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 THE COALITION FOR 21ST CENTURY MEDICINE AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

JEFFREY A. LAMKEN
Counsel of Record
MICHAEL G. PATTILLO, JR.
MOLOLAMKEN LLP
The Watergate, Suite 660
600 New Hampshire Ave., NW
Washington, D.C. 20037
(202) 556-2000
jlamken@mololamken.com

DAVID JANG
MOLOLAMKEN LLP
540 Madison Ave.
New York, NY 10022

Counsel for Amicus Curiae

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D.C. 20002

QUESTION PRESENTED

Whether the isolated BRCA1 and BRCA2 DNA molecules claimed by Myriad—which do not exist in nature and are the product of human ingenuity and intervention—are patent-eligible subject matter under 35 U.S.C. § 101.

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

IN THE

Supreme Court of the United States

NO. 12-398

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 THE COALITION FOR 21ST CENTURY MEDICINE AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

INTEREST OF *AMICUS CURIAE*[1]

Amicus Curiae the Coalition for 21st Century Medicine represents diagnostic technology companies, clinical laboratories, researchers, physicians, venture capitalists,

[1] Pursuant to Supreme Court Rule 37.6, counsel for *amicus curiae* states that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. Counsel's fees incurred to prepare this brief were paid by AbbVie, Inc. Otherwise, no person or entity other than *amicus curiae* or its counsel made a monetary contribution to this brief's preparation or submission. All parties consented to the filing of this brief. Copies of the letters granting consent have been filed with the Clerk.

and patient advocacy groups who believe that continuous diagnostic innovation is needed to enhance treatment decisions and improve patient outcomes.

This case concerns whether material derived from human genes—isolated DNA—is patentable subject matter under Section 101 of the Patent Act. *Amicus* believes that efforts to undermine DNA sequence patents in the United States endanger this future by pushing investors away from molecular diagnostics technology. Without their continued investment, private industry will no longer be able to support the same breadth of expensive and complex research, development, and commercialization of these critical health care products. This will cause serious harm to the well-being of patients who would otherwise benefit from personalized medicine. In view of *amicus*'s role in the genetic diagnostic field, it has a unique perspective on and a keen interest in the question presented.

SUMMARY OF ARGUMENT

I. Section 101 of the Patent Act defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. However, "laws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981). Consequently, if the question presented in this case truly were whether "human genes" are "patentable," Pet. Br. i, the answer would be "no"; the human genome is a natural phenomenon. But Myriad's patents do not claim "human genes." They claim "isolated DNA" in a form that does not exist in nature or the human body—a lab-made, "nonnaturally occurring * * * composition of matter," a "product of human ingenuity having a distinctive name, character, and use." *Diamond* v. *Chak-*

rabarty, 447 U.S. 303, 309-310 (1980) (alterations omitted). Isolated DNA is chemically distinct from genomic or "native" DNA found in the human body; it is found nowhere in nature; and it has scientific and medical applications that native DNA does not. It is patentable subject matter even though native DNA is not.

II. Patent protection is essential to advancing human understanding of genomics and developing new genetic diagnostic and therapeutic products that will improve public health and quality of life.

A. Personalized medicine is a new field that is revolutionizing the healthcare industry by using genetic diagnostics to tailor treatments to patients' individual genetic makeups. The research and development activities needed to make discoveries in this field, to transform those discoveries into useful products, and to obtain the necessary regulatory approval for use of those products, however, is expensive, time-consuming, and risky. Given the significant investment and substantial risk required, the incentives afforded by the patent system are critical to ensuring the advancement of gene-based diagnostics and therapeutics and unlocking the potential of personalized medicine in the United States.

B. By requiring disclosure of genetic innovations—and requiring sufficient disclosure to allow others to practice the innovation—patents advance the store of human knowledge, creating springboards for further innovation. Patents allow private-sector competitors to collaborate on new advances by eliminating fears that innovative intellectual property might be appropriated. And coupling patented technologies with appropriate licensing practices has permitted the private and public sectors to collaborate and transform the fruits of academic research into products that improve public health.

III. Petitioners claim that granting protection for isolated DNA will enable patentees to prohibit all research on particular genes, and will give patentees exclusive rights over future applications that are neither disclosed in the patent nor technically achievable at the time the patent application is filed. Existing patent law doctrines, however, amply address those concerns. A statutory safe harbor allows certain research and uses that would otherwise be infringing for purposes of seeking federal regulatory approval necessary to bring competing products to market once the patent expires. And the Patent Act's written description and enablement requirements prohibit patentees from claiming exclusive rights in innovations unless they in fact developed them, disclose them, and provide a written description sufficient to permit others reasonably skilled in the art to make and use them. This Court should not distort Section 101 to address concerns that Congress has spoken to in other sections of the Patent Act.

IV. Petitioners and *amici* also argue that patents on isolated DNA inhibit innovation and restrict patient access to new diagnostics and therapeutics. The PTO, however, has been issuing patents on isolated DNA for 30 years, and the empirical evidence refutes the parade of horribles petitioners and *amici* attempt to conjure. The allegation that research is impeded is unsupported. To the extent patients have sometimes been denied access to innovative new genetic tests and treatments, that has been a result of the insurance industry's failure to keep abreast of medical advances that can help their insureds, not a limit imposed by patent protection.

ARGUMENT

I. ISOLATED DNA GENERATED THROUGH HUMAN INTERVENTION—THE COMPOSITION OF GENETIC MATTER AT ISSUE HERE—IS PATENTABLE SUBJECT MATTER

Section 101 of the Patent Act defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. This Court has construed Section 101 broadly, explaining that "Congress plainly contemplated that the patent laws would be given wide scope." *Bilski* v. *Kappos*, 130 S. Ct. 3218, 3225 (2010). "[L]aws of nature, natural phenomena, and abstract ideas," however, are not patentable under Section 101. *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981). This case concerns whether a patent on a specific composition of matter derived from human genetic material—"isolated DNA"—is patentable subject matter under Section 101. Under this Court's precedent, the answer is "yes."

