 1341; *Comcast IP Holdings I, LLC*, 2014 WL 3542055, at *2.

As to the second step in this process, in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), the Supreme Court recently reaffirmed the framework to be used in order to distinguish patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts:

> 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?" To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. We have described step two of this analysis as 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."

CLS Bank Int'l, 134 S. Ct. at 2355 (certain citations omitted); *see also Prometheus*, 132 S. Ct. at 1294; *Parker v. Flook*, 437 U.S. 584, 594 (1978). As to the search for an "inventive concept," it is clear that the steps in the claimed processes (apart from the natural laws themselves) must involve more than "'well-understood, routine, conventional activit[ies]'" previously known in the industry. *CLS Bank Int'l*, 134 S. Ct. at 2357, 2359 (quoting *Prometheus*, 132 S. Ct. at 1294); *see also Prometheus*, 132 S. Ct. at 1300 ("[S]imply appending conventional steps, specified at a high level of generality, to laws of nature . . . cannot make those laws . . . patentable."). For example, a claim that simply states the law of nature, while adding the words "'apply it[,]'" will not transform an unpatentable law of nature into a patent-eligible application of such a law. *CLS Bank Int'l*, 134 S. Ct. at 2358; *Prometheus*, 132 S. Ct. at 1294.

B. Analysis

1. Defendants' Motion is Not Premature

Plaintiff initially asserts that Defendants' Motion is premature because certain "factual predicates to the Motion" exist, and because claim construction is required prior to a Section 101 analysis. (D.I. 13 at 7-10) The Court disagrees.

As to the first question, Plaintiff suggests that fact issues preclude granting of the Motion, asserting that Defendants have made certain necessary "factual assertions" in support of their Motion that lack "evidentiary support[.]" (*Id.* at 7-8) The Court will further address these arguments below. But for now, as a general matter, the Court notes its view that Plaintiff has consistently failed to articulate *why* there are any disputed areas of fact relevant to resolution of

the Motion.[5]

With regard to the second question, although in a number of cases claim construction may be a necessary prerequisite to engaging in a Section 101 analysis, it will not always be so. Instead, as the Federal Circuit has noted, there are circumstances in which it is feasible for a court to resolve a Section 101-related motion without need for claim construction. *See, e.g.*, *CyberFone Sys., LLC v. CNN Interactive Grp., Inc.*, 558 F. App'x 988, 992 n.1 (Fed. Cir. 2014) ("There is no requirement that the district court engage in claim construction before deciding [Section] 101 eligibility."); *Bancorp Servs. L.L.C. v. Sun Life Assurance Co. of Canada*, 687 F.3d 1266, 1273 (Fed. Cir. 2012) (noting that while claim construction may often be necessary in such circumstances, there is "no flaw in the notion that claim construction is not an inviolable prerequisite to a validity determination under [Section] 101"); *cf. I/P Engine, Inc. v. AOL Inc.*, — F. App'x — , 2014 WL 3973501, at *12 (Fed. Cir. Aug. 15, 2014) (Mayer, J., concurring) (explaining that "there are clear advantages to addressing [S]ection 101's requirements at the

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[5] Even in the context of claims made under 35 U.S.C. §§ 102-103, which require that a factfinder utilize a "clear and convincing" evidence standard in adjudicating factual disputes relating to the question of patent validity, the Supreme Court has noted that this "clear and convincing" standard does not apply to the resolution of pure questions of law. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242-43 (2011); *see also id.* at 2253 (Breyer, J., concurring) ("[T]he evidentiary standard of proof applies to questions of fact and not to questions of law" such that "a factfinder must use the 'clear and convincing' standard where there are [factual] disputes about, say, when a product was first sold or whether a prior art reference had been published."). Thus, in such cases "[w]here the ultimate question of patent validity turns on the correct answer to legal questions. . . [the clear and convincing standard] has no application." *See id* at 2253 (Breyer, J., concurring); *see also id.* at 2242-43. In this matter, regarding a challenge under Section 101, it is clear at least that the ultimate question of patent eligibility is a legal one. And, as noted above, Plaintiff has not plausibly suggested the existence of disputed fact issues that, when such facts were construed in the light most favorable to it, would preclude resolution of the motion at the pleading stage.

outset of litigation[,]" including that, *inter alia*, "[p]atent eligibility issues can often be resolved without lengthy claim construction").

