

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 FOR *AMICUS CURIAE*
LYNCH SYNDROME INTERNATIONAL
IN SUPPORT OF RESPONDENTS**

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INTEREST OF *AMICUS CURIAE*¹

Amicus Lynch Syndrome International (“LSI”) is an all-volunteer organization founded and governed by Lynch syndrome survivors, their families, and health care professionals who treat Lynch syndrome. LSI funds research and educates the general public and health care professionals about Lynch syndrome. By enhancing survivability, LSI creates hope and positively impacts thousands of lives worldwide.

Lynch syndrome is an inherited genetic disorder. Relative to the general population, people with Lynch syndrome have a greatly increased risk of developing one or more fatal cancers by early middle age. Lynch syndrome cancers tend to be more aggressive and do not have the extended “dwell time” of other cancers. Genetic screening can, in many cases, confirm whether an individual has Lynch syndrome. Because carriers of Lynch syndrome prematurely develop aggressive cancers, an individual with a confirmed diagnosis of Lynch syndrome can be monitored aggressively so that cancer development is caught early, when treatment is most effective. Readily available, reliable, approved, and comprehensive genetic testing is thus

¹ Counsel for all parties have consented to the filing of this brief, and their consents have been lodged with the Clerk of this Court. No counsel for any party had any role in authoring this brief, and no person other than the named *amicus* and its counsel has made any monetary contribution to the preparation and submission of this brief. *See* Rule 37.

of the highest import for individuals with Lynch syndrome.

As new Lynch genes and gene variants are discovered, it is imperative that tests be developed to identify them. If such tests are not developed, some Lynch syndrome patients will not be diagnosed early – or at all – and will not be monitored aggressively. Consequently, Lynch syndrome cancers that otherwise could have been caught and effectively treated at an early stage will be inadequately diagnosed and treated, resulting in unnecessary suffering and untimely death for these patients.

Genetic tests for these new and variant genes will be created and commercialized either by next generation start-up biotechnology companies or by existing diagnostic companies. Next generation start-up biotechnology companies need venture capital funding to exist, but venture capitalists will not provide funding unless the technology that the start-ups are developing can be patented and protected from copyists. Similarly, larger companies will not invest the money required to produce a reliable test unless they can be assured of a return on their investment by way of protection from copyists. This protection can be provided by method-of-use patents and kit patents, and need not necessarily come from composition-of-matter claims such as claim 1 of Myriad's U.S. Patent No. 5,837,492. However, an overly broad approach to the claims before this Court could inadvertently and adversely impact method-of-use patents and kit patents.

Thus, *amicus* LSI has a strong interest in ensuring that any holding by the Court is narrowly crafted, does not restrict method-of-use or kit patents, and thus does not foreclose patent eligibility for future genetic tests, including future Lynch syndrome genetic tests.² Specifically, any holding of the Court should be limited to the issue at hand, *i.e.*, whether claims to human genes recite a composition of matter patent-eligible under 35 U.S.C. § 101.



SUMMARY OF ARGUMENT

Genetic tests should remain patent-eligible to the broadest extent possible. The broad scope of patent-eligible subject matter under 35 U.S.C. § 101 is well-established. Moreover, the development, approval, and commercialization of new genetic tests are made possible primarily by patent eligibility. Indeed, as new Lynch syndrome genes and gene variants are discovered, new tests to detect such genes and variants must be developed: The earlier patients with those genetic markers can be diagnosed, the sooner they can receive the more aggressive monitoring that will prolong their lives. The information provided by genetic testing not only enhances survivability but

² As explained more fully *infra* in Point III, the references herein to patents for “genetic tests” include patents for the use of particular molecules, including DNA molecules, in such tests.

also permits intelligent decision-making concerning the right to procreate and have a family.

The development and commercialization of genetic tests require significant amounts of capital, but capital sources will not provide the necessary funding unless the newly developed tests will have patent protection. Only patent protection will assure the capital sources of a sufficient investment return to make the provision of funding worthwhile.

Accordingly, any holding of the Court should be limited to the issue of whether claims to human genes recite a composition of matter patent-eligible under 35 U.S.C. § 101 and should neither restrict method-of-use or kit patents nor foreclose patent eligibility for future genetic tests, including future Lynch syndrome genetic tests.