A. Isolated DNA Constitutes A New Composition Of Matter, Not A Natural Phenomenon

Notwithstanding petitioners' request that this Court decide whether "human genes" are "patentable," Pet. Br. i, that is not the question before the Court. If it were, the answer would be a straightforward "no." "Human genes" exist in nature, inside the human body. And it is well-settled that compositions of matter as they exist in nature—such as human genes in the form of native DNA—are not patentable subject matter. See *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309-310 (1980); *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). An inventor must actually invent something to earn the exclusive right to practice the invention. No one may

patent the basic phenomena and products of nature, which are "free to all men and reserved exclusively to none." *Funk Bros.*, 333 U.S. at 130, 131.

But Myriad's patents do not claim the human genome or "native" DNA—DNA as it naturally exists inside the human body. As a result, whether "human genes" can be patented is not the proper question before the Court. Instead, the question is whether the *isolated DNA* molecules claimed by Myriad are patentable subject matter consistent with Section 101. Unlike native DNA, isolated DNA is a product of human ingenuity and intervention. Unlike native DNA, isolated DNA exists nowhere in nature. And isolated DNA, because it is distinct from native DNA, serves functions that native DNA cannot.

Native DNA in the human body consists of a molecule, comprised of multiple nucleotides, anchored within a complex and much larger genomic structure. Pet. App. 257a-263a. Multiple segments of DNA constitute a gene, the unit responsible for producing proteins encoded by the thousands of nucleotides within each gene. *Id.* at 258a-259a. Genes are arrayed on complex structures called chromosomes; forty-six chromosomes together contain the 25,000 genes in the human nuclear genome. *Id.* at 259a, 262a. The human genome, replicated within most cells in the human body in combination with the mitochondrial genome, carries all genetic material determining the hereditary traits of each person. *Id.* at 258a-259a & n.6. The linear DNA of chromosomes is held in complex 3D shapes by companion proteins to form chromatin. Proteins bound to DNA also modify expression of the genes. Those interstitial elements help determine the characteristics of native DNA; for instance, the proteins within a chromosome bind to DNA molecules and modulate their structure and function. *Id.* at 262a.

Isolated DNA molecules are different. They are not found in nature. Rather, scientists employ one of a variety of processes to isolate DNA from the cellular material in which it is embedded. Pet. App. 19a-20a; see generally Tan & Yiap, *DNA, RNA, and Protein Extraction: The Past and the Present*, J. Biomed. & Biotech., 2009. What those methods have in common is that they work radical changes on the native chromosomatic material. In nature, genes are part of a larger, undifferentiated DNA molecule. By, among other things, cleaving the covalent bonds within the sugar-phosphate backbone holding together a DNA molecule, scientists create an entirely new molecule, consisting solely of the isolated DNA, that did not exist before. Pet App. 51a. These snippets of genetic material are literally isolated from, among other things, the protein glue that influences the structure and function of native DNA. As the Federal Circuit observed, isolated DNA thus "exist[s] in a distinctive chemical form—as distinctive chemical molecules—from DNA[ ] in the human body." *Ibid.* Isolated DNA stands free not only from other elements of a native DNA molecule, but also from the larger structures of the chromosome.[2]

Isolated DNA also serves different functions than naturally occurring molecules within the human genome. Isolation of DNA has historically enabled a means of sequencing, the process of decoding the informational con-

[2] Like isolated DNA, cDNA is manually divorced from the broader structures and biological functions of the human genome. cDNA differs from isolated DNA in that it is the product of further laboratory synthesis that excludes intron sequences found in native DNA. Pet. App. 20a. The creation of cDNA thus requires even more human intervention and inventiveness than isolated DNA. But that is a distinction of degree, not kind.

tent of nucleotides within a gene. And as recognized in the decision below, isolated DNA also finds application as "probes" and "primers" that are used in genetic tests for the diagnosis and treatment of illness. Pet. App. 82a-84a.

Indeed, for isolated DNA to function as a "probe" that detects genes associated with particular diseases or responsiveness to particular treatments, Pet. App. 264a, it must be calibrated precisely. Probes exploit the fact that a DNA strand, consisting of a sequence of nucleotide bases, will "pair" or "hybridize" predictably with a strand containing the complementary sequence (so 5'-AA-TT-3' hybridizes with 5'-TT-AA-3'). *Id.* at 265a. An isolated DNA probe can be created by exposing a DNA sequence to high heat or alkalinity, causing the familiar "double helix" structure of a DNA molecule to be disrupted, splitting the molecule into its two strands of complementary nucleotides. Alberts *et al.*, *Molecular Biology of the Cell* 8-25 (4th ed. 2002). The nucleotides of the isolated DNA probe are labeled, typically with a radioactive material or a fluorescent dye, so that they can be seen or detected later. The probe sequence is then mixed with a sample of genetic material from the patient. Any unhybridized material is removed. The laboratory then looks for the labeled nucleotides. If they remain—having hybridized with the complementary DNA sequence—that indicates that the gene being tested for was present. See Pet. App. 82a.[3] Native DNA cannot be used for probes; its nucleotide sequences are bound up with other matter and cannot hybridize with other native DNA.

---

[3] An isolated DNA primer similarly latches onto a segment of native DNA, but is then typically used to replicate the target DNA billions of times over through a process called polymerase chain reaction amplification. Pet. App. 264a-265a, 271a. This allows the clinician to better analyze the sequence of the DNA in the target sample.

More important, isolated DNA probes can work only if they uniquely and closely reflect the nucleotides that comprise the gene or mutation being tested for, among the billions of undifferentiated nucleotides that comprise the human genome. If the isolated DNA probe includes excess material, that may prevent hybridization even if the genetic mutation being tested for is present; or, it may cause spurious hybridization where the mutation is not present. Likewise, if the isolated DNA probe includes too little material, false results are possible. The development and creation of isolated DNA probes that can be used to identify and treat disease thus requires the inventor to discover and then isolate the precise portion of the DNA needed to achieve a match—no more, no less. Far from reflecting an effort to clip a chunk off the double helix, isolating a particular gene is like carving out the precise shape for a key that will reliably fit in one, and only one, of a billion locks. That requires human intervention, great ingenuity, and extraordinary precision. And when someone figures out how to do that, it should be patentable.

B. This Court's Cases Confirm That Isolated DNA Developed Through Human Intervention Represents Patentable Subject Matter

This Court's decisions in *Chakrabarty* and *Funk Brothers* confirm that isolated DNA, such as the isolated BRCA genes at issue here, represent patentable subject matter.

