IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENETIC TECHNOLOGIES LTD.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 12-394-LPS
	:	
BRISTOL-MYERS SQUIBB COMPANY,	:	
	:	
Defendant.	:	

GENETIC TECHNOLOGIES LTD.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 12-396-LPS
	:	
MERIAL LLC,	:	
	:	
Defendant.	:	
	:	

MEMORANDUM OPINION

October 30, 2014
Wilmington, Delaware

STARK, U.S. District Judge:

Presently before the Court are Defendants' motions to dismiss under Federal Rule of Civil Procedure 12(b)(6). Defendants argue that the patents-in-suit are directed toward unpatentable subject matter under 35 U.S.C. § 101. The Court agrees that claim 1 of United States Patent No. 5,612,179 ("the '179 patent") impermissibly claims a natural phenomenon and, therefore, grants Defendants' motions with regard to this claim. With respect to any remaining asserted claims, the Court denies the motions without prejudice to renew.

I. PROCEDURAL BACKGROUND

On May 25, 2011, Genetic Technologies Ltd. ("GTG" or "Plaintiff") filed a patent infringement action in the District Court for the District of Colorado against several defendants, including Bristol-Myers Squibb Company ("BMS") and Merial LLC ("Merial") (collectively, "Defendants"), alleging infringement of the '179 patent. *See Genetic Techs. Ltd. v. Agilent Techs., Inc.*, C.A. No. 11-1389-WJM-KLM D.I. 1 (D. Colo. May 25, 2011). In March 2012, the pending claims against BMS and Merial, respectively, were severed and transferred to this District. *See id.* at D.I. 314 (D. Colo. March 28, 2012).

On March 29, 2012, GTG filed its First Amended Complaint in this District against BMS, alleging infringement of the '179 patent as well as United States Patent No. 5,851,762 ("the '762 patent") (collectively, "the patents-in-suit"). (C.A. No. 12-394 D.I. 2) On that same day, GTG filed its First Amended Complaint in this District against Merial, again alleging infringement of the '179 patent.[1] (C.A. No. 12-396 D.I. 2)

[1]GTG also alleged infringement of the '179 patent against Pfizer, Inc. ("Pfizer") (C.A. No. 12-395 D.I. 2), Natera Inc. ("Natera") (C.A. No. 12-1737 D.I. 1), and Histogenetics LLC ("Histogenetics") (C.A. No. 12-1738 D.I. 1). Histogenetics filed a motion for judgment on the

Generally, the '179 patent relates to a method for detecting alleles of a genetic locus and haplotypes by amplifying genomic DNA with a primer pair spanning a non-coding sequence in genetic linkage with the allele to be detected. The '762 patent generally relates to a genomic mapping method based on the ability to identify haplotypes of individuals through analysis of non-coding region sequence variation patterns.

On February 3, 2014, BMS and Merial filed motions to dismiss for failure to state a claim on the basis that the patents-in-suit are directed to patent ineligible subject matter under 35 U.S.C. § 101. (C.A. No. 12-394 D.I. 35; C.A. No. 12-396 D.I. 52) The parties completed briefing on March 17, 2014. (C.A. No. 12-394 D.I. 36, 43, 48, 49; C.A. No. 12-396 D.I. 58, 63, 64[2]) The Court heard oral argument on the motions on April 4, 2014. (*See* D.I. 51) ("Tr.")

II. BACKGROUND[3]

The patented technology relates to deoxyribonucleic acid ("DNA"). The building blocks of DNA, known as "nucleotides," consist of four bases: adenine ("A"), cytosine ("C"), guanine

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pleadings on the basis of § 101 (C.A. No. 12-1738 D.I. 51), but the case was dismissed on August 15, 2014 (C.A. No. 12-1738 D.I. 74). The action involving Natera has been transferred to the Northern District of California. (C.A. No. 12-1737 D.I. 42) Natera and Pfizer have not joined the pending motions. GTG also alleged infringement against Laboratory Corporation of America Holdings, Laboratory Corporation of America, and 23andMe Inc. of United States Patent No. 7,615,342 ("the '342 patent"). (C.A. No. 12-1736 D.I. 1) These defendants filed a motion to dismiss on the basis of § 101 as well (C.A. No. 12-1736 D.I. 9), which was referred to Magistrate Judge Christopher J. Burke (C.A. No. 12-1736 D.I. 21). On September 3, 2014, Judge Burke recommended granting the motion. (C.A. No. 12-1736 D.I. 31) The case was dismissed on September 9, 2014. (C.A. No. 12-1736 D.I. 32)

[2]For simplicity, in the remainder of this Opinion the Court refers to the "D.I." number in C.A. No. 12-394, unless otherwise indicated.

[3]For purposes of evaluating the pending motions, it is appropriate for the Court to derive this background primarily from the allegations in the operative Complaints, including the patents-in-suit, which are attached to them.

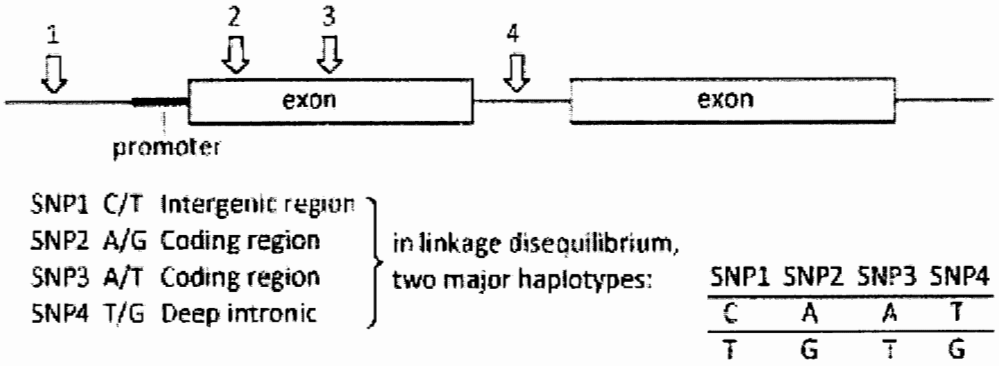
("G"), and thymine ("T"). (Second Amended Complaint ("SAC") at ¶ 7) The nucleotides form pairs with one another – G pairs with C and T pairs with A – in order to form the double helix structure of DNA. (*Id.*) Stretches of this DNA sequence form genes, the units of heredity in an organism. (*Id.* at ¶ 8) Genes contain regions for coding proteins, known as "exons," as well as non-coding regions, known as "introns." ('179 patent at 5:40-50, 60:4-5) The DNA of different individuals varies significantly, and a variation among individuals' genetic sequences at a particular site in the genome is called a "polymorphism," which can occur in both coding and non-coding regions. (*See* SAC at ¶¶ 9, 13) A genetic variation in the coding region of a gene is called an "allele." (*Id.* at ¶ 9) Certain alleles are correlated with particular traits or diseases. (*See* '179 patent at 1:27-2:10; SAC at ¶ 9)

