No. 12-398

In The
Supreme Court of the United States

THE 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 OF KALI N. MURRAY AND ERIKA R. GEORGE AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

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[1] Petitioners gave their blanket consent for *amici* to file briefs on October 3, 2012. Respondents have consented to the filing of this brief on January 28, 2013. No counsel representing any party to the case authored this brief in whole or in part, and no counsel or party made any monetary contribution to the preparation or submission of the brief.

Institutional affiliation is provided for informational purposes only.

has written extensively on civil rights issues, particularly their effects on women.

SUMMARY OF THE ARGUMENT

The public's interest in the constitutional patent system is varied. An individual patent, like an invalid statute, can impose significant harm on a range of social interests. Among these social harms may be the communicative barriers imposed on the physician-patient relationship, the communicative barriers placed on researchers who seek to use the relevant information contained within a patent, and the communicative barriers placed on advocates who seek to ensure public health by disseminating information to impacted communities. The United States Court of Appeals for the Federal Circuit ("Federal Circuit"), therefore, erred below by failing to address these social harms.

Myriad's patents in human genes and related methods fail the constitutional prerequisite of invention. An authoritative testing of the validity of these patents under the common law exceptions to Section 101 of the Patent Act of 1952 is necessary to end the injury imposed upon individual and organizational plaintiffs who find that their ability to give and receive information under the First Amendment has been improperly impeded. Further, the injuries

emanating from Myriad's patents violate the dignity interests embodied in the Thirteenth Amendment.

We respectfully urge the Court to recognize that Myriad's patents currently violate a number of constitutional rights, injuring both individual and organizational plaintiffs, and, for this reason, should be invalidated.

ARGUMENT

I. PATENTS ON HUMAN GENES ARE NOT INVENTIONS PROTECTED BY PATENT LAW.

A. Art. I, § 8, Clause 8 of the United States Constitution Mandates that Invention is a Constitutional Prerequisite for Patent Protection.

Article I, Section 8, Clause 8 grants to Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. Art. I, § 8, cl. 8. This constitutional grant creates a parallel equivalence: it protects Authors in their Writings and protects Inventors in their Discoveries. *Eldred v. Ashcroft*, 537 U.S. 186, 223 (2003) ("[T]he grant of exclusive rights to their writings and discoveries is intended to encourage the creativity of "Authors and Inventors.") (Stevens, J., dissenting). Where "the *sine qua non* of copyright is originality," the *sine qua non*

of patent is invention. *Feist Pubs. Inc. v. Rural Tel. Serv. Co., Inc.*, 499 U.S. 340, 345 (1990). Aptly summarized, "[i]nvention – both for patent eligibility *and* for patentability – thus require[s] *creativity in the application* of scientific discoveries; that is, more than merely applying the discoveries to a new use, as reflected in the particular machinery or method steps described and claimed in the patent." Joshua D. Sarnoff, *Patent-Eligible Inventions After* Bilski: *History and Theory*, 63 HASTINGS L.J. 53, 69 (2011) (emphasis in original) (citing Giles S. Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393, 393-94 (1960)).

The requirement of invention serves the same purpose as its textual equivalent, "originality" in copyright law, that is, ensuring a basic level of independent creation by the inventor. *Compare Feist*, 499 U.S. at 345 ("Original, as the term is used in copyright, means only that the work was independently created by the author (as opposed to copied from other works), and that it possesses at least some minimal degree of creativity") *with* William Callahan Robinson, *A Treatise on the Law of Patents* 103 (1890) ("An invention is the result of an inventive act."). The requirement of invention in patent law, though – unlike that of copyright – requires more than a minimum degree of creativity and – unlike that of copyright – has been the subject of statutory clarification in § 103 of the Patent Act of 1952. Section 103 requires that an inventor demonstrate an objective claim to a creative act by demonstrating that the

invention was non-obvious based on a series of objective factors, including the scope and content of the prior art, the person having ordinary skill in the art, and the differences between the prior art and the claimed invention. The existence of more specific codification, under § 103, of *what* level of creativity is required, does not mean that the separate invention inquiry under the common law exclusion principle has been eliminated. Rather, it suggests that the question should be focused on assessing whether an inventive act is an independent creation of the inventor.

