No. 12-398

IN THE

Supreme Court of the United States

ASSOCIATION FOR MOLECULAR PATHOLOGY, *et al.*,

Petitioners,

v.

MYRIAD GENETICS, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR CANAVAN FOUNDATION, CLAIRE ALTMAN HEINE FOUNDATION, MARCH OF DIMES FOUNDATION, FACING OUR RISK OF CANCER EMPOWERED, NATIONAL ASSOCIATION FOR PSEUDOXANTHOMA ELASTICUM, AND OVARIAN CANCER NATIONAL ALLIANCE AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Each of the patient groups who submit this Amicus Brief have a direct and immediate need for the Court to address the issues in this patent case and to correct the errors in the analysis and decision produced in this matter by the U.S. Court of Appeals for the Federal Circuit.

Canavan Foundation is a non-profit organization with the mission to provide funding for research efforts to find an effective therapy for, raise awareness of, and to help avoid Canavan disease through carrier screening and prenatal testing. Despite efforts to sponsor low cost screening for potential carriers of Canavan's disease, a doctor and hospital who patented the relevant gene have prevented the group's efforts to provide free or inexpensive screening programs.

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or a party made a monetary contribution intended to fund the preparation or submission of this brief. No party or entity other than amici, their members, or their counsel, made a monetary contribution to this brief's preparation or submission. Counsel of record received timely notice of the intent to file the brief under Supreme Court Rule 37. Petitioners have filed a letter with the Clerk of the Court granting consent to the filing of any and all amicus curiae briefs. Respondents' letter granting amici consent to file has been filed with the Clerk of the Court.

Claire Altman Heine Foundation (CAHF) is a non-profit organization dedicated to establishing pan-ethnic carrier screening for Spinal Muscular Atrophy (SMA)—the number one genetic killer of children under two. In CAHF's experience, the use of patent rights relating to the gene responsible for SMA has reduced access to SMA carrier screening.

Facing Our Risk of Cancer Empowered (FORCE) is a non-profit organization whose mission includes providing people with information and resources to determine whether they are at high risk for breast and ovarian cancer due to family history or genetic predisposition.

March of Dimes Foundation is a non-profit organization dedicated to improving the health of babies by preventing birth defects, premature birth and infant mortality. March of Dimes' mission and research are adversely affected by patents on gene sequences.

National Association for Pseudoxanthoma Elasticum (NAPE) is a non-profit organization and the original Pseudoxanthoma Elasticum (PXE) patient support group in the United States, committed to providing education for afflicted individuals and families. NAPE opposes gene patents because they interfere with research and development of diagnostic and therapeutic tools.

Ovarian Cancer National Alliance (OCNA) is a non-profit organization and the foremost advocate for women with ovarian cancer in the United

States. OCNA opposes gene patents because such monopolies impede research on ovarian cancer and restrict access to genetic testing for the disease.

SUMMARY OF THE ARGUMENT

The central issue of this case is whether human genetic material, or a segment of the human genome, upon isolation and/or extraction from the body, constitutes patent eligible subject matter as defined in 35 U.S.C. § 101 . To be clear, the patents now at issue do not claim a means of isolating or extracting the gene; they claim the gene itself as invention. The U.S. District Court held that the genes as defined in the patent claims are "products of nature" and fall squarely within the judicially recognized exceptions to patentable subject matter. On appeal, the Federal Circuit panel affirmed the lower court's invalidation of all but one of Myriad's method claims but reversed its invalidation of composition claims holding that the genetic sequences themselves were patent eligible. The panel was divided and produced three separate opinions, including one concurrence and one dissent. Writing for the majority, Judge Lourie concluded that the mere *isolation* of a gene sequence was alone sufficient to qualify the genetic material as a product of human invention, despite the fact that the nucleotide sequence of the gene had not been altered, added to, reduced, or manipulated in any way.

On Plaintiffs' first Petition, this Court issued an order granting certiorari, vacating the Federal Circuit's decision and remanding this case to the

Federal Circuit for further proceedings in light of this Court's decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) . On remand, the same Federal Circuit panel affirmed its previous decision and issued a new set of opinions that are substantially identical to those issued previously. This result is unsurprising in view of the fact that the majority declared this Court's *Mayo* decision categorically irrelevant to composition of matter claims at issue in *Myriad*. Accordingly, the post-remand decision of the Federal Circuit does nothing to resolve the conflicting court opinions over this important issue of patent law.