Indeed, in cases where the basic character of a Section 101 dispute was clear to a district court prior to claim construction, courts have resolved such issues on a defendant's motion filed pursuant to Rule 12. In doing so, to the extent the plaintiff asserted there was any need for claim construction, those courts have adopted the meaning proposed by the plaintiff for the terms in question for purposes of addressing the motion. *See UbiComm, LLC v. Zappos IP, Inc.*, Civil Action No. 13-1029-RGA, 2013 WL 6019203, at *3 n.2, *6 (D. Del. Nov. 13, 2013) (resolving defendant's motion to dismiss on patent eligibility grounds, and adopting constructions most favorable to the plaintiff in doing so); *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Assoc.*, Nos. 12-2501 (MAS)(TJB), 12-6960(MAS)(TJB), 2013 WL 3964909, at *5 (D.N.J. July 31, 2013) (rejecting the plaintiff's argument that motion to dismiss on patent eligibility grounds was premature because claim construction had not yet occurred, since "the basic character of the claimed subject matter in dispute in [the] action is clearly evident to the [c]ourt and no further construction of the claims is required[,]" and evaluating the Section 101 issue by giving the relevant claim terms the meaning most favorable to the patentee) (internal quotation marks omitted); *see also Gametek LLC v. Zynga, Inc.*, Nos. CV 13-2546 RS, CV-13-3089-RS, CV-13-3472-RS, CV-13-3493-RS, 2014 WL 1665090, at *3 & n.3-4 (N.D. Cal. Apr. 25, 2014); *Clear with Computers, LLC v. Dick's Sporting Goods, Inc.*, — F. Supp. 2d —, 2014 WL 923280, at *3-4 (E.D. Tex. Jan. 21, 2014).

Here, as is further discussed below, there is only one term in claim 1 that (according to Plaintiff) even arguably implicates an issue of claim construction—the term "predicting."

Because the subject matter relating to the Motion is clear and because the Court does not otherwise see a benefit to postponing adjudication of the Motion,[6] the Court will consider the Motion's merits, assuming that the one term at issue has the meaning ascribed to it by Plaintiff.

2. Claim 1 of the '342 Patent Cannot Withstand a Section 101 Analysis

The crux of this dispute concerns whether the claimed method recites merely a patent-ineligible law of nature, or instead claims a patent-eligible application of that law of nature.[7] Defendants argue that asserted claim 1 of the '342 Patent "analyze[s] a gene sample from a patient using conventional technology, identif[ies] a relationship based on a newly-discovered natural law, and use[s] that relationship to predict an outcome"—subject matter that is not patentable under Section 101 in accordance with relevant precedent. (D.I. 14 at 10) For its part, Plaintiff argues that the claimed method is patentable because its steps "recite[] [a] specific application[,]" (D.I. 13 at 11, 16), such that there is an "inventive step" directing the claim to more than just the natural law, (Tr. at 47-48).

In assessing the patentability of claim 1, the decisions in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65 (Fed. Cir. 2012) and *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303 (Fed. Cir. 2012), are especially instructive. Thus, the Court will preface its own analysis of the

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[6] *Cf. Data Distrib. Techs., LLC*, 2014 WL 4162765, at *8 (declining to address motion filed pursuant to Rule 12(b)(6) seeking dismissal of claims as patent ineligible, until after claim construction, in part due to the "density of the [patent-in-suit] with its 100 claims").

[7] There is no dispute that since claim 1 is a method claim, it falls within a Section 101 statutory class. *See, e.g.*, *Comcast IP Holdings I, LLC*, 2014 WL 3542055, at *3 (method claims fall within statutory class of processes); *UbiComm, LLC*, 2013 WL 6019203, at *3 & n.1 (same).

claim with an examination of the holdings of these decisions.

a. Supreme Court and Federal Circuit Precedent: *Prometheus*, *PerkinElmer*, and *Myriad*

In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), the patents at issue claimed processes that help physicians who use thiopurine drugs for treatment of autoimmune diseases to determine whether a given dosage level is too high or too low for a particular patient. *Prometheus*, 132 S. Ct. at 1294. When patients ingest thiopurine compounds, the drug is metabolized, causing metabolites to form in the bloodstream. *Id.* at 1295. The same dosage affects people differently, causing different concentrations of thiopurine metabolites in different people. *Id.* Too high a dose carries the risk of harmful side effects, while too low a dosage could be ineffective. *Id.* Prior to the issuance of the patents, scientists were aware of a general correlation between the therapeutic efficacy of a particular dose of a thiopurine drug and the resulting concentration of thiopurine metabolites in a person's blood, but did not know the precise correlations. *Id.* The discoveries embodied in the patents at issue solved this problem, conveying findings that thiopurine concentrations beyond a certain level indicated that the dosage is likely too high for the patient, while concentrations lower than a certain level indicated that the dosage is likely too low to be effective. *Id.* The claims recited the specific steps of "administering" the thiopurine drug and "determining" the resulting metabolite concentration in the patient's blood, "wherein" a concentration above or below specific thresholds indicated a need to adjust the subsequent drug dose. *Id.*