The constitutional prerequisite of invention, therefore, serves to explain its embodiment in statutory and common law content of patent law. Statutory recognition of this prerequisite has been included in some form since § 1 of the Patent Act of 1790 granted invention to those who had "invented or discovered" patentable subject-matter. Patent Act of 1790, ch. 7, § 1 (1790); *see also* Patent Act of 1836, ch. 357, 5 Stat. 117 (July 4, 1836); Patent Act of 1870, ch. 230, 16 Stat. 198-217 (July 8, 1870); Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792.[2] The separate statutory

[2] The separate requirement of invention embodied in the terms "invents or discovers" should also not be conflated with the separate clause that defines the categories of patentable subject-matter. These basic categories of subject-matter reflects another constitutional requirement which restrict patents to those that are "useful arts." Chisum summarizes that "[t]he general purpose of the statutory classes of subject matter is to limit patent protection to the field of applied technology . . . 'the

(Continued on following page)

requirement embodied in § 101 has often been conflated with § 103. These requirements are not the same. Section 101 requires that an invention originates with the inventor. The question of *what level* of creativity is embodied in § 103. Section 103 replaces what had often been a difficult inquiry into the inventor's state of mind at the time of invention. *See McClain v. Ortmayer*, 141 U.S. 419, 427 (1891) ("[T]he truth is, the word [invention] cannot be defined in such manner as to afford any substantial aid in determining whether a particular device involves an exercise of the inventive faculty."); *Graham v. John Deere Co. of Kansas City*, 86 S. Ct. 684, 691 (1966). As this Court has recognized, conflating these two requirements will create significant legal uncertainty in the application of these principles. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1304 (2012).

Likewise, the exclusionary principles embodied by the common law also embody the constitutional prerequisite of invention by suggesting "laws of nature, physical phenomena, and abstract ideas" are not patentable. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Diamond v. Chakrabarty*, 447

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useful arts.'" 1 *Chisum on Patents* 6-7 (2010) (citing U.S. Const. Art. I, § 8, cl. 8). Since inception, the term "useful arts" essentially meant "helpful or valuable trades." Edward C. Waltersheid, *To Promote the Progress of Useful Arts: American Patent Law and Administration*, 1798-1836, 51 (1998) (defining what the term meant in 1797).

U.S. 303, 309 (1980)) (internal quotation marks omitted). These common law exceptions then both specify "when an eligible 'invention' has been created within the statutory classes of things and process enumerated in section 101," Sarnoff, *supra* at 93, as well as "reflect the *absence* of fulfillment of the critical statutory requirement of section 101 that a person 'invents or discovers' one of the specified classes of subject matter, and are not exceptions to those classes of subject matter." *Id.* (emphasis in original).

These exclusionary principles suggest that ours is a constitutional system with dual objectives. Our constitutional patent regime seeks not only to incentivize the creative activity of a patent claimant but also to protect the preconditions for creative activity by preserving certain types of information such as the laws of nature, physical phenomena and abstract ideas from aggressive claims that would serve to block access to these basic building blocks of scientific inquiry and information exchange. *See infra* at 14. As this Court recognized in *Eldred v. Ashcroft*, 537 U.S. at 217, the communicative impact of a patent differs in kind from a copyright, as a patent represents a "monopoly of expression" that differs in kind from a copyright. A "copyright gives the holder no monopoly on any knowledge" while the grant of a patent prevents the "full use by others of the inventor's knowledge." *Id.* Thus, the constitutional prerequisite of invention as embodied in Section 101, and the exclusionary principle embodied in the common law exceptions, serve to ameliorate the expressive harms

that may result from a grant of an undue "monopoly of expression" to an improvidently granted patent. In this, they serve as "built-in First Amendment accommodations." *Golan v. Holder*, 132 S. Ct. 873, 890 (2012).[3] Thus, the common law exceptions to patentable subject matter are analogous to the idea-expression dichotomy, 17 U.S.C. § 102(b) (2006), and the fair-use exception within patent law, § 107, which provide similar protection within copyright law of First Amendment values.

B. Patents in Human Genes and Related Claim Methods Do Not Require a Basic Level of Creativity and Therefore are Not Inventions within the Statutory and Common Law Meaning of Invention.