In *Funk Brothers*, the Court addressed whether a mixed bacteria culture for inoculating legumes was patentable. 333 U.S. at 130-131. It previously had been thought that multiple strains of bacteria could not be mixed in an inoculant because they would inhibit one another; as a result, different inoculants containing differ-

ent bacteria were used on different types of legumes. *Id.* at 129-130. The patentee discovered that there were certain strains of bacteria that did not have such a mutually inhibitive effect, and therefore could be mixed to create a single inoculant that could be applied to many different types of legumes. *Ibid.* This Court held that the mixed culture was not patentable. While the Court recognized that the patentee had discovered the non-inhibitive properties of the bacteria strains, the Court stressed that he did "not create [the] state of * * * non-inhibition in the bacteria." *Id.* at 130. Rather, those "qualities are the work of nature." *Ibid.* The Court noted that there was no change worked in the species of bacteria as a result of the patentee's efforts, and "no enlargement of the range of their utility"; rather, "[e]ach species has the same effect it always had," and "act[s] quite independently of any effort of the patentee." *Id.* at 131. The Court held that because the bacteria were a product of nature rather than a product of human invention, they were not patentable. *Id.* at 132.

By contrast, in *Chakrabarty*, this Court held that a human-altered bacteria was patentable subject matter under Section 101. 447 U.S. at 310. There, the inventor had inserted several plasmids into a naturally occurring bacteria that gave it the ability to break down the components of crude oil—a property "possessed by no naturally occurring bacteria." *Id.* at 305. Unlike the naturally occurring bacteria in *Funk Brothers*, the bacteria in *Chakrabarty* were "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name, character, and use." *Id.* at 309-310 (alterations omitted). The bacteria had "markedly different characteristics from any found in nature and * * * the potential for significant utility." *Id.* at 310.

Because the "discovery is not nature's handiwork," but the inventor's, it was found to be "patentable subject matter under § 101." *Ibid.*

Isolated DNA is far closer to the patent-eligible bacteria in *Chakrabarty* than the ineligible bacteria in *Funk Brothers*. Like the bacteria in *Chakrabarty*, the isolated DNA molecules coding for BRCA1 and BRCA2 exist nowhere in nature—they are "a nonnaturally occurring * * * composition of matter," *Chakrabarty*, 447 U.S. at 309, with a chemical structure distinct from any molecule found in the human body. Nor does the isolated BRCA DNA merely "serve the ends nature originally provided." *Funk Bros.*, 333 U.S. at 131. Instead, it has "markedly different characteristics" with "the potential for significant utility." *Chakrabarty*, 447 U.S. at 310. Indeed, petitioners themselves assert that isolated DNA has applications for research that genomic DNA does not. See Pet. Br. 9, 41. The isolated BRCA1 and BRCA2 genes also provide the basis for clinically useful diagnostic tools, such as probes and primers, that can detect mutations associated with a risk of breast and ovarian cancers and guide therapeutic responses. See pp. 8-9, *supra*. Those uses are related to the operation of the native BRCA1 and BRCA2 genes, but they are functionally distinct, having new medical applications that demonstrably improve survival rates and quality of life. See Schwartz *et al.*, *Long-Term Outcomes of BRCA1/BRCA2 Testing: Risk Reduction and Surveillance*, 118:2 Cancer 510, 516 (Jan. 15, 2012) ("the receipt of a positive BRCA1/2 test result is likely to have a favorable effect on long-term breast and ovarian cancer outcomes"). Unlike with the bacteria in *Funk Brothers*, the hugely beneficial applications of the isolated BRCA DNA would not exist "independently of any effort of the patentee," 333 U.S. at 131,

but are made possible solely through human intervention in the creation of a new, isolated DNA molecule that did not exist before. Isolated DNA is a "product of human ingenuity," with "different characteristics" from and the "potential for significant utility" beyond genomic DNA. *Chakrabarty*, 447 U.S. at 309, 310. Accordingly, it is patentable subject matter under Section 101.

II. Gene Patents Are Crucial To Developing Promising New Diagnostic Tools And Therapies

A. Gene Patents Are Necessary To Ensure Financial Incentives To Undertake Research and Development In Emerging Fields

Personalized medicine has the promise to revolutionize the healthcare industry. It uses genetic diagnostics to determine which treatments will work for certain patients—and which will not. But it is an extremely resource-intensive and risky field. The costs of bringing a single product to market are high, and failures numerically dwarf successes. Patent protections are critical to providing the necessary financial incentives for investment in this promising field.

1. Physicians, clinicians, and researchers have long recognized that people with the same disease often respond very differently to the same treatment. Traditional medicine relies on a trial-and-error approach to that problem, prescribing different courses of treatment until finding what works best for a particular patient. Personalized medicine, by contrast, identifies in advance the treatments that most likely will work for a particular patient and those that will not. It does so by using diagnostic tests to obtain information about molecular "biomarkers"—such as gene sequence variations, gene or protein expression levels, or metabolites—that are corre-

lated with particular disease characteristics. See Personalized Medicine Coalition, *The Case for Personalized Medicine* 2-4 (3d ed. 2011), available at http://www.personalizedmedicinecoalition.org/sites/default/files/files/Case_for_PM_3rd_edition.pdf ("*The Case for Personalized Medicine*"). Tests showing that a patient possesses particular biomarkers are used for diagnosis, prognosis, predicting the future risk of disease, or selecting treatment regimens particularly suited (and excluding regimens unsuited) to that patient. *Id.* at 4-7. Patients can receive an early diagnosis, followed by highly individualized treatment that maximizes efficacy while minimizing the potential for side effects and adverse reactions that would result from undesirable treatments. *Id.* at 4-6. Health care costs decline as well, as insurers avoid paying for tests and/or treatment regimens that later prove to be unnecessary. *Id.* at 7.

As with biotechnology generally, the research and development activities needed to make advances in personalized medicine are extremely costly.[4] The first task is to find associations between a biomarker and a disease or drug response. *The Case for Personalized Medicine* 9. A company must then design a test—isolating the appropriate DNA sequence and probe—to permit identifying the relevant biomarker in a fashion that is accurate, robust, and replicable. Clinical trials are required to demonstrate and validate the clinical utility of the association. See generally Staples *et al.*, *The Role of the Academic Medical Center in Advancing Personalized Health Care* 83 ("*Advancing Personalized Health Care*"), in HHS,

[4] In 2011, publicly traded companies in the United States invested more than $17 billion in biotechnology-related research and development. Ernst & Young, *Beyond Borders: Global Biotechnology Report 2012*, at 27 (2012).

