United States Court of Appeals for the Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD, ARUPA GANGULY, PhD, WENDY CHUNG, MD, PhD, HARRY OSTRER, MD, DAVID LEDBETTER, PhD, STEPHEN WARREN, PhD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, and KATHLEEN RAKER,

Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

and

MYRIAD GENETICS, INC.,

Defendant-Appellant,

and

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of the University of Utah Research Foundation,

Defendants-Appellants.

Appeal from the United States District Court for the Southern District of New York in Case No. 09-CV-4515, Senior Judge Robert W. Sweet.

BRIEF OF AMICI CURIAE AMERICAN MEDICAL ASSOCIATION, AMERICAN SOCIETY OF HUMAN GENETICS, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN OSTEOPATHIC ASSOCIATION, AMERICAN COLLEGE OF LEGAL MEDICINE, AMERICAN COLLEGE OF EMBRYOLOGY, AND THE MEDICAL SOCIETY OF THE STATE OF NEW YORK IN SUPPORT OF PLAINTIFFS-APPELLEES

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June 15, 2012

CERTIFICATE OF INTEREST

Counsel for *Amici* Medical Organizations certifies the following:

1. The full name of every party or amicus represented by me is:

The American Medical Association, the American Society of Human Genetics, the American College of Obstetricians and Gynecologists, the American Osteopathic Association, the American College of Legal Medicine, the American College of Embryology, and the Medical Society of the State of New York.

2. The name of the real party in interest represented by me is:

The American Medical Association, the American Society of Human Genetics, the American College of Obstetricians and Gynecologists, the American Osteopathic Association, the American College of Legal Medicine, the American College of Embryology, and the Medical Society of the State of New York.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of any party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for any party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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STATEMENT OF INTEREST OF AMICI CURIAE[1]

Gene sequence information is integral to physicians' determination of which diseases a patient might be suffering from and which treatments might benefit or harm that patient. *Amici* are organizations of health care professionals concerned about the effect of gene sequence patents on the practice of medicine. Such patents interfere with diagnosis, treatment, and research and contravene the United States Supreme Court's long-standing precedents about the scope of patentable subject matter, which was reiterated in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012).

***Amicus Curiae* American Medical Association (AMA),** a non-profit organization, is the largest professional association of physicians, residents, and medical students in the United States. The AMA joins this brief on its own behalf and as a representative of the Litigation Center of the American Medical Association and the State Medical Societies.

***Amicus Curiae* American Society of Human Genetics (ASHG)** is a non-profit organization consisting of over 8,000 professionals in the field of human genetics including researchers, clinicians, academicians, and counselors.

***Amicus Curiae* American College of Obstetricians and Gynecologists**

[1] The Court has invited filing of amicus briefs without consent or leave of court. No part of this brief was authored or funded by counsel for any Party, person, or organization besides *Amici* and their counsel.

(ACOG) is a non-profit organization of over 51,000 health care professionals dedicated to providing quality health care to women. Over 90% of Board-certified obstetricians and gynecologists in the U.S. are affiliated with the College.

***Amicus Curiae* American Osteopathic Association (AOA),** with over 44,000 members, is the largest professional association of osteopathic physicians. The AOA promotes osteopathic medicine, a holistic approach to prevent, diagnose, and treat illness, disease, and injury.

***Amicus Curiae* American College of Legal Medicine (ACLM)** is the nation's most prominent professional society comprised primarily of members holding degrees in both medicine and law. The society serves medical and legal professionals and advises health policymakers.

***Amicus Curiae* American College of Embryology (ACE)** develops and maintains professional standards for embryologists. Its members offer a number of clinical services, including pre-implantation diagnosis—a technique used to test an embryo for genetic diseases before the embryo is transferred into the uterus of a woman.

***Amicus Curiae* Medical Society of the State of New York (MSSNY)** is a voluntary association of approximately 24,000 licensed physicians, residents, and medical students in all specialties in New York.

SUMMARY OF THE ARGUMENT

This Court has requested briefs on the applicability of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012) to Myriad's isolated DNA claims and to method claim 20 of the '282 patent. Order, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 2010-1406 (Fed. Cir. Apr. 30, 2012). Nature's handiwork is excluded from patentability. *Prometheus*, 132 S.Ct. at 1293; *Bilski v. Kappos*, 130 S.Ct. 3218, 3225 (2010). Just as a patent involving a law of nature must have an "inventive concept" that does "significantly more than simply describe these natural relations" (*Prometheus*, 132 S.Ct. at 1294, 1297), a patent involving a product of nature must have an inventive concept that involves significantly more than describing the product of nature. Indeed, the claimed invention must be "markedly differently" from what occurs in nature. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

The patent claims at issue in this case, covering isolated DNA and cDNA, which are described by their genetic sequences, are invalid under 35 U.S.C. § 101 and under the *Prometheus* analysis because they are patents on products of nature without an inventive concept and because isolated DNA and cDNA are not markedly different from what occurs in nature. Similarly, correlations between gene sequences and disease, as well as those between treatments and cell growth, are unpatentable laws of nature.

ARGUMENT

I. Section 101 Prohibits Patents on Laws of Nature and Products of Nature.

"'Laws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289, 1293 (2012) (citations omitted). A newly-discovered phenomenon of nature must be "treated as though it were a familiar part of the prior art" and free for all to use. *Parker v. Flook*, 437 U.S. 584, 591-92 (1978). *See also Bilski*, 130 S.Ct. at 3230. This is true no matter what the costs were to discover nature's handiwork.

In *Prometheus*, the U.S. Supreme Court clarified the following points: 1) Section 101 is a bright line prohibition against patentability. 132 S.Ct. at 1293. 2) In a patentability analysis, Section 101 is a separate and threshold analysis. *Id*. at 1304. 3) To be patentable, an invention involving a law of nature or a product of nature must have an "inventive concept" that is "significantly more" than the law of nature or product of nature itself. *Id*. at 1294 (citing *Flook*, 437 U.S. at 594; *Bilski*, 130 S.Ct. at 3230).

The U.S. Supreme Court in *Prometheus* also explained the concerns about fostering innovation that undergird Section 101. The Supreme Court reiterated the tenet "that patent law not inhibit further discovery by improperly tying up the future use of laws of nature." *Prometheus*, 132 S.Ct. at 1301. A Section 101

analysis requires courts to ask "how much future innovation is foreclosed relative to the contribution of the inventor." *Id.* at 1303.

A. Myriad's Claims Must Be Analyzed Under Section 101.

For over 150 years, the U.S. Supreme Court has held that products of nature are not patentable (*Chakrabarty*, 447 U.S. at 309), nor are isolated or purified products of nature (*American Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 594 (1874)), nor are synthetic products that are not markedly different from what is found in nature (*Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884)). The Supreme Court has repeatedly held that compositions of matter involving products of nature or isolated products of nature must be "markedly different" from what occurs in nature to be patentable. *See, e.g.*, *Chakrabarty*, 447 U.S. at 309-10; *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11-12 (1931); *Cochrane*, 111 U.S. at 311; *American Wood-Paper Co.*, 90 U.S. (23 Wall.) at 594. "[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter." *Prometheus*, 132 S.Ct. at 1293; *Chakrabarty*, 447 U.S. at 309 (citing *Funk Bros.*, 333 U.S. at 130). Even when a newly-discovered law of nature or product of nature is novel and nonobvious, it is still unpatentable under Section 101. *Prometheus*, 132 S.Ct. at 1304. Applying

these long-standing precedents, Myriad's isolated DNA claims, cDNA claims, and method claim 20 are invalid.

B. Isolated DNA Is an Unpatentable Product of Nature.

Myriad's composition of matter claims involving gene sequences are not unconventional or novel creations and do not involve an "inventive concept." The term "isolated" adds nothing of significance to the claims. As this Court stated in *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, "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.'" 499 F.3d 1293, 1302 (Fed. Cir. 2007) (quoting *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007)). In *Prometheus*, the Supreme Court applied a similar test and determined that even when additional steps are added to a law of nature, "[t]hese additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim" if they involve "well-understood, routine, conventional activity already engaged in by the scientific community." 132 S.Ct. at 1298.

Nor does the breaking of covalent bonds make isolated DNA patentable. The breaking of covalent bonds (itself a natural process that occurs in the body) is not an "inventive concept" and does not make the gene sequence "markedly different" and therefore patentable subject matter. The change in chemical bonds

is insignificant because the isolated gene sequence is the same string of nucleotides that exists in the cell. Additionally, because the claims are written in terms of the genetic sequence, patentability should be determined by an analysis of the genetic sequence, not by the chemical structure.

C. cDNA Is an Unpatentable Product of Nature.

cDNA is useful in the laboratory because it has the same nucleotide sequence and contains the same information as found in the exons of naturally occurring DNA and can perform the same functions as a full nucleotide sequence or DNA molecule. Bruce Alberts et al., Molecular Biology of the Cell 469-546 (4th ed. 2002).

Myriad's use of routine chemical tools to synthesize cDNA lacks the inventive concept for patentable subject matter. cDNA is not "markedly different" from the sequence as it occurs within the chromosome. As the Supreme Court held in *Cochrane* about a synthetic version of a dye, "[c]alling it artificial alizarine *did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially*." 111 U.S. at 311 (emphasis added).

Once the gene's naturally occurring DNA sequence—an unpatentable product of nature—is known, synthesis of cDNA is a routine mainstay of the art of biologists and chemists. Allowing a patent on cDNA would be a disproportionate reward in relation to what the alleged inventor contributed.

D. The Method Described in Claim 20 Is Unpatentable Subject Matter.

The U.S. Supreme Court described the invalid claims in *Prometheus*, 132 S.Ct. 1290-91, as follows:

> Each claim recites (1) an "administering" step—instructing a doctor to administer the drug to his patient—(2) a "determining" step—telling the doctor to measure the resulting metabolite levels in the patient's blood—and (3) a "wherein" step—describing the metabolite concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, and informing the doctor that metabolite concentrations above or below these thresholds "indicate a need" to decrease or increase (respectively) the drug dosage.

Myriad's claim 20 is analogous, containing (1) an "administering" step, where a cell containing an altered BRCA1 gene causing cancer is grown in the presence of a potential therapeutic compound; (2) a "determining" step, where the growth of the cell with the potential therapeutic is compared to the growth of a control cell; and (3) a "wherein" step describing that a slower growth of the cell in the presence of a compound indicates a cancer therapeutic.

The "administering" step in *Prometheus* only served to identify who would be interested in the correlation, physicians who used thiopurine drugs to treat patients. *Id*. Likewise, the "administering" step of Myriad's claim 20 only serves to identify who would be interested in the law of nature—physicians or researchers using or studying cancer therapeutics. The "determining" step in *Prometheus* told the physician to measure the patient's metabolite levels using routine methods. *Id.*

Similarly, the "determining" step in claim 20 tells the physician or researcher to measure the growth of the cells—a routine activity for physicians and scientists in the field. The "wherein" step in both instances simply tells the physician or researcher about the relevant natural law. Therefore, this Court should hold claim 20 to be invalid.

II. The United States Patent and Trademark Office Erred in Granting Gene Sequence Patents and Its Erroneous Decision Should Not Be Given Deference.

The United States Patent and Trademark Office (USPTO) ignored the U.S. Supreme Court's precedents and applied invalid reasoning to grant patents on genetic sequences and, consequently, its decision should not be accorded deference. The USPTO relied on the 1873 grant of a patent to Louis Pasteur for a purified yeast and on a lower court decision upholding a patent for isolated and purified adrenaline. *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001); *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911), *affirmed*, 196 F. 496 (2d Cir. 1912). However, Pasteur never enforced his patent, so there was no judicial assessment of whether the patent was valid. Maurice Cassier, *Louis Pasteur's Patents: Agri-Food Biotechnologies, Industry and Public Good*, *in* Living Properties, 39 (Jean-Paul Gaudillière, *et al.*, eds., 2009). Moreover, the Pasteur patent and *Parke-Davis* preceded the Supreme Court's decision in *American Fruit Growers*, 283 U.S. 1. As noted shortly thereafter by

Pasquale J. Federico (later Commissioner of Patents and principal drafter of the 1952 Patent Act), in light of *American Fruit Growers*, a claim like Pasteur's "would now probably be refused by the examiner, since it may now be doubted that the subject-matter is capable of being patented." Pasquale J. Federico, *Louis Pasteur's Patents*, 86 Science 327 (1937). Thus, the USPTO acted in error when it began granting patents on gene sequences.

In addition, allowing patents on the claims at issue in this case in contravention of the Section 101 requirements would encourage more patents on laws of nature and products of nature to the detriment of innovation and with grave risks to medical practice and medical research.

III. Upholding Myriad's Patent Claims Would Be a Detriment to Further Innovation.

Laws of nature and products of nature are not man-made inventions. Laws of nature and natural phenomenon are "the basic tools of scientific and technological work... [a]nd so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them… ." *Prometheus*, 132 S.Ct. at 1301 (citations omitted).

This inhibition on future innovation is particularly true with patents on isolated DNA and cDNA. There is no way to "invent around" gene patents. Because an isolated gene sequence is identical to the sequence of the gene in the body, a patent holder can prevent scientists and clinicians from undertaking any

genetic research related to a disease arising from a mutation in that gene.

A survey of directors of laboratories that perform DNA-based genetic tests indicated that over half (53%) had been impeded from developing tests due to gene patents. Cho Decl. ¶ 10; Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 Journal of Molecular Diagnostics 3 (2003). Similarly, 49% of ASHG members had to limit their research due to gene patents. Issac Rabino, *How Human Geneticists in U.S. View Commercialization of the Human Genome Project*, 29 Nature Genetics 15 (2001).

If the patent claims at issue in the case are upheld, physicians will be unable to provide whole genome sequencing and multiplex testing, where the sequences of numerous genes are tested at once. Secretary's Advisory Committee on Genetics, Health, and Society, *Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, 49 (Apr. 2010), http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf [hereinafter "SACGHS"]. For example, as many as 80 genes predispose people to asthma. G. Malerba and P.F. Pignatti, *A Review of Asthma Genetics: Gene Expression Studies and Recent Candidates*, 46 Journal of Applied Genetics 93 (2005). For a complete diagnosis, all those genetic sequences could be analyzed in one test. But genetic sequence patents mean that a single test cannot be used. The patient's tissue sample must be sent to multiple laboratories, increasing costs and

introducing additional chances of error.

The technology exists to allow the sequencing of a person's entire genome of approximately 20,000 genes at an affordable rate. "The goal of completely sequencing a human genome for $1,000 is in sight." W. Gregory Feero, Alan E. Guttmacher, and Francis S. Collins, *Genomic Medicine – An Updated Primer*, 362 New England Journal of Medicine 2001, 2008 (2010). Whole genome sequencing offers the possibility of personalized medicine, where the patient can take preventive measures to minimize his or her risk for a wide range of genetic diseases. However, patents on genetic sequences impede the deployment of a whole genome analysis for patients. Sulston Decl. ¶ 38; Ledbetter Decl. ¶ 24. Even under the conservative estimate that 3% of gene sequence claims would block genetic diagnostic testing, "a full-genome sequence analysis would still infringe several hundred patents." Robert Cook-Deegan and Christopher Heaney, *Patents in Genomics and Human Genetics*, 11 Annual Review of Genomics and Human Genetics 383, 414 (2010).

A. Myriad's Contributions Do Not Justify the Threat to Innovation.

In a Section 101 analysis, courts need to weigh "how much future innovation is foreclosed relative to the contribution of the inventor." *Prometheus*, 132 S.Ct. at 1303. Myriad's contribution to the sequencing and identification of the BRCA1 and BRCA2 genes was minor in comparison to what their patents

foreclose. Myriad used common techniques to isolate, sequence, and clone the BRCA1 and BRCA2 genes. Further, Myriad did not identify the sequence on its own. Myriad had significant scientific aid and financial support, including from the U.S. government. Controversy surrounds the question of whether Myriad even sequenced the BRCA2 gene first. Rachel Nowak, *NIH in Danger of Losing Out on BRCA1 Patent*, 266 Science 209 (1994); Robert Dalpé *et al.*, *Watching the Race to Find the Breast Cancer Genes*, 28 Science, Technology, and Human Values 187 (Apr. 2003). Yet Myriad's BRCA1 and BRCA2 exclusive patents allow the company to foreclose any isolation or sequencing of the genes by physicians and researchers and therefore preclude vast amounts of research and medical applications.

Moreover, gene sequence patents are not necessary to incentivize the discovery of genes and the development of genetic tests. SACGHS, *supra*, at 30. "[P]atents were not needed to develop genetic tests for hearing loss, SCA [spinocerebellar atrophy], breast cancer, LQTS [long-QT syndrome], Canavan disease, and HH [hereditary hemochromatosis]. Indeed, all of these tests were on the market before the test offered by the relevant patent-rights holder." *Id*. at 31. Many geneticists are willing to undertake the research to discover genes and develop genetic tests without the possibility of a patent. In fact, in a study of ASHG members, 61% of those in industry, 78% of those in government, and 77%

of academic scientists stated that they disapproved of patenting DNA. Rabino, *supra*, at 15-16.

B. Invalidation of Myriad's Patent Claims Is Not Only Required by Section 101, It Is Consistent with Scientific and Medical Ethics Codes.

Scientists have long-standing, historically recognized duties to freely disseminate their discoveries of products of nature and laws of nature and not to subject those discoveries to private property rights. *See, e.g.*, Robert K. Merton, On the Shoulders of Giants: A Shandean Postscript (1985). Medical professionals, too, recognize the ethical duty to share scientific knowledge, rather than to patent it.

As *Amicus* AMA's Ethics Opinion 9.095 states, "The use of patents, trade secrets, confidentiality agreements, or other means to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical." American Medical Association, Opinion 9.095 – The Use of Patents and Other Means to Limit Availability of Medical Procedures, (adopted June 1995), http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9095.shtml. Similarly, *Amicus* ACOG's ethics opinion states, "Patents on medical or surgical procedures are ethically unacceptable." The American College of Obstetricians and Gynecologists, *ACOG Committee Opinion Number 364: Patents, Medicine,*

and the Interests of Patients, 109 Obstetrics & Gynecology 1249, 1252 (May 2007) (ACOG reaffirmed their position in 2009). Additionally, "[b]ecause a patent claiming a gene as a composition of matter enables a patent holder to control future applications of the patented gene or sequence, such patents should not be granted." *Id.* Just as patent law recognizes that discoveries of nature must be widely shared to promote innovation, physicians' and scientists' ethical duties recognize that laws of nature and products of nature must be treated as prior art and shared to benefit the public and to encourage innovation.

CONCLUSION

We respectfully request this Court to hold that isolated DNA, cDNA, and the process described in claim 20 of the '282 patent are ineligible for patenting under 35 U.S.C. § 101. It is crucial to patient care and to medical research that the products of nature and the basic laws of nature that Myriad has sought to propertize be freely shared, used, and analyzed.

Respectfully submitted,

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June 15, 2012

United States Court of Appeals
for the Federal Circuit

ASSOCIATION FOR MOLECULAR V PTO, 2010-1406

CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr. being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Professor Lori Andrews, Counsel for *Amicus Curiae AMA, et al.* to print this document. I am an employee of Counsel Press.

On the **15th Day of June 2012**, I served the within **Brief of Amicus Curiae AMA, et al.** upon:

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Additionally, counsel for Amici Curiae known to be appearing at the time of filing will be emailed a copy of this brief.

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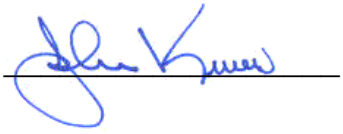
June 15, 2012



CERTIFICATE OF COMPLIANCE

I certify that:

1. This brief complies with the page limit of 15 pages stated by this Court in its April 30, 2012 order, in that the body of this brief – not including the cover page, table of contents, table of authorities, Appendix, and certificates – contains 15 pages, including the statement of interest, summary of argument, headings, footnotes, quotations, signature lines, and date.
2. This brief complies with the type face requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Office Word 2007 in a proportionally spaced typeface: Times New Roman, font size 14.

Dated:
June 15, 2012

Lori B. Andrews