Patents should not be granted to human genes because genes – much like the factual compilations at issue in *Feist* – do not owe their origin to an act of inventorship. 499 U.S. at 345. No one truly "invents" natural occurrences or scientific principles. *E.g., In re Norris*, 179 F.2d 970, 972 (C.C.P.A. 1950); *Reynolds v. Emaus*, 87 F. Supp. 451, 453 (W.D. Mich. 1949). "This

[3] The existence of such "built-in" accommodations may not, however, preclude a direct constitutional harm that may arise from the existence of an improvidently granted patent, *see infra*, Section II. An improvidently granted patent, may like an poorly drafted statute, create such significant constitutional harm to such a wide range of plaintiffs, that further remedies may be had beyond the scope of the statutory patent regime.

Court, however, has recognized that too broad an interpretation of this exclusionary principle could eviscerate patent law." *Mayo Collaborative Services*, 132 S. Ct. at 1293. "[A]ll inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id.* The constitutional question, as embodied in its statutory and common law forms, then, is how to distinguish between a non-protected natural occurrence, abstract ideas, or scientific principle, and a patented invention. *See id.*

The answer is a simple one: in order to assess whether an invention should be accorded the relevant patent protection, a basic inquiry must be made whether the invention originates with the inventor. U.S. Const. Art. I, § 8, cl. 8 (granting "to . . . Inventors the exclusive Right to *their*. . . . *Discoveries*.") (emphasis added). Patentable inventions originate with inventors; invention is the result of *their* inventive act. The contours of this test are suggested by this Court's analysis in *Feist*, 499 U.S. at 347. In *Feist*, this Court stated that factual information was not original because a fact's origin does not stem from the acts of any one author. *Id.* ("The first person to find and report a particular fact has not created the fact; he or she has merely discovered its existence."). The existence of information that has been discovered does not reside with the discoverer. *Id.* Rather, the information existed before it was discovered and for that reason, the information is not original. The distinction Justice O'Connor draws is "one between

creation and discovery." *Id.* This Court has concluded that facts, including scientific ones, are not original and therefore do not warrant copyright protection. *Id.* at 347-48, 350.

Myriad's "discovery" of the BRCA gene was mere discovery of already existing facts; thus, the claims in the human gene did not originate with Myriad. *See Feist*, 499 U.S. at 347. Myriad has failed to demonstrate at all that the origins of its improvidently granted patent resulted from independent creation. Myriad did not locate the human gene at issue. Rather, Dr. Mary-Claire King led a team of researchers to initially map the human gene at issue (and did not receive a patent for this "discovery" of a naturally occurring process). *See* Jeff M. Hall et al., Linkage of Early-Onset Familial Breast Cancer to Chromosome 17q21, 250 SCIENCE 1684 (1990).[4] Myriad did not invent a new sequencing technique to identify the nucleotide order of BRCA genes; Myriad merely applied known sequencing techniques to identify the nucleotide order of BRCA genes. *See Ass'n for*

[4] *See also* Shobita Parthasasrathy, *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care*, 185-86 (2007) ("British scientists, health-care professionals, and activists asserted that even if genes were inventions that could be patented and owned, discovering the BRCA genes entailed a collective effort involving researchers, women, and funding bodies in Britain as well as the United States . . . Some geneticists pointed out that Myriad's claims to sole ownership were particularly offensive because most Britons . . . credited Mike Stratton, not Myriad, with finding the BRCA2 gene.")

Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329, 1373 (2011).

Myriad's claim to an inventive act is its *isolation* of the human gene. The inventiveness of this claim is unpersuasive. An inventive act within the context of a naturally occurring material requires a marked change in functionality of the purified substance in order to sustain a claim of patentability. *In re Merz*, 97 F.2d 599, 601 (1938) (holding that there was no right to a patent on a purer version of ultramarine, but recognizing that if a claimed article is "of such purity that it differs not only in degree but in kind it may be patentable"); *see also In re King*, 107 F.2d 618, 620 (C.C.P.A. 1939) (same, for purified vitamin C); *In re Marden*, 47 F.2d 958, 959 (C.C.P.A. 1931) (same, for purified vanadium); *Gen. Elec. Co. v. DeForest Radio Co.*, 28 F.2d 641, 643 (3d Cir. 1928) (same, for purified tungsten). A demonstration of an inventive act within natural substances is only sustainable if the "purification" results in a product with such distinct characteristics that it becomes "for every practical purpose a new thing commercially and therapeutically." *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D. N.Y. 1911); *see also Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 161-64 (4th Cir. 1958).