Personalized Health Care (Nov. 2008). Bringing a single diagnostic product to market thus typically requires years of research and testing and tens of millions of dollars in investment—reaching over $100 million under certain circumstances. See *id.* at 84-85. If one adds the costs of the many, many more efforts that fail in development, fail to make it to market, or fail to succeed in the market, the costs become staggering: Only 30% of biological therapeutics that make it as far as human trials succeed, and many more never make it even that far. See, *e.g.*, Grabowski, *Follow-On Biologics*, 7 Nature Reviews Drug Discovery 479, 481 (2008). And still more therapeutics, even if technically successful, may never achieve commercial success. See, *e.g.*, Human Genetics Comm'n, *Intellectual Property and DNA Diagnostics: A Report of a Seminar on the Impact of DNA Patents on Diagnostic Innovation* 5-6 (Oct. 2010), available at http://www.institutoroche.es/web/pdf/2011/humangeneticscommision.pdf ("*Intellectual Property and DNA Diagnostics*"); *Advancing Personalized Health Care* 85.

Regulatory burdens—although often necessary—further increase costs. The FDA, for example, is increasingly requiring that diagnostic products going through the premarket approval process satisfy the same clinical and premarket criteria as those usually reserved for pharmaceuticals and medical devices. See Food and Drug Administration ("FDA"), *Draft Guidance for Industry and Food and Drug Administration Staff—In Vitro Companion Diagnostic Devices* 8-10 (July 14, 2011) ("FDA, *Draft Guidance*"); Press Release, FDA, *FDA To Host Public Meeting on Oversight of Laboratory-Developed Tests* (June 16, 2010), available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm215766.htm. Moreover, insurance companies, which

pay the vast majority of health care dollars, often demand validating data before approving a test for reimbursement. See Nat'l Ctr. for Health Statistics, *Health, United States, 2011: With Special Feature on Death and Dying* 8 (2012), available at http://www.cdc.gov/nchs/data/hus/hus11.pdf. These further barriers increase costs dramatically. See *Intellectual Property and DNA Diagnostics* 5-6.

At the end of the day, the rewards for successfully running the research and regulatory gauntlets are not especially rich. Diagnostic products generally offer a very low rate of return on investment, particularly in light of the staggering amounts required for their development. See *Personalized Health Care* 83-85; see generally Kling, *Diagnosis or Drug? Will Pharmaceutical Companies or Diagnostics Manufacturers Earn More from Personalized Medicine?*, 8 EMBO Rep. 903 (2007).

2. Given those substantial costs, the high risk of failure, and the modest financial return, patents are critical to promising investors the realistic possibility of a reasonable financial return from diagnostic products. In a recent report on the subject, the President's Council of Advisors on Science and Technology concluded:

> The ability to obtain strong intellectual property protection through patents has been, and will continue to be, essential for pharmaceutical and biotechnology companies to make the large, high-risk R&D investments required to develop novel medical products, including genomics-based molecular diagnostics.

President's Council of Advisors on Science and Technology, *Priorities for Personalized Medicine* 21 (2008).

Indeed, there appears to be broad consensus among regulators, industry participants, and legal commentators that patent protections are vital "to incentivize the significant investment required" for clinical research in the area of personalized medicine. Toneguzzo, *Impact of Gene Patents on the Development of Molecular Diagnostics*, 5 Expert Op. Med. Diag. 273, 275 (2011).[5] As the Federal Circuit explained below, these are the very types of investments the patent laws are intended to promote and protect: "Patents on life-saving material and processes, involving large amounts of risky investment, would seem to be precisely the types of subject matter that should be subject to the incentives of exclusive rights." Pet. App. 44a.

Petitioners thus are mistaken to suggest that, once a clinically useful genetic test has been invented and its workings publicly disclosed, society would benefit more if the invention were left unpatented and free for all to use. See, *e.g.*, Pet. Br. 8 (asserting that, but for Myriad's patents, third parties could offer BRCA testing for free); *id.* at 45 (asserting that, but for Myriad's patents, third parties could offer BRCA testing at a lower price than Myr-

---

[5] See Nat'l Research Council, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* 20, 25 (Merrill & Mazza eds., 2006) ("intellectual property protection is essential to * * * enable firms to garner the sustained investments needed for diagnostic and drug development and testing"); Paci *et al.*, *Impact of DNA Patents on Pharmacogenomics Research and Development: Economic and Policy Issues*, 71 Drug Dev. Res. 485, 490 (2010) (patent protections "can stimulate private investments in an underexploited field with great potential for innovation and public health"); Sung, *Alarming Challenges Facing Medical Technology Innovation*, 6 J. Bus. & Tech. L. 35, 55-56 (2011) ("Tinkering with patent eligibility * * * may bring unforeseeable consequences, including the unfortunate chilling of future innovation.").

iad). That approach begins by assuming the elephant—it starts by positing that the invention would exist even if patent protection were unavailable. In the biotechnology field, that rarely would be true. Absent the limited period of exclusivity afforded by patents, private actors could not justify the investment required to invent new genomics-based diagnostic tools. Fewer genetic tests would be available at any price.

B. Patents Promote Innovation And Socially Beneficial Cooperation

Patents do more than create incentives for innovation. By requiring inventors to disclose genetic inventions and enable their use in public filings, patents advance the state of human knowledge, spurring still further innovation. Moreover, because patents offer protection for intellectual property despite (indeed, because of) disclosure, patents also facilitate the collaboration among entities, including potential competitors, necessary to get life-saving products to market.

1. A patent represents "a carefully crafted bargain" in which the patentee is granted "an exclusive monopoly for a limited period of time" in exchange for "the public disclosure" of a new invention. *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). The inventor must describe the advance in detail and provide enough information to enable others to practice it themselves. 35 U.S.C. § 112. The inventor also must "set forth the best mode contemplated by the inventor * * * of carrying out the invention." *Id.* § 112(a).

That bargained-for disclosure accelerates innovation at the same time that it protects the patentee's investment in the invention. Requiring full disclosure does not merely ensure that the public will be able to freely use the invention immediately upon the patent's expiration.