Gene patents create a monopoly over information that is foundational for biological and medical sciences. By authorizing such monopolies, the Federal Circuit's decision sets a precedent that impedes research and innovation in the natural sciences. It is therefore inimical to the goals of innovation and growth for which the U.S. patent laws were designed.

In addition to its deviation from this Court's jurisprudence on fundamental issues affecting the scope and purpose of patent law, the Federal Circuit's decision authorizes patent practices that will severely compromise efforts in the U.S. to diagnose and treat chronic and life threatening diseases. The adverse effects of gene patents on science and healthcare are profound and wide ranging.

As the patient groups who submit this brief are keenly aware, the Federal Circuit's decision not only subverts the constitutionally grounded purposes of the patent laws but ushers in a set of commercial practices that are injurious to the health and welfare of U.S. citizens. For these reasons, we urge the Court to grant Petitioner's request for Writ of Certiorari.

ARGUMENTS IN SUPPORT OF REVIEW

I. THIS CASE HAS PROFOUND AND FAR REACHING CONSEQUENCES FOR MEDICAL SCIENCE, THE QUALITY OF AND ACCESS TO HEALTH CARE, AND THE LIVES OF PATIENTS AND THEIR FAMILIES

This case exemplifies how too much patent protection can impede our collective efforts to minimize the pain and suffering caused by fatal diseases. Patents like those at issue raise testing costs and simultaneously impede the development of more accurate and reliable diagnostic tools. The results are concretely and tragically experienced by patients and their families whose suffering might have been minimized or prevented altogether by more effective and less expensive means of testing for the genetic disposition to certain life threatening diseases. It is therefore no exaggeration to say that the consequences of affording patent protection to human genes can be lethal.[2]

Advocates of gene patenting, such as the Respondent, argue that upholding the district court's opinion would impede innovation and compromise patient diagnosis and treatment. But there is no factual support for those assertions. To the contrary, unless the district court's decision is

[2] *See infra* pp. 11-12.

upheld, the result will be less research, deficiency in diagnosing diseases, and worse outcomes for patients. The adverse consequences of gene patents are no longer speculative; there is ample empirical evidence of their detrimental effects.

A. *Adverse Consequences of Myriad's Patents*

As a consequence of its patents, Myriad gained the *exclusive right* to perform genetic testing and research on the BRCA1 and BRCA2 genes in the United States. But, when one party such as Myriad controls all testing of a gene sequence, it has no incentive to develop further knowledge of gene mutations affecting the risk of breast cancer or improve the quality of testing. Indeed there are several scientific studies that demonstrate the significant limitations of Myriad's test.[3] According to one study published in 2006, the test Myriad employs to detect breast cancer risk does not take into account significant possible mutations of the gene that correlate with a susceptibility to breast cancer. Tom Walsh et al.,

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[3] *See* Maurizia Dalla Palma et al., *The Relative Contribution of Point Mutations and Genomic Rearrangements in BRCA1 and BRCA2 in High-Risk Breast Cancer Families*, 68 Cancer Research 7006, 7011 (2008) (finding 8% of non-Ashkenazi Jewish test subjects carried a BRCA mutation not detectable by Myriad's standard test); Allison W. Kurian et al., *Performance of BRCA1/2 Mutation Prediction Models in Asian Americans*, 26 J. Clinical Oncology 4752, 4754-56 (2008) (finding that the models used by Myriad underestimate the prevalence of BRCA1/2 mutations among Asian American women by a full 50%).

Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer, 295 J. Am. Med. Ass'n 1379, 1379-1388 (2006). In the study, researchers sampled DNA from 300 members of high-risk families that had received negative test results from Myriad. *Id.* The researchers used six methods to search DNA for breast cancer gene mutations, and found that 12% of the patients studied carried rearrangements of BRCA1 or BRCA2 that were not included in Myriad's array. *Id.*[4] Despite this and other empirical evidence that Myriad's test is deficient and often produces ambiguous results even with the mutations it checks, Myriad, as a result of its DNA sequence patents, remains in sole control of how or whether any new research on the BRCA genes will be conducted and/or incorporated into the tests that it offers.