No marked change in functionality occurs within the context of isolated genes. Booth, Katherine, *Isolated DNA Patents: Incentivizing Medical Research or Selling Human Identity: Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 40

J.L. MED. & ETHICS 413, 414-15 (2012). Isolated genes are not materially different from their native counterparts. *Id.* Genetic coding sequence that is the subject of each of the BRCA gene claims remains the same whether the gene is in the human body or isolated (although chemical bonds may be altered through the process). 5 Alberts et al., *The Molecular Biology of The Cell* 552 (2008) (DNA sequencing involves the cutting of chromosomal DNA into fragments and the inserting of said DNA fragments into a self-replicating genetic element.). The only difference between the naturally occurring genes, like BRCA, and an isolated DNA sequence is that the isolated sequence has essentially been "cut" as a fragment from the original, naturally occurring sequence. *See id.* Indeed, isolated genes may be better analogized to "new mineral discovered in the earth," or the "new plant found in the wild." *See Chakrabarty*, 447 U.S at 309.

Ultimately, Myriad has failed to demonstrate at all that the isolated genes' origins lie in Myriad's inventive act. Their respective patents in human genes are not sustainable as an invention in a constitutional sense, as embodied in the relevant statutory and common law forms.[5]

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[5] Myriad may be able to claim (like the compilations at stake in *Feist*) that its related methods are the subject of an inventive act. *See Feist*, 499 U.S. at 348. The method claims, however, may be subject to other constitutional infirmities, as discussed *infra* in Part II.

II. GRANTING PATENTS ON HUMAN GENES AND RELATED METHODS PLACES A RANGE OF CONSTITUTIONAL VALUES AT RISK.

A. Assessing Whether Human Genes are Patentable Requires an Analysis of All Relevant Constitutional Provisions.

An improvidently granted patent may cause direct constitutional harm to those interested in a properly functioning patent system. Social interests in a functioning patent system are many and varied: scientists, researchers, and engineers creating advances in technology; manufacturers and designers implementing and vending these advances in the marketplace; and consumers putting these inventions and discoveries to their own uses. Although these stakeholders benefit from patent policy functioning properly, they are also uniquely positioned to suffer direct constitutional harms that stem from the issuance of such patents.

As discussed *supra*, the specific doctrinal content of patent law may have speech protective elements, such as the constitutional perquisite of invention, as embodied in its statutory and common law forms. The existence of such "built-in" accommodations may not be sufficient in *all* cases. An improvidently granted patent may like a poorly drafted statute, create such significant constitutional harm to such a wide range of plaintiffs, that further remedies beyond the scope of the internal doctrinal content of patent law merit consideration.

Here, stakeholder plaintiffs are at risk of suffering a variety of direct constitutional harms, caused by the issuance of patents on genetic material, that include direct harm to speech interests under the First Amendment, and dignity interests under the Thirteenth Amendment. Although the issuance of a copyright or patent will, necessarily, impact speech rights in some capacity, the issuance of a patent over genetic material itself is a substantial and impermissible intrusion into the speech rights of numerous potential third party plaintiffs, including researchers, patients, physicians and research groups. Likewise, the issuance of an improvidently granted patent may intrude upon the dignity interests associated with the Thirteenth Amendment.[6]

[6] This is why the Declaratory Judgment Act exists as an alternative procedural vehicle in patent law insofar as it requires an into "*all the circumstances* . . . there is a substantial controversy, between parties having adverse legal interests." *MedImmune v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). The Declaratory Judgment Act therefore exists as an integral alternative vehicle within the context of patent infringement because it permits diverse kinds of injury-in-fact to be alleged by diverse categories of declaratory judgment plaintiffs. The remedial structure of the Declaratory Judgment implies an inquiry into the standing of a respective plaintiff is not necessarily dependent on equivalent standing under the Patent Act. Interested third-party plaintiffs, therefore, must be allowed to bring constitutional claims of harm.

B. Human Gene Patents and Their Related Methods Place First Amendment Values at Risk by Improperly Impeding the Exchange of Ideas and Access to Important Information.