It also allows other inventors to build on the work of those who have gone before them. See *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945). The disclosures required by our patent system thus allow everyone to stand on the shoulders of giants (as well as lesser innovators). The USPTO reports that "roughly 90 percent of all pending patent applications are published at eighteen months." FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* 26 (Oct. 2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf. Companies utilize that knowledge base to develop further advances that build on the patented technology. See Toneguzzo, 5 Expert Op. Med. Diag. at 275 ("the evidence shows that patents do not inhibit research leading to new discoveries and, in fact, may in some cases stimulate it through the disclosure of innovations").

The requirements that patents contain a detailed description of the invention, enable others to practice the invention, and set forth the best mode of implementing it, make patents particularly powerful tools for the advancement of knowledge. Those seeking to understand the invention do not need to re-invent a hidden or omitted step or detail. Nor do those who seek to understand the optimal implementation of the invention need to waste time and effort reverse-engineering the product or trying to cobble it together using disparate, incomplete sources of public information, such as academic articles.

2. Strong patent protection also permits the establishment of cooperative arrangements necessary to bring life-saving products promptly to market—arrangements that might otherwise prove impossible. For example, the first semi-synthetic penicillins like ampicillin—critical to overcoming staphylococci resistant to biological penicil-

lins—owed their development and their prompt availability to strong patent protection. See Taylor & Silbertson, *The Economic Impact of the Patent System* 258-259 (1973). Developed by a British company, ampicillin held life-saving potential for numerous applications. But the innovator lacked experience in large-scale pharmaceutical manufacturing. It therefore partnered with a more experienced American pharmaceutical company to develop manufacturing techniques, exchanging information and licenses. *Id.* at 258. "[H]ad effective sole patent protection been unavailable in the U.S.A.," however, "it would have been extremely difficult to persuade [the American manufacturing expert] to divulge its manufacturing know-how" in return for distribution rights, delaying or even imperiling the life-saving antibiotic's global distribution. *Id.* at 259.

Today, the field of "companion diagnostics" provides a similar example of how patent protection fosters life-saving cooperation. Through companion diagnostics, personalized medicine utilizes genetic testing to identify from the outset which treatments will benefit a patient and which will not. See FDA, *Draft Guidance* 6-7. Companion diagnostics thus permits treatments that are custom-tailored to a patient's unique genetic profile, preventing the needless suffering and wasteful spending that results when a patient tries drug regimens that do not work for her.

The development and commercialization of companion diagnostics, however, requires collaboration, including the sharing of clinical samples, data, and other information among various industry participants. For example, Roche and Abbott Laboratories together made one of the first significant advances in this area, leveraging the power of a companion diagnostic in connection with Her-

ceptin® (trastuzumab). *See* PricewaterhouseCoopers LLP, *The New Science of Personalized Medicine: Translating the Promise into Practice* 7 (Oct. 2009). Herceptin® is a drug developed by Roche's affiliate Genentech, Inc., to treat a particularly aggressive form of breast cancer. Although only a small portion of those suffering from breast cancer will benefit from Herceptin®, for that subpopulation the drug is extraordinarily effective, increasing survival periods by an average of 25%. It is also highly effective in lowering the risk that early-stage breast cancer will return. *Ibid.*

Because of personalized medicine, Herceptin® treatment can now be targeted to the subset of the population for whom it has that life-saving and life-extending potential. Abbott developed and commercialized the first diagnostic test to identify those patients who exhibit overexpression of a protein known as human epidermal growth factor receptor type 2 ("HER-2") due to a genetic anomaly. That overexpression of the HER-2 protein is associated with certain particularly aggressive cancers. Most importantly, it also predicts whether the patient will have a dramatic response to treatment with Herceptin®. Thus, HER-2 companion diagnostics not only identifies patients who will respond to Herceptin®, it also helps identify patients who will not, avoiding the costs and life-threatening delays associated with unnecessary Herceptin® treatment. See Hillner & Smith, *Do the Large Benefits Justify the Large Costs of Adjuvant Breast Cancer Trastuzumab?*, 25 J. Clinical Oncology 611, 612 (2007); see generally Dendukuri *et al.*, *Testing for HER2-positive Breast Cancer: A Systematic Review and Cost-Effectiveness Analysis*, 176 Can. Med. Ass'n J. 1429 (2007). Herceptin® and its companion diagnostic tests for HER-2 have had a major impact in the treat-

ment of cancer, including metastatic breast cancer. See Tan & Swain, *Ongoing Adjuvant Trials with Trastuzumab in Breast Cancer*, 30 Seminars in Oncology 54, 54 (2002). The development of companion diagnostics for Herceptin® thus illustrates the success of personalized medicine and the promise it holds for the future of the health-care industry.

Absent patent protection, some companies might resist the kinds of collaboration that enable such advances in companion diagnostics for fear that competitors will appropriate their technology without compensation and undercut them in the market because the competitors do not have the same research and development costs to recoup. The disclosures and exchange of information underpinning industrial cooperation and the development of collaborative technologies such as companion diagnostics would be squelched.

3. Patents also permit universities and nonprofit research institutions to maximize their impact on public health through partnerships with private industry.

Such partnerships have proven critical in the fight against cystic fibrosis, a genetic disorder that afflicts approximately 30,000 Americans. The University of Michigan, Johns Hopkins, and the Hospital for Sick Children in Toronto, Canada all hold patents covering DNA sequences relating to and methods of detecting mutations of the *CFTR* gene, which causes cystic fibrosis. Chandrasekharan *et al.*, *Impact of Gene Patents and Licensing Practices on Access to Testing for Cystic Fibrosis* 5-6 (2010) ("*Cystic Fibrosis Study*"), in Secretary's Advisory Comm. on Genetics, Health, & Soc'y, HHS, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (2010) ("SACGHS Report"). By granting non-exclusive licenses for their patents, they

spawned a multitude of diagnostic kits for cystic fibrosis: Luminex has created and received FDA approval for its Tag-It cystic fibrosis diagnostic kit, which tests for 39 mutations and 4 variants of the *CFTR* gene. *Id.* at 7-8. And several other manufacturers have "prepar[ed] FDA approved diagnostic tests to compete in the CF testing and screening markets," including Nanogen and Third Wave (subsequently acquired by Hologic). *Ibid.*

None of those tests would have been possible absent the patented discoveries licensed to the companies by the University of Michigan, Johns Hopkins, and the Hospital for Sick Children. The cystic fibrosis example thus illustrates how "patenting and licensing decisions" may "allow for significant research" of a gene and its mutations "without unduly hindering patient access or commercial markets. These practices also preserve strong patent protection and the accompanying investment incentives for possible therapeutic discoveries arising from the same DNA patents." *Cystic Fibrosis Study* 21.