ARGUMENT

I. Genetic Tests Should Remain Patent-Eligible to the Broadest Extent Allowed by Law

The Constitution provides Congress with the power to “promote the Progress of Science and the useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries.” U.S. Const. art. I, § 8, cl. 8. To that end, Congress established the broad ambit of patent-eligible subject matter in 35 U.S.C. § 101: “Whoever invents or discovers any new and useful process,

machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

This Court has noted the breadth of patent-eligible subject matter: “In choosing such expansive terms . . . modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.” *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (citation omitted). “Congress took this permissive approach to patent eligibility to ensure that ‘ingenuity should receive a liberal encouragement.’” *Id.* at 3225 (citations omitted). Genetic tests have fallen squarely within the four corners of Section 101 for over a decade, as evidenced by the average yearly entry of 3,482 U.S. patents and patent applications into the DNA Patent Database for the period 1996-2011.³

Insofar as Section 101 also sets forth a “utility requirement,”⁴ no one argues that genetic tests are not useful. Indeed, many arguments for denying patent eligibility to Myriad’s claims paradoxically rely on the utility of genetic testing, as evidenced by an

³ *DNA Patent Database*, available at <http://dnapatents.georgetown.edu/>.

⁴ *See, e.g.*, U.S. Patent and Trademark Office, Guidelines for Examination of Applications for Compliance with Utility Requirement, available at <http://www.uspto.gov/web/offices/pac/mpep/s2107.html> (referring to “utility requirements of 35 U.S.C. 101 and 112”).

unmet demand for genetic testing driven by underlying economic factors.⁵

This reliance is not surprising because genetic testing, if reliable and comprehensive, can provide life-changing information.⁶ In contrast, inaccurate genetic testing can result in “misdiagnosis, inappropriate and/or delayed treatment, anxiety and in rare cases, even death.”⁷

Lynch syndrome provides an example of an unmet need for accurate, approved, reliable, readily available, and comprehensive genetic testing. New Lynch syndrome genes, and new variants of existing Lynch syndrome genes, continue to be discovered.⁸ Such testing for these new and variant Lynch syndrome genes would be life-changing and likely will come about only if genetic testing remains patent-eligible.

In sum, the breadth of Section 101, the urgent unmet need for new genetic tests, and the fact that development and commercialization of new genetic

⁵ See U.S. Dept. of Health & Human Servs., *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests: Report of the Secretary’s Advisory Committee on Genetics, Health, and Society* (Apr. 2010).

⁶ See Kathy L. Hudson *et al.*, *Oversight of US genetic testing laboratories*, 24 *Nature Biotechnology* 1083 (2006) (“Hudson”).

⁷ *Hudson* at 1089.

⁸ See *Genetic Testing*, available at <http://www.lynchcancers.com/index.php/genetic-testing>.

tests are made possible primarily by patent eligibility make it imperative that genetic testing remain patent-eligible.

II. If Genetic Tests Are Held Patent-Ineligible, Unnecessary Patient Suffering and Untimely Patient Death Will Result

Many genetic disorders disproportionately and adversely impact small subsections of the population. One such disorder is Lynch syndrome, which is also known as hereditary nonpolyposis colon cancer. Colon cancer is the third most common cancer diagnosed in men and women, with 101,340 new cases diagnosed annually.⁹ Colon cancer causes about 50,000 deaths annually – approximately 9% of all cancer deaths.¹⁰ Up to 80% of Lynch syndrome individuals will develop colorectal cancer, with an average onset age of 42 years (versus 70 years for non-inherited colorectal cancer).¹¹ Table 1 below presents the lifetime risk of cancer development in patients with Lynch syndrome versus the general population.¹²

⁹ American Cancer Society, *Cancer Facts & Figures 2011* (“*Cancer Facts*”), at 12.

¹⁰ *Cancer Facts* at 12.

¹¹ Vincent W. Yang, M.D., Ph.D., *Population-Based Screening and Cascade Testing for Lynch Syndrome: Are We There Yet?* Presentation at Medicine Grand Rounds, Loyola University Medical Center, Mar. 27, 2012 (“*Yang*”), slides 11-12.

¹² *Yang*, slide 12.

Table 1. Lifetime cancer risk: Lynch syndrome versus general population.¹³

Type of Cancer	Persons with Lynch syndrome (%)	General Population (%)
Colorectal	80-85	5-6
Endometrial	64-71	2-3
Ovarian	20	1-2
Gastric	13	1
Kidney	12	1
Bladder	8-12	1-3
Brain	4	0.6
Pancreatic	~3.7	~0.5
Bile Duct	2	0.6
Small Bowel	1-4	0.01

Recent studies also suggest increased risk for cancers of the prostate and breast when Lynch syndrome is present.¹⁴

