

**In The
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 FOR THE SOUTHERN BAPTIST CONVENTION AS *AMICUS CURIAE* IN
SUPPORT OF PLAINTIFFS-APPELLEES AND ARGUING FOR AFFIRMANCE**

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December 8, 2010

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* certifies the following:

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

The Southern Baptist Convention.

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

The Southern Baptist Convention.

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

None.

4. The names of all law firms and the partners or associates that appeared for the 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 AMICUS CURIAE¹

The patents at issue in this lawsuit were granted on two genes related to breast cancer and ovarian cancer and on all ways of looking at those genes to determine if a person has a predisposition to cancer. These patents, exclusively licensed to Myriad, violate the religious principle of *Amicus Curiae* that the human body and its parts should not be owned, a belief akin to the legal principle that products of nature, laws of nature and natural phenomena are not subject matter eligible for patent protection. And, significantly, because the gene patents at issue cover everyone's *BRCA1* and *BRCA2* genes, the patents put the members of the *Amicus Curiae* in the untenable position of being personally subject to patents that violate their religious beliefs.

Amicus Curiae **The Southern Baptist Convention** is America's largest non-Catholic denomination with more than 16.2 million members in over 44,000 churches nationwide. Southern Baptists hold the belief that the genetic code should not be owned. Southern Baptist Convention, *Resolution on the Patenting of Animal and Human Genes* (June 1995), available at <http://www.sbc.net/resolutions/amResolution.asp?ID=570>.

¹ The Parties have consented to the filing of this brief. No part of this brief was authored by counsel for any Party. No Party, Party's counsel, or person other than the *Amicus Curiae*, its members, or its counsel contributed money that was intended to fund preparing or submitting the brief.

SUMMARY OF ARGUMENT

The patenting of human genes is an affront to humanity. The possibility of obtaining a patent on a person's genes also encourages physicians and researchers to treat people in a dehumanizing way. For many people, the patenting of genes also violates their religious beliefs.

The patent system exists to encourage invention. But, in the case at bar, Myriad did not invent the breast cancer genes, their sequences, or the correlations between certain mutations in those gene sequences and breast cancer. Yet patents on the gene sequences and correlations have been improperly issued.

Basic principles of patent law provide that products of nature and laws of nature are unpatentable subject matter. Whether viewed from the secular belief that gene sequences and correlations are part of the prior art created by nature—or from the religious belief that they were created by a divine Creator—the result is the same. *Amicus Curiae* the Southern Baptist Convention urge this Court to uphold the District Court's decision and invalidate the Myriad patent claims at issue.

ARGUMENT

I. Upholding Myriad's Patent Claims Would be Harmful to All Individuals, No Matter What Their Religious Beliefs

The patenting of human genetic sequences conflicts with the unique nature of *Homo sapiens*. “So God created man in His own image, in the image of God He created him . . .” *Genesis* 1:27. Human life is sacred and possesses unique value derived from the Creator. This Judeo-Christian belief that each person is created by God in His own image is the root of the U.S. legal system’s reverence for the individual. Theodosius Dobzhansky, *The Pattern of Human Evolution, in The Uniqueness of Man* 45 (J. Roslansky ed., 1969). This reverence for the individual as the result of divine origin is expressed in the Declaration of Independence: “We hold these truths to be self-evident, that all men are created equal, and that they are endowed by their Creator with certain unalienable rights . . .” This concept is present in Anglo-American jurisprudence implicit in the old English law notion of man as *liber et legalis homo* (a free and lawful man). Norman St. John-Stevas, *Law and the Moral Consensus, in Life or Death: Ethics and Options* 44 (D. Labby ed., 1968); Francis Pizzulli, *Asexual Reproduction and Genetic Engineering: A Constitutional Assessment of the Technology of Cloning*, 47 *S. Cal. L. Rev.* 476, 507-508 (1974).

The U.S. legal system protects the individual in many ways, such as through the fundamental constitutional right to personal privacy. This case presents this

Court with the opportunity to protect the intrinsically unique value derived from our divine origin by finding Myriad's patents on our genetic material to be invalid.

The patenting of human genetic material attempts to wrest ownership from God and commodifies human biological materials and, potentially, human beings themselves. Human beings are pre-owned. We belong to the sovereign Creator. We are, therefore, not to be killed without adequate justification (e.g., in self-defense) nor are we, or our body parts, to be bought and sold in the marketplace. The image of the Creator pervades human life in all of its parts. Furthermore, the right to own one part of a human being is the right to own all the parts of a human being. This right must not be transferred from the Creator to a company. *See generally* Richard D. Land & C. Ben Mitchell, *Patenting Life: No*, 63 *First Things* 16, 20-22 (1996).

Beyond the harm of usurping the Creator's role, transferring the rights of ownership of human beings from the Creator to Myriad has caused harm in the health care setting. Myriad's patents on gene sequences (products of nature) and correlations (laws of nature) grant the company the ability to prevent others from providing testing for mutations in the *BRCA1* and *BRCA2* gene sequences that are associated with a higher risk for breast cancer. Breast cancer is a serious health issue for women across the U.S., where one in eight women in the United States will develop breast cancer before they are ninety-five. Sean Altekruze et al., *SEER*

Cancer Statistics Review, 1975-2007, National Cancer Institute (2010), available at http://seer.cancer.gov/csr/1975_2007/. However, Myriad's patents on gene sequences and correlations prevent women from receiving affordable *BRCA1* and *BRCA2* testing and from receiving second opinions. Second opinions are particularly important because women base crucial surgical decisions on the results of these tests. Further, Myriad does not screen for all mutations associated with breast cancer, so some women may receive results that indicate that Myriad does not know whether the mutation causes breast cancer or not, causing anxiety which may lead to needless prophylactic surgeries such as mastectomies (removal of breasts) or oophorectomies (removal of ovaries). *Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcomm. on Cts., the Internet and Intell. Prop. of the H. Judiciary Comm.*, 110th Cong. 47 (2007) (statement of Dr. Wendy Chung). See also Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives With Health Needs*, 2 Hous. J. of Health L. and Pol'y 65 (2002).

None of these harms needs to occur. There are sound legal grounds to invalidate the patent claims at issue and this Court should do so.

Beyond the harm to patients in the health care setting, allowing patents on genes diminishes the humanity of all of us. Such patents commodify humans and profoundly alter the relationship between individuals and researchers, turning

people into treasure troves due to possibility of patenting products of nature from people's bodies.

After John Moore's surgery for hairy cell leukemia, his doctor kept asking him to return to provide samples of blood, sperm, bone marrow, and other tissue. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990). Without Moore's knowledge or consent, his doctor created a cell line from Moore's tissue, named it the Mo cell line, patented it, and then sold rights to the cell line to a biotechnology firm. *Id.*

When Moore found out that his cells were U.S. Pat. No. 4,438,032, he felt that his integrity had been violated, his body exploited, and his tissue turned into a product: "My doctors are claiming that my humanity, my genetic essence, is their invention and their property. They view me as a mine from which to extract biological material. I was harvested." John Vidal & John Carvel, *Lambs to the Gene Market*, *The Guardian*, Nov. 12, 1994, at 25.

When the California Supreme Court considered the issue, it ruled that Moore could not sue for theft of his property (his cells), but that his right to informed consent had been violated. Justice Mosk dissented from the majority's grant to the doctor and a biotechnology company of a property right in the patient's tissue. Justice Mosk noted that "our society acknowledges a profound ethical imperative to respect the human body as the physical and temporal expression of the unique

human persona.” *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 515-516 (Cal. 1990) (Mosk, J. dissenting). He reviewed previous exploitations of the human body that have been since abolished—slavery, indentured servitude, and debtor’s prison—and stated:

Yet their specter haunts the laboratories and boardrooms of today’s biotechnological research-industrial complex. It arises wherever scientists or industrialists claim, as defendants claim here, the right to appropriate and exploit a patient’s tissue for their sole economic benefit—the right, in other words, to freely mine or harvest valuable physical properties of the patient’s body. . . . “Such research tends to treat the human body as a commodity—a means to a profitable end. The dignity and sanctity with which we regard the human whole, body as well as mind and soul, are absent when we allow researchers to further their own interests without the patient’s participation by using a patient’s cells as the basis for a marketable product.”

Id. at 515-516 (citation omitted).

And harvest they do. For over a decade, Ashkenazi Jewish families of children with Canavan disease and non-profit foundations provided tissue and money to a geneticist so that he could sequence the genetic mutation that caused this devastating neurological disease. *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

The families intended that the genetic sequence be used to develop a genetic test, so couples could be tested to see if they were carriers of a gene mutation that might affect their children. They had contacted this particular geneticist because he had been active in Tay-Sachs screening, where inexpensive genetic testing was

undertaken in schools and synagogues, as well as in doctors' offices, to alert Ashkenazi Jewish individuals to their risk of having a child with that disorder. *Id.*

When the doctor identified the gene sequence, though, he and his hospital patented it without the knowledge or consent of the tissue sources. And when the families and non-profit foundations convinced medical providers to offer Canavan gene testing for free, the hospital with the patent shut down the free testing. Lucinda Hahn, *Owning a Piece of Jonathon*, *Chicago Magazine* 83, 88-89 (May 2003). When the families and foundations sued, the Southern District of Florida held that the plaintiffs had no property right to their tissue. However, the court ruled they could maintain a cause of action for unjust enrichment since “the facts paint a picture of a continuing research collaboration that involved Plaintiffs also investing time and significant resources in the race to isolate the Canavan gene.” *Id.* at 1073-74.

Research on people's body parts to find genes—often without the individuals' informed consent—is common but violates medical ethics tenets and many individuals' religious beliefs. Court cases have recognized that a patient's religious beliefs should be taken into consideration in determining what is proper handling of their bodies and their body parts. *See, e.g., Lott v. State of N.Y.*, 225 N.Y.S.2d 434 (Ct. Cl. 1962); *Kohn v. U.S.*, 591 F. Supp. 568 (E.D.N.Y. 1984).

In the Orthodox Jewish community, for example, unauthorized use of body tissue violates religious beliefs which require that the body be buried whole. If a person's leg is amputated during his or her life, arrangements are made to store that body part for burial with the individual after death. Henry Fitzgerald, Jr., *Woman Awarded \$1.25 Million in Suit; Funeral Home Must Compensate for Losing Mother's Amputated Legs*, Sun-Sentinel (Fort Lauderdale), May 16, 1997, at 1B. Yet a pathologist removed Albert Einstein's brain after his death and undertook research seeking a gene for aneurysm without prior consent from Einstein or his family members. Rabbis have asked the pathologist for Einstein's brain so that it could be buried, allowing the scientist to rest in peace. Lori Andrews & Dorothy Nelkin, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* 9-16 (Crown Publishers 2001).

Within a year of the granting of the first *BRCA1* gene patent to Myriad's assignors, the Southern Baptist Convention adopted a resolution denouncing the patenting of human genes. Southern Baptist Convention, *Resolution on the Patenting of Animal and Human Genes* (June 1995), available at <http://www.sbc.net/resolutions/amResolution.asp?ID=570>. The Southern Baptist Convention holds the belief that "[m]arketing human life is a form of genetic slavery. Instead of whole persons being marched in shackles to the market block, human gene sequences are labeled, patented, and sold to the highest bidders. That

researchers and biotechnology companies are applying for the patents clearly signals the shocking direction of current genetic technology. That the U.S. Patent Office would grant such applications is absolutely chilling.” Southern Baptist Convention, *BRCA – Statement of Support from the Ethics & Religious Liberty Commission, Southern Baptist Convention*, May 12, 2009, available at <http://www.aclu.org/free-speech/brca-statement-support-ethics-religious-liberty-commission-southern-baptist-convention>. See also Richard D. Land & C. Ben Mitchell, *Patenting Life: No*, 63 *First Things* 16 (1996).

The World Council of Churches brings together 349 churches, denominations and church fellowships in more than 110 countries and territories throughout the world, representing over 560 million Christians. Just as the Southern Baptist Convention opposes gene patenting, “[t]he World Council of Churches is opposed to the buying and selling of human body parts. This includes the patenting of human genes. The dignity of the human person is irreconcilable with any commodification of human life. Human life is commodified when its value is weighed against another value. This is what happens when human life is patented. Such patenting gives power over human life to specific human beings that cannot be justified. Life ultimately belongs to God. The patenting of human life is in opposition to this conviction.” World Council of Churches, *Genetic, Agriculture and Human Life*, document from the Justice, Peace and Creation

Team, approved by WCC Executive Committee Porto Alegre, Brazil, General Assembly Feb. 2006.

The United Methodist Church, too, has spoken out against gene patents. “In 1995, we organized a campaign of religious leaders calling for an end to the patenting of life, and the building blocks of life, including genes. In the intervening years, we have been dismayed that tests for the presence of genes associated with some diseases like cancer have been controlled in the US by a few organizations. This is not the case in Europe where the United Methodist Church has many local congregations, but it is sadly still the case in the US.” United Methodist Church, *BRCA Statement of Support: United Methodist Board of Church and Society*, May 12, 2009, available at <http://www.aclu.org/free-speech/brca-statement-support-united-methodist-board-church-and-society>.

For Judaism, “the fundamental issue here is whether human genes, even mutated, ‘isolated’ or ‘purified’ human genes are ‘natural,’ i.e., part of nature. Generally speaking, genes and genetic sequences have been treated by the courts and PTO not as human body-parts or as human tissue, but much like other chemical compositions that are patentable. However, Jewish legal ethics would take the position that as either natural entities or as ‘extensions of nature,’ human DNA and human genes are part of nature, not ‘man-made,’ not merely a chemical, and therefore ineligible to become patented entities protected by a property right.”

Rabbi Byron L. Sherwin, Ph.D, *Patents and Patients: Human Gene Patenting and Jewish Legal Ethics*, available at http://www.thehumanfuture.org/commentaries/gene_patents/genepatents_commentaries_sherwin01.pdf.

As Rabbi Sherwin notes, gene patenting raises “the specter of genetic discrimination and evokes memories of the demonic eugenic social policies of Nazi Germany during the Holocaust. Indeed, references to the Holocaust have been evoked by some of the most articulate opponents of the patenting of human tissues and human genes. For example, the eminent biologist, Erwin Chagroff, has discussed the sometimes predatory and exploitative practices of the biotech and pharmaceutical industries to secure monopolistic patents on human genes and tissues as ‘an Auschwitz in which valuable enzymes, hormones, and so on will be extracted instead of gold teeth.’” *Id.* (citation omitted).

Amicus Curiae the Southern Baptist Convention support genetic research to address the 4,000 genetic diseases. But, in the words of the Ethics & Religious Liberty Commission of the Southern Baptist Convention, “while we have been generally supportive of the advance of genetic science, lauding its potential for good, we are equally concerned about the potential for abuses. We view the patenting of human genes as a particularly egregious abuse of genetic technology.” Southern Baptist Convention, *BRCA – Statement of Support from the Ethics & Religious Liberty Commission, Southern Baptist Convention*, May 12, 2009,

<http://www.aclu.org/free-speech/brca-statement-support-ethics-religious-liberty-commission-southern-baptist-convention>.

Appellant Myriad and its *Amici* BIO and PhRMA argue that gene patenting is an economic necessity to encourage the discovery of genes.² Appellants' Br. 3-4, 12; BIO Br. 24-25; PhRMA Br. 15-18. The same arguments were made by plantation owners about how slavery was an economic necessity. As with slavery, some entities (such as Myriad) benefit economically. But the benefit to certain companies is not worth the medical, personal, and religious harms to us all.

Gene patents are an affront from both a secular and a religious viewpoint. Upholding the District Court's decision in this case would be beneficial to all humankind.

II. Gene Sequences and Correlations Between Gene Sequences and Cancer are Unpatentable Subject Matter Under 35 U.S.C. § 101 and Under Article I, Section 8, Clause 8 of the U.S. Constitution

A long line of patent law precedents has held that products of nature and laws of nature are not patentable subject matter under 35 U.S.C. § 101 and under Article 1, Section 8, Clause 8 of the U.S. Constitution. *See, e.g., Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) ("The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered

² Studies of scientists show this argument is not valid. Many geneticists are willing to discover, identify, sequence, and undertake genetic testing without the patent incentive. *See, e.g., Isaac Rabino, How Human Geneticists in U.S. View Commercialization of the Human Genome Project*, 29 Nat. Genetics 15 (2001).

in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’” (citations omitted); *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O’Reilly v. Morse*, 56 U.S. 62, 112-121 (1854); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853); *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 594 (1874). See also Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 Stan. L. Rev. 303 (2002); John M. Conley and Robert Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II)*, 85 J. Pat. & Trademark Off. Soc’y 371 (2003); John M. Conley, *Gene Patents and the Product of Nature Doctrine*, 84 Chi. Kent L. Rev. 3 (2009). Myriad’s patents improperly claim both products of nature and laws of nature.

A. Gene Sequences are Unpatentable Subject Matter Under 35 U.S.C. § 101 and Under Article I, Section 8, Clause 8 of the U.S. Constitution

Myriad’s patents claim the *BRCA1* and *BRCA2* breast cancer gene sequences. For example, claim 1 of U.S. Patent No. 5,747,282 claims: “An

isolated DNA coding for a *BRCA1* polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.” Myriad’s patents’ specifications state:

An “isolated” or “substantially pure” nucleic acid (e.g., an RNA, DNA or a mixed polymer) is one which is substantially separated from other cellular components which naturally accompany a native human sequence or protein, e.g., ribosomes, polymerases, many other human genome sequences and proteins. The term embraces a nucleic acid sequence or protein which has been removed from its naturally occurring environment, and includes recombinant or cloned DNA isolates and chemically synthesized analogs or analogs biologically synthesized by heterologous systems.

U.S. Pats. Nos. 5,693,473; 5,747,282; 5,837,492; 5,709,999; 5,710,001; 5,753,441; 6,033,857.

Based on the fact that it has isolated the DNA, i.e. taken it out of the body, Myriad’s assignor has patented the DNA. However, the fact that a gene is removed from a cell and its cellular components does not make it patentable subject matter under § 101. Like a “new plant found in the wild,” these gene sequences occur naturally in the human body. These gene sequences were not created by man and therefore are not patentable under 35 U.S.C. § 101 and the U.S. Constitution.

Patents are granted to inventors, not to people who discover a product of nature, even if they isolate or purify that product of nature or improve upon it. In *Funk Brothers*, 333 U.S. at 130, the patent applicant had mixed several types of root nodule bacteria capable of inoculating the seeds of plants. The U.S. Supreme

Court held that the mixture was not patentable because the combination of bacteria species did not produce a new invention. The Court stated that “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.* at 131. Similarly, the person claiming ownership of an isolated gene is seeking a monopoly on its natural functions—the ability of a gene sequence to anneal to its complementary strand (which allows diagnosis) and the ability to produce proteins.

In *American Wood-Paper*, 90 U.S. (23 Wall.) at 594, the U.S. Supreme Court held further that an isolated and purified product of nature is not patentable if the product functions in a way that is not significantly different than what occurs in nature, stating:

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 obtained cannot be called a new manufacture.

Id. at 593-94.

In the 1931 case of *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931), the United States Supreme Court invalidated the product claims on oranges and other fruit treated with a borax solution because the resulting fruit/boric

compound combination was not a manufacture under the 35 U.S.C. § 31, the precursor to § 101 of the Patent Act of 1952. The Court stated:

Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange, fit only for the same beneficial uses as theretofore.

Id. at 11-12.

The Court then stated that applying labor to an article does not necessarily make the resulting product a manufacture. “Washing and scouring wool does not make the resulting wool a manufacture of wool. Cleaning and ginning cotton does not make the resulting cotton a manufacture of cotton.” *Id.* at 12.

Similarly in *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884), the U.S. Supreme Court held that synthetic products that were made to function as their natural counterparts functioned were not patentable subject matter. *Cochrane* involved a synthetic version of a dye that already existed in nature (alizarine), but the synthetic version had a brighter hue. The Court held that “calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially, for the first time, from anthracine, if it was set forth as alizarine, a well known substance.” *Id.* at 311.

Many lower court cases have followed the U.S. Supreme Court precedent that isolated and purified products of nature are not patentable. *See, e.g., In re Marden* (Marden I), 47 F.2d 957 (C.C.P.A. 1931) (purified uranium); *In re Marden* (Marden II), 47 F.2d 958 (C.C.P.A. 1931) (purified vanadium); *In re Merz*, 97 F.2d 599 (C.C.P.A. 1938) (purified ultramarine dye); *Dennis v. Pitner*, 106 F.2d 142 (7th Cir. 1939) (purified cube plant root); *Gen. Elec. Co. v. DeForest Radio Co.*, 28 F.2d 641 (3d. Cir. 1928), *cert. denied*, 278 U.S. 656 (1928) (purified tungsten); *Ex parte Latimer*, Dec. Comm'r Pat. 123 (1889) (purified pine needle fiber). Even with respect to variations on originally patentable inventions, purification is not sufficient to make the substance patentable. *See also Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1302 (Fed. Cir. 2007) (“Ordinarily, one expects a concentrated or purified ingredient to retain the same properties it exhibited in a mixture, and for those properties to be amplified when the ingredient is concentrated or purified; isolation of interesting compounds is a mainstay of the chemist’s art.”).

The characteristics and function of a gene reside in the gene sequence. These characteristics and functions (the active portion of the gene sequence) have not been changed in “isolated” DNA. Similarly, any labor expended by Myriad’s assignors in isolating the DNA sequence or isolating the coding region to form cDNA does not transform the natural product into a manufacture. The resulting

molecules and genetic sequences are not markedly different than the molecules that occur in the body. *Chakrabarty*, 447 U.S. at 310. They are “fit only for the same beneficial uses as theretofore,” just as the treated oranges in *American Fruit Growers* did not gain any new functions by the application of the borax. *See Am. Fruit Growers, Inc.*, 283 U.S. at 12.

B. Correlations Between Gene Sequences and Cancer are Unpatentable Subject Matter Under 35 U.S.C. § 101 and Under Article I, Section 8, Clause 8 of the U.S. Constitution

Myriad’s patents also improperly contain claims to correlations between certain mutations and a higher risk for breast cancer. Claim 2 of U.S. Patent No. 6,033,857, for example, claims: “a method for diagnosing a predisposition for breast cancer in a human subject which comprises *comparing* the germline sequence of the *BRCA2* gene or the sequence of its mRNA in a tissue sample from said subject with the germline sequence of the wild-type *BRCA2* gene or the sequence of its mRNA, wherein an alteration in the germline sequence of the *BRCA2* gene or the sequence of its mRNA of the subject indicates a predisposition to said cancer.” These correlation patents cover the relationship between the presence of a mutation in the *BRCA1* or *BRCA2* gene and the risk of cancer. These relationships are laws of nature, just like Einstein’s $E=mc^2$ or the law of gravity and are not patentable subject matter under 35 U.S.C. § 101 and the U.S. Constitution.

Moreover, Myriad's method claims directed to "comparing" and "analyzing" cover the mental process of merely comparing two gene sequences and recognizing a difference. The Supreme Court has held that claims to mental processes are not patentable. "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." *Flook*, 437 U.S. at 589 (quoting *Benson*, 409 U.S. at 67). Myriad's method claims cover a mental process and are not patentable subject matter.

If Myriad had claimed a gene sequencing machine or had claimed a new method of sequencing genes, this would be a patentable invention. Instead, Myriad's method claims rely on someone else's patented technology and old sequencing methods to sequence genes. Myriad's claims do not even recite the steps (however performed) of obtaining the information for the analysis or comparison, and thus cover *solely* the mental act of recognizing a similarity or a difference. In fact, "[a]nalyzing' or 'comparing' would be understood by one of ordinary skill in the art to mean looking at the sequence to determine its characteristics, or looking at two or more things to determine if there is a difference." A2480. Steps of isolating and sequencing the gene cannot be read into the claim, because to do so would violate the prohibition against incorporating

claim limitations from the specification. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005).³

Moreover, an unpatentable process cannot be transformed into a patentable process by adding insignificant extra-solution activity. *See Bilski v. Kappos*, 130 S. Ct. 3218, 3230 (2010); *Flook*, 437 U.S. at 590; *In re Grams*, 888 F.2d 835, 839-840 (Fed. Cir. 1989); *In re Schrader*, 22 F.3d 290, 294 (Fed. Cir. 1994). The “transformation must be central to the purpose of the claimed process.” *In re Bilski*, 545 F.3d 943, 953 (Fed. Cir. 2008).

In addition, Myriad’s claimed “process” involves nothing more than a use of the *BRCA1* and *BRCA2* sequences—or small segments of these gene sequences. Since the sequences themselves are unpatentable products of nature, Myriad cannot obtain a monopoly on their use through a process claim.

³ Myriad relies on *Prometheus, Inc. v. Mayo Collaborative Services* to argue that its method claims involve a transformation. 581 F.3d 1336 (Fed. Cir. 2009), *certiorari granted, judgment vacated, and remanded*, 130 S. Ct. 3543 (2010). But even if the sample-taking step could be read into the claims, the Myriad patents are distinguishable from the patent in *Prometheus* because no drug is administered to alter the normal function of the body.

CONCLUSION

The patent-eligibility issue is a “threshold test” before other requirements of patent law are applied to the purported invention. *Bilski*, 130 S. Ct. at 3230. The starting point for any analysis of patent-eligibility is the question, “What did the patent applicant invent?” *See, e.g.*, U.S. Pat. and Trademark Off., Official Gazette Notices, Nov. 22, 2005, Section II. With respect to the sequence and correlation claims, what did Myriad invent? With respect to the sequence and correlation claims, Myriad and its assignor did not invent anything. Myriad’s patents on the *BRCA1* and *BRCA2* gene sequences and correlations are invalid patents on products of nature and laws of nature. Moreover, they infringe upon the religious beliefs of many people who believe in the sanctity of divine creation. Consequently, the claims at issue in the case should be invalidated and the District Court decision upheld.

Dated: December 8, 2010

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Counsel for Amicus Curiae the Southern Baptist Convention hereby certifies

that:

1. The brief complies with the type-volume limitation of the Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B)(i) in that the body of this brief – not including the cover page, table of contents, table of authorities, Appendix, and certificates – contains 5137 words as determined by Microsoft Word 2007, including the statement of interest, summary of argument, headings, footnotes, quotations, signature lines, and date; and

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Dated: December 8, 2010

Francis Pizzulli

**DECLARATION OF AUTHORITY
PURSUANT TO FED. CIR. R. 47.3(d)**

I, Lawson Forgy, hereby declare under penalty of perjury that I am duly authorized to sign on behalf of Counsel for *Amicus Curiae* Francis Pizzulli, as he is unavailable to do so himself.

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