The Supreme Court held that the claims failed the Section 101 subject-matter eligibility test. *Id.* at 1305. The Court's analysis began by noting that the patents "set forth laws of

nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Id.* at 1296. This relationship is a law of nature, the *Prometheus* Court explained, because it "exists in principle apart from any human action." *Id.* at 1297. It did not matter to the Court that a human action (administration of the drug) was required to trigger a manifestation of the relationship in a particular patient, because the relation itself is an "entirely natural process[]"—a result of the way in which the body metabolizes thiopurine compounds. *Id.*

Thus, the relevant inquiry before the Court became "whether the claims d[id] significantly more than simply describe these natural relations"; did they "add *enough*" to the natural law to stand as patent-eligible applications of the natural law? *Id.* (emphasis in original). The Court found that the additional steps of the claims, while not natural laws themselves, were insufficient to transform the nature of the claims. *Id.*

Specifically, the Court found that "the 'administering' step simply referred to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs." *Id.* "[T]he 'wherein' clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient." *Id.* And the "'determining' step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever" well-known process he wished to use. *Id.* at 1297-98. Finally, the Court explained that looking at the three steps as an ordered combination added nothing new to the laws of nature: "Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws

when treating their patients." *Id.* at 1298; *see also id.* at 1299-1300 (explaining that the claimed "steps . . . must be taken in order to apply the laws in question" and thus "the effect is simply to tell doctors to apply the law somehow when treating their patients"). Beyond informing the relevant audience about a specific law of nature, any additional steps in the claims "consist of well-understood, routine, conventional activity already engaged in by the scientific community[.]" *Id.* at 1298. "[T]he three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations." *Id.* Thus, the claims were not sufficient patent-eligible applications of the natural correlations. *Id.*

The *Prometheus* Court also emphasized its concern that patent law should "not inhibit further discovery by improperly tying up the future use of laws of nature." *Id.* at 1301. Though the laws of nature at issue in the claims before the Court were narrow ones with limited application, the sweeping nature of the claims threatened to tie up future innovation premised upon the natural laws. *Id.* at 1302. For example, "they threaten[ed] to inhibit the development of more refined treatment recommendations . . . that combine Prometheus' correlations with later discovered features of metabolites, human physiology or individual patient characteristics." *Id.* And "[t]he 'determining' step [in the patents-in-suit] too is set forth in highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways." *Id.* For the *Prometheus* Court, the fact that the claims at issue implicated the concern of "t[ying] up too much future use of laws of nature simply reinforce[d] [its] conclusion that the processes described in the patents are not patent eligible[.]" *Id.*

The patent claims at issue in *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65 (Fed. Cir.

2012), a post-*Prometheus* decision issued by the Federal Circuit, ultimately met the same fate as those in *Prometheus*. *PerkinElmer*, 496 F. App'x at 73. The claims before the *PerkinElmer* Court were directed to specific screening methods to estimate the risk of fetal Down's syndrome, using markers from the first and second trimesters of pregnancy. *Id.* at 66. The representative claim at issue covered a multi-step method of: (1) measuring the levels of certain biological markers from both the first and second trimester of pregnancy; and (2) determining whether an increased risk of Down's syndrome existed by comparing those markers. *Id.* at 66-67.

The Court first concluded that the claims contained a law of nature. *Id.* at 70. The claims recited "the relationship between screening marker levels and the risk of fetal Down's syndrome" which is a "natural process, an eternal truth that 'exists in principle apart from any human action.'" *Id.* (quoting *Prometheus*, 132 S. Ct. at 1297). Next, the *PerkinElmer* Court turned to the question of whether the patentee "added enough to the statements of ineligible subject matter to direct the claims, not to the ineligible concepts themselves, but to applications of those concepts." *Id.* at 70-71.

The *PerkinElmer* Court found that the patentee had not. *Id.* at 71. The "measuring" steps of the claims merely told "the users of the process to measure the screening markers through whatever known method they wish." *Id.* Indeed, the patent's specification indicated that the measurements be obtained through "known methods." *Id.* (internal quotation marks and citation omitted). Since the steps only instructed the user "'to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field[,]'" they were insufficient to transform an ineligible law of nature into a patent-eligible application of the natural law. *Id.* (quoting *Prometheus*, 132 S. Ct. at 1298). The "determining" step did not save

the claims either. That step recited the "ineligible mental step of 'comparing' the measured markers 'with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies' to determine the risk of fetal Down's syndrome." *Id.* (internal citation omitted). The Court found that "[t]he statistical information mentioned in this step is insufficient to make the claim patent eligible because it is well-understood, conventional information[,]" citing to the specification of the patent for support. *Id.*