B. *Adverse Effects of Gene Patenting Generally*

Myriad's patents provide but one example of the adverse effects on innovation of patents that preempt natural phenomena. In April 2010, the U.S. Department of Health and Human Services issued the Secretary [of Health and Human Services]'s Advisory Committee on Genetics,

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[4] The number of missed mutations may be even higher. According to Institute Curie geneticist Dr. Dominique Stoppa-Lyonett, Myriad's test may miss up to 20% of the expected BRCA1 mutations. Steve Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. Nat'l Cancer Inst. 80, 80 (2002).

Health, and Society, Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests (2010) [hereinafter "SACGHS"]. The report found that research in the field of genetics has already begun to suffer as a consequence of gene patents. "Patents are already hindering the development of multiplex tests. Laboratories utilizing multiplex tests are already choosing not to report medically significant results that pertain to patented genes for fear of liability." SACGHS at 3. As a consequence of their chilling effects on genetic research, the existence and enforcement of gene patents discourage the development of better quality testing methods. "Neither sample sharing nor competition is possible when an exclusive-rights holder prevents others providing testing. As a result, significant concerns about the quality of a genetic test arise when it is provided by a patent protected sole provider." SACGHS at 4.

Perhaps most directly and immediately of concern to the groups who submit this brief, the practice of patenting human genetic material has already proven to increase the costs of diagnostic procedures, restrict patient access to existing genetic testing, and preclude the availability of better tests and of second opinions of the often ambiguous results of current testing methods. *See* SACGHS at 1-6.

C. *Salient Cases of Individual Hardship*

There can be no doubt that patents on human genes worsen patient outcomes. The harm that can result from patenting human genes is dramatically illustrated in the case of familial Long QT syndrome (LQTS), a disorder of the heart's electrical system that affects 1 in 3,000 newborns and can result in sudden death. Misha Angrist, et al, *Impact of Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome*, SACGHS at Appendix A, F-1. The disease has been correlated to mutations within three particular genetic sequences. *Id.* A company obtained a patent and exclusive license to the mutated genes for purposes of offering a diagnostic test but did not do so for two years because the exclusively-licensed laboratory went into bankruptcy. *Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcomm. on Courts, the Internet and Intellectual property of the H. Comm. on the Judiciary*, 110th Congress 35 (2007) (statement of Dr. Marc Grodman). During that time, the company nevertheless sought to enforce the patent against other parties who could have provided genetic testing for LQTS. *Id.* at 40. In the case of at least one patient, a ten year-old girl named Abigail who presented with an arrhythmia, death was preventable. *Id.* If the patent holder had made testing available, the cause of Abigail's arrhythmia would have been identified as LQTS, and the

appropriate therapies could have been prescribed, such as beta-blocker drugs, implantable cardioverter-defibrillators, and avoidance of certain arrhythmia triggers. *Id.* ; Angrist, SACGHS at Appendix A, F-1.

In another well publicized case, Ashkenazi Jewish families of children with Canavan disease and non-profit foundations provided tissue and money for over a decade to a geneticist so that he could sequence the genetic mutation that caused this devastating neurological disease. The purpose was to provide a low cost screening and prenatal testing program for identifying potential carriers of the disease. Unfortunately, when the doctor identified the relevant gene sequence for carriers of the mutation, he and his hospital patented it without the knowledge or consent of the tissue sources. *See Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003). When the Canavan Foundation and its constituents convinced medical providers to offer Canavan gene testing for free, the hospital threatened to enforce its patent and shut down the free testing.

D. *The Practice of Gene Patenting Discourages Patient Participation, and Thereby Limits the Fundamental Resource for Genetic Research*

Patient concern over the ultimate use of their personal tissue samples and genetic information has become a serious issue in genetic

research. Patients have sued to stop use of their biological and genetic material in light of patent-holders' financial gain, undisclosed later uses, and restrictive licensing practices. *See Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990); *Greenberg*, 264 F. Supp. 2d 1064 ; *Washington Univ. v. Catalona*, 490 F.3d 667 (2007). Ignoring the role of patients in genetic research and innovation discourages patient participation, "the only irreplaceable, critical resource . . . in the discovery of [a] gene." Jon Merz, *Discoveries: Are There Limits on What May Be Patented?*, WHO OWNS LIFE? (2002).