Early efforts at determining genetic differences among individuals focused on directly analyzing the coding region of genes (exons) to detect alleles. (SAC at ¶ 9) Although variations were also known to exist in non-coding DNA, these non-coding regions (introns) were largely dismissed as irrelevant, garnering the epithet "junk DNA." (*Id.* at ¶ 15)

Through the work of a company called Genetype AG and Dr. Malcolm Simons, it was discovered that there can be a correlation between variations in non-coding introns and coding region alleles. (*Id.* at ¶ 16) Through what is referred to as meiosis, duplicate chromosomes exchange stretches of DNA (in a process called chromosomal crossover), resulting in shuffled chromosomes. (*Id.* at ¶ 11) Certain regions of each chromosome, however, tend to be inherited together with only rare shuffling. (*Id.*) These stretches are said to be linked or in "linkage

disequilibrium."[4] (*Id.*) Coding region alleles at adjacent loci that are inherited together are known as a haplotype. (*Id.* at ¶ 12) Dr. Simons discovered that single nucleotide polymorphisms ("SNPs") in non-coding DNA regions can also be in linkage disequilibrium with SNPs in coding regions of DNA. (*Id.* at ¶ 17)

The Amended Complaint depicts a hypothetical partial genomic DNA sequence (shown below) illustrating this linkage phenomenon. Arrows 1, 2, 3, and 4 each represent a SNP at four sites in the sequence:



(*Id.* at ¶¶ 13, 17) SNPs 1 and 4 are in non-coding regions, while SNPs 2 and 3 are in coding regions (both in the first exon). (*Id.*) As the Amended Complaint explains, in this hypothetical sequence "SNPs 2 and 3 contribute to phenotypic variation, and they are in linkage disequilibrium with SNPs 1 and 4 because a gene is a unit of inheritance, meaning that everything within the gene is linked and inherited as a block." (*Id.*) Therefore, the genotypes of SNPs 1-4 are correlated, with SNPs 1 and 4 serving as "surrogate markers" for SNPs 2 and 3.

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[4]The '179 patent specification states: "The term 'linkage disequilibrium,' as used herein, refers to the co-occurrence of two alleles at linked loci such that the frequency of the co-occurrence of the alleles is greater than would be expected from the separate frequencies of occurrence of each allele. Alleles that co-occur with frequencies expected from their separate frequencies are said to be in 'linkage equilibrium.'" ('179 patent at 5:25-30)

(*Id.* at ¶ 17) The genotypes of SNPs 2 and 3 can be detected by determining the genotype of SNP 1 or SNP 4, as shown in the table above. (*Id.*)

Throughout a genome, various groups of SNPs are in linkage disequilibrium and, thus, exhibit the non-coding/coding correlations. (*Id.* at ¶ 19) Details of each correlation can vary and, in some instances, no correlation exists. (*Id.*)

Prior to the patents-in-suit, it was common for scientists studying DNA to "amplify" the portion of interest by making additional copies to allow for analysis. ('179 patent at 2:45-60, 3:5-12, 3:39-45, 5:55-6:3, 12:53-65) A common method for amplifying DNA was "polymerase chain reaction," also known as "PCR." ('179 patent at 2:45-60, 3:5-12; SAC at ¶ 25) In PCR generally, a pair of short, man-made strands of DNA, called a "primer pair," which each match a specific short nucleotide sequence along complimentary strands of DNA, can be used in conjunction with an enzyme known as a "polymerase" to create copies of particular stretches of the DNA sequence. (*See* '179 patent at 2:45-60, 3:5-12, 5:66-6:3, 6:10-13; SAC at ¶¶ 23-24) Also in the prior art was another well-established technique for analyzing amplified DNA: restriction fragment length polymorphism ("RFLP") pattern. ('179 patent at 1:50-53)

III. LEGAL STANDARDS

A. Motion to Dismiss

In order to survive a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *See id.* at 663.

The court "must accept as true the factual allegations in the complaint and all reasonable inferences that can be drawn therefrom." *Nami v. Fauver*, 82 F.3d 63, 65 (3d Cir. 1996). However, the court "need not accept as true threadbare recitals of a cause of action's elements, supported by mere conclusory statements." *Iqbal*, 556 U.S. at 678.

"In deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010). A court may also take judicial notice of the prosecution histories, which are "public records." *See Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000); *see also generally Lum v. Bank of Am.*, 361 F.3d 217, 222 n.3 (3d Cir. 2004).