The experience of the Wisconsin Alumni Research Foundation ("WARF") is similar. WARF has developed a program to license its patents broadly on a non-exclusive basis. WARF, *Licensing Process*, http://www.warf.org/industry/index.jsp?cid=1. It seeks out partnerships with any company that:

- "sees the likely commercial benefit to itself of one of WARF's technologies developed at the [University of Wisconsin]-Madison";
- "has the capability to develop early-stage technology (typical of university research) and is willing to make a reasonable effort to commercialize it";

- "is able to demonstrate its serious intent by paying a reasonable licensing fee and reimbursing patent costs associated with the technology"; and
- "is willing to share some of the benefits of the commercial use of the technology with WARF and the UW-Madison through payment of a reasonable royalty on product sales."

Ibid. WARF "shares in the development risk by requiring a reasonable license fee and a royalty that is received only after a product or process is being sold or otherwise used." *Ibid.* WARF's broad licensing practices generate significant revenue—over $54 million in 2008 alone. *Licensing Revenue 2008*, OnWisconsin Magazine, http://onwisconsin.uwalumni.com/departments/licensing-revenue-2008. But WARF benefits in other ways as well, attracting "additional 'margin of excellence' research funding to the UW-Madison," and knowing that "the inventions of the UW-Madison faculty" will be put "to work for the maximum benefit of society." WARF, *Licensing Process*, http://www.warf.org/industry/index.jsp?cid=1.

For example, a WARF subsidiary (WiCell Research Institute) broadly licenses its stem cell lines, fulfilling over 900 stem cell licenses since 1999 and shipping stem cells to more than 500 researchers around the world. WARF News, *United States Patent And Trademark Office Upholds Key WARF Stem Cell Patent* (Feb. 28, 2008), http://www.warf.org/news/news.jsp?news_id=224. Those licenses have allowed pharmaceutical companies, research entities, and universities to rely on stem cell technology to devise new ranges of therapies that would otherwise be inaccessible to the public.

WARF's non-exclusive licensing practices have also spawned numerous start-ups to commercialize UW-

Madison's patents. In the field of genetic research alone, those start-ups include LifeGen Technologies LLC (acquired by Nu Skin Enterprises Inc.), Mirus Bio LLC (acquired by Roche), NimbleGen Inc. (also acquired by Roche), and Third Wave Technologies (acquired by Hologic). WARF, *WARF Startups*, http://www.warf.org/startups/index.jsp?cid=44. WARF's experience is yet more proof that, far from hindering innovation in the field of genetics, patents actually spur innovation and benefit the public.

III. PETITIONERS' AND THEIR *AMICI*'S POLICY ARGUMENTS ARE MISPLACED

Petitioners and *amici* assert a host of policy-based arguments that, they contend, counsel against finding isolated DNA to be patentable subject matter under Section 101. They assert that patents on isolated DNA stymie further research and innovation on the genes at issue. See, *e.g.*, Pet Br. 42. They complain that patents on isolated DNA grant patentees rights in applications of the DNA beyond those disclosed in the patent. See *id.* at 41; Br. of AARP 7-8; Br. of Prof. Eileen M. Kane 25. And they claim that isolated DNA patents restrict patient access to life-saving genetic diagnostic tests. *Ibid.* These arguments are overblown as a doctrinal matter—well settled patent-law principles beyond Section 101 already directly address each of those purported concerns. It is thus not surprising that those concerns are also belied by the empirical evidence. The PTO has been issuing patents on isolated DNA for over 30 years, yet there is scant evidence that the problems about which petitioners and *amici* warn have materialized. This Court should not distort the Section 101 analysis in the name of solving problems that do not exist.

A. Requirements Other Than Subject Matter Patentability Appropriately Limit The Scope And Preemptive Effect Of Gene Patents

Petitioners invoke patent policy in support of narrowing the scope of patentable subject matter under Section 101. "The § 101 patent-eligibility inquiry," however, "is only a threshold test" in patentability analysis. *Bilski*, 130 S. Ct. at 3225. That limited test should not be treated as a panacea for all concerns relating to the scope and preemptive reach of isolated DNA patents. Other well settled patent law doctrines already address the issues petitioners raise, properly balancing the interests this Nation's patent laws seek to protect.

The Hatch-Waxman Act Safe Harbor. Petitioners contend that Myriad's patent on isolated DNA gives it "the authority to prevent all study" of "the two human genes," *i.e.*, native BRCA1 and BRCA2. Pet. Br. 42. But Myriad has no such "authority." As a scientific matter, isolating DNA is not "a necessary step" in researching native genes. *Id.* at 41. A variety of non-infringing technologies are available to study DNA or detect genetic mutations without isolation. See Resp. Br. 47. And petitioners are also incorrect as a legal matter. In the Hatch-Waxman Act, Congress specifically carved out a safe harbor from infringement for research and other activities "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). The exemption provides "wide berth for the use of patented drugs [and other inventions] in activities related to the federal regulatory process." *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). Congress thus specifically authorized companies to conduct research to develop new

products that might otherwise infringe a patent, and pursue federal regulatory approval of those products, during the patent's exclusivity period so that they may be ready to begin commercial sale as soon as the patent expires. See H.R. Rep. No. 98-857, at 45-46 (1984).

Written Description. Nor can proper patents for isolated DNA "undermine the patent system" by giving the patentee "the right to any applications of isolated DNA without disclosing them." Pet. Br. 41. Section 112's written description requirement prohibits just that. Section 112 requires that the specification contain a "written description of the invention * * * in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the same." 35 U.S.C. § 112(a). That requirement ensures (among other things) that patentees adequately describe their inventions in the patent's specification in exchange for the right to exclude others from practicing the invention. See *Bonito Boats, Inc.* v. *Thunder Craft Boats Inc.*, 489 U.S. 141, 150 (1989) ("The applicant * * * who is willing to reveal to the public the substance of his discovery * * * is granted 'the right to exclude others from making, using or selling the invention throughout the United States'" for a certain period.). It thus enshrines a "delicate balance" between the benefit to the public of the invention's disclosure, and the interest of the inventor in protecting the invention. *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002).