And finally, an examination of the claims as a whole failed to "make the ineligible mental step and natural law patent-eligible." *Id.* The claims lacked a significant, inventive step, as "anyone who wants to use this mental step or natural law must follow the claimed process." *Id.* Moreover, "there [was] no requirement that a doctor *act* on the calculated risk" of Down's syndrome; instead, the claims at most offered "'a suggestion' that the doctor take the mental determination into account when assessing the patient." *Id.* (quoting *Prometheus*, 132 S. Ct. at 1297) (emphasis added). Thus, the *PerkinElmer* Court held that the claims recited patent-ineligible subject matter under Section 101. *Id.*

In contrast, in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303 (Fed. Cir. 2012), a panel of the Federal Circuit held that a claim directed to a screening method for cancer treatment was patent eligible under Section 101. *Myriad*, 689 F.3d at 1337.[8] The

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[8] In addition to the method claims discussed hereafter, the *Myriad* Court also assessed the patentability of certain composition claims, finding that those claims (directed to isolated DNA molecules) recited patent-eligible subject matter. *Myriad*, 689 F.3d at 1325. The decision as to the composition claims alone was taken up by the Supreme Court, and in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), the Supreme Court affirmed in part and reversed in part the Federal Circuit's decision. *Myriad*, 133 S. Ct. at 2120. The Court here focuses on the portions of the Federal Circuit's opinion that were not appealed to the Supreme Court, as those portions (involving method claims) are more directly relevant to claim 1 of the '342 Patent.

claimed process at issue consisted of growing host cells transformed with a mutated BCRA gene; putting certain of these cells in the presence of a compound suspected of being a cancer therapeutic; keeping certain other of these cells apart from such a compound; determining the growth rate of the host cells in both groups; and comparing such growth rates (wherein a slower growth rate of host cells in the presence of such a compound is indicative of a cancer therapeutic). *Id.* at 1310. In holding that this claim covered patent-eligible subject matter, the *Myriad* Court explained that it amounted to more than the simple application of a law of nature, since it involved the application of certain steps to transformed, man-made cells that were *not* the product of nature. *Id.* at 1336. Thus, these man-made cells were themselves patent-eligible subject matter, and "once one has determined that a claimed composition of matter is patent-eligible subject matter, applying various known types of procedures to it is not merely applying conventional steps to a law of nature." *Id.*

The Federal Circuit also found that certain other method claims at issue in *Myriad* were patent ineligible under Section 101. *Id.* at 1335. Most of these claims involved "comparing" or "analyzing" a patient's BRCA sequence with the normal, or "wild-type," sequence, in order to identify the presence of cancer-predisposing mutations. *Id.* at 1309. The Court concluded that these claims were not directed to patent-eligible subject matter because they "recite[] nothing more than the abstract mental steps necessary to" compare or analyze different nucleotide sequences. *Id.* at 1334. The claims failed to "apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process that is claimed." *Id.* at 1334-35. The Court was unpersuaded by the plaintiff's contention that the methods necessarily included the steps of extracting DNA from a human sample and

sequencing the BRCA DNA molecule, as these operations must occur before one may "compare" nucleotide sequences. *Id.* at 1335. The claims themselves did not include steps involving extracting or sequencing, and the plain meanings of "comparing" and "analyzing" did not implicate extracting, sequencing, or otherwise processing a human sample. *Id.* The Court accordingly found these claims to be indistinguishable from the claims in *Prometheus* that the Supreme Court had found were not patent eligible under Section 101. *Id.*

b. Application to the Instant Case

Here, resolution of Defendants' Motion turns on whether asserted claim 1 of the '342 Patent suffers from the same flaws as the claims found not to be patent eligible in *Prometheus*, *PerkinElmer* and *Myriad*, or instead is directed to a patent-eligible application of a natural law.

(1) Whether Claim 1 Contains a Law of Nature

The first step in analyzing the patent eligibility of the method claim at issue is to determine whether it is directed to a law of nature. *See Prometheus*, 132 S. Ct. at 1296-97; *see also CLS Bank Int'l*, 134 S. Ct. at 2355. The *Prometheus* Court defined "law of nature" in a broad manner: "[A] patent that . . . describes [a relationship that is the consequence of entirely natural processes] sets forth a natural law." 132 S. Ct. at 1297; *see also Genetic Techs. Ltd. v. Agilent Techs., Inc.*, — F. Supp. 2d —, 2014 WL 941354, at *3 (N.D. Cal. Mar. 7, 2014) ("[A]ll *Prometheus* requires is the correlation [between genomic variation in non-coding and coding regions of DNA, at issue in the case] be the product of entirely natural processes.").

Claim 1 of the '342 Patent sets out the correlation between a particular genetic variation and sprinting, strength or power performance: "the presence of two copies of the 577R allele is positively associated with potential sprinting, strength, or power performance." ('342 Patent, col.