The Court of Appeals for the Federal Circuit has stated that to grant dismissal of a patent infringement suit at the pleading stage for lack of patentable subject matter, "the ***only*** plausible reading of the patent must be that there is clear and convincing evidence of ineligibility." *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1339 (Fed. Cir. 2013), *cert. granted, judgment vacated sub nom. WildTangent, Inc. v. Ultramercial, LLC*, —— U.S. ——, 134 S. Ct. 2870 (2014) (emphasis in original). Subsequently, the Supreme Court vacated and remanded the Federal Circuit's decision in *Ultramercial* for further consideration in light of the Supreme Court's ruling in *Alice Corp. v. CLS Bank Int'l*, 573 U.S. ——, 134 S. Ct. 2347, 189 L. Ed. 2d 296 (2014). *See WildTangent*, 134 S. Ct. at 2870. Therefore, *Ultramercial* no longer has precedential effect. *See Cnty. of Los Angeles v. Davis*, 440 U.S. 625, 634 n.6 (1979) ("[O]ur 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, 611 (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).

Nevertheless, the Court finds the reasoning in *Ultramercial* at least persuasive here insofar as it concerns the procedural mechanics of a § 101 challenge at the 12(b)(6) stage – particularly the significant burden on a movant given the limited factual record, if any, before the Court. In addition, *Ultramercial* is now pending on remand before the Federal Circuit, putting the substantive § 101 question in light of *Alice* before that Court, which may well respond by reinstating the "only plausible reading" standard for § 101 challenges arising at the pleading stage under Rule 12(b)(6). Finally, while the Federal Circuit made clear in *Ultramercial* that it will be "rare" that patent ineligibility is evident at the pleading stage such that a patent suit can be dismissed on this basis, *see* 722 F.3d at 1338, the instant matter presents such a rare case. Hence, application of *Ultramercial* would not alter the outcome here.

IV. DISCUSSION

A claim is unpatentable if it merely informs a relevant audience about certain laws of nature, even newly-discovered ones, and any additional steps collectively consist only of well-understood, routine, conventional activity already engaged in by the scientific community. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. ——, 132 S. Ct. 1289, 1298, 182 L. Ed. 2d 321 (2012). The claim involved here, claim 1 of the '179 patent, does just that and no more.[5] Consequently, as explained below, the claimed subject matter is ineligible under §

[5]The parties dispute whether there is a case or controversy over all claims of the patents-in-suit, particularly as GTG has yet to identify its asserted claims. The Court addresses the eligibility of claim 1 of the '179 patent. By separate order, the Court will direct the parties to apply the analysis set out here to the remaining claims of the '179 and '762 patents and then advise the Court whether further disputes remain.

101.

A. Patentable Subject Matter

First, the Court discusses the legal standards applicable to the issue of patentable subject matter. Pursuant to 35 U.S.C. § 101, an applicant may obtain a patent on a new and useful (1) "process," (2) "machine," (3) "manufacture," or (4) "composition of matter," or "any new and useful improvement thereof." Although § 101 generally encompasses "anything under the sun that is made by man," "laws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond v. Diehr*, 450 U.S. 175, 182, 185 (1981).

The concern driving these exceptions is pre-emption. *See Alice*, 134 S. Ct. at 2354; *Mayo*, 132 S. Ct. at 1294 (stating case law "warn[s] us against upholding patents that claim processes that too broadly preempt the use of a natural law").[6] "[T]oo broad an interpretation of this exclusionary principle could eviscerate patent law," however, as all inventions "at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 132 S. Ct. at 1293. Therefore, courts must distinguish between patents that claim the "building blocks" of human ingenuity – and "'would risk ***disproportionately tying up*** the use of the underlying'" natural laws, *Alice*, 134 S. Ct. at 2354-55 (quoting *Mayo*, 132 S. Ct. at 1294, 1303) (emphasis added) – and those patents that "integrate the building blocks into something more, thereby 'transform[ing]' them into a patent-eligible invention," such that they pose no

[6]Laws of nature, natural phenomena, and abstract ideas are "the basic tools of scientific and technological work." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ——, 133 S. Ct. 2107, 2116, 186 L. Ed. 2d 124 (2013). "'[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,' thereby thwarting the primary object of the patent laws." *Alice*, 134 S. Ct. at 2354 (quoting *Mayo*, 132 S. Ct. at 1293).

comparable risk of pre-emption, *id.* at 2354-55.

In discussing this distinction, the Supreme Court has recently reiterated that courts are to apply the two-step framework set out in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* A court first determines "whether the claims at issue are directed to one of those patent-ineligible concepts." *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 132 S. Ct. at 1296-97). If so, a court then "consider[s] the elements of each claim both individually and as 'an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (citing *Mayo*, 132 S. Ct. at 1298). At this second step, courts examine whether "a process that focuses upon the use of a natural law also contain[s] other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Mayo*, 132 S. Ct. at 1294. Most recently, the Federal Circuit has held that if "'the additional elements' do not supply an 'inventive concept' in the physical realm of things and acts – a 'new and useful application' of the ineligible matter in the physical realm – that ensures that the patent is on something 'significantly more than' the ineligible matter itself," the claim is outside the scope of § 101. *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1353 (Fed. Cir. 2014) (quoting *Alice*, 134 S. Ct. at 2355, 2357).

In keeping with these principles, "'[p]henomena of nature, ***though just discovered***, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.'" *Mayo*, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)) (emphasis added). Rather, 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." *Id.* at 1294 (internal alterations and quotation marks omitted).

When the steps of the claim "must be taken in order to apply the [natural] laws in question," the claim is not necessarily anything more than a dictate to apply the law of nature. *Mayo*, 132 S. Ct. at 1299-300; *see also id.* at 1294 ("[T]o transform an unpatentable law of nature into a patent-eligible ***application*** of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'") (emphasis in original) (citing *Benson*, 409 U.S. at 71-72). If the additional elements or steps in the claimed process, "apart from the natural laws themselves," involve only "well-understood, routine, conventional activity previously engaged in by researchers in the field" at the relevant time, they are insufficient. *Mayo*, 132 S. Ct. at 1294; *see also Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1354-55 (Fed. Cir. 2012) ("*AMP*"), *aff'd in part and rev'd in part on other grounds sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ——, 133 S. Ct. 2107, 186 L. Ed. 2d 124 (2013) ("*Myriad*"). Similarly, 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." *Mayo*, 132 S. Ct. at 1298; *see also Bilski v. Kappos*, 561 U.S. 593, 610-11 (2010) ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment'") (quoting *Diehr*, 450 U.S. at 191); *Bilski*, 561 U.S. at 612 (limiting abstract idea to a "field of use" does not confer eligibility) (citing *Parker v. Flook*, 437 U.S. 584 (1978)).