Petitioners insinuate (at 41) that Myriad's claims exceed what the inventors had discovered when they filed their patent application. The written description requirement prevents such overreaching claims. The very "purpose of the written description requirement is to prevent an applicant from later asserting that he in-

vented that which he did not; the applicant for a patent is therefore required to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Amgen Inc.* v. *Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). A patentee has no claim for infringement on an invention that is not disclosed.

Enablement. Petitioners contend (at 41) that isolated DNA patents improperly grant exclusive rights over all uses of a gene, "including future uses not yet * * * technically achievable." But that argument is foreclosed by Section 112's "enablement" requirement. Under it, the specification must describe the invention in sufficient detail to enable a person skilled in the art "to make and use the full scope of the claimed invention without undue experimentation." *Genentech, Inc.* v. *Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir.) (quotation marks omitted), cert. denied, 522 U.S. 963 (1997); see also *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261, 271 (1916). In evaluating enablement, courts look to the breadth of the claims and the existence of working examples at the time of filing the patent application. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The specification must enable the use of the *full scope* of the claims. *MagSil Corp.* v. *Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012). If a patentee attempted to extend its claims to forms or applications of isolated DNA that were not "technically achievable" at the time of the application, those claims could be invalidated on enablement grounds. Petitioners' concerns are therefore addressed by existing patent law.[6]

---

[6] That is not to suggest that Section 112 (or other provisions of the Patent Act) may "substitute" for the patentable-subject-matter inquiry under Section 101. *Mayo Collaborative Servs.* v. *Prometheus*

B. Empirical Evidence Shows That Gene Patents Do Not Impede Research Or Patient Access To Genetic Testing

Historical experience likewise contradicts petitioners' and their *amici*'s claim that, unless the Court restricts Section 101's scope to exclude isolated DNA from patent-eligibility, patentees will impede scientific progress by preventing study of related genomic material, Pet. Br. 42, and restrict patient access to genetic testing, see, *e.g.*, Br. of AARP 7-8; Br. of Prof. Eileen M. Kane 25. Indeed, while petitioners and their *amici* rely heavily on the 2010 SACGHS Report to support their argument that genetic patents impede scientific research and patient access, the empirical case studies underlying the report refute those assertions.

1. Notwithstanding petitioners' and their *amici*'s repeated invocation of the SACGHS Report, *e.g.*, Pet. Br. 42-43, 44; Br. of Int'l Ctr. for Tech. Assessment, *et al.* 17, the studies underlying the SACGHS Report refute their claims. While the SACGHS Report voiced concern that patents *theoretically* could restrict genetic research and development, it conceded that, in reality, the "empirical research suggest[s] that research is not hampered" by patents. SACGHS Report 88. Indeed, the case studies on which the SACGHS Report purports to base its recommendations repeatedly conclude that patents have *not* inhibited follow-on research:

- "Concerns regarding inhibition of research due to the *HFE* gene patents do not seem to be sup-

---

Labs., Inc., 132 S. Ct. 1289, 1304 (2012). No provision of the Patent Act, alone or in concert with any other doctrine, justifies the issuance of a patent over a composition of matter that is not a product of human innovation. But isolated DNA clears that threshold requirement. See pp. 5-12, *supra*.

ported. Substantial basic research, including identification of genes and mutations associated with other types of hemochromatosis has continued. Similarly, research on improved methods for detection of *HFE* mutations has also progressed." Chandrasekharan *et al.*, *Impact of Patents and Licensing Practices on Access to Genetic Testing for Hereditary Hemochromatosis* 3 (2009) ("*Hemochromatosis Study*") (SACGHS Report at app. A, pt. E).

- "We have not found any evidence that CF gene patents impeded subsequent basic or clinical research." *Cystic Fibrosis Study* 20.
- "There is no evidence that patents have had a positive or negative impact on hearing loss genetics research." Chandrasekharan & Fiffer, *Impact of Patents and Licensing Practices on Access to Genetic Testing for Hearing Loss* 4 (2009) ("*Hearing Loss Study*") (SACGHS Report at app. A, pt. D).
- "[W]e have no evidence that the virtual LQTS monopoly from 2003-2008 has had any stifling effect on research * * *." Angrist *et al.*, *Impact of Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome* 24 (2009) ("*LQTS Study*") (SACGHS Report at app. A, pt. F).
- "[No] evidence of a chilling effect in the basic science arena for either FAP or HNPCC." Cook-Deegan *et al.*, *Impact of Patents and Licensing on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancer* 27 (2009) ("*Breast, Ovar-*

ian, and Colon Cancers Study") (SACGHS Report at app. A, pt. A).

- "[N]ot f[inding] patents to be a significant impediment to research on [Alzheimer's Disease.]" Skeehan *et al.*, *Impact of Patents and Licensing Practices on Access To Genetic Testing for Alzheimer's Disease* 14 (2009) ("*Alzheimer's Study*") (SACGHS Report at app. A, pt. B).

- "It is clear that the Tay-Sachs gene patent did not stifle research as it was never enforced. * * * [T]hough the Canavan patent could in theory have impeded research until 2003, it does not anymore." Colaianni *et al.*, *Impact of Patents and Licensing Practices on Access to Genetic Testing and Carrier Screening for Tay-Sachs and Canavan Disease* 14 (2009) ("*Tay-Sachs and Canavan Study*") (SACGHS Report at app. A, pt. H).