29:50-61) Thus, according to the claim, if a person has two copies of the 577R allele, he is likely to be a better sprinter than if he did not. Like the correlations at issue in *Prometheus* and *PerkinElmer* found to be natural laws, the link between a particular genetic variation and the potential for elite athletic performance embodied in Claim 1 is "a natural process, an eternal truth that 'exists in principle apart from any human action.'" *PerkinElmer*, 496 F. App'x at 70 (quoting *Prometheus*, 132 S. Ct. at 1297). The correlation is the handiwork of nature—man did not do anything to bring about this relationship.[9]

(2) Whether Claim 1 Amounts to a Patent-Eligible Application of a Natural Law

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[9] In its briefing, Plaintiff appears to assert that there is a potential factual dispute as to whether "the presence of two copies of the 577R allele [being] positively associated with potential sprinting, strength, or power performance 'merely involves a discovery of a fact about the world.'" (D.I. 13 at 7) But Plaintiff never explains what the factual dispute is. And the ultimate question of whether the correlation described in the claim is a natural law is a legal issue, one that may be decided here by the Court on this record.

During oral argument, Plaintiff's counsel asserted that a factual dispute exists between the parties with respect to what is the *particular natural law* at issue here. (Tr. at 33; *see also* D.I. 13 at 2 (contending that the '342 Patent "does not claim a law of nature")) While Defendants claim that the correlation between the 577R allele and sprinting strength is the natural law at issue, Plaintiff "do[es not] think that that's really the natural law that's described in the patent." (Tr. at 33) Rather, the natural law that Plaintiff believes is described in the patent is "the ACTN3 protein [may] promote [the] formation for muscle fibers or alter glucose metabolism in response to training or that the ACTN3 protein may have been evolutionarily optimized to minimize the damage caused by eccentric muscle contraction[]." (*Id.* at 33-34 (citing to '342 Patent, col. 22:31-36)) While these latter natural principles are indeed referred to in the patent, the pertinent analysis looks to whether the patent *claims* a law of nature—i.e., whether the *claims* of the patent contain such a law. *See Prometheus*, 132 S. Ct. at 1296-97 (noting that the "question before us is whether *the claims* do significantly more than simply describe" natural relations, and looking to the claims of the patent in finding that they recited natural laws) (emphasis added); *PerkinElmer*, 496 F. App'x at 70 (same). Claim 1 of the '342 Patent, at issue here, very clearly recites the natural correlation upon which the Defendants focus (i.e., that two copies of the 577R allele are positively associated with athletic performance). ('342 Patent, col. 29:59-61) There can be no genuine factual dispute that this is the natural law relevant as to claim 1.

Because claim 1 of the '342 Patent recites a natural law, the key question becomes whether it "add[s] *enough* to [its] statement[] of the correlation[] to allow the process[] [it] describe[s] to qualify as" a patent-eligible process that *applies* the natural law. *Prometheus*, 132 S. Ct. at 1297 (emphasis in original); *see also CLS Bank Int'l*, 134 S. Ct. at 2355; *PerkinElmer*, 496 F. App'x at 70-71. Courts examining this question tend to look first to each step of the claim, and then to the claim as a whole. *Prometheus*, 132 S. Ct. at 1297-98; *PerkinElmer*, 496 F. App'x at 71; *see also Smartgene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 56 (D.D.C. 2012) ("The Court views Claim 1 as a whole but still finds it useful to examine the claim in steps for the purposes of its [Section 101] analysis of the claim as a whole.").

Here, claim 1 is directed to a new method for predicting sprinting, strength, or power performance in individuals based upon the correlation assertedly discovered by the researchers associated with the '342 Patent: that people with a particular genetic variation are more likely to preform better in sprinting-related sports those without it. ('342 Patent, col. 29:50-61; *see also id.,* col. 3:10-13) The claimed method consists of three steps: an "analyzing" step, a "detecting" step, and a "predicting" step, (*id.*, col. 29:50-61), which the Court addresses in turn.

First, the "analyzing" step is insufficient to make the claim patent eligible. It merely tells the users of the method to analyze a sample obtained from a person for the presence of genetic variations in the ACTN3 gene, without further specification as to how the sample should be analyzed. (*Id.*, col. 29:52-54) The claim clearly does not recite a new, innovative method for such analyzation, which could be one way to effect a different outcome here. *See Myriad*, 133 S. Ct. at 2119 ("Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent."); *Ariosa*

Diagnostics, Inc. v. Sequenom, Inc., — F. Supp. 2d — , 2013 WL 5863022, at *10 (N.D. Cal. Oct. 30, 2013) (noting that "had the inventors of the [patent-in-suit] created an innovative method of performing DNA detection while searching for paternally inherited cffDNA, such as a new method of amplification or fractionation, those claims would be patentable").