B. The Claim Concerns a Process

The present invention claims methods for amplifying and analyzing correlations between different regions of a DNA sequence. It is undisputed that the claimed invention is a "process"

(as opposed to a machine, manufacture, or composition of matter). *See Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1341 (Fed. Cir. 2013) ("First, the court must identify 'whether the claimed invention fits within one of the four statutory classes set out in § 101.'") (quoting *CLS Bank Int'l v. Alice Corp. Pty.*, 717 F.3d 1269, 1282 (Fed. Cir. 2013), *cert. granted*, 134 S. Ct. 734 (2013), *aff'd*, 134 S. Ct. 2347 (2014)). Thus, the Court will turn to determining whether one of the exceptions to eligibility applies to this particular process.

C. The Claim Recites a Natural Phenomenon[7]

The correlations between variations in non-coding regions of DNA – formerly known as "junk DNA" – and variations in coding regions of DNA – specifically, alleles – are natural phenomena. A correlation that preexists in the human body is an unpatentable phenomenon. *See, e.g.*, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 135 (2006) (finding correlation between homocysteine in human body fluid and vitamin deficiency is "natural phenomenon"). In *Mayo* 132 S. Ct. at 1296-97, the Supreme Court evaluated a patent related to the correlation between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. 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 ("The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body – entirely natural processes."). Therefore, in

[7]GTG cites to several recent reexaminations conducted by the Patent and Trademark Office ("PTO") related to certain claims of the patents-in-suit. (*See* D.I. 43 at 7-8) The reexams, however, did not consider § 101. (*See* Tr. at 51; *see also* 35 U.S.C. § 302 (limiting reexams to grounds of invalidity based on "prior art"))

Mayo, the patent claiming that natural correlation merely set forth a natural law. *See id.*

Here, the correlations involved in claim 1 preexist in the human body. More specifically, the correlations involve a form of "linkage disequilibrium" where (i) variations in the non-coding region DNA sequence are genetically linked to (ii) the presence of alleles in the coding regions. The variations, known as polymorphisms, are naturally occurring in the DNA sequence. The linkage is a result of entirely natural processes in which these sequences are inherited as a block.

Plaintiff contends these correlations are not a natural phenomenon or law because any given genetic linkage is not universal, is "not present in all species or even amongst other individuals of a particular species," and "may not have existed in the past and may not exist in the future" due to evolutionary inherency. (SAC at ¶ 21) Plaintiff insists that a natural phenomenon must be an immutable, scientific truth. The Court disagrees. Plaintiff cites no authority for so broad a proposition. Moreover, Plaintiff's position is inconsistent with the reasoning of *Mayo*, which acknowledges that a natural phenomenon may vary across organisms. *See* 132 S. Ct. at 1295 (explaining "the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently"). Thus, patent law does "not distinguish[] among different laws of nature according to whether or not the principles they embody are sufficiently narrow." *Id.* at 1289.

Therefore, just as the relationship at issue in *Mayo* was entirely a consequence of the body's natural processes for metabolizing thiopurine, so too is the correlation here (between variations in the non-coding regions and allele presence in the coding regions) a consequence of the naturally occurring linkages in the DNA sequence. *See also Genetic Techs. Ltd. v. Agilent Techs., Inc.*, — F.Supp.2d —, 2014 WL 941354, at *3 (N.D. Cal. Mar. 7, 2014) (stating

correlations between variation in non-coding and coding regions alone are unpatentable natural laws despite not being "universal" or "immutable scientific truths"). Regardless of whether the correlations change over time due to evolution or are not identical across every organism, the genetic correlations here exist apart from any human action.[8] Accordingly, Plaintiff's arguments are unavailing.

D. The Claim's Additional Steps Do Not Give Rise to an "Inventive Concept"

Having determined that claim 1 recites a process focused on a natural law, the Court must now determine whether the additional steps in the claim are sufficient to satisfy patent eligibility. Specifically, "do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that ***apply*** natural laws?" *Mayo*, 132 S. Ct. at 1297 (emphasis in original).

When the newly discovered DNA correlations are set aside and the additional steps are examined, claim 1 of the '179 patent is ineligible. The asserted claim recites a series of steps to manifest the natural law – that is, to detect the natural correlations between coding and non-coding sequences. The added steps used to discern these correlations consist only of routine and conventional techniques. The patent specification states this outright, making this one of the (perhaps rare) occasions in which further factual development and claim construction are not necessary and invalidity can properly be determined at the 12(b)(6) stage.[9] Without any

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[8] *See also Agilent*, 2014 WL 941354, at *3 ("GTG concedes that the correlations between genomic variation in non-coding and coding regions are naturally occurring.").

[9] There is no factual dispute over what the correlations consist of, allowing the Court to separate the additional steps from the natural phenomenon without additional fact finding that might otherwise be required. The parties have only disputed the separate question of whether those "linkage disequilibrium" correlations constitute a "law of nature," which the Court has

inventive steps employed before the correlation is detected, the claims might still meaningfully limit themselves to an application of this newly-discerned DNA correlation. However, it is undisputed here that once the correlation is detected, the claim stops. Hence, under the guidance of *Mayo* and *Myriad*, the additional steps do not add enough to transform the claim on a natural phenomenon into patent eligible subject matter.

1. '179 Patent - Claim 1

The Court concludes the only plausible reading of claim 1 of the '179 patent is that its additional steps, which consist only of routine and conventional techniques, fail to give rise to an "inventive concept," such that when, taken as a whole, the claim does not provide meaningful limitations that restrict the natural correlation to an application.