A committee of Australia's Senate specifically studied Myriad's patent and licensing practices for BRCA1 and BRCA2 in that country and concluded that "patents over human genes and biological materials have not hindered research, particularly medical research, in Australia." Legal and Constitutional Affairs Legislation Comm., *Report on Patent Amendment (Human Genes and Biological Materials) Bill* 62 (2011), available at http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=legcon_ctte/completed_inquiries/2010-13/patent_amendment/report/report.pdf.[7] To the contrary,

[7] The assertion that Myriad's BRCA1/2 patents stifle study of those portions of the human genome is further belied by the number of published academic studies on BRCA1/2 during the life of Myriad's patents. Petitioners and their *amici* cite more than a dozen.

the report found, "patents have encouraged and contributed to research and development activities" because "[p]atents allow researchers to attract investment to pursue the development of new inventions and allow companies to mitigate the risk associated with developing costly new products." *Ibid.*[8]

Numerous other studies focused on the effect of gene patents have reached similar conclusions: "[T]he evidence shows that patents do not inhibit research leading to new discoveries and, in fact, may in some cases stimulate it through the disclosure of innovations." Toneguzzo, 5 Expert Op. Med. Diag. at 275; see generally Caulfield, *Human Gene Patents: Proof of Problems?* 84 Chi.-Kent L. Rev. 133, 135-139 (2009) (reviewing numerous studies and finding no evidence of constraints on research). A 2005 survey of scientists involved in biomedical research likewise found that "patenting does not seem to limit research activity significantly, particularly among those doing basic research." Walsh *et al.*, *Patents, Material Transfers and Access to Research Inputs in Biomedical Research* 3 (Sept. 20, 2005) ("Walsh, *Patents & Access*"); see also Walsh *et al.*, *View From the Bench*, 309 Science 2002 (2005). And an earlier study found that patents "rarely precluded the pursuit of worthwhile projects." Walsh *et al.*, *Working Through the Patent Problem*, 299 Science 1021, 1021 (2003). When requested, licenses were often available at minimal or no cost. Walsh, *Patents & Access* 17. "Thus, not only are barriers or delays rare, but costs of access for research purposes are negligible." *Ibid.*

---

[8] The Federal Court of Australia recently upheld the validity of Myriad's BRCA1 and BRCA2 patents in that country. *Cancer Voices Australia* v. *Myriad Genetics, Inc.* [2013] FCA 65 (Austl.).

2. Nor does the SACGHS Report support the contention, Br. of AARP 7-8; Br. of Prof. Eileen M. Kane 25, that gene patents prevent patients from accessing genetic testing. A passage cited by the AARP does suggest that some patients seeking BRCA testing have been unable to do so due to "Myriad's decision not to accept particular insurers." SACGHS Report 43. But the only relevant "evidence" cited by the Report for that assertion are *allegations in the complaint in this case.* See *id.* at 43 & n.118, 44 & n.120. Allegations in a complaint are not evidence; and the Report cites nothing more to support any such assertions.

Meanwhile, the rigorously documented case study on BRCA testing attached to the SACGHS Report sharply undercuts any suggestion that it was Myriad's patents that impeded patient access. Instead, any problems appear to have resulted from the insurance industry's failure to respond to medical progress with sufficient alacrity:

- "[C]overage and reimbursement practices of insurers and other payers are crucial. *** [I]nsurance companies are slow to respond to claims for genetic tests *** ." *Breast, Ovarian, and Colon Cancers Study* 31.
- As of late 1995—the year that Myriad filed applications for the patents at issue here—"only 4% of insurance providers *** had granted coverage of BRCA testing." *Id.* at 37. But, by 2008, "Myriad ha[d] established contracts or payment agreements with over 300 carriers and ha[d] received reimbursement from over 2500 health plans." *Id.* at 32.

- Insurers now cover "roughly 95% of those requesting tests, and reimburse[ ] to cover 90% of their charges." *Id.* at 37.

The facts gathered in the case study refute *amici*'s counter-intuitive charge that Myriad would refuse insurance dollars and sabotage widespread utilization of BRCA testing in the process.

Even beyond the BRCA-specific case study, the SACGHS Report refuted efforts to blame patient-access problems on patent protection. It found no evidence of access issues being caused by patents (as opposed to insurance coverage), even where patents are exclusively licensed. And it observed that "the case studies generally found that for patented tests that were broadly licensed"—a common industry practice favored by most major innovators—"there was *no evidence* of patient access problems." SACGHS Report 42 (emphasis added). Indeed, the SACGHS-commissioned study on cystic fibrosis found "no evidence that patents have significantly hindered access to genetic tests." *Cystic Fibrosis Study* 2. Another study found that "[p]atents do not appear to have significantly impeded patient or clinical access for hearing loss genetic testing." *Hearing Loss Study* 26. And the study on genetic testing for hemochromatosis found that "testing is widely available from multiple sources," and that there is "little evidence bearing on the impact of patents on consumer utilization." *Hemochromatosis Study* 4, 5.[9]

---

[9] Indeed, the SACGHS Report identifies only *one potential* example of exclusively licensed patents restricting patient access—LQTS testing. There, based on evidence that was "acknowledg[ed]" to be "incomplete," SACGHS Report 42, a study concluded that "access problems *may* have occurred * * * during an 18-month period due to patent enforcement," "*if* there were patients seeking the test at that

Alarmist rhetoric should not obscure the empirical evidence. For 30-plus years, the PTO has granted patents on isolated DNA. See Pet. App. 61a. But the parade of horribles petitioners and their *amici* posit has not come to pass. Narrowing Section 101's scope to exclude man-made isolated DNA, by contrast, would threaten investment and medical progress at this critical juncture. This Court has previously made clear that it "is without competence to entertain" policy-based pleas to limit the scope of Section 101: "Whatever their validity, the contentions now pressed on [the Court] should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts." *Chakrabarty*, 447 U.S. at 317. Because isolated DNA meets the requirements for patentable subject matter, it should be patentable. Petitioners' theory that gene patents are too important or too basic a building block to be patented is, at this late date, better addressed to the political branches.

CONCLUSION

The judgment of the Federal Circuit should be affirmed.

---

time," but "[w]hether there were such patients is not documented," *id.* at 44 (emphases added). The one example the SACGHS Report could muster—"incomplete" evidence showing patients "may" have had access problems "if" any patients existed at all—does not establish that even exclusive licensing of patents has restricted patient access, much less caused a significant problem or actual health effects.

Respectfully submitted.

JEFFREY A. LAMKEN
Counsel of Record
MICHAEL G. PATTILLO, JR.
MOLOLAMKEN LLP
The Watergate, Suite 660
600 New Hampshire Ave., NW
Washington, D.C. 20037
(202) 556-2000
jlamken@mololamken.com

DAVID JANG
MOLOLAMKEN LLP
540 Madison Ave.
New York, NY 10022

Counsel for Amicus Curiae
The Coalition for 21st Century
Medicine

MARCH 2013