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 DRS. LARRY GEIER, WILLIAM HARB, ADAM OFER, AND DONALD APTEKAR AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

PAUL D. MARGOLIS
JENNER & BLOCK LLP
353 N. Clark Street
Chicago, IL 60654
(312) 222-9350

MATTHEW S. HELLMAN
Counsel of Record
JOSHUA M. SEGAL
ESTEBAN M. MORIN*
JENNER & BLOCK LLP
1099 New York Ave., NW
Washington, DC 20001
(202) 639-6000
mhellman@jenner.com

**Admitted only in California; supervised by principals of the Firm.*

Counsel for Amici Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

INTERESTS OF *AMICI CURIAE*[1]

Amici are a group of practicing physicians whose primary obligation is to provide their patients with the best medical care possible. In this capacity, amici view BRCA1 and BRCA2 testing as vital tools that empower patients to better plan for their future medical needs and take preventative steps when necessary. Amici have worked with Myriad in the past to promote awareness of genetic testing, and their experiences with Myriad belie the notion that patenting human genes results in harm to human health. To the contrary, Myriad has directed substantial resources towards making BRCA testing widely available, and in doing so, has saved thousands of lives.

Dr. Larry J. Geier, M.D., is an oncologist and Assistant Professor at the University of Kansas Medical Center in Kansas City, KS. He is board-certified in Internal Medicine, Medical Oncology, and Hematology, and specializes in genetic risk assessment and the management of genetic cancers. As one of the leading oncologists in the country, Dr. Geier serves as a resource for other physicians

---

[1] Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici* and their counsel made a monetary contribution to its preparation or submission. Petitioners' blanket letter of consent to the filing of amicus briefs has been filed with the Clerk's office. Respondents' consent to the filing of this brief is being filed with the Clerk's office together with the brief.

nationwide and speaks at multiple conferences each year.

Dr. William Harb, M.D., is a colorectal surgeon based in Nashville, TN. He is board-certified in General Surgery and Colon and Rectal Surgery, and has a clinical focus on inherited colon cancer. In this capacity, Dr. Harb has kept at the forefront of genetic testing, and published numerous articles on colon and rectal surgery. As a colorectal surgeon in private practice, he has regularly utilized genetic testing for the betterment of his patients.

Dr. Adam Ofer, M.D., is the Director of Gynecology at the Norwalk Hospital in Norwalk, CT. He is board-certified in Obstetrics and Gynecology, with a special focus on preventative care, hereditary risk assessment, and minimally-invasive surgical techniques. Throughout his career, Dr. Ofer has embraced new technologies and procedures to better serve his patients.

Dr. Donald Aptekar, M.D., is a gynecologist based in Denver, CO. He is board-certified in Obstetrics and Gynecology, and has over thirty years of experience serving a largely female client base. Dr. Aptekar has dedicated his career to identifying and treating hereditary breast and ovarian cancer, and has utilized BRCA testing to save the lives of several patients.

SUMMARY OF ARGUMENT

1. The briefs filed by petitioners and their amici assert that patenting human genes leads to a slew of

adverse consequences for human health and medical research. But the impact of Myriad Genetics' BRCA patents belies this notion. Numerous studies demonstrate that Myriad has benefited the field of medicine on multiple fronts. Myriad has raised awareness of BRCA testing among physicians and patients, and in turn, has helped thousands of individuals discover that they are vulnerable to breast and ovarian cancer and take preventative measures. In addition to bringing attention to BRCA testing, Myriad has successfully made its tests widely accessible. Working with healthcare providers and funding its own programs to provide testing to individuals in difficult economic circumstances, the company has made BRCA testing available to 95% of appropriate American patients. Finally, far from hindering cancer research, Myriad has played a key role in supporting both internal and third-party cancer research.