In *Mayo*, the inventor claimed a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: "(a) ***administering*** a drug providing 6–thioguanine to a subject having said immune-mediated gastrointestinal disorder" and "(b) ***determining*** the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder." *Mayo*, 132 S. Ct. at 1295 (quoting '623 patent-in-suit at 20:10–20) (emphasis added). In addition to these steps, the claim contained two other limitations: "(c) ***wherein*** the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject" and (d) "***wherein*** the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject." *Id.* (emphasis added).

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concluded they do (as explained above).

The Court held that the "administering" step simply referred to the relevant audience (e.g., doctors using those drugs to treat patients), the "determining" step "tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field," and the "wherein" steps simply tell a doctor in greater detail about the natural law itself. *Id.* at 1297-98. The Court concluded the claims "inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id.* Thus, the steps were "not sufficient to transform unpatentable natural correlations into patentable applications." *Id.*

Here, likewise, the steps of claim 1 of the '179 patent add nothing more to the natural linkage correlation than routine activity already well known in the field. Claim 1 recites:

> A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising:
>
> a) ***amplifying*** genomic DNA with a primer pair that spans a non-coding region sequence, ***said primer pair defining*** a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and
>
> b) ***analyzing*** the amplified DNA sequence to detect the allele.

('179 Patent at 59:57-67) (emphasis added) The additional steps consist of the (i) "amplifying" and (ii) "analyzing" limitations, along with (iii) a descriptive limitation about what kind of DNA sequence the primer pair in the amplifying step delineates.

As with the "administering" and "determining" steps in *Mayo*, the "amplifying" step here tells scientists to engage in "well-understood, routine, conventional activity previously engaged

in" by those in the field. *Mayo*, 132 S. Ct. at 1298. According to the patent itself, all of the techniques it discloses for DNA amplification, including PCR analysis, were previously well known methods. (*See generally* '179 patent 2:45-60, 3:5-8, 3:39-45, 12:53-64; SAC at ¶¶ 14, 23-25) The use of "primers" for amplification was also well known.[10] (*See, e.g.*, '179 patent at 2:45-60; D.I. 37 at A109 ('179 Patent Prosecution History) (Am. in Resp. to Office Action of Jan. 13, 1994) ("[M]ethods of selecting primers to amplify a selected region of DNA are well known."); *id.* at A126-27 (Resp. to Office Action of May 17, 1994) (stating examiner was "clearly aware" amplification was a technique readily practiced by those in the field at the relevant time))

In GTG's view, the claims are "unconventional methods" because they teach amplifying genomic DNA with a primer pair that ***spans an intron sequence and defines a DNA sequence in genetic linkage with an allele to be detected***. (D.I. 43 at 4) (emphasis added) In its Second Amended Complaint, GTG concedes "PCR amplification was known" but contends "no one had used a primer pair to amplify non-coding DNA to define a DNA sequence in genetic linkage with a coding region allele in order to detect that allele." (SAC at ¶ 25; *see also* Tr. at 46 (conceding primers, which Plaintiff likens to "scissors," are in prior art, but arguing "the use of scissors to cut a particular region of DNA . . . is new")) Therefore, GTG's argument is that directing conventional amplification techniques to discern a newfound natural correlation – linkage

[10]"Primer pair" is expressly defined in the patent as "a set of primers including a 5' upstream primer that hybridizes with the 5' end of the DNA sequence to be amplified and a 3' downstream primer that hybridizes with the complement of the 3' end of the sequence to be amplified." ('179 patent at 5:66-67, 6:1-3) The patent further states: "It is well understood that for each primer pair, the 5' upstream primer hybridizes with the 5' end of the sequence to be amplified and the 3' downstream primer hybridizes with the complement of the 3' end of the sequence." (*Id.* at 38:39-42)

disequilibrium between non-coding sequences and alleles – constitutes an "unconventional" amplification technique for detecting those alleles.

GTG fails to separate the unpatentable natural law from the purportedly unconventional "amplifying" technique. *Mayo* sets out that when "the steps in the claimed processes (***apart from the natural laws themselves***) involve well-understood, routine, conventional activity previously engaged in by researchers in the field," the subject matter is ineligible without more. 132 S. Ct. at 1294 (emphasis added). Claim 1 here directs a geneticist to a particular set of DNA sequences: those containing the natural "linkage disequilibrium" correlation. However, apart from the natural phenomenon – of a DNA sequence that spans a non-coding region in linkage disequilibrium with a coding-region allele – claim 1 only recites amplifying a DNA sequence using routine and conventional amplification techniques. Therefore, GTG's argument fails.[11]

GTG urges the Court to follow *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, —— F.Supp.2d ——, 2014 WL 941354 (N.D. Cal. Mar. 7, 2014), which denied a motion to dismiss after the defendant there failed to persuade the *Agilent* court the '179 patent is patent ineligible. The Court here declines to do so.[12] As an initial matter, the *Agilent* court largely did not reach the

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[11]Recently, in multi-district litigation captioned *In re BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litig.*, the District of Utah applied *Mayo* and rejected a similar attempt to argue that the claimed steps were not "routine and conventional" because the primers were designed using the discovery of a new sequence, i.e., the BRCA1 and BRCA2 gene sequences. *See* No. 2:13-CV-00640-RJS, 2014 WL 931057, at *51 (D. Utah Mar. 10, 2014) (analyzing § 101 ineligibility under "likelihood of success"). The Court concluded that "[a]side from the patent ineligible, naturally occurring nucleotide sequence of the BRCA1 and BRCA 2 genes, the other steps set forth in the Method Claims are conventional activities that were well-understood and uniformly employed by those working with DNA at the time." *Id.*

[12]The *Agilent* court provided a thorough, well-reasoned, and helpful consideration of the specific arguments presented by the defendant there (Agilent) in support of its motion, and emphasized the high burden facing defendants seeking dismissal based on a section § 101

question of whether the additional steps involved "routine and conventional" techniques because it found Agilent improperly conflated § 101 with §§ 102 and 103. *See id.* at *4. However, on a separate but related point, the court did find, "The application of primer pair amplification to intron sequences . . . may well have been 'novel and unconventional.' As discussed herein, whether those in the field would consider applying genomic amplification to non-coding regions conventional or routine is a factual question better addressed at a later stage." *Id.* at *4 n.9 (refusing to find GTG's "novel and unconventional" position necessarily inconsistent with patentee's concession during prosecution that it did not invent genomic amplification using primer pair).