The Canadian College of Medical Geneticists' official statement on gene patents addresses the needs of patients and other research participants who donate their time and personal biological samples "altruistically with a motivation to promote better care for others." Julie Richer et al., *CCMG statement on gene patents*, 82 CLIN. GENET. 405-407 (2012). Granting a patent to a single individual or entity in effect "fails to recognize the essential public investment in this process of collaboration and discovery . . . [and] fails to respect the wishes of patients who generously contribute with the hope of helping others," an oversight that "may have damaging effects on the future of genetic medicine by limiting the willingness of our patients to participate in future research endeavors." *Id.*

Indeed, as the role of personalized medicine and whole-genome sequencing rapidly expands,

some geneticists support transparency between researchers and patients as not only a moral and ethical imperative, but also in the best interest of researchers and innovation. Misha Angrist, *You never call, you never write: why return of 'omic' results to research participants is both a good idea and a moral imperative*, 8(6) PMC 651-657 (Dec. 2011).

E. *The Practice of Patenting Human Genes Impinges on Constitutional and Common Law Rights of Privacy and Autonomy*

The Constitutional values of liberty and autonomy require that individuals should be treated as ends in themselves and not merely as means. Furthermore, "our society acknowledges a profound ethical imperative to respect the human body as the physical and temporal expression of the unique human persona." *Moore*, 793 P.2d at 515-16 (Mosk, J. dissenting). The practice of patenting human DNA commodifies human cells *and* the encoded information that guides cellular development. Genetic sequences lay the groundwork for individual identity. It makes little sense to observe a Constitutionally based prohibition on patenting human embryos while allowing a commercial monopoly on segments of an individual's genetic blueprint.

In addition to commodifying human life, patenting human genes impinges on common law and Constitutional rights of privacy. The

Constitutional right of privacy extends to the right to make fundamental decisions that affect self-identity, procreation and the use of one's own body. These privacy interests extend to the right to control one's own DNA. As the Ninth Circuit has observed, "[o]ne can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up." *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998).

II. RESOLVING THE ISSUE OF WHETHER HUMAN DNA IS PATENT ELIGIBLE SUBJECT MATTER IS CRUCIAL TO MAINTAINING THE PATENT BALANCE BETWEEN REWARDING EXISTING RESEARCH AND ENSURING OPPORTUNITY FOR INNOVATION

As this Court recognized in *Mayo*, the scope of patent-eligible subject matter is not limitless but instead reflects a balance of values. The patent offers a limited monopoly in exchange for information and does so to encourage innovation in the arts and sciences for the public good. The courts have recognized that just as insufficient patent protection fails to incentivize, too much patent protection obstructs the exchange of information necessary for innovation. Hence, for over 150 years, courts have disallowed patent claims that impede future innovation by preempting or broadly covering natural phenomena or natural laws: "The Court has repeatedly emphasized … a concern that patent law not

inhibit further discovery by improperly tying up the future use of laws of nature." *Mayo*, 132 S. Ct. at 1301; *see O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-20 (1854) .

In *Mayo*, this Court reaffirmed its prior teaching that patent eligible subject matter under § 101 is limited by exclusions for natural phenomena, laws of nature, and abstract ideas. It reiterated the rationale for these exclusions:

> "Phenomena 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." And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.

Mayo, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

With these fundamental concerns in mind, this Court held *Mayo's* patent claims invalid because they effectively do nothing more than describe natural phenomena, *i.e.* correlations governed by natural laws. Steps such as administering an amount of the drug, determining the metabolite concentration, and inferring the need for a change in dosage contributed nothing inventive to the correlations governed by nature that lay at the core of the claimed invention. "[A]

process that focuses upon the use of a natural law [must] also contain 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." *Id.* at 1294 (citing *Parker v. Flook*, 437 U.S. 584, 594 (1978)). Focusing on the absence of an "inventive concept," this Court concluded that well-known procedures for administering and determining contributed nothing of ingenuity to the claims.