2. Amici's own personal experiences verify that Myriad's BRCA1 and BRCA2 patents have benefitted physicians and patients alike. Every day, practicing physicians rely on BRCA testing to counsel and treat patients at risk of developing breast and ovarian cancer. But only a decade ago, such testing was viewed as a controversial and "niche" diagnostic. Under Myriad, amici have witnessed BRCA testing blossom into a widely recognized, widely available medical tool. As a result of the company's awareness campaigns, more people than ever are being tested, and physicians are better able to serve their patients. Amici believe that Myriad's efforts to

responsibly use and license its patents confirm the wisdom of permitting genes to be patented.

3. Amici also adamantly disagree with the notion that patenting human genes is inherently unethical. A practicing physician's highest obligation is to her patients, and it is beyond dispute that Myriad has helped nearly one million patients better plan for their future medical needs by providing BRCA testing. In this regard, Myriad's efforts have been ethically laudable, and easily outweigh concerns about hindering future research.

ARGUMENT

I. MYRIAD'S EFFORTS TO MAKE BRCA TESTING WIDELY ACCESSIBLE AND PROMOTE CANCER RESEARCH DEMONSTRATE THE SALUTARY EFECTS OF PATENTING GENETIC MATERIAL.

The briefs filed by petitioner and the American Medical Association (AMA), among others, urge that patenting genetic material impedes the quality of health care and stymies medical research. *See, e.g.*, Pet. Br. 56-58; AMA Br. 9-11, 13-15. Yet the manner in which Myriad has used its patents – as well as the positive impact that Myriad has had among patients, physicians, and researchers – belies that notion.

A. Increased Awareness Of BRCA Testing Among Physicians And Patients Confirms The Wisdom Of Allowing Patents On Genetic Material.

Petitioners and their amici suggest that allowing genetic material to be patented means that the technology will languish in a dark corner, with the public unable to reap the technology's benefits. *See, e.g.*, Pet. Br. 56-58; AMA Br. 13-15. Myriad's activities with respect to the BRCA1 and BRCA2 patents over the past two decades cast serious doubt on that conjecture.

Perhaps most significantly, Myriad has raised awareness of BRCA testing among physicians and patients. The record in this case reflects that, as the holder of patents on BRCA1 and BRCA2, Myriad invested over $200 million in awareness campaigns and education programs. Decl. of Mark Skolnick, Ph.D., J.A. 502. These efforts included establishing a 300-person sales force to call oncologists, surgeons, and OB/GYNs across the country to discuss the benefits of BRCA testing and personally meet with medical professionals to answer questions. Decl. of Gregory Critchfield, M.D., J.A. 345. Myriad also organized over three hundred "speaker programs," which have provided physicians with the opportunity to learn about BRCA testing from leaders in their field and discuss it with their peers. *Id.* at 345-46. Critically, as part of these programs, the company employed well-trained and well-versed genetic counselors who did not simply push BRCA testing, but ensured that physicians understood the testing

process so they could determine when it was appropriate to recommend it to patients. *Id.* at 345.

Myriad's efforts have helped to fill a problematic gap in physicians' knowledge about genetic testing. It is vital that physicians be fully aware of the medical and ethical implications of BRCA testing before recommending it to a patient. Yet as recently as 2006, many physicians lacked basic knowledge about such testing despite regular inquiries from their patients. Melanie F. Myers et al., *Genetic Testing for Susceptibility to Breast and Ovarian Cancer: Evaluating the Impact of a Direct-to-Consumer Marketing Campaign on Physicians' Knowledge and Practices*, 8 Genet. Med, 361 (2006). Myriad's efforts helped remedy this situation; physicians in cities where the company ran marketing campaigns were more than twice as likely to have received educational materials about BRCA testing. *Id.* at 363. More informed doctors provide better advice to their patients and, according to another recent study, are twice as likely to order genomic testing as their less-informed peers. *Physician Survey Shows Education Big Factor in PGx Adoption*, GenomeWeb (Oct. 23, 2009), http://www.genomeweb.com/dxpgx/physician-survey-shows-education-big-factor-pgx-adoption. By educating physicians, Myriad has ensured that BRCA testing becomes an integral part of the battle against breast and ovarian cancer.