To use the *Agilent*'s court's statements in the way GTG suggests here would risk collapsing the natural law into the additional steps in the same manner discussed (and rejected) above. *Mayo* requires that the additional steps be viewed apart from the natural law. Otherwise, whenever a natural law is newly discovered, any "additional step" – no matter how routine or conventional in that field – could be tacked onto it and become patent eligible by virtue of the fact it takes advantage of the naturally occurring phenomenon. *See Mayo*, 132 S. Ct. at 1300 ("[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."). Here, GTG's application of the otherwise conventional technique of amplifying a DNA sequence to the newly-discovered natural law does not make its claim patent eligible.

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challenge on a 12(b)(6) motion. This Court reaches a different conclusion on the instant motion based on its conclusion that the moving defendants here, BMS and Merial, have carried their burden, a conclusion that is not necessarily inconsistent with the conclusion reached by the *Agilent* court based on the record and arguments before it.

Consequently, the "amplifying" step is insufficient to meaningfully limit the claims. *See Mayo*, 132 S. Ct. at 1298 ("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.") (internal punctuation omitted).[13]

The "said primer pair" limitation merely recites the natural phenomenon itself – the linkage correlation – just as the "wherein" steps in *Mayo* recited the characteristics of the metabolite correlations. *See id.* at 1297 ("[T]hese clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decision[-]making (rather like Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant)."). The primer pair must define a DNA sequence that has enough non-coding region sequence nucleotides in "genetic linkage" with the allele such that when amplified, the sequence is characteristic of the allele. In short, the DNA sequence must contain the correlation. The limitation sets forth a condition that is inherently required in order to implement the natural law and, therefore, does nothing to impart an "inventive concept."

Finally, the "analyzing" step is akin to the "determining" step in *Mayo*, which told the physician to determine the level of the relevant metabolites in the blood "through whatever

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[13]GTG also contends that Defendants' arguments regarding "conventional and obvious" steps conflate the § 101 analysis with the other requirements of patentability, namely §§ 102 and 103. The Court disagrees. *Bilski*, *Diehr*, *Flook*, and *Benson* all "rest their holdings upon section 101, not later sections." *Mayo*, 132 S. Ct. at 1303. In announcing that "conventional and obvious" post-solution steps are insufficient to transform an ineligible law of nature, these cases instruct courts to examine well-known techniques and routine practices, which may at times overlap with or implicate the prior art. *See also id.* at 1304 ("§ 101 patent-eligibility inquiry and . . . the § 102 novelty inquiry might sometimes overlap."). The Court finds Defendants properly limit their arguments to a § 101 eligibility framework and do not conflate it with the distinct analysis of the prior art that would be involved in a novelty or obviousness challenge under §§ 102 and 103.

process the doctor or the laboratory wishes to use." *Id.* at 1297-98. Here, the relevant audience is simply instructed to analyze the amplified DNA sequence to detect the allele through whatever method the scientist chooses, a step which does not meaningfully limit the claim. *See also Agilent*, 2014 WL 941354, at *6 (stating "analyzing" step of claim 1 of '179 patent "does not require any particular method of analysis or explain how the allele is to be detected; such general instructions provide no direction to the relevant audience and do not meaningfully limit the claim"). Furthermore, analyzing the "DNA sequence to detect an allele" is inherently required in order to use the natural law.[14]

When viewed as "an ordered combination," the "amplifying," "primer pair defining," and "analyzing" steps together do not alter the outcome here. Indeed, as with the steps in *Mayo*, the "steps as an ordered combination add[] nothing to the laws of nature that is not already present when the steps are considered separately." *Mayo*, 132 S. Ct. at 1298.

2. '762 Patent

In light of the limited analysis the parties provided in their briefing and during oral argument on the patent eligibility of the '762 patent – which includes ten steps in claim 1 alone – the Court will require additional assistance from the parties to apply the foregoing analysis to the '762 patent (and to the remaining claims of the '179 patent as well).

E. Machine or Transformation Test

Plaintiff contends that claim 1 of the '179 patent is patent eligible because it satisfies the

[14]In addition, the specification states that all of the techniques to accomplish the "analyzing" step (RFLP pattern analysis) disclosed in the specific embodiments of the invention are well known. ('179 patent at 16:28-29)

machine or transformation test in three ways. First, in GTG's view, the claims require amplification, which "must be performed with a machine." Second, primers are tools, and therefore the method claims use "machines." Finally, the output of amplification is man-made DNA, which also makes the claims transformative. Plaintiff's arguments are unpersuasive.

The "machine or transformation test" is "not a definitive test of patent eligibility, but only an important and useful clue." *Mayo*, 132 S. Ct. at 1296 (discussing *Bilski*, 561 U.S. 593). Therefore, contrary to GTG's suggestion, the Supreme Court has "neither said nor implied that the test trumps the 'law of nature' exclusion." *Id.* at 1289 (finding test did not confer eligibility even though claims involved transforming human body by administering drug, and transforming blood by analyzing metabolite levels). As the Federal Circuit has noted, "to impart patent-eligibility to an otherwise unpatentable process under the theory that the process is linked to a machine, the use of the machine 'must impose meaningful limits on the claim's scope.'" *Fort Properties, Inc. v. Am. Master Lease LLC*, 671 F.3d 1317, 1323 (Fed. Cir. 2012). Given these principles, the three grounds GTG proposes to satisfy the machine or transformation test all fail.