¹³ For Lynch-related pancreatic cancer data in Table 1, see Fay Kastrinos *et al.*, *Risk of Pancreatic Cancer in Families With Lynch Syndrome*, 302 *J. Am. Med. Ass'n* 1790 (2009). For Lynch-related endometrial and kidney cancer data in Table 1, see Markku Aarnio, *Clinicopathological Features and Management of Cancers in Lynch Syndrome*, 2012 *Patholog. Res. Int.* 350309 (2012). For Lynch-related ovarian cancer data in Table 1, see Cleveland Clinic Genomic Medicine Institute, *Lynch Syndrome*, available at http://my.clevelandclinic.org/Documents/genomics/Lynch%20Syndrome_Fact%20Sheet.pdf. For Lynch-related bladder cancer data in Table 1, see R.S. van der Post *et al.*, *Risk of urothelial bladder cancer in Lynch syndrome is increased, in particular among MSH2 mutation carriers*, 47 *J. Med. Genet.* 464 (2010).

¹⁴ See C.M. Bauer *et al.*, *Hereditary prostate cancer as a feature of Lynch syndrome*, 10 *Fam. Cancer* 37 (2011); M.D. Walsh
(Continued on following page)

Lynch syndrome is inherited. The form of inheritance is known as autosomal dominant inheritance, meaning that a child need only receive a defective gene from one parent to inherit Lynch syndrome.¹⁵

Lynch syndrome genes increase cancer risk by inhibiting repair of mistakes made in genetic replication. “Variations in the *MLH1*, *MSH2*, *MSH6*, and *PMS2* genes increase the risk of developing Lynch syndrome. All of these genes are involved in the repair of mistakes . . . [in] DNA replication.”¹⁶ Mutations in any of these genes may prevent proper repair of DNA replication mistakes, leading to development of cancer. Because Lynch syndrome mutations affect both men and women, the defective repair genes are more important, in terms of clinical significance, than the genes for breast cancer susceptibility, *BRCA1* and *BRCA2*.

Genetic testing is crucial for individuals with Lynch syndrome and their families. “A positive result for Lynch syndrome (HNPCC) makes one a ‘mutation carrier’ and . . . serves as verification of having an increased risk of cancer.”¹⁷ Because of the early onset, increased frequency, and aggressiveness of cancers associated with Lynch syndrome, persons diagnosed

et al., *Lynch Syndrome-Associated Breast Cancers: Clinicopathologic Characteristics of a Case Series from the Colon Cancer Family Registry*, 16 *Clin. Cancer. Res.* 2214 (2010).

¹⁵ Yang, slide 11.

¹⁶ *Lynch Syndrome*, available at <http://ghr.nlm.nih.gov/condition/lynch-syndrome>.

¹⁷ *Genetic Testing*.

with Lynch syndrome are given elevated cancer monitoring and surveillance. “Regular screening examinations . . . can result in . . . the diagnosis of cancers at an early stage, when they are most treatable.”¹⁸ Through preventive measures like early diagnosis and surveillance, “enhanced quality of life and longevity can be achieved and individuals and families can be protected from cancer.”¹⁹

If genetic tests are not developed for new Lynch syndrome genes and for new variants of known Lynch syndrome genes, some Lynch syndrome patients will not be diagnosed early and hence will not be given elevated cancer monitoring and surveillance. Aggressive Lynch syndrome cancers that otherwise could have been caught and effectively treated at an early stage will go undiagnosed and untreated, resulting in unnecessary suffering and untimely death for these patients.

Genetic tests for these new and variant genes are likely to be created and commercialized either by next-generation start-up biotechnology companies or by existing, larger diagnostic companies. As discussed more fully *infra* in Point III, next-generation start-up biotechnology companies need venture capital funding to exist, but venture capitalists will not provide funding unless the technology being developed by such companies can be patented. Similarly,

¹⁸ *Cancer Facts* at 1.

¹⁹ *Lynch Syndrome International*, available at <http://www.lynchcancers.com/>.

large companies will direct their research and development efforts elsewhere if a copyist is immediately able to reproduce a genetic test without the research and development required to create the first test on the market.

In particular, the commercialization of new genetic tests depends on their underlying patent eligibility. For example, Myriad's BRCA1/2 test was initially developed at a university with federal grant research money. However, it was patent protection for the test that led venture capitalists to invest in Myriad, with the result that the test is now publicly available. Moreover, the patents at issue expire in the next few years. Accordingly, the system worked properly: A company received a financial incentive for commercializing the test; obtained, and will soon use up, a period of time in which it has an exclusive right to make the test; and, as a result, the test is now widely obtainable. Upon expiration of the patents, the test will soon become even more widely obtainable, and the cost at which the test is made will likely drop as competitors enter the market. Moreover, the tests are heavily regulated both in the United States and abroad. While Lynch syndrome victims are hoping to have the same type of new tests available, an unnecessarily broad holding by this Court here could inadvertently dash those hopes by relegating victims to potentially unregulated one-off tests of doubtful accessibility.