In addition to raising awareness among physicians, the record here establishes that Myriad has devoted millions of dollars to educating patients

about BRCA testing. Critchfield Decl., J.A. 346. Through advertisements on television and in other mass media, the company has offered information about hereditary breast and ovarian cancer and encouraged at-risk patients to speak with their physicians to determine if BRCA testing is appropriate. *Id.* These advertisements were designed to effectively convey the importance of BRCA testing to healthy family members of cancer patients. *Id.*; *see also* DGR Evans et al., *Comparison of Proactive and Usual Approaches to Offering Predictive Testing for BRCA1/2 Mutations in Unaffected Relatives*, 75 Clin. Genet. 124 (2009) (discussing the effectiveness of proactive approaches to patient education). The advertisements ran nationwide, including in remote rural areas. Critchfield Decl., J.A. 346. As a result of these and other efforts to raise public awareness of the availability of BRCA testing, almost one million patients nationwide have undergone such testing. Critchfield Decl., J.A. 346-47; *Brief History of Myriad*, Myriad Genetics, http://www.myriad.com/about-myriad/history/ (last visited Mar. 12, 2013).

Beyond the sheer number of people who have received BRCA testing, several studies confirm that Myriad's patient-directed campaigns have increased awareness of BRCA testing among the very people who are most at risk. For example, one group of researchers studied the impact of an intensive five-month, direct-to-consumer Myriad awareness campaign. Jan T. Lowery et al., *The Impact of Direct-to-consumer Marketing of Cancer Genetic Testing on Women According to Their Genetic Risk*,

10 Genet. Med. 888 (2008). The campaign was targeted at women between the ages of 25 and 54, especially those with a family history of breast cancer. *Id.* at 888. After the campaign was completed, the researchers took extensive surveys, and concluded that women with an increased genetic risk were more likely to recall seeing Myriad's advertisements than women who were less appropriate candidates for BRCA testing. *Id.* at 892. Moreover, nearly half of the high-risk women who recalled encountering the advertisements stated they were more interested in testing. *Id.* Other studies have confirmed this outcome, and demonstrate that Myriad's awareness campaigns effectively encourage testing among patients vulnerable to breast cancer. *See, e.g.*, Judy Mouchawar et al., *Impact of Direct-to-Consumer Advertising for Hereditary Breast Cancer Testing on Genetic Services at a Managed Care Organization: A Naturally-Occurring Experiment*, 7 Genet. Med. 191 (2005); Centers for Disease Control and Prevention, *Genetic Testing for Breast and Ovarian Cancer Susceptibility: Evaluating Direct-to-Consumer Marketing – Atlanta, Denver, Raleigh-Durham, and Seattle, 2003*, MMWR Wkly. Rep. (July 16, 2004), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5327a1.htm.

The evidence from multiple BRCA awareness studies is clear. Myriad, the holder of the BRCA patents, has significantly increased awareness of the BRCA test's utility. And it has done so both among physicians and among patients, including those at highest risk. Indeed, because of the potential for "free riders," it is hard to imagine a single company

undertaking such massive educational efforts without the exclusivity conferred by a patent.

B. Myriad's Activities Demonstrate That Patenting Genetic Material Does Not Price Patients Out Of Testing.

The AMA's brief criticizes genetic patents on the ground that they supposedly inflate the price that a patient must pay for testing. AMA Br. 11-13. In this way, the argument goes, such patents place genetic testing out of reach for many who would benefit from it. Once again, the record does not support these assertions.

The record here establishes that Myriad has made BRCA testing broadly available to patients nationwide. The company has worked to maximize the number of insurance plans that cover BRCA testing; to date, Myriad has established over 400 contracts with private insurance companies, state-run Medicaid programs, and Medicare. Critchfield Decl., J.A. 347-48; *see also* E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 Genet. Med. S39, S42 (2010) (discussing Myriad's efforts to build a network of insurers). Since July 2007, patients have thus received reimbursement for testing under more than 80,000 insurance plans across the country, paying average out-of-pocket costs of less than $100. Critchfield Decl., J.A. 348. Acknowledging that insurance is not universally available, Myriad has also implemented a financial assistance program that provides free testing to low-income, uninsured patients. *Id.* As a result of these efforts, *approximately 95% of all*

patients in the United States have access to BRCA testing. Press Release, Myriad Genetics, *Supreme Court of the United States to Hear Isolated DNA Patent Case* (Nov. 20, 2012), http://investor.myriad.com/releasedetail.cfm?ReleaseID=724300.

To be sure, there may well be instances in which cost prevents a patient from undergoing BRCA testing. But in a fee-for-service health care system, there always will be some patients who are priced out of particular treatments or diagnostics. And to the extent that high costs to consumers result from the fact that the isolated BRCA genes are patented, the same could easily be true of any *other* patented medical technology. There is no reason to think that *gene* patents are particularly likely to have this effect. Indeed, the evidence suggests that the patents at issue in this case have *not* inflated the prices that patients pay for genetic testing. To the contrary, Myriad has striven to keep its rates commensurate with companies offering other types of full-sequence genetic testing – regardless of whether patents are involved. Critchfield Decl., J.A. 349.

Consistent with these efforts, studies have found no obvious price premium attributable to Myriad's exclusive patent rights. One recent study examined the prices charged by different companies for a variety of genetic tests. *See* Robert Cook-Deegan et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers with Colon Cancers*, 12 Genet. Med.

S15 (2010). The researchers took particular interest in comparing the cost of BRCA testing and Lynch Syndrome testing, the latter of which is covered by patents that are not enforced.[2] *Id.* at S20-22. Despite acknowledging fears that Myriad would use its monopoly to overcharge patients for BRCA testing, *id.* at S28-29, the study found no clear link between the costs of genetic testing and the existence of exclusive patent rights. *Id.* at S30. Specifically, it found that "prices for BRCA1 and 2 testing do not reflect an obvious price premium attributable to exclusive patent rights . . . and indeed, Myriad's per unit costs are somewhat *lower* for BRCA1/2 testing than testing for colorectal cancer susceptibility." *Id.* at S15 (emphasis added). The same year, an NIH draft report reached a similar conclusion: "no evidence was found that patents and exclusive licenses have consistently led to higher prices for genetic tests." National Institutes of Health, Office of Biotechnology Activities, *Revised Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* 35, Feb. 2, 2010, *available at* http://oba.od.nih.gov/oba/SACGHS/

---

[2] Lynch Syndrome, also known as hereditary nonpolyposis colorectal cancer (HNPCC), is the most common type of inherited colorectal cancer. R. Cook-Deegan et al., 12 Genet. Med. at S20. As with breast cancer, certain genes predispose an individual to developing Lynch Syndrome. *Id.* at S20. But unlike BRCA, the Lynch Syndrome gene patents were filed by universities and never enforced. Accordingly, a variety of providers, including Myriad, offer patients Lynch Syndrome testing. *Id.* at S21.

SACGHS%20Patents%20Report%20Approved%202-5-20010.pdf.

The importance of Myriad's awareness campaigns and efforts to keep BRCA testing affordable cannot be understated. These two endeavors have created a framework in which women can easily learn about BRCA testing, can consult with knowledgeable physicians to determine if testing is appropriate for them, and face little economic hardship if they decide to proceed. All of this suggests that patents on isolated human genes do not, in fact, have the adverse consequences that petitioners and their amici assert.

C. The History of Myriad's Patents Confirms that Gene Patents Do Not Unduly Impede Scientific Research.

Besides arguing that gene patents somehow impede access to health care, petitioners and their amici also contend that they constrain scientific and medical research. *See, e.g.*, Pet. Br. 56-58; AMA Br. 13-15. But, as an initial matter, such constraints are inherent in our patent system, which provides that in exchange for disclosure of his or her invention, the inventor has the time-limited right to exclude others from practicing that invention – even if they wish to practice it to achieve further innovation. *See, e.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice

the invention."). Thus, all medical and scientific patents, at some basic level, have the potential to constrain research for a period of time.

In any case, the record shows that the patents here have not had the harmful effects on research that petitioners and their amici claim. By way of background, the development of BRCA testing was itself a significant advancement in cancer research – and one that likely could not have been achieved without the promise of patentability. Myriad was founded because a group of experienced, talented scientists could not receive adequate public funding to pursue their search for BRCA1. Skolnick Decl., J.A. 500. In its early years, Myriad relied heavily on large investments from venture capitalists and corporate collaborators. *Id.* at 500-01. Fueled by these resources, as well as "a spirit of cooperation, urgency, and camarader[ie] . . . that is rare in academia," the Myriad team broke new ground by discovering BRCA1 in 1994. *Id.* at 501. Subsequently, Myriad discovered BRCA2 in late 1995, and in doing so corrected serious errors in a proposed structure of that gene that a competitor was seeking to patent. *Id.* at 500; Decl. of Sean Tavtigian, J.A. 507-09; *see also* Gold & Carbone, 12 Genet. Med. at S41-42 (discussing the origins of Myriad and the company's early discoveries). If not for Myriad, it is uncertain when BRCA1 testing would have become available, or if the patented BRCA2 structure would remain forever flawed.

In the years since Myriad discovered the BRCA genes, the company has continued to make

significant contributions in the field of cancer research. Myriad has published well over 100 articles in peer-reviewed journals and scientific meetings, and helped build a comprehensive central online repository for information on BRCA mutations. Critchfield Decl., J.A. 335; Breast Cancer Information Core, Nat'l Human Genome Research Inst., http://www.research.nhgri.nih.gov/bic/ (last visited March 12, 2013). The company also adopted an expansive collaboration policy with far-reaching benefits in the cancer research community. For example, Myriad has worked with hundreds of outside researchers and participated in more than 100 outside programs and studies since 1994. Critchfield Decl., J.A. 333. Acting under similar principles, the company has facilitated external research by providing genetic materials for free to researchers at over 30 institutions, and by signing a Memorandum of Understanding with the National Cancer Institute to provide discounted research testing services to scientists. *Id.*; Tom Reynolds, *NCI-Myriad Agreement Offers BRCA Testing at Reduced Cost*, 92 J. Nat'l Cancer Inst. 596 (2000).

To be sure, certain plaintiffs in this case contend that they personally have been deterred from pursuing research because of genetic patents. *See, e.g.*, Decl. of Ellen T. Matloff, J.A. 623; Supp. Decl. of Harry Ostrer, J.A. 722-23. Neutral studies, however, indicate that such deterrence is uncommon. As one recent survey of such studies concluded, there is no evidence that genetic patents "acted as a research impediment in the past 30 years," and "[t]he number of reported patent lawsuits involving gene patents is

practically nonexistent." Jim Greenwood, *Gene Patents Do Not Hinder Academic Research*, 9 Nature Methods 1039 (2012); *see also* CJ Murdoch & Timothy Caulfield, *Commercialization, Patenting and Genomics: Researcher Perspectives*, 1 Genet. Med. 22, 22.4 (2009) ("[L]ittle is said to suggest that the progress of research itself is in fact being seriously hindered. . . . [T]here is [also] little evidence that gene patents are being aggressively enforced."); John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 Science 2002, 2003 (2005) ("Our results offer little empirical basis for claims that restricted access to IP is currently impeding biomedical research."); Decl. of Joseph Straus, J.A. 571-75. Legal experts examining the topic, for their part, have similarly concluded that there is little reason to fear that genetic patents will stifle medical or scientific advancement. *See* Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. Rev. 563, 605 (2012) (arguing that genetic patents do not hinder research and that more patent protection may be needed); W. Nicholas Price II, *Unblocked Future: Why Gene Patents Won't Hinder Whole Genome Sequencing and Personalized Medicine*, 33 Cardozo L. Rev. 1601, 1631 (2012) (concluding that genetic patents are far less significant barriers to whole-genome sequencing or personalized medicine than is sometimes assumed).