With regard to GTG's argument that the claims require use of a machine to amplify the DNA, the asserted claims do not tie amplification to a "particular machine" and, therefore, do not meet the machine or transformation test on these grounds. *See Bilski*, 130 S. Ct. at 3225-26;[15] *CyberFone Sys., LLC v. Cellco P'ship*, 885 F. Supp. 2d 710, 716 & n.5 (D. Del. 2012), *aff'd sub nom. Cyberfone Sys., LLC v. CNN Interactive Grp., Inc.*, 558 F. App'x 988 (Fed. Cir. 2014)

[15]Under the test, a process may be patentable if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." *Bilski*, 561 U.S. at 602.

(rejecting argument that "sending of exploded data transactions over a channel . . . also requires a machine" because "plaintiff only summarily makes this argument and does not indicate ***what*** type of machine is required") (emphasis in original). Here, the use of machines generally does not impose a meaningful limit on claim scope.

GTG devotes a single line of its brief to its second argument that the claims are also tied to a machine, and thus patentable, because the well-known primers are a man-made tool that is used to selectively amplify DNA. Even if primers could be characterized as machines, GTG's argument cannot prevail. Carried to its logical conclusion, accepting GTG's position would mean that any time a claim covering a natural law also employs a well-known, routine, or conventional man-made implement – such as a basic thermometer to take a patient's temperature, a conventional syringe to introduce a known drug, or a primer for beginning DNA amplification – this machine would confer patentability. Such a result would eviscerate the holding in *Mayo* regarding the ineligibility of "conventional or routine" steps. Relatedly, such a conventional machine would always trump the "law of nature" exception. *See Mayo*, 132 S. Ct. at 1303.

Plaintiff's third argument, by which it contends that amplified DNA is "man-made," relies chiefly on Plaintiff's interpretation of the Supreme Court's decision in *Myriad* regarding cDNA. According to GTG, *Myriad* stands for the proposition that "man-made DNA that is molecularly different from naturally occurring DNA is patent eligible in of itself;" based on this reading, GTG contends that because "amplified DNA is molecularly distinct and distinguishable from naturally occurring DNA from which it was derived," it, too, is "man-made." (D.I. 43 at 22) This, in GTG's view, makes its methods using amplified DNA patent eligible: "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." *See AMP*, 689 F.3d at 1336.[16]

Plaintiff misreads *Myriad*. First, *Myriad* did not address the broad category of "man-made DNA" GTG describes here; nor did it establish such a sweeping principle of eligibility. Instead, in *Myriad*, the Supreme Court specifically addressed the patent eligibility of (i) "isolated native DNA," which it found ineligible, and (ii) "cDNA," which it held was eligible on the basis that it was a synthesized DNA sequence from which the non-coding regions had been removed and, thus, did not occur in nature. *See* 133 S. Ct. at 2116-19; *see also In re BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litig.*, 2014 WL 931057, at *45 ("Plaintiffs are incorrect in contending that the [*Myriad*] Court found all synthetic DNA to be patent eligible.").

GTG's attempt to liken amplified DNA to cDNA contradicts the reasoning of *Myriad* and related Federal Circuit precedent, which focus on what ***the claims recite*** rather than unclaimed chemical differences identified post-hoc during litigation. GTG concedes that "like cDNA, the nucleotide sequence of amplified DNA is dictated by the naturally occurring DNA," but contends "the process of amplification does not copy the methylation status of the DNA and incorporates cytosines into the final product instead of the naturally occurring 5-methylcytosines." (D.I. 43 at 22; *see also* SAC at ¶ 27) However the Supreme Court and Federal Circuit analyses lead to the conclusion that changing a DNA molecule's "methylation" and removing it from its context in the genome do not confer patent eligibility if the claim is directed to the genetic sequence – i.e., the genetic information – rather than the chemical composition of the physical DNA molecule.

[16]The Court is mindful that cases such as *Myriad* concerned composition claims only, not method claims. However, GTG's arguments rest on the supposition that the claims here are patent eligible because they incorporate a man-made composition.

In *Myriad*, before ruling on the cDNA claims, the Court held Myriad's composition claims over the isolated native DNA sequence containing the BRCA1 and BRCA2 genes were not patent eligible, despite the fact that "isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." *Myriad*, 133 S. Ct. at 2118. The Court reasoned that Myriad's "claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA," but rather "focus on the ***genetic information*** encoded in the BRCA1 and BRCA2 genes." *Id.* (emphasis added). By contrast, the Court found the claims on cDNA presented no such problem because removal of the non-coding region sequence "unquestionably creates something new," even though the coding regions are retained. *Id.* at 2119 ("[C]reation of a cDNA sequence from mRNA results in an ***exons-only molecule*** that is not naturally occurring.") (emphasis added).[17] However, the Court emphasized that a "very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA." *Id.*

Similarly, in *AMP*, in which the Federal Circuit analyzed the eligibility of the method claims that were not subject to review in *Myriad*, the Federal Circuit based its determination on what the claims recited rather than on unclaimed differences in chemical composition. *See AMP*, 689 F.3d at 1334, *cert. granted in part*, 133 S. Ct. 694 (U.S. 2012), *aff'd in part, rev'd in part*, 133 S. Ct. 2107 (reversing eligibility ruling for isolated DNA composition claims). In an attempt

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[17]The Court found that synthesis of cDNA using mRNA results in "the inverse of the mRNA's inverse image of the original DNA, with one important distinction: Because the natural creation of mRNA involves splicing that removes introns, the synthetic DNA created from mRNA also contains only the exon sequences." *Myriad*, 133 S. Ct. at 2112.

to read a transformative step into the "abstract mental processes" of "comparing" or "analyzing" two gene sequences, the patentee argued that the specifications showed that the claim term "sequence" refers "not to information, but rather to a physical DNA molecule, whose sequence must be determined before it can be compared." *Id.* at 1335. The Federal Circuit rejected this argument, finding "the claims only recite mental steps, not the structure of physical DNA molecules." *Id.* (holding claimed methods indistinguishable from ineligible claims in *Mayo* that recite only "administering" and "determining" steps).