Indeed, the specification of the '342 Patent indicates that the user of the process may employ any number of well-known methods to analyze the sample. For instance, when introducing the description of several embodiments of the claimed process, the specification notes that "[i]t will be obvious . . . to one skilled in the art that practicing the various embodiments does not require the employment of all or even some of the specific details outlined herein. In some cases, well known methods or components have not been included in the description." ('342 Patent, col. 4:30-35) As this "analyzing" step essentially tells users to analyze the sample through whatever known processes they wish to use, it, like the "measuring" step in *PerkinElmer*, amounts to a simple instruction to them to "'engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field.'" *PerkinElmer*, 496 F. App'x at 71 (quoting *Prometheus*, 132 S. Ct. at 1298). Indeed, at oral argument, Plaintiff did not really attempt to argue that claim 1 is directed to an inventive method of "analyzing" such a sample, and did not appear to dispute that the "analyzing" step itself employs routine, conventional processes. (*See, e.g.*, Tr. at 36-37 (Plaintiff's counsel explaining that "[p]atents are just combinations of known elements put together" and accusing Defendants of merely "parsing the patent in little pieces and saying that's routine, that's routine and not looking at the patent claim as a whole"); *id.* at 48 (Plaintiff's counsel acknowledging, when

asked how the "analyzing" step is "transformative[,]" that "I haven't figured that out yet"))[10] "Purely conventional or obvious pre-solution activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Prometheus*, 132 S. Ct. at 1298 (internal quotation marks and citations omitted); *see also PerkinElmer*, 496 F. App'x at 71.

Second, the "detecting" step fares no better. It simply tells users of the process to detect the presence of two 577R alleles in the sample, again without specifying any particular method for doing so. ('342 Patent, col. 29:55-57) The patent's specification teaches that users of the process can choose from multiple well-known detection methods. (*See, e.g.*, *id.* at col. 11:1-2 ("Various forms of amplification are well known in the art and any such known method may be used."); *id.* at col. 13:52-55 (same)) And, just as with the "analyzing" step, Plaintiff has not explained how, in light of the patent's language, claim 1 could be said to be directed to a method of "detecting" the alleles that involves anything more than the employment of a routine, conventional process. Therefore, this step, like the "analyzing" step (and like the "determining" step at issue in *PerkinElmer*), consists of the use of well-understood, routine, and conventional

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[10] To the contrary, in its briefing, Plaintiff did appear to baldly assert that there may be factual disputes about whether certain of the steps of claim 1 (including the "analyzing" step) do, in fact, involve the use of well-known, conventional methods. (D.I. 13 at 7-8 (asserting, without more, that disputes exist as to the following factual assertions by Defendants: "that 'taking a sample of something and analyzing it, without more, are conventional steps, specified at a high level of generality'" and that claim 1 "'does not even include *routine* additional steps'") (emphasis in original) (internal quotation marks and citations omitted)) To the extent that Plaintiff is truly persisting in this suggestion, even after oral argument, the Court concludes that no real disputed fact issue exists. The language of the '342 Patent has obviated the claim that there can be any real factual dispute as to the "analyzing" step (or to the next, "determining" step). And again, Plaintiff has not made any concrete suggestion that demonstrates this conclusion is incorrect.

activity by those in the field at the time of the invention. *PerkinElmer*, 496 F. App'x at 71.

Third, the "predicting" step, which tells users of the process to predict the athletic performance of the person based on the presence of two 577R alleles in the sample, amounts to no more than an "instruction [to] apply the [natural] law." *Prometheus*, 132 S. Ct. at 1297 (internal quotation marks omitted) (noting that Archimedes could not have "secured a patent for his famous principle of floatation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float"). In contending otherwise, Plaintiff utilizes a dictionary definition of "predict": to "declare or indicate in advance" or to "say that something will happen in the future[.]" (D.I. 13 at 10 (internal quotation marks and citation omitted)) In doing so, Plaintiff contends this third step is more than a mental step, in that it "*requires the act* of declaring or stating the potential sprinting, strength or power performance of the human." (D.I. 13 at 10 (emphasis in original); *see also* Tr. at 48-50 ("the predicting step is transformative . . . because it converts a physical element which is the presence or absence of the 577R allele into an announcement or statement"))[11] To carry out the "predicting" step, then, the user of the process merely verbalizes the patentee's discovery of the recited natural law—i.e., that if the specific genetic variation is present, the person will have

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[11] In their opening brief, Defendants asserted their view that this "predicting" step was a "mental step" only—one that "can be done in the human mind and [] does not transform or change the outside world in any tangible way." (D.I. 9 at 5, 8) At oral argument, Defendants' counsel conceded that, in light of the procedural posture of the case, "it [is] reasonable to defer to the construction suggested by the [Plaintiff] which is that there's an affirmative act of an oral statement." (Tr. at 10) As it indicated it would above, the Court therefore assumes that the meaning of "predicting" is consistent with the dictionary definition proffered by Plaintiff. (Were the meaning of the term instead to be that suggested by Defendants—i.e., that "predicting" amounts to a "mental prediction"—the ultimate result of the Court's analysis would be no different.).