The Court has long acknowledged that "the rights and welfare of the community must be fairly dealt

with and effectually guarded” in the patent system. *Kendall v. Winsor*, 62 U.S. 322, 329 (1858). “A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the ‘Progress of Science and useful Arts.’” *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (quoting U.S. Const. art. I, § 8, cl. 8).

New genetic tests are urgently needed and will serve the public interest. Such tests obviate unnecessary patient suffering and reduce untimely patient death.

For all of these reasons, patent eligibility for future genetic tests, including future Lynch syndrome genetic tests, must not be foreclosed.

III. Patent Eligibility Determines Whether Life-Changing Genetic Tests Will Be Developed, Approved, and Commercialized

A. Patents are the basis for the biotechnology industry

Patents are *the* basis for the biotechnology industry. Patents “give rise to the innovation that results in the creation of [genetic] diagnostics and treatment options based thereon”²⁰ Should this Court hold

²⁰ Suzannah Sundby and Eric Mirabel, *No One Is Patenting Your Genes: The Ripple Effect if Isolated DNA Claims Are Made* (Continued on following page)

invalid any of Myriad's composition-of-matter claims to DNA fragments, it should be careful not to limit the ability of innovators to patent *uses* of such DNA fragments, as well as kits employing such fragments and other diagnostic innovations that lie beyond the grant of *certiorari*.

B. Venture capitalists will not fund startups whose technology cannot be patented

“[W]ithout patent protection for Biotech inventions, no one would be willing to make the substantial investment required to research, develop and bring . . . small market products through the multi-year FDA approval process.”²¹ Because Lynch syndrome occurs in approximately 1 in 1,000 live births,²² the percentage of Lynch syndrome carriers in the general population is relatively small. Lynch syndrome carriers therefore cannot provide a “mass market” for genetic diagnostics.

Patent Ineligible, IP Watchdog, Dec. 14, 2012, available at <http://www.ipwatchdog.com/2012/12/14/no-one-is-patenting-your-genes-the-ripple-effect-if-isolated-dna-claims-are-made-patent-ineligible/id=31437/> (“*Ripple Effect*”).

²¹ *Ripple Effect*.

²² Yang, slide 11; cf. H. Hampel *et al.*, *The Search for Unaffected Individuals with Lynch Syndrome: Do the Ends Justify the Means?* 4 *Cancer Prev. Res.* 1 (2011) (estimating that up to 1 in 370 individuals may have Lynch syndrome).

Patents provide much needed protection and incentive to develop new genetic diagnostic assays in such small markets, including new Lynch syndrome genetic diagnostic assays. Absent patent protection, these new assays “will likely go the way of treatments and medicines for orphan diseases prior to the 1983 Orphan Drug Act”²³ No “patents for isolated DNA and diagnostics means ‘one size fits all’ as the investment in R&D will only be made for what can be sold for the masses. Say ‘goodbye’ to personalized medicine.”²⁴ “Personalized medicine” involves tailoring therapeutics for individual patients through diagnostic tests for genetic mutations known as biomarkers. Such therapeutic tailoring is essential for the survival of Lynch syndrome families. In the words of one Lynch syndrome cancer survivor: “Without personalized medicine, entire families have and will continue to be wiped out.”²⁵

Venture capitalized companies, including biotechnology companies, are inherently at risk of failure. The risk exists regardless of the definition of failure. “If failure means liquidating all assets, with investors losing all their money, an estimated 30% to

²³ *Ripple Effect*.

²⁴ *Ripple Effect*.

²⁵ For a personal oral history of a family devastated by Lynch syndrome cancers, see *Workshop 6: Cancer Genetics* – Judi Ruggiero-Reed, available at <http://www.youtube.com/watch?v=rw7OCX9otsw> (“*Ruggiero-Reed*”).

40% of high potential U.S. start-ups fail”²⁶ “If failure is defined as failing to see the projected return on investment . . . then more than 95% of start-ups fail”²⁷ Approximately 75% of “venture-backed firms in the U.S. don’t return investors’ capital.”²⁸ In view of these long odds, Myriad’s survival, due largely to patent-eligibility for its genetic tests, has been a miracle for BRCA1 and BRCA2 patients: Without Myriad, it is possible that only fragmented and potentially unregulated testing would be available. Lynch syndrome patients desperately need access to the quality testing that Myriad has been able to provide to BRCA1 and BRCA2 patients.

Investment in biotechnology companies, especially in start-up genetic diagnostic companies, is even riskier because such investment is long-term. In “the decade since the initial sequencing of the human genome, other anticipated advances – such as the rise of genetics based personalized medicine – have yet to take off.”²⁹ “It takes much longer than you’d like to believe when you make the first investment.”³⁰ Indeed,

²⁶ Deborah Gage, *The Venture Capital Secret: 3 Out of 4 Start-Ups Fail*, *The Wall Street Journal*, Sept. 19, 2012, available at <http://online.wsj.com/article/SB10000872396390443720204578004980476429190.html> (“*Venture Capital Secret*”).

²⁷ *Venture Capital Secret*.

²⁸ *Venture Capital Secret*.

²⁹ Joanna Glasner, *The Gene Scene*, *Venture Capital Journal*, Feb. 25, 2013.

³⁰ *The Gene Scene* (quoting Bill Ericson, managing director of Mohr Davidow Ventures).

“the genetics-based diagnostics space seems to be an area where there’s more venture capital going in than being returned to investors.”³¹ Long-term financial risks associated with funding biotechnology companies, and the small market for many genetic diagnostic tests, make the availability of patent protection a mandatory prerequisite to the development of such tests.

C. Academia is no substitute for the biotechnology industry

If diagnostic genetic testing were held patent-ineligible, academia could not assume the biotechnology industry’s key role in developing next-generation diagnostic tests. Academia might still continue such research, but is unlikely to “spend, more appropriately risk, millions to conduct the additional R&D to take that basic research and make a product available to the public so that one can have medical treatment that is personalized for that person[.]”³² Federal budgetary constraints make this scenario even more unlikely: “With the current budget constraints on our Federal Government, it’s not likely that we’ll see additional Federal research grants for universities to conduct basic research that results in potential products, *e.g.*, diagnostic tests, which are essential

³¹ *The Gene Scene.*

³² *Ripple Effect.*

for personalized medicine.”³³ At present, there is no hope of expanded government funding for academic research sufficient to allow academic researchers to expend the capital needed to produce a regulated, high-quality, broadly available test.

Any ruling by this Court that diminishes or casts doubt upon the patent eligibility of genetic diagnostic testing risks killing the goose (the biotechnology industry) that lays the golden eggs (*e.g.*, genetic diagnostic testing). In this case, one of the golden eggs could be a test to help Lynch syndrome victims avoid or better treat cancer.

IV. Allowing Genetic Tests to Remain Patent-Eligible Will Allow Patients to Make Informed, Intelligent Decisions Concerning the Exercise of Constitutional Rights Previously Affirmed by This Court

Courts have not significantly appreciated the positive impact that diagnostic genetic testing has on individual constitutional rights, and the negative impact that a decision rendering diagnostic genetic tests patent-ineligible would have on such rights.

Individual constitutional rights include, but are not limited to, the right of privacy of married persons including access to contraception; the power of parents to control the education of their children; and

³³ *Ripple Effect*.

family sanctity. *See, e.g., Griswold v. Connecticut*, 381 U.S. 479 (1965); *Moore v. East Cleveland*, 431 U.S. 494 (1977); *Zablocki v. Redhail*, 434 U.S. 374 (1978).

The life-changing information provided by diagnostic genetic tests allows patients to make informed, individual decisions regarding the exercise of their constitutional rights. Using Lynch syndrome as an example, genetic diagnostic testing can help individuals intelligently decide whether to form a family; whom to form a family with; whether or not to have children; whether or not to adopt in lieu of naturally conceiving children; and whether and how long to use contraception. Moreover, absent genetic testing, Lynch syndrome parents cannot properly prepare or educate their children regarding how to survive and to navigate the health-care system.

Foreclosure of patent eligibility for future genetic tests would result in failure to develop new genetic tests. Thus, some individuals would not be able to ascertain their genetic carrier status for conditions such as Lynch syndrome. Should this Court issue a decision that renders genetic testing patent-ineligible, the Court would be consigning a vulnerable minority of individuals to an ignorance of their genetic status that would meaningfully impede the exercise of their constitutional rights. It would also

allow Lynch syndrome to continue to devastate families across generations.³⁴

◆

CONCLUSION

Because of the importance of genetic testing to the Lynch syndrome community and because of the importance of patent eligibility to the developers of new genetic tests, LSI urges the Court to issue a narrow holding that does not foreclose future patents on genetic testing.

Respectfully submitted,

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³⁴ *Ruggiero-Reed.*