D. Myriad's Promotion and Use of Its Patents Has Benefited Practicing Physicians and Their Patients.

In the course of practice, amici have observed the benefits and evolution of BRCA testing. Before Myriad obtained its patents and began offering a way of detecting BRCA mutations, physicians could provide few answers to patients about their individual risk of developing breast and ovarian cancer. Although family history provided some clues about a patient's vulnerability, the science was far from exact. *See* Martha L. Slattery & Richard A. Kerber, *A Comprehensive Evaluation of Family History and Breast Cancer Risk: The Utah Population Database*, 270 J. Am. Med. Ass'n 1563 (1993). This posed serious problems for patients deciding whether prophylactic treatment was appropriate, especially given the surprisingly high rate of mammographic errors and unnecessary mastectomies performed each year. *See* Wendie A. Berg, L. Gutierrez, et al., *Diagnostic Accuracy of Mammography, Clinical Examination, US, and MR Imaging in Preoperative Assessment of Breast Cancer*, 233 Radiology 830 (2004); Stephanie Saul, *Prone to Error: Earliest Steps to Find Cancer*, N.Y. Times, July 19, 2010, at A1. The advent of BRCA testing, however, radically changed this situation for the better.

BRCA testing has allowed amici and other physicians to provide their patients with a clearer understanding of their risk of cancer. Specifically, if a patient's BRCA test is positive, physicians can

alert her that there is a significant chance that she will develop breast or ovarian cancer and can provide personalized preventative treatment. Sining Chen & Giovanni Parmigiani, *Meta-Analysis of BRCA1 and BRCA2 Penetrance*, 25 J. Clinical Oncology 1330 (2007); *see also* Donald Aptekar, *Why I Test My Patients*, Learn About HBOC, http://learnabouthboc.com/stories/ (last visited Mar. 12, 2013). In this way, BRCA testing allows physicians to better assist the rapidly growing number of young women who develop advanced breast cancer, and ultimately, to save lives. *See* Denise Grady, *Study Sees More Breast Cancer at Young Age*, N.Y. Times, Feb. 27, 2013, at A13.

Amici view the increasing awareness of BRCA testing among physicians and patients as an indisputably positive trend, and credit Myriad for effectively promoting its patents. Prior to Myriad's awareness campaigns, few practicing physicians were informed of the benefits or availability of BRCA testing. *See* Critchfield Decl., J.A. 344-45. Now, amici and thousands of their colleagues regularly rely upon BRCA testing in counseling and treating patients. This revolution was largely facilitated by Myriad, which has encouraged discussion about genetic testing between doctors and at-risk patients.

In amici's experience, moreover, Myriad's tests are of the highest quality. The company's status as the sole provider of BRCA testing has provided it with an unparalleled genetic library. As a result, Myriad (in amici's experience) provides fewer inconclusive results, and is able to provide better

information than companies that compete to provide other types of genetic tests. *See also* Charis Eng et al., *Interpreting Epidemiological Research: Blinded Comparison of Methods Used to Estimate the Prevalence of Inherited Mutations in BRCA1*, 38 J. Med. Genet. 824 (2001) (validating the accuracy of Myriad's testing methods); Critchfield Decl. 350-55. Amici thus consider Myriad to be the most reliable genetic testing provider in the United States, and view the company's BRCA patents as an asset for their patients.

II. PATENTING GENETIC MATERIAL IS NOT INHERENTLY UNETHICAL.

The AMA's brief urges that genetic patents – which have helped hundreds of thousands of patients worldwide – are inherently unethical. *See* AMA Br. 36-37. The brief argues that "physicians' and scientists' ethical duties recognize that laws of nature and products of nature must be treated as prior art and shared to benefit the public and to encourage innovation." *Id.* at 37. Yet as discussed above, there is little empirical evidence to support the claim that genetic patents hinder research or scientific advancement. *See* Greenwood, 9 Nature Methods at 1039. Even more problematically, the AMA's position elevates hypothetical concerns over the realities that medical professionals face on a daily basis. As the AMA itself recognizes, practicing physicians have an ethical obligation to provide their patients with the best care possible: "The relationship between patient and physician[s] is based on trust and gives rise to physicians' ethical

obligations to place patients' welfare above their own self interest and above obligations to other groups, and to advocate for their patients' welfare." Am. Med. Ass'n Ethics Opinion 10.015, The Patient-Physician Relationship. Particularly in view of Myriad's responsible stewardship of the patents implicated by BRCA testing – which has undoubtedly saved countless lives – the AMA's across-the-board condemnation of genetic patents is indefensible.

That condemnation is also questionable, moreover, in light of the rapidly shifting views of ethics in the field of genetics. Over the past thirty years, scientists and academics have often decried nascent genetic technologies as unethical. But what was initially condemned has often found widespread acceptance. For example, paternity testing and in vitro fertilization (IVF) were ethically scrutinized when they first became available to the public, only to become widely accepted a few short years later. *See* Ronald Bailey, *Warning: Bioethics May Be Hazardous to Your Health*, Reason (Aug./Sept. 1999), *available at* http://reason.com/archives/1999/08/01/warning-bioethics-may-be-hazar. Likewise, when this Court was considering the patentability of microorganisms, scientists offered a "gruesome parade of horribles," "suggesting that genetic research may pose a serious threat to the human race." *Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980). The patents were nevertheless upheld, and three decades later, none of the dire forecasts have come to fruition. *See* Holman, 80 UMKC L. Rev. at 599.

Indeed, the story of BRCA testing itself confirms that ethical views are liable to shift over time. When BRCA testing was first made available, some argued that it was unethical to inform patients whether they carried the genes. Bailey, *Warning*; *see also* Danielle Simmons, *Bioethics in Genetics*, 1 Nature Educ. 1 (2008), *available at* http://www.nature.com/scitable/topicpage/bioethics-in-genetics-42093; Francis S. Collins, Director, Nat'l Center for Human Genome Research, Statement on Advances in Genetic Research and Technologies: Challenges for Public Policy before the S. Comm. on Labor and Human Resources (July 25, 1996), *available at* http://www.genome.gov/10002351. If enshrined in law, this paternalistic view would have drastically limited a patient's ability to make informed decisions about issues of literally vital medical importance. Fortunately, it became accepted practice for physicians to share and discuss BRCA test results with their patients. Given this background, it would be the height of irony to now condemn genetic patents as unethical. *See* Ronald Bailey, *Gene Testing Irony: Once Restricted, Now a Right?*, Reason.com Hit & Run Blog (Apr. 2, 2010, 3:05 pm), http://reason.com/blog/2010/04/02/gene-testing-irony-once-restri.

As this Court explained in upholding the validity of patents on microorganisms, when faced with controversial policy choices, the judiciary must neither "brush them aside as fantasies generated by fear of the unknown, [n]or . . . act on them." *Diamond*, 447 U.S. at 317. Rather, the ethics of genetic patents are a "matter of high policy for

resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot." *Id*

CONCLUSION

The judgment of the Federal Circuit should be affirmed.

Respectfully submitted,

PAUL D. MARGOLIS
JENNER & BLOCK LLP
353 N. Clark Street
Chicago, IL 60654
(312) 222-9350

MATTHEW S. HELLMAN
Counsel of Record
JOSHUA M. SEGAL
ESTEBAN M. MORIN*
JENNER & BLOCK LLP
1099 New York Ave., NW
Washington, DC 20001
(202) 639-6000

**Admitted only in California; supervised by principals of the Firm.*

March 14, 2013 *Counsel for Amici Curiae*