Most recently, in *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014), the Federal Circuit again rejected several unclaimed chemical and phenotypical differences as a basis for eligibility of composition claims on the first cloned animal. *See id.* at 1338 (affirming finding of ineligibility because "Dolly's" genetic identity to her donor parent rendered her unpatentable and "any difference in mitochondrial DNA between the donor and cloned mammals is . . . unclaimed").

Here, claim 1 is undisputedly directed to genetic information. More precisely, the claim recites a method for detecting a coding region allele using genomic DNA, specifically a naturally occurring ***non-coding region sequence***, which is amplified and analyzed. The claim is focused on the information in that genetic sequence, and the "linkage disequilibrium" between variations in the non-coding region sequence and variations in the coding region sequence, not the chemical structure of the molecule. It is undisputed that the genetic information in the amplified sequence is the same – nucleotide after nucleotide, in the same order – as the native DNA sequence. (*See* D.I. 43 at 22) ("[T]he nucleotide sequence of amplified DNA is dictated by the naturally occurring DNA.") Therefore, although amplification is carried out in a laboratory by a human, it

is a replication of the native DNA sequence, resulting in a mirror image of the naturally-occurring genetic information. The claims do not ***depend*** on the altered methylation. The chemical changes that may indeed occur during amplification are unrelated to the claimed method and, therefore, do not impose a meaningful limitation.[18]

For these reasons, the Court declines to follow *Agilent* on this point. *Agilent* observed that "GTG does not provide any explanation why the absence of this methylation is important to their claimed method," but nonetheless concluded that "considering the averment that the amplification step creates a chemically distinguishable molecule, no clear and convincing evidence indicates an absence of transformation." *Agilent*, 2014 WL 941354, at *7. The *Agilent* court took the averment in the complaint as governing (at the Rule 12(b)(6) stage) on the machine or transformation question. Here, however, even while taking the factual averments in the amended complaints as true and in the light most favorable to GTG, and accepting that amplified DNA "does not copy the methylation status of the DNA and incorporates cytosines into the final product instead of the naturally occurring 5-methylcytosines to GTG," it is clear that the ***claim*** does not in any way depend on that difference in chemical composition. Hence, the Court is compelled (even at this early stage of the litigation) to conclude that claim 1 is not patentable.

The Court concludes, therefore, that the machine or transformation test is not satisfied, nor does it provide a basis for finding claim 1 here is meaningfully limited.

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[18]At the hearing, Plaintiff described amplification as a "copy machine." (Tr. 43-44)

F. Defendants' Motions Are Not Premature[19]

1. Factual Disputes

GTG suggests there are "numerous factual issues" underlying Defendants' motions but fails to explain how any factual dispute prevents Defendants from satisfying their (albeit heavy) burden. An alleged infringer raising an invalidity defense bears the burden of proving invalidity by clear and convincing evidence. *See Microsoft Corp. v. i4i Ltd. P'ship*, —— U.S. ——, 131 S. Ct. 2238, 2242, 180 L. Ed. 2d 131 (2011) (analyzing burden on validity challenges brought under §§ 102, 103); *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."). In *Ultramercial*, the Federal Circuit explained that dismissal on eligibility grounds is typically inappropriate at this preliminary 12(b)(6) stage in large part due to the "presence of factual issues coupled with the requirement for clear and convincing evidence." *Ultramercial*, 722 F.3d at 1339. However, after viewing all factual allegations in the complaint as true, and drawing all reasonable inferences therefrom in Plaintiff's favor, the only plausible reading of claim 1 here is that it claims only patent ineligible

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[19]The Court has reviewed Plaintiff's Notice of Subsequent Authority (D.I. 56), advising of the recent decision in *Genetic Techs. Ltd. v. GlaxoSmithKline, LLC*, No. 1:12-CV-299-CCE-JL, slip op. at 3 (M.D.N.C. Aug. 22, 2014), in which defendant GlaxoSmithKline's ("GSK") motion to dismiss the '179 patent on the basis of § 101 was denied. The Court's disposition here is unaltered by the *GlaxoSmithKline* decision, which was largely based on a rejection of GSK's argument that the Supreme Court's recent decision in *Alice* required dismissal of the action. *See id.* at 1-3 (distinguishing *Alice*'s "computer implementation of an abstract idea" as arising in "a completely different factual context" and "different procedural context," i.e., summary judgment). Moreover, in finding that GSK had not provided "clear and convincing evidence of ineligibility," the *GlaxoSmithKline* court relied on GTG's same allegations "that the methods of the patents were neither routine nor conventional" – despite the fact that, once more, these allegations in GTG's complaint do not separate the natural law from the additional steps, as is required under *Mayo*. These allegations fold the newly-discovered natural law into the additional steps and use it as the basis for a factual dispute that the step cannot be "routine or obvious." In this Court's view, GTG's approach renders its arguments unavailing.

subject matter. Accordingly (and perhaps unusually), no factual disputes render premature Defendants' request for a determination of invalidity at this early stage.

2. Claim Construction

GTG also contends that claim construction is necessary before the Court can determine patent eligibility. The Court disagrees. GTG has identified no claim term in dispute that could alter the Court's conclusions. Also, the Court finds no factual disputes underlying the scope of the claims that prevent it from finding Defendants have met their high burden on the issue of ineligibility. As discussed above, the only plausible reading of the claims is that there is clear and convincing evidence that they cover only ineligible natural correlations between non-coding sequences and alleles. Defendants' motion, therefore, is not premature.

V. CONCLUSION

For the reasons stated above, the Court finds claim 1 of the '179 patent recites only ineligible subject matter under § 101. Defendants' motions to dismiss will be granted with respect to this claim. The Court will require further input from the parties before it can determine whether all of the other asserted claims of the patents-in-suit are invalid, if this question even remains in dispute.

An appropriate Order follows.