Myriad's improvidently granted patents in human genetic material and associated diagnostic methods inhibit the communicative discourse that would otherwise occur in academic fields devoted to genomic science and in clinical health care settings. In particular, human gene patents create "monopolies of expression" that prevent searching inquiry in the context of the scientist's laboratory and sharing information fully in the context of the physician's office. Public health communications and counseling efforts are similarly curtailed. *See* David Lange & H. Jefferson Powell, *No Law: Intellectual Property in the Image of An Absolute First Amendment* 305 (2009).

Specific constitutional harm can be significant and direct under the relevant factual circumstances. Research organizations have claimed that Myriad's enforcement of its patents in basic genetic information prevents their members from undertaking further scientific inquiry. Individual researchers, clinicians and health care providers maintain that Myriad's enforcement of its patents has chilled research and compromised communications with patients. As a result other patients are denied access to information important for making crucial medical decisions with respect to an appropriate course of care in consultation with their health care providers.

1. Human Gene Patents Harm Communicative Discourse in Scientific Communities.

First Amendment values instruct that a vibrant marketplace of ideas requires open access to the storehouse of knowledge. As this Court explained in *Red Lion Broadcasting Co. v. FCC*, "[I]t is the purpose of the First Amendment to preserve an uninhibited marketplace of ideas in which truth will ultimately prevail, rather than to countenance monopolization of that market, whether it be by the Government itself or a private licensee." *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 390 (1967). An improvidently granted patent may remove essential information from the marketplace of ideas and "contract the spectrum of available knowledge" inconsistent with "the spirit of the First Amendment." *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965).

Scientific inquiry necessarily involves shared discourse between researchers within a discipline; patents granted in these "vocabulary" or "building blocks" of discourse may impede such freedom. *See* Barry P. McDonald, *Government Regulation or Other "Abridgments" of Scientific Research: The Proper Scope of Judicial Review Under the First Amendment*, 54 EMORY L. REV. 979, 997 (2005) (advocating a strict standard of review for actions which "significantly curtail a given area of research by impeding the data gathering efforts and thus curtail scientific expression related to that research"); *see also Laboratory Corp. of America v. Metabolite Labs., Inc.*, 548 U.S.

124, 125 (2006) (An improperly issued patent can force researcher's to engage in "costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using that patented information, sometimes prohibitively so.")

Human gene patents restrain academic inquiries and scientific processes crucial to innovation and natural world comprehension. "In science, the relation between experiment and free thought is familial. Although the pursuit of knowledge is not the summum bonum but only one good among many, one hesitates to impede it or to set a precedent that might be used to inhibit other socially controversial precedent." Stephen Breyer & Richard Zeckhauser, *The Regulation of Genetic Engineering*, 1 Man & Medicine 1, 12 (1975).

Human gene patents inhibit scientific innovation in this area because this genetic material constitutes a "staple" public good that needs to be accessible to a range of users as a basic precondition for inquiry and innovation. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) (This Court prohibits the issuance of patents when the issuance "restrict[s] free access to materials already available."); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5-6 (1966). This Court also cautions against enlarging a patent monopoly "without regard to the innovation, advancement or social benefit gained thereby." *Id.* This reflects a judgment that patent protection in certain cases impedes, rather than promotes,

scientific progress. *See Metabolite Labs., Inc.*, 548 U.S. 124, 127-28 (Breyer, J., dissenting).

2. Patents on Diagnostic Methods Impede Access to Information in Health Care Contexts.

Claims on diagnostic methods associated with human genetic material impede access to information, thus harming patients' and the general publics' "right to receive information and ideas" that pertain to health risks. *See, e.g., Stanley v. Georgia*, 394 U.S. 557, 564 (1969); *see also Kleindienst v. Mandel*, 408 U.S. 753, 762-63 (1972) (citing cases).

The right to receive information is an inherent corollary of the right of free speech explicitly guaranteed by the Constitution. *See, e.g., Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 756-57 (1976). The right to receive ideas follows ineluctably from the sender's First Amendment right to send them for "dissemination of ideas can accomplish nothing if otherwise willing addressees are not free to receive and consider them." *Lamont v. Postmaster General*, 381 U.S. 301, 308 (1965) (Brennan, J., concurring). As the right to receive ideas is a necessary predicate to the recipient's meaningful exercise of his own rights of speech, press, and political freedom, the ability to receive information about genes is predicate to being at liberty to make meaningfully informed decisions in matters concerning health and bodily integrity.