potential for elite performance in sprinting, strength, or power sports.[12]

However, simply stating out loud that the person will have relatively greater sprinting, strength or power performance due to the presence of the genetic variation (as compared to what would be expected in the absence of the variation) does not amount to an "'application of the law of nature *to a new and useful end.*'" *Prometheus*, 132 S. Ct. at 1294 (quoting *Funk Bros.*, 333 U.S. at 130) (emphasis added); *see also Davison Chem. Corp. v. Joliet Chems.*, 179 F.2d 793, 795 (7th Cir. 1950) (explaining that to be patentable, the application of a natural law "must be novel and inventive in character" and concluding that claimed process was unpatentable where the patentee "merely transferred to paper his discovery of a scientific fact"). This limitation fails to elevate the claim to something significantly more than the natural principle itself. Just as conventional pre-solution activity does not turn an unpatentable law of nature into a patent-eligible application, neither does "insignificant post-solution activity . . . transform an unpatentable principle into a patentable process." *Diehr*, 450 U.S. at 191-92; *cf. Flook*, 437 U.S. at 590 (recognizing that "[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula"). By Plaintiff's own definition, the "prediction" step requires a physical act—the act of declaring or stating the potential sprinting, strength or power performance of the human— but the mere presence of this physical step does not render the claim patent eligible. It does not require the process user to do anything in light of the

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[12] In setting out its allegations of Defendants' infringement of claim 1 of the '342 Patent, Plaintiff's Complaint similarly alleges that Defendants analyze a customer's sample, detect the presence of 577R alleles, and then simply "use the presence of two 577R alleles *to predict* the potential sprinting, strength, or power performance of the human because the presence of two copies of the 577R allele is positively associated with potential sprinting, strength, or power performance." (D.I. 1 at ¶ 19 (emphasis added))

correlation (aside from simply declaring it). *Cf. Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1067-68 (Fed. Cir. 2011) (finding that claim of a patent directed to a single step of reviewing effects of known immunization schedules was directed to patent-ineligible subject matter, as it did "not including putting this knowledge to practical use[,]" while a claim that required the "further act of immunization in accordance with a lower-risk schedule" moved the claim from "abstract scientific principle to specific application").

As Defendants note, if the Court accepted Plaintiff's theory that the "predicting" step here turns the claimed method into an innovative application of the natural law, then the decision in *Prometheus* "would have had to come out the other way if the claim[s] had simply required that the doctors affirmatively state their findings rather than read them in their head." (Tr. at 8; *see also id.* at 46 (Plaintiff's counsel explaining that claim 1 of the '342 Patent is different from the claims at issue in *Prometheus* because the steps in the claims at issue in *Prometheus* "didn't require the doctor to . . . do anything")) Yet there would have been nothing more innovative about the claims at issue in *Prometheus* if the physicians there were required to "predict" (to say out loud the outcome of their mental observation) rather than simply "determine" those findings (by, *inter alia*, simply making the mental observation itself). The "predicting" step at issue here fails to provide the "practical assurance" sought by the *Prometheus* Court that the "process is more than a drafting effort designed to monopolize the law of nature itself." *Prometheus*, 132 S. Ct. at 1297.[13]

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[13] Just as a comparison to the analysis in *Prometheus* is unhelpful to Plaintiff, the same holds true for a comparison to the claimed process in *PerkinElmer*. It does not stand to reason that the Federal Circuit—having found the "determining" step there (requiring doctors to take the mental step of comparing measured markers with certain observed frequency distributions for marker levels regarding Down's syndrome, in order to determine the risk of fetal

Indeed, if the nature of the "predicting" step here could add enough to the claim to turn it into an inventive application of the natural law, then any natural correlation (e.g., that a genetic variation results in a higher likelihood of having a particular disease) could be patented by simply requiring the process user to "predict"—or verbalize—the consequence of that natural law. This would allow the sort of monopoly on natural laws themselves that the *Prometheus* decision unequivocally intended to prevent.