A. *The Federal Circuit's Majority Decision Wrongly Disregards the Lessons of* Mayo *as Irrelevant to Composition of Matter Claims*

The Federal Circuit majority diminished the applicability of this Court's § 101 jurisprudence by dismissing the relevance of *Mayo* and constructing an arbitrary bright line rule instead of flexible standards provided by this Court. First, this Court remanded this case for further analysis by the Federal Circuit in light of this Court's *Mayo* decision *even though the previous Petition was directed solely to the isolated DNA claims*. Nevertheless, the Federal Circuit dismissed the applicability of *Mayo* to those same isolated DNA claims, holding: "Mayo does not control the question of patent-eligibility of such claims. They are claims to compositions of matter, expressly authorized as suitable patent-eligible subject matter in § 101." *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1325 (Fed. Cir. 2012). In

addition, the Federal Circuit majority dismisses the applicability of the *Mayo* decision's principles of preemption because "a composition of matter is not a law of nature." *Id.* at 1331 .

In essence, the Federal Circuit majority determined that the principles and reasoning employed by this Court to analyze subject matter eligibility of process claims are entirely without bearing on or benefit for analyzing subject matter eligibility of composition of matter claims. Using this erroneous logic, the majority simply waved off this Court's admonitions to take guidance from *Mayo*.

B. *The Federal Circuit Majority's Analysis of Patent Eligibility of Human Genetic Sequences is Irreconcilable With This Court's Decisions Governing the Scope of Patentable Subject Matter*

The need for this Court's resolution of whether isolated DNA is patent-eligible is facially apparent from the fact that the four federal judges addressing it employed different analyses. The judiciary needs clarification from this Court. Furthermore, this Court has not addressed the patent eligibility of compositions and manufactures under the judicially created exceptions for natural phenomena since its treatment of this issue in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) more than 30 years ago. Advances in the life sciences over this period make imperative a further

clarification of the application of this exception to § 101.

1. The Federal Circuit's Misapplication of *Funk Bros.* and *Chakrabarty*

The Federal Circuit majority has now twice concluded that Myriad's isolated DNA claims were patentable subject matter by virtue of being "isolated" from their natural environment of the human genome. *Ass'n for Molecular Pathology*, 689 F.3d 1303 (Fed. Cir. 2011) . According to the majority's opinion, isolation requires the breaking of covalent bonds at each end of a gene segment and thereby resulted in a composition having "markedly different characteristics" from the characteristics of the same sequence of nucleotides occurring in the larger genome. *Id.* .at 1328. Although the Federal Circuit relied on the language of *Chakrabarty*, it deviated significantly from the analytic approach taken by *Chakrabarty* and its predecessor, *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), both of which make clear that function must also be considered.

In *Funk Bros.*, this Court acknowledged that the claimed composition of bacteria was new and useful, but concluded that "[i]t is no more than the discovery of some handiwork of nature and hence is not patentable." *Id.* at 131. Significantly, the Court did not address the structural characteristics of the composition in determining whether it was a

product of nature as opposed to a human manufacture. Instead, the Court observed:

> The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

Id. Under a similar analysis, this Court in *Chakrabarty* held that patent claims for a genetically enhanced bacterium capable of decomposing oil more effectively was a human manufacture, and therefore fell within subject matter patentable under § 101. In reaching this decision, the Court said nothing about chemical structural differences in explaining how the claimed bacteria were markedly changed. Instead, it differentiated the claimed subject matter by observing that it had a petroleum degrading capability "which is possessed by no naturally occurring bacteria." *Chakrabarty*, 447 U.S. at 305. The analysis in both cases turns on assessing whether the claimed invention describes any performance advantage beyond those inherent in the natural components.

Judge Lourie essentially ignored the "markedly different characteristics" analysis of *Chakrabarty* opting instead to employ a test of "any chemical change" regardless of the claims of the

invention. Hence, the majority opinion looks solely for a difference in composition regardless of how small or irrelevant to the properties claimed in the patent. This distortion of "markedly different characteristics" undermines the prior construction of *Chakrabarty* and *Funk Bros.*, which considered structural and functional differences with natural phenomena.

If *Funk Bros.* and *Chakrabarty* guide away from a narrow concern with structural chemical differences in assessing patent eligibility of biological technology, *Mayo* reinforces the view that changes incidental to the isolation and purification of natural material do not render it patentable.