Physicians and patients enjoy a protected freedom of expression in the context of the physician-patient relationship that is compromised by patents on the diagnostic methods claimed by Myriad. An early formulation of the right to receive information was advanced in the context of the physician-patient relationship. In *Griswold v. Connecticut*, the Supreme Court held the "right of freedom of speech and press includes not only the right to utter or to print, but [also] . . . the right to receive . . . " *Id*. The Supreme Court has rejected restraints on freedom of expression that would place physicians in an "undesired and uncomfortable straightjacket." *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52, 67 (1976). Because it remains the responsibility of the physician to ensure that appropriate information is conveyed to their patients based on the condition of the patient, *City of Akron v. Akron Ctr. for Reproductive Health*, 462 U.S. 416, 443 (1983), the Supreme Court has consistently cleared "obstacles in the path of the doctor" upon whom patients are entitled to rely for advice in connection with health care decisions. *Id.* (citing *Whalen v. Roe*, 429 U.S. 589, 604 n.33 (1977)). In the physician-patient relationship, patients expect that physicians will not withhold relevant information regarding care options and consequences. *Rust v. Sullivan*, 500 U.S. 173, 211 n.3 (Blackmun, J., dissenting) ("[I]n our society, the doctor-patient dialogue embodies a unique relationship of trust . . . each of us attaches profound importance and authority to the words of advice spoken by the physician."); *id.* at 218; *Conant v. Walters*, 309 F.3d 629, 644 (9th

Cir. 2002) (Kozinski, J., concurring) (explaining that "the harm to patients from being denied the right to receive candid medical advice is far greater than the harm to doctors from being unable to deliver such advice" and noting that "for patients who suffer from horrible disabilities. . . . [e]nforcement of the federal policy [would] cut such patients off from competent medical advice and leave them to decide on their own"). Physicians seeking to provide complete information to a patient concerning a predisposition for developing breast or ovarian cancer allege they have been constrained by the patents at issue.

The diagnostic methods in question also provide significant restraints on public health advocates in the dissemination of genetic information to targeted communities. The ability of communities to receive information about health-related risks is crucial for a functional public health system. *See* Wendy Parmet, *Public Health and Constitutional Law: Recognizing the Relationship*, 10 J. HEALTH CARE L. & POL'Y 13, 22 (2007). Speech is crucial to the dissemination of relevant health care information. Wendy Parmet & Jason Smith, *Free Speech and Public Health: A Population-Based Approach to the First Amendment*, 39 LOY. L.A. L. REV. 363, 376 (2006) ("[S]peech helps to mold the informational environment, which itself serves as one of the many factors that influence a population's health."). The specific diagnostic patents here may cause significant harm within a newly developing field of public health, by limiting speech within the context of genetic counseling. Genetic

counselors within these organizations would serve as the messengers of crucial health information, were their First Amendment rights not curtailed by the existence of an invalid patent in the diagnostic methods associated with this patent. *See generally* Alexandra Minna Stern, *Telling Genes: The Story of Genetic Counseling in America* (2012) (assessing the role of genetic counseling in public health communications). While genetic counselors would like to offer systematic gene diagnosis, the diagnostic methods patents at issue here may offer a significant barrier to such efforts.

C. Human Gene Patents Implicate the Respect for Human Dignity Inherent in the Non-Commodification Principle Embodied in the Thirteenth Amendment.

The Thirteenth Amendment provides that "[n]either slavery nor involuntary servitude . . . shall exist in the United States." U.S. Const. amend. XIII. Among its other meanings, the Thirteenth Amendment can be seen to prohibit ownership of and control over another human being for pecuniary gain. George Rutherglen, *State Action, Private Action, and the Thirteenth Amendment*, 94 VA. L. REV. 1367, 1382 (2008) (observing that Congressional passage of the Thirteenth Amendment "concerned rights directly opposed to one another: what the slaveowners lost in property rights, the slaves gained in freedom"); *see also Plessy v. Ferguson*, 163 U.S. 537, 542 (1896)

(defining slavery as "the absence of a legal right to the disposal of his own person, property, and services"). The Thirteenth Amendment prohibition of a property claim in a person suggests a constitutional recognition that eliminating a category of property interest in humans may act to preserve the human dignity inherent in a claim of personhood. *See generally* Leslie Meltzer Henry, *The Jurisprudence of Dignity*, 160 U. PA. L. REV. 169, 202 (2011) (discussing dignity). This principle could aptly be termed a non-commodification principle. *See Moore v. California Regents*, 793 P.2d 479, 515-17 (Cal. 1990) (Arabian, J., concurring) (expressing concern that commercialization of human cells could endanger the basic concept of human dignity violating the Thirteenth Amendment).

The non-commodification principle contained within the Thirteenth Amendment has been recognized within the domestic and international patent regime itself. In 2011, Congress prohibited a patent from issuing "on a claim directed to or encompassing a human organism." *See* 35 U.S.C. § 101 (2012); Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). The United States Patent and Trademark Office in 1987 recognized that "[a] claim directed to or including within its scope will not be considered to be 'patentable subject matter' [because] the grant of a property right in a human being is prohibited by the Constitution." U.S. Patent and Trademark Office, PTO Policy on Patenting of Animals (April 7, 1987), *reprinted in* U.S. Congress,

Office on Technology Assessment, New Developments in Biotechnology: Patenting Life 93 (1990). The non-commodification principle has also been recognized in the international patent regime. For example, the European Council Convention of Human Rights and Biomedicine, provides that "the human body and its parts shall not . . . give rise to financial gain." Convention on Human Rights and Biomedicine art. 21, *opened for signature* Apr. 4, 1997, E.T.S. No. 164, *available at* http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm; *see also* Deryck Beyleveld & Roger Brownsword, *Human Dignity, Human Rights, and Human Genetics*, 61 MOD. L. REV. 661, 671 (1998) (Commercializing human genes must be conducted on the "basis of free choice" in order to protect parties in those circumstances when there are "significant asymmetries of information and bargaining strength between the parties.")

Patents in human genes do not claim the whole person; however, genetic material is a constituent element of any person and is essential to and embodied within every human life form. Our current patent regime provides insufficient ethical guidance to ensure that patents are properly granted in genetic material. For example, while the European Patent Office has recognized that the potential isolation of genetic material may be patentable, it has done so only after ensuring that those who have donated the basic material have done so in a consensual, non-coercive manner. *See* In re Relaxin, EPO 6/1995, 398-99 ("With regard to the isolation of mRNA from tissue taken

from pregnant women, the proprietor stated that the women who donated tissue consented to do so within the framework of necessary gynecological operations.") Our patent examination process lacks these essential procedural safeguards. This further suggests that human patent genes create substantial constitutional harm under the Fourteenth Amendment as well as the Thirteenth Amendment, and thus should be subject to searching judicial intervention into whether such claims should be made permissible through an individualized patent examination process that lacks sufficient constitutional safeguards for the rights of third-parties that may be impacted by an improvidently granted patent. See Beyleveld & Brownsword, 61 MOD. L. REV. at 676 ("[W]e might seek ways of strengthening [consent] procedures or we might advocate a general prohibition on gene commerce (as the lesser of two evils, and for the sake of protecting the interests of vulnerable agents").

CONCLUSION

Patents on human genes serve to limit paths of inquiry rather than spur innovation. Human gene patents operate as roadblocks, forcing detours and delaying new discoveries. This result runs counter to the incentive structure that informs the patent system that rewards those who "invent and discover." Myriad's patents on human genes fail the constitutional requirement of invention, embodied in its

statutory form because they do not derive from a basic level of creativity.

The existence of human gene patents and related diagnostic methods run counter to the core values protected in the First Amendment. The First Amendment exists to protect the marketplace of ideas and promote access to the storehouse of knowledge. Patents on diagnostic methods associated with human genetic material serve to restrict access to knowledge, to reduce the communicative conduct of scientific inquiry and to retard services that could improve the public's information concerning health risks.

These patents in effect place a price on the building blocks of humanity and personhood. This implicates the non-commodification principle embodied in the Thirteenth Amendment and threatens the liberty and dignity of persons protected by the Constitution.

For these reasons, we respectfully ask this Court to invalidate Myriad's patents.

Respectfully submitted,

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