Lastly, looking to claim 1 as a whole, the steps in combination do not make the natural law and insignificant post-solution activity into patent-eligible subject matter. For one thing, the claim does not recite a method utilizing any man-made, patent-eligible subject matter such as that at issue in *Myriad*. Nor are Plaintiff's other arguments availing. Plaintiff asserts that the claim recites patent-eligible subject matter because when its steps are taken as a whole, the claim "recite[s][a] specific application[][.]" (D.I. 13 at 11) But recitation of an application is not enough; rather, the claim must recite an application that amounts to "significantly more than a patent upon the natural law itself[.]" *Prometheus*, 132 S. Ct. at 1294. Claim 1 does not do so. *See id.* at 1297; *Ariosa Diagnostics, Inc.*, 2013 WL 5863022, at *9 ("[U]se of a newly discovered . . . law of nature . . . will not render a claim patentable if the use of that . . . law of nature . . . is the only innovation contained in the patent."). Instead, as in *Prometheus*, considering claim 1's three steps adds nothing to the laws of nature that is not already present when the steps are considered separately. *Prometheus*, 132 S.Ct. at 1298. Anyone who wants to make sure of the natural law at issue (the correlation between the presence of two copies of the 577R allele and

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Down's syndrome) insufficient to render the claims patent eligible—would instead have deemed the method patentable had it additionally required the physician to simply declare those results out loud. *See PerkinElmer*, 496 F. App'x at 71.

positive sprinting, strength, or power performance) must first have a sample of their DNA analyzed, have the presence of the two alleles detected, and have then the tester communicate the results (e.g., "You have two copies of the 577R allele, so you are likely to be a better sprinter than those without this variation."). Just as in *Prometheus*, this combination "amounts to nothing significantly more than an instruction to [testers] to apply the applicable laws[.]" *Prometheus*, 132 S. Ct. at 1298; *see also PerkinElmer*, 496 F. App'x at 71.[14]

Additionally, in examining whether a claim is patent eligible under Section 101, a court should consider whether the claim poses a risk of preempting the law of nature contained in the

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[14] Plaintiff argues to the contrary that the PTO has allowed "numerous patents to issue with claims having combinations of process steps like Claim 1 of the '342 Patent[,]" and that these claims "demonstrate that Claim 1 of the '342 Patent is patent eligible under 35 U.S.C. § 101 in view of [*Prometheus*]." (D.I. 13 at 11-15) Yet whether or not these other claims are or are not like claim 1 of the '342 Patent, the relevant focus here is on claim 1—not on patents and claims that are not in-suit, are not subject to the instant Motion, and are not the subject of full briefing and argument before the Court.

Additionally, Plaintiff also relies heavily on the machine-or-transformation test in arguing that claim 1 is patent eligible under Section 101. (*Id.* at 15-16; *see also* Tr. at 42-45, 47-48 (arguing that claim 1 is an "inventive step" and "is directed to [more than] merely the natural law" because the three steps of the claim meet the machine-or-transformation test)) The machine-or-transformation test is one tool that courts use to determine whether certain process claims may be patent eligible; the test is met if the claims are: "(1) [] tied to a particular machine or apparatus, or (2) [] transform[] a particular article into a different state or thing." *Bilski*, 130 S. Ct. at 3224 (internal quotation marks and citation omitted). However, as Defendants point out, (D.I. 14 at 6-7), the Supreme Court has held that the machine-or-transformation test is non-dispositive in these types of cases—a claim can still pass the test, but fail the Section 101 law of nature inquiry. *Prometheus*, 132 S. Ct. at 1303 ("[I]n stating that the 'machine-or-transformation' test is 'an important and useful clue' to patentability, we have neither said nor implied that the test trumps the 'law of nature' exclusion.") (quoting *Bilski*, 130 S. Ct. at 3225-27 (emphasis omitted)); *see also PerkinElmer*, 496 F. App'x at 72 (explaining that since the machine-or-transformation test does not trump the law of nature exclusion, even if the test were satisfied, the claims at issue would remain unpatentable). Thus, even assuming that the machine-or-transformation test could somehow be met here, that does not mean that the claim is patent eligible under Section 101.

claim. *Prometheus*, 132 S. Ct. at 1301-02. Certain of the steps of claim 1 of the '342 Patent are set forth in "general language[,]" without specifying the particular analytical or detection methods that the process user should utilize. *Id.* at 1302. They therefore threaten to inhibit the development of new processes that make use in some way of the claimed method for analyzing and detecting the particular genetic variation. *Id.* Furthermore, because claim 1 does not confine its reach to a particular inventive *application* of the recited natural correlation, there is a danger that future innovation based on the correlation will be stifled. "The presence here of the basic underlying concern that [claim 1 of the '342 Patent] tie[s] up too much future use of laws of nature simply reinforces [the Court's] conclusion that the process[] described in [claim 1] [is] not patent eligible." *Id.*

IV. CONCLUSION

For the foregoing reasons, the Court concludes that claim 1 of the '342 Patent is not eligible for patent protection under 35 U.S.C. § 101, and therefore recommends that Defendants' Motion to Dismiss be GRANTED as to claim 1 of the '342 Patent. The Court further recommends that if the District Court ultimately affirms this Court's recommendation on the Motion as it relates to claim 1, that the District Court simultaneously order Plaintiff to provide notice as to whether any other claims of the patent-in-suit will be asserted here, or whether the case should be closed.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss

of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: September 3, 2014

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE