

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 Writ of Certiorari to the United States Court of
Appeals for the Federal Circuit

**BRIEF FOR *AMICI CURIAE* OF THE ETHICS
& RELIGIOUS LIBERTY COMMISSION OF
THE SOUTHERN BAPTIST CONVENTION
AND PROF. D. BRIAN SCARNECCHIA IN
SUPPORT OF PETITIONERS**

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INTEREST OF THE *AMICI CURIAE*¹

The patents at issue in this lawsuit were granted on two genes related to breast cancer and ovarian cancer and on using those genes to determine if a person has a predisposition to cancer. These patents, exclusively licensed to Myriad Genetics, Inc., violate the religious principle of *Amici 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. Significantly, because the gene patents at issue cover everyone's BRCA1 and BRCA2 genes, the patents put the *Amici 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,

¹ No counsel of a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief and no person other than amici curiae, its members, or its counsel made a monetary contribution to its preparation or submission.

Petitioners have provided written consent, on file with the clerk, to the filing of briefs in support of either, or neither, party, and respondents provided consent, on file with the clerk, for the filing of this brief on Jan. 31, 2013.

Resolution on the Patenting of Animal and Human Genes (June 1995), available at <http://www.sbc.net/resolutions/amResolution.asp?ID=570>.

Amicus Curiae Prof. D. Brian Scarnecchia, M.Div., J.D. is an Associate Professor of Law at Ave Maria School of Law in Naples, Florida where he has taught Property Law and Bioethics. He is also the Director of the Human Life Studies program at Franciscan University of Steubenville in Steubenville, Ohio. He is the author of *BIOETHICS, LAW AND HUMAN LIFE ISSUES: A CATHOLIC PERSPECTIVE ON MARRIAGE, FAMILY, CONTRACEPTION, ABORTION, REPRODUCTIVE TECHNOLOGY, AND DEATH AND DYING* (2010). He is also the founding president of International Solidarity and Human Rights Institute (ISHRI), a non-governmental organization (NGO) in consultative status with the United Nations. Scarnecchia believes that the patenting of DNA sequences treats as private property what is a part of the common and innate nature of the human person. Patents on DNA sequences will open the door to further commodification of the gene pool reflecting a eugenic mentality as, for instance, in germ line cell therapy. For these reasons, individually and as a president of ISHRI, he presents this brief to the Court.

SUMMARY OF THE ARGUMENT

Products of nature, which are gifts given to all of humanity by God, cannot be exclusively claimed by an individual or corporation. The genetic code is a divine gift and an intrinsic, inseparable part of

human existence. Permitting a corporation or person to own this fundamental component of a person corrupts the relationships between human beings and the Creator, and between human beings. The person should not be treated as a commodity for sale to the highest bidder, and property must be recognized in a way that respects all of the members of society. These principles are prevalent in Christian theology, and several religious organizations specifically oppose gene patents on these grounds.

These moral principles regarding patents are reflected both in American law and the international community. Patent law emphasizes that the human body is not subject to ownership. Likewise, America's rich legal tradition has provided strong protections against the control of the person by others. The international community echoes these ideals in their opposition to human gene patents. Permitting human DNA patents violates the spirit of patent and property law by permitting a single entity to claim a product of nature, thereby asserting control over the human genetic patrimony. This results in harms to all people, especially vulnerable people who are in the greatest need of options and access in medicine.

ARGUMENT

Myriad Genetics' patents claim the BRCA1 and BRCA2 breast cancer gene sequences. These sequences are isolated nucleic acids. Isolated nucleic acids (e.g., RNA, DNA, or a mixed polymer) are acids that are separated from other cellular components

that naturally accompany a native human sequence or protein. Because all that it has done is remove the DNA from the body, Myriad Genetics' assignor has patented the DNA.

Myriad Genetics argues that this Court should grant exclusive ownership rights over genetic material that is essential to human existence. It seeks to commodify this information, disregarding its intrinsic value and nature as a divine gift. In doing so, Myriad Genetics ignores the values that are interwoven into the laws and morals of American society.

This case presents this Court with an opportunity to preserve the constitutional foundation of the U.S. patent system, while extinguishing serious threats to the values on which our nation was built.

I. The Genetic Code is a Necessary Part of Human Existence, Created by God.

DNA is necessary for human existence. Christian churches hold as a core principle that God created DNA. Granting ownership of DNA upsets the fundamental relationship between human beings and God, both because it commodifies the human body—degrading its dignity within creation—and consigns an essential part of the human genetic patrimony to private ownership. Numerous churches have expressed concern over the patenting of genetic material for these reasons.

A. The genetic code is necessary for human existence.

DNA is not simply a chemical sequence that can be manipulated and owned by scientists—it is essential to human existence. DNA holds a dignified place in creation—it is not a human invention, but a divine one. It is the “biological blueprint for human beings as images of God.” Mark J. Hanson, *Religious Voices in Biotechnology: The Case of Gene Patenting*, HASTINGS CENTER REP. 1, 4 (1997). Similar to a “new plant found in the wild,” the gene sequences claimed by Myriad Genetics occur naturally in the human body. *Diamond v. Chakrabarty*, 100 S. Ct. 2204, 2209 (1980) (emphasis added) (quoting and contrasting *Funk Bros. Seed Co.*, 68 S. Ct. 440, 441 (1948)). DNA, a gift written into nature itself, is not appropriate material for private patents. See John Paul II, *Message of the Holy Father for Lent 2002*, Oct. 4, 2001, available at http://www.vatican.va/holy_father/john_paul_ii/messages/lent/documents/hf_jp-ii_mes_20020205_lent-2002_en.html at para. 2 [hereinafter *Lenten Message*] (“[B]ecause it is gift, life can never be regarded as a possession or as private property, even if the capabilities we now have to improve the quality of life can lead us to think that man is the ‘master’ of life.”). The genetic code is at the heart of humanity’s existence and cannot be owned, any more than the “immortal soul of Christianity” can be controlled by humans. DOROTHY NELKIN & M. SUSAN LINDEE, *THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON* 40 (2004). President Bill Clinton spoke to the exalted nature of the gift of DNA when

he announced the completion of the Human Genome Project in 2000: “Today we are learning the language in which God created life.” President Bill Clinton, Remarks on the Completion of the First Survey of the Entire Human Genome Project (June 26, 2000), *available at* http://www.ornl.gov/sci/techresources/Human_Genome/project/clinton2.shtml.

B. Ownership of DNA upsets the fundamental relationships between God and humanity, and between human beings.

Allowing anyone to claim ownership over the very material that constitutes the human body reverses the roles of the Creator and the created. Like any effort to claim ownership over the person, it results in “an audacious usurpation of the Divine prerogative, a daring infringement of the law of nature, and a base over-throw of the very foundations of the social compact.” William Lloyd Garrison, *Declaration of Sentiments of the American Anti-Slavery Convention*, Dec. 6, 1833, *available at* <http://utc.iath.virginia.edu/abolitn/abeswlgct.html>. Specifically, granting private exclusive rights over a part of the human body—especially one as central to human existence as DNA—degrades humanity, dropping it from its special role in creation to a mere species of property. Second, as an essential part of God’s creation, human DNA should be held in common by all humanity so that it can be put to the service of all of its members.

Humanity's genetic material grants individuality, even as it ties all people together. "All men have the stars, but they are not the same things for different people." ANTOINE DE SAINT-EXUPÉRY, *THE LITTLE PRINCE* 85 (Katherine Woods trans., 1943). This combination of common patrimony with individual effects is a fundamental aspect of genes echoed by religious leaders, and it confers moral responsibilities: "The originality of every person is a consequence of the particular relationship that exists between God and a human being from the first moment of his existence and carries with it the obligation to respect the singularity and integrity of each person, even on the biological and genetic levels." Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae on Certain Bioethical Questions*, Sept. 8, 2008, available at http://www.vatican.va/roman_curia/congregations/cf_aith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html.

The gene, as a chemical compound, operates according to the natural laws of the genetic code. See Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 710 (2004). The genetic code, operating in accordance with the natural laws set forth by the Creator, is a product of the divine mind. This Court has made clear that although natural substances can be extracted from their source, "the extract is the same, no matter from what it has been taken." *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 594 (1874). The genetic code is a

component of divine creation, both within and outside the body.

Attempting to divvy up the person to the highest bidder for commercial purposes runs the “serious risk of suppressing the person’s very nature” and reducing him to a mere object. See John Paul II, Address to the Pontifical Academy of Sciences (Oct. 28, 1994), *available at* <http://www.its.caltech.edu/~nmcenter/sci-cp/sci941111.html> [hereafter “Pontifical Address”]; Samuel J. Kerstein, *Kantian Condemnation of Commerce in Organs*, *available at* <http://www.philosophy.umd.edu/Faculty/SKerstein/Kantiancondemnation.pdf> (allowing people to commodify parts of themselves degrades them to the level of mere objects, robbing them of freedom, dignity, and self-respect).

C. These Principles Run Throughout Christian Theology.

Many major religious denominations have vehemently opposed patents over genetic material, including the Southern Baptist Convention, the Catholic Church, the United Methodist Church, and the World Council of Churches. Their viewpoints address the risk genetic patents pose to the sacred relationship between humans and their Creator posed by genetic patents.

1. The Southern Baptist Convention

The Southern Baptist Convention believes that every human being is made in God’s image and possesses unique value derived from humanity’s

intimate relationship with him. “So God created man in His own image, in the image of God He created him” *Genesis* 1:27 (New Living Translation). Human dignity flows from this relationship, and “[h]uman DNA symbolizes something essential about humans themselves, and, as such, raises the issue of human dignity.” Miriam Schulman, *Of SNPS, TRIPS, Human Dignity: Ethics and Gene Patenting*, 1 BIOPROCESS INT’L J. 26 (2003). The patenting of human genetic material is an attempt to seize the power of, and ownership over, creation from God. “God wrote those sequences of C, G, A & T. It is heresy, or at least plagiarism, for [anyone else] to claim to do so.” James Boyle, *Enclosing the Genome: What the Squabbles Over Genetic Patents Could Teach Us*, 50 ADVANCES IN GENETICS 97 (2003), available at <http://web.law.duke.edu/ip/pdf/enclosing.pdf>. This principle is seen throughout the Judeo-Christian tradition that forms the basis for the moral principles of our legal tradition.

2. The Catholic Church

The Catholic Church is devoted to the protection of human dignity and the “incomparable worth of every human person.” See, e.g., John Paul II, *Evangelium Vitae*, Mar. 25, 1995, para. 2, available at http://www.newadvent.org/library/docs_jp02ev.htm. “With the new prospects opened up by scientific and technological progress,” Pope John Paul II noted, “there arise new forms of attacks on the dignity of the human being. *Id.* at para. 4. “Respect for life requires that science and technology should always be at the service of man and his

integral development,” respecting human dignity as a primary obligation. *Id.* at para. 81.

Gene patenting does not show this respect. It asserts exclusive rights over “[God’s] gift, his image and imprint, [the] sharing in the breath of life.” *See id.* at para. 39. In an address to the Pontifical Academy of Science, Pope John Paul II emphasized that dignity and DNA are bound to each other: “Man cannot be separated from his DNA any more than he can be separated from his spirit.” *Pontifical Address, supra*. He then charged the Academy, and all genetic researchers, not to lose sight of this core of human existence in the pursuit of scientific progress—urging them to “take into consideration the metaphysical and moral questions that become even more pressing when the certitude obtained by science is seen in relation to the whole truth about man.” *Id.* Myriad Genetics has not done so, attempting to isolate genetic information and contradicting the truth that the human person is not mere chattel to be parceled out.

3. The United Methodist Church

The United Methodist Church has also expressed concerns about human gene patenting, proclaiming that the ownership of genetic information is a violation of “the sanctity of God’s creation and God’s ownership of life”. Steven Goldberg, *Gene Patents and the Death of Dualism*, 5 S. CAL. INTERDISC. L.J., 25, 34 (1996). The church believes that “humans and animals are creations of God, not humans, and as such should not be patented as human inventions.”

Ronald Cole-Turner, *Religion and Gene Patenting*, 270 SCI. 52 (1995). This position gained world-wide attention and was featured on the front page of the *New York Times*. Goldberg at 34.

In 1988, the church formed a committee to address the religious and moral implications of gene patenting. The committee drafted ethical recommendations against gene patenting that were eventually adopted in the 1996 Joint Appeal—a statement released by 200 religious leaders from various religions addressing gene patents. 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-methodistboard-church-and-society>. These leaders called for an end to the patenting of genetic material and expressed grave concerns about recent decisions on the part of the Patent Office.

4. The World Council of Churches

The World Council of Churches (WCC) brought the danger of genetic patents to the attention of religious communities in 1989 when it published *Biotechnology: Its Challenges to the Church and World*. It has remained a leader in this important struggle. At a 1999 United Nations meeting, the WCC joined over 80 signatories representing indigenous peoples in opposing the patenting of human genetic material. “The 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, Justice, Peace and Creation Team, *Genetic, Agriculture and Human Life*, approved by the WCC Executive Committee General Assembly Feb. 2006.

This statement was issued on behalf of over 560 million Christians in member churches worldwide and shows a clear concern for the potential degradation of human dignity. See World Council of Churches, *Who We Are*, <http://www.oikoumene.org/en/who-are-we.html>. Myriad Genetics’ gene patents, by commodifying human life, are an affront to these universally recognized principles of human dignity.

II. These Theological and Moral Principles are Reflected in American Law and the International Community.

Private property rights over natural resources are recognized for their ability to promote human flourishing. They do not exist to promote selfish gain. Rather, they protect and serve humanity. Accordingly, both American law and the international community affirm that there should be

limits on private property rights over elements of creation, including the human body.

A. Patent law

Patent law considers utility to be of the highest importance in deciding whether to grant property rights. “A [patent] application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research.” *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (holding that to satisfy the “substantial” utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public). Process and product claims must lead to a result that can be used for some substantial and specific practical end. Michael Risch, *Everything is Patentable*, 75 TENN. L. REV. 591, 607 (2008).

More than a century of legal precedent has established that products and laws of nature are not patentable subject matter, because granting exclusive rights over them would limit further development by others. *See, e.g. Chakrabarty, supra*, at 309 (“Laws of nature, physical phenomena, and abstract ideas are manifestations of nature, free to all men and reserved exclusively to none.”); *Funk Bros.* at 130; *Am. Wood-Paper Co.* at 594. The exceptions to 35 U.S.C. § 101 safeguard the constitutional command that patents be granted to inventors only for the purpose of promoting scientific progress—thereby setting a high standard for patent claims involving products of nature. *See* U.S. CONST., art. I, § 8, cl. 8.

B. Property in the person

The genetic code has been recognized as the “most intimate commons of all,” gifted to humanity as a whole by the Creator. JEREMY RIFKIN, *THE BIOTECH CENTURY* 41 (1998). No DNA sequence should be the property of one individual or organization. Daniel Kevles, *Vital Essences and Human Wholeness: The Social Readings of Biological Information*, 65 S. CAL. L. REV. 255, 277. “Scientific work aimed at securing a quality of life more in keeping with human dignity is admirable, but it must never be forgotten that human life is a gift”—one that has been entrusted to all of humanity and must be “received without pay and to be placed without pay at the service of others.” *Lenten Message, supra*, at para. 2. Genetic material, essential to the human person, cannot justly be consigned as property to another.

1. The rejection of human beings as property in law

The privatization of humanity is not a new concern for the American legal system. As this country struggled to eradicate slavery, abolitionists argued that the commodification of human beings was an intolerable evil that not only degraded those being bought and sold, but all of society. A person, Frederick Douglass argued, has a “self-evident” right to be free of ownership by others. Frederick Douglass, *The Horrors of Slavery and England’s Duty to Free the Bondsman: An Address Delivered in Taunton, England (Sept. 1, 1846)*, available at <http://www.yale.edu/glc/archive/1081.htm>. Douglass

asserted that God gave him “these hands, this head, these shoulders,” and that to claim possession over even one aspect of another person’s body “strikes down all right in striking down one right.” *Id.* Denying someone ownership over an aspect of the person, the abolitionists saw, does not deprive him of his property—it restores the gift of life to the one entrusted with it by God. *See* Garrison, *supra*, at 69. (“Freeing the slave is not depriving [the slaveholder] of property, but restoring it to its rightful owner.”). The Thirteenth Amendment to the U.S. Constitution, following the abolitionists in rejecting ownership over the person, banned “slavery and involuntary servitude,” thus rendering unconstitutional the commodification of human beings. U.S. CONST., amend. XIII.

More recently, Justice Stanley Mosk of the California Supreme Court addressed concern over ownership of the human body in his dissent in the landmark 1990 case, *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 515-16 (Cal. 1990). Treating human material as property, he wrote,

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 516 (citing Mary Taylor Danforth, *Cells, Sales, And Royalties: The Patent's Right To A*

Portion Of The Profits, 6 YALE L. & POL'Y REV. 179 (1988)).

Justice Mosk recognized that the law respects the human body as a unique expression of the self and thus prohibits exploitation of that body. Exploiting the human body in order to further scientific process brings to mind prohibited exploitations of the body, including slavery, cruel and unusual punishments, and indentured servitude. *Id.* at 515.

2. The rejection of human beings as property in religion.

The Southern Baptist Convention agrees with Justice Mosk that allowing ownership of human genetic material is akin to condoning exploitation. “Marketing 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 the U.S. Patent Office would grant such applications is absolutely chilling.” Ethics & Religious Liberty Commission, Southern Baptist Convention, *BRCA – Statement of Support from the Ethics & Religious Liberty Commission*, 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 Roman Catholic Church, along with many in the Christian, Jewish, and Islamic traditions, emphasize the fact humans exist in interdependency and have a responsibility for their neighbor’s well-

being. Although scientific progress is to be encouraged, it becomes an injustice when its fruits are “distributed in such a way that unjust inequalities are actually increased or even rendered permanent.” John Paul II, *Jubilee 2000 Debt Campaign*, Sept. 23, 1999, available at http://www.vatican.va/holy_father/john_paul_ii/messages/pont_messages/1999/documents/hf_jp-ii_mes_19990923_jubilee-2000-debt-campaign_en.html. Intervening in human genetics is not an inherent problem, for all human beings are called to participate in the creative work of God. However, to give anyone control over another person’s body results in the “unjust domination of man” and corrupts the relationships between human beings. *Dignitas Personae* at para. 27.

Human gene patenting has grim implications because it turns the person into a form of property. Granting ownership of humanity’s most fundamental genetic matter opens the door for companies to demand more—putting the rest of the human body at risk of commodification as well. This Court has a responsibility to protect individual freedom by refusing to let human genetic material be commodified and sold. Myriad Genetics threatens the sanctity of the genome and the integrity of the person by seeking a patent.

C. The international community

The United Nations has also expressed concern over gene patents, recognizing that “the human genome is the property of ‘Humanity’” and a part of our “common heritage.” Brian Gargano, *The*

Quagmire of DNA Patents: Are DNA Sequences More Than Chemical Compositions of Matter?, 2005 SYRACUSE SCI. & TECH. L. REP. 3, 5 (Spring 2005). Since this declaration, the idea of common responsibility for the human genome has been adopted across Europe and affirmed by both the U.S. National Research Council and the American Society of Human Genetics. *Id.* British Prime Minister Tony Blair and U.S. President Bill Clinton issued a joint statement declaring the human genome to be a gift from God that is common to all humanity, and as such not something that can be bought and traded among scientists. *Id.* The Roman Catholic Church has condoned the actions of the European directive, finding that the bans against modifying the foundational identity genetic identity of human beings helps to fill in a “legislative gap.” Jean-Louis Tauran, *The Defense of Life in the Context of International Policies and Norms*, Feb. 11, 2000, available at http://www.vatican.va/roman_curia/secretariatstate/documents/rc_seg-st_doc_20000211_tauran-acdlife_en.html. Patenting human genes—products of nature—is recognized as a gross violation of this common responsibility worldwide.

III. Allowing Patents of DNA Violates the Purposes of Patent and Property Law.

Allowing patents of human genetic material implicates core concerns of intellectual property law by creating a monopoly over a fruitful vein for research that should be part of the common property of all humanity. Allowing patents on basic tools of

research violates both the requirement that patent law further innovation and the community purposes of property.

A. Patent law exists to encourage innovation.

The U.S. patent system is designed to incentivize research and innovation. Upholding human DNA patents harms this purpose. See Lori Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403 (2005). The proposition that human DNA is patentable defies over a century of this Court's precedent, which has repeatedly emphasized that "laws of nature, physical phenomena, and abstract ideas are not patentable subject matter," because discoveries of nature are open to study by all who would innovate for the greater good. *Chakrabarty, supra*, at 303.

This Court has consistently recognized that monopolizing natural phenomena through the grant of a patent promotes selfish gain, at the expense of innovation that can benefit everyone. See generally *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012). This danger becomes acute when a patented process forecloses more future invention than the underlying discovery justifies. *Id.*; see also Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315 (2011).

Myriad Genetics has violated this long-held principle by claiming exclusive rights over facts of nature. Myriad Genetics has not found a unique use for DNA. Merely removing a gene from its cell and

cellular components does not make it patentable subject matter. Removing the BRCA genes from the body does not significantly transform them in any way. Similar in their origins to a “new plant found in the wild,” these gene sequences occur naturally in the human body. *See Chakrabarty, supra*, at 309-10. This “invention” is “fit only for the same beneficial uses as theretofore.” *See Am. Fruit Growers, Inc. v. Brogdex Co.*, 51 S. Ct. 328, 330 (1931) (denying a patent for borax-treated oranges where they do not gain any new functions from the treatment).

Having no practical use in isolation, genome sequences provide basic knowledge that must be interpreted and employed as a tool for future research. JOHN SULSTON, WHO OWNS YOUR BODY: NOBEL LAUREATE OPPOSES GENE PATENTS 125-27 (2006). From this natural function of human DNA it follows that the only particular “application” of Myriad’s patent over the isolated DNA sequence is to further additional research on breast cancer, an enterprise dependent on collective innovation.

The proposed “application” of Myriad Genetics’ isolated DNA sequence is not sufficiently useful to warrant exclusive ownership rights over human DNA and thereby foreclose others from “conventional [research] activity previously engaged in by those working in the field.” *See Prometheus, supra*, at 1299. This Court rejected a similar application in *Prometheus* because “the grant of patents that tie up [the] use [of the underlying natural laws would] inhibit future innovation premised upon them” and would prevent “more

future invention than the underlying discovery could reasonably justify.” *Id.* at 1301. Upholding Myriad Genetics’ patents, and thus foreclosing essential BRCA testing alternatives for breast cancer patients, harms vulnerable people. Myriad Genetics’ patents cannot be “designed around” by other companies to avoid infringement. In light of the impossibility of developing and perfecting BRCA testing, the consequence of this monopoly over BRCA1 and BRCA2 will be less innovation and poorer health outcomes. *See* Sulston, *supra*, at 125-27.

B. Property should be used for the good of the community.

Humans are meant to claim property for the good of others as well as for themselves. Eight hundred years ago, Thomas Aquinas wrote that “man should not consider his material possessions as his own, but as common to all, so as to share them without hesitation when others are in need.” THOMAS AQUINAS, *SUMMA THEOLOGIAE* II-II 66.2 (Fathers of the English Dominican Province trans., 2d ed. 1920). *available at* <http://www.newadvent.org/summa/3066.htm#article2>. Property rights exist to further development, especially at the service of the poor, sick, and vulnerable—“[t]hey are recognized to that end, and are limited by it.” *State v. Shack*, 277 A.2d 369, 372 (N.J. 1971). Pope John Paul II described the belief that “the goods of this world are originally meant for all” as “a characteristic principle” of the Christian faith. John Paul II, *Sollicitudo Rei Socialis*, para. 42, Dec. 30, 1987, *available at* http://www.vatican.va/holy_father/john_paul_ii/encyc

licals/documents/hf_jpii_enc_30121987_sollicitudo-rei-socialis_en.html. He advocated respect for the common nature of knowledge in particular, stating that “the results of research should be made available to the whole scientific community and cannot be the property of a small group.” *Id.*

The property rights claimed by Myriad Genetics have not furthered innovation, and therefore have not advanced the public good. Myriad Genetics has twice used them to strong-arm its competition out of BRCA research. *See generally Myriad Genetics, Inc. v. OncorMed, Inc.*, No. 2:97-cv-0035 (D. Utah 1997); *Myriad Genetics, Inc. v. Univ. of Pa.*, No. 2:98-cv-829 (D. Utah 1998). “Ownership of this kind has no justification, and represents an abuse in the sight of God and humanity.” John Paul II, *Centesimus Annus*, para. 43, May 1, 1991, *available at* http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_ip-ii_enc_01051991_centesimus-annus_en.html. While genetic research undoubtedly yields valuable scientific information and advances in health care, it must not foreclose research that could benefit society and its most marginalized members.

Myriad Genetics’ financial stake in these patents and profit motive will conflict with the interests of the people with the greatest need for access to science based on genetic research. *See Kane, supra*, at 707. The court below failed to consider the grave consequences of allowing patent claims over human DNA—namely, the sweeping foreclosure of critical opportunities for innovation in genetic research that

could help the neediest people in society. *Ass'n for Molecular Pathology v. United States PTO*, 689 F.3d 1303, 1354 (Fed. Cir. 2012).

The use of human genetic material has vast potential for people in great medical need, along with spiritual, social, and moral implications. This Court should be wary of granting ownership over the divine gift of biological components to the highest bidder, thereby excluding countless others from developing further uses for them. The gift of human genetic material more appropriately belongs to the whole species, so that it can be studied and used for everyone's gain.

IV. Myriad Genetics' Patents Harm Vulnerable People.

Granting a gene patent, in violation of the core principles described above, would be contrary to the Christian value of seeking the welfare of vulnerable people. Dwayne Hastings, a Southern Baptist, writer explains that “[i]t is scripturally incumbent upon Christians to work for the health and wholeness of all Americans, especially in light of the crisis of uninsured and underinsured Americans” Dwayne Hastings, *U.S. Health Care System in Crisis*, 1 FAITH AND FAMILY VALUES MAGAZINE 6 (2008), available at <http://faithandfamily.com/documents/pdf/magazine/2008-1.pdf>. For years, American Catholic bishops have urged the country to undertake a “new commitment to meeting the health care needs of our people, especially the poor and vulnerable.” U.S. Conference of Catholic Bishops,

Health Care for All, available at <http://old.usccb.org/sdwp/national/brochure1.pdf> [hereinafter *Health Care for All*]. Baptists, Catholics, and other Christians believe Jesus' words, that "God blesses those who hunger and thirst for justice, for they will be satisfied," and believe that providing access to health care is key to honoring God's will. *Matthew* 5:6 (New Living Translation).

Myriad Genetics' patents do not help sick and vulnerable people access the medical technology they need. First, Myriad Genetics' patents would place diagnostic genetic testing beyond the means of many uninsured and underinsured Americans. Second, they would prevent many people from getting a second option when faced with the threat of breast cancer. These problems raise grave ethical concerns and undermine the case for Myriad Genetics to be granted exclusionary rights over the BRCA1 and BRCA2 genes.

A. Myriad genetics' patents create barriers to health care.

The BRCA1 and BRCA2 gene sequences are associated with a significantly higher risk for breast cancer. Breast cancer is a devastating disease—in 2012 alone, nearly 230,000 new cases of invasive breast cancer were diagnosed in this country. In their lifetime, one in eight women will develop invasive breast cancer. American Cancer Society, *Breast Cancer: Key Statistics*, available at <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-key-statistics>.

Myriad Genetics is the sole provider of genetic testing for the BRCA1 and BRCA2 genes in the United States by virtue of its patents. Myriad Genetics has taken advantage of the lack of competition and has driven the testing costs to a prohibitive level. Many women are unable to afford the inordinate \$2,680 one of its tests costs. Cancer Institute of New Jersey, *Health Professionals Workshop Information: Case Studies*, available at http://www.umdnj.edu/cigenweb/health_pro/workshop.htm. (“With . . . the significant cost (currently Myriad Genetics charges \$2680 for full sequencing), many patients decide on their own not to have testing.”). By preventing access to an early detection test, Myriad Genetics has essentially eliminated the ability of these women to avoid even more expensive treatments for cancer in its later stages, such as mastectomies or chemotherapy.

Genetic testing itself is not inherently expensive, and several groups have expressed outrage at the prices charged by Myriad Genetics. Some have gone so far as to ignore patents held by Myriad Genetics over this information in other countries. For example, a French geneticist is now offering comparable genetic testing for significantly less. Lori Andrews, *Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL’Y, L., & ETHICS 403 (2005).

As believers in Christ who healed many people in both soul and body during his ministry without asking anything in return, Christians cannot sit silently and watch Myriad Genetics make medicine

too expensive for the least brothers and sisters of the human family. “It is inconceivable that a nation so blessed by God and so dedicated to the proposition that all men are created equal would allow some of its citizens” to go without access to medical technology. Hastings, *supra*, at 6. Health care is “among those basic rights which flow from the sanctity and dignity of human life”—not from the ability to pay. *Health Care for All, supra*, at 1.

B. Preventing alternative genetic testing techniques creates barriers to second opinions.

Every person who desires to do so should be free to obtain a second opinion when confronted with a cancer diagnosis. Myriad Genetics does not offer a complete test for all mutations associated with breast cancer, which results in a high prevalence of unclear results from their tests. Scientific peer review shows that Myriad Genetics’ tests fail to detect ten to twenty percent of expected mutations in the BRCA1 mutation alone. Andrews, *supra*, at 403. This uncertainty is causes man women to have needless mastectomies or oophorectomies. *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). The danger of incorrect diagnoses prompted France to challenge Myriad Genetics’ patents, just as the Association for Molecular Pathology does today. Andrews, *supra*, at 403.

If this Court upholds Myriad Genetics' patents over the isolated BRCA1 and BRCA2 sequences, the availability of alternative testing techniques and medical second opinions to patients who are forced to make imperative life decisions will be restricted. Patents and licensing practices create barriers impeding access to accurate diagnostic genetic testing by removing the patient's choice. Andrew S. Robertson, *The Role of DNA Patents in Genetic Test Innovation and Access*, 9 NW. J. TECH. & INTEL. PROP. 377, 9 (2011). These harms are especially evident because the patent holder, Myriad, has issued an exclusive license, restricting all BRCA1 and BRCA2 genetic testing to a single laboratory. *Id.* Myriad Genetics' patents over the isolated BRCA sequences, by preventing second opinions and obstructing access to top-quality testing, eviscerates the breast cancer patient's access to necessary alternatives.

The harmful effects of human gene patenting can be prevented. Allowing Myriad Genetics to patent gene sequences would be devastating to patients and innovators nationwide. This Court has the opportunity to bring peace of mind to the women across the country facing a devastating disease. The invalidation of Myriad Genetics' patents will give breast cancer patients access to much-needed alternatives, which is itself a religious obligation—while preserving other vital religious values that form the foundation of the legal system in the United States.

CONCLUSION

For the foregoing reasons, amici curiae respectfully requests that this Court vacate the judgment of the Federal Circuit and reinstate the judgment of the District Court.

Respectfully submitted,

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