2. The Proper Application of *Mayo*

In *Mayo*, this Court questioned whether: "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. The correlative question in this case is whether the process of isolating DNA and the attendant changes that occur at the terminal ends of an isolated gene make it different *enough* to *transform* it in any defining way. Based on this Court's reasoning in *Funk Bros.*, *Chakrabarty*, and now *Mayo*, the answer is no. Isolating a natural substance is not an inventive step. As the Federal Circuit recognized in *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir.

2007), "isolation of interesting compounds is a mainstay of the chemist's art," and that "[i]f it is known how to perform such an isolation doing so 'is likely the product not of innovation but of ordinary skill and common sense.'" *Id.* at 1302 (citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007)). Secondly, the structural change that occurs as a consequence of isolation—breaking covalent bonds—has no bearing on what DNA is or does. Such changes do not alter the claimed or defining *properties* of DNA. It is not *enough* to identify slight molecular differences in the ends of a complex polymer chain if such differences bear no relationship to any change in the properties claimed or any inventive concept or solution to a problem.

In this case, the patent claims describe a sequence of nucleotides or amino acids without regard to miniscule differences in molecular characteristics of terminal points. The patents at issue do not teach the importance or value of the terminal ends of the isolated DNA. In fact, the importance associated with the terminal ends of the composition relied on by the Federal Circuit majority is undermined by the claims to "at least 15 nucleotides" that cover numerous compositions with different terminal ends. For example, claim 6 of the Patent No. 5,747,282 for "an isolated DNA having at least 15 nucleotides of the [nucleotide sequence set forth in SEQ ID NO:1]" covers over 17 million compositions at least 15 nucleotides long

within the 5,914 nucleotide sequence.[5] Such differences at the terminal ends are irrelevant to the structure of the nucleotide sequence or coding function that defines DNA.

3. Isolation Does Not Transform a Genetic Sequence Into a Human Manufacture

The fact that a segment of DNA—the encoding sequence—is obtained through human initiative does not transform what is natural and inherent in the sequence of nucleotides or bring about any new capabilities. Regardless of the human ingenuity and labor required to isolate, extract or purify a segment of human DNA, the sequence of nucleotides remain a product of nature. As stated by this Court over a century ago:

> There are many things well known and valuable in medicine or in the arts which may be extracted from...substances. But the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when

[5] The 17 million compositions would not include the claimed compositions having at least 15 nucleotides of SEQ ID NO:1 but not found within the 5,914 nucleotides listed in SEQ ID NO:1.

> obtained cannot be called a new manufacture.

American Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566, 593-94 (1874) .[6]

III. MYRIAD'S CLAIM FOR "COMPARING" CELL GROWTH RATES IS DIRECTED TO PATENT INELIGIBLE NATURAL LAWS

The district court held claim 20 of the '282 Patent invalid because it is directed to the abstract mental processes of the scientific method itself.

On an initial review the Federal Circuit reversed the district court, finding Claim 20 patent eligible. Subsequently, this Court vacated the Federal Circuit's opinion in light of this Court's decision in *Mayo* and remanded the case. Following this Court's remand in light of *Mayo*, the Federal Circuit again found claim 20 of the '282 Patent valid based upon the use of "transformed cells." The reliance solely upon "transformed cells" to find patent eligibility ignores the analysis and application of this Court's decision in *Mayo*.

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[6] *See also Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884) (finding artificial alizarine derived from a precursor substance and having the same properties as those found in natural alizarine was not patentable); *Ex parte Latimer*, 1889 Dec. Comm'r Pat. 123 (finding purified pine needle fiber not patentable).

A. *Using "Transformed Cells" Does Not Render a Method Patent-Eligible Under* Mayo

Without citing any authority, the Federal Circuit majority asserts that "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." *Ass'n for Molecular Pathology*, 689 F.3d at 1336. Based upon this reasoning, the Federal Circuit incorrectly found the use of transformed eukaryotic cells sufficient to make the entire method claim patent eligible without regard to the claimed steps.

The basis for this conclusion is flawed in light of *Mayo* because the method in *Mayo* used "thiopurine drugs" that are likely patent eligible under § 101,[7] yet the method of testing their proper dosage remained patent ineligible. *Mayo* did not consider the potential patent eligibility of *a product* used in the method sufficient to render the method itself eligible.[8] Based upon *Mayo*, a method claim limited to the use of conventional and routine steps applied to a natural law is not rendered patent-eligible under § 101 by the mere inclusion of a

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[7] They would be likely be unpatentable under §§ 102 and 103 based upon prior art.

[8] Ironically, despite dismissing the relevance of *Mayo* to products of nature, the Federal Circuit's analysis reduces the patent eligibility of a process claim to the question of whether one of the compositions used is not a product of nature.

potentially patent-eligible product used in the process.

Moreover, the mere inclusion of a potentially patent eligible product within a process would not constitute "an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself" as required by *Mayo*. *Mayo*, 132 S. Ct. at 1294 (citing *Parker v. Flook*, 437 U.S. 584, 594 (1978)).

B. *The Claimed Steps Add Nothing of Significance to the Natural Laws*

Claim 20 is directed to three main steps: (1) growing two transformed eukaryotic host cells with altered BRCA1 genes, one in the presence of a compound and one in the absence of the compound; (2) determining the rates of growth for each of the host cells; and (3) comparing the growth rates of the host cells. The claim further indicates that "a slower rate of growth of the host cell in the presence of the compound is indicative of a cancer therapeutic."

The growing step (1) is analogous to the "administering" step of the Prometheus claims—a step that simply told doctors to provide thiopurine drugs to patients as they had previously. *Mayo*, 132 S. Ct. at 1297. In the present case, the growing steps do no more than direct a scientist to grow eukaryotic host cells, a process that was known and routinely performed. *See* '282 Patent Col. 27 Lns.

41-52 (acknowledging that "propagation of mammalian cells [which are a type of eukaryotic host cells] in culture is per se well known."). In both cases, this claimed routine and conventional step included the utilization of a potentially patent-eligible product—*i.e.* thiopurine drugs in *Mayo* and a transformed eukaryotic cell in the present case.

Similarly, the determining step (2) is equivalent to the "determining" step in *Mayo*. In *Mayo*, the "determining" step told the doctor to determine the level of metabolites "through whatever process the doctor or the laboratory wishes to use." *Mayo*, 132 S. Ct. at 1297. In the present case, the '282 Patent does not explain the process beyond stating that "the rate of growth of the host cells is measured," indicating that methods of measuring the rate of growth would be known in the art. *See* '282 Patent Col. 31 Lns. 46-53. Accordingly, these steps instruct the scientists to perform conventional activity to measure growth rates of cells in each environment (*i.e.* the presence or absence of the compound).

The final comparing step instructs the scientists to look at the results of each growth rate measurement. This step is equivalent to comparing metabolite levels with those required by the Prometheus claims. A comparison of results is a conventional and routine aspect of scientific testing that is exemplified by the scientific method.

Finally, the wherein clauses in both the Prometheus claims and Myriad's '282 Patent claim identify relevant natural laws. In this case, the natural law provided in the wherein clause is the natural correlation between a slower growth rate in the presence of a compound indicating a potential cancer therapeutic.

C. *Application of the Scientific Method to a Natural Phenomena is an Abstract Process*

Claim 20 is nothing other than the application of scientific method to evaluate natural effects of compounds on the growth rate of host cells. In simple terms, this is a test wherein you (1) prepare a test sample having the hypothesized element (*i.e.*, the compound) and a control sample without the hypothesized element; (2) allow a reactionary process to occur; (3) observe the results of both samples; and (4) draw a conclusion related to the original hypothesis (*i.e.*, whether the compound is indicative of a cancer therapeutic). Applying the scientific method using routine and/or conventional steps does not add any significance to the natural laws and does not make them patentable applications.

CONCLUSION

As the history and diversity of judicial opinions in this case reveal, federal courts need guidance so they can distinguish between products that are predominantly, if not entirely, the work of nature (and therefore ineligible for patent protection) from those that are sufficiently changed by virtue of human ingenuity to qualify as patent eligible subject matter under § 101. This case, more than any other, illustrates why the building blocks of human knowledge, including the human genome, should not be subject to monopoly through patent law. Extending patent protection to human genes results in less, not more, innovation in a sphere of research activity where innovation and freedom from monopoly are vital to the prevention and treatment of life threatening diseases. For the reasons herein, Amici respectfully request that this Court accept this case for review.

Respectfully submitted,

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