Syllabus

ASSOCIATION FOR MOLECULAR PATHOLOGY ET AL. *v.* MYRIAD GENETICS, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 12–398. Argued April 15, 2013—Decided June 13, 2013

Each human gene is encoded as deoxyribonucleic acid (DNA), which takes the shape of a "double helix." Each "cross-bar" in that helix consists of two chemically joined nucleotides. Sequences of DNA nucleotides contain the information necessary to create strings of amino acids used to build proteins in the body. The nucleotides that code for amino acids are "exons," and those that do not are "introns." Scientists can extract DNA from cells to isolate specific segments for study. They can also synthetically create exons-only strands of nucleotides known as complementary DNA (cDNA). cDNA contains only the exons that occur in DNA, omitting the intervening introns.

Respondent Myriad Genetics, Inc. (Myriad), obtained several patents after discovering the precise location and sequence of the BRCA1 and BRCA2 genes, mutations of which can dramatically increase the risk of breast and ovarian cancer. This knowledge allowed Myriad to determine the genes' typical nucleotide sequence, which, in turn, enabled it to develop medical tests useful for detecting mutations in these genes in a particular patient to assess the patient's cancer risk. If valid, Myriad's patents would give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes, and would give Myriad the exclusive right to synthetically create BRCA cDNA. Petitioners filed suit, seeking a declaration that Myriad's patents are invalid under 35 U. S. C. § 101. As relevant here, the District Court granted summary judgment to petitioners, concluding that Myriad's claims were invalid because they covered products of nature. The Federal Circuit initially reversed, but on remand in light of *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U. S. 66, the Circuit found both isolated DNA and cDNA patent eligible.

Held: A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring. Pp. 589–596.

(a) The Patent Act permits patents to be issued to "[w]hoever invents or discovers any new and useful . . . composition of matter," § 101, but "laws of nature, natural phenomena, and abstract ideas" "'are basic tools of scientific and technological work'" that lie beyond the domain of pat-

ent protection, *Mayo*, 566 U. S., at 70, 71. The rule against patents on naturally occurring things has limits, however. Patent protection strikes a delicate balance between creating "incentives that lead to creation, invention, and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention." *Id.*, at 92. This standard is used to determine whether Myriad's patents claim a "new and useful . . . composition of matter," § 101, or claim naturally occurring phenomena. Pp. 589–590.

(b) Myriad's DNA claim falls within the law of nature exception. Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes. *Diamond* v. *Chakrabarty*, 447 U. S. 303, is central to the patent-eligibility inquiry whether such action was new "with markedly different characteristics from any found in nature," *id.*, at 310. Myriad did not create or alter either the genetic information encoded in the BRCA1 and BRCA2 genes or the genetic structure of the DNA. It found an important and useful gene, but groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry. See *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.*, 333 U. S. 127. Finding the location of the BRCA1 and BRCA2 genes does not render the genes patent-eligible "new . . . composition[s] of matter," § 101. Myriad's patent descriptions highlight the problem with its claims: They detail the extensive process of discovery, but extensive effort alone is insufficient to satisfy § 101's demands. Myriad's claims are not saved by the fact that isolating DNA from the human genome severs the chemical bonds that bind gene molecules together. The claims are not expressed in terms of chemical composition, nor do they rely on the chemical changes resulting from the isolation of a particular DNA section. Instead, they focus on the genetic information encoded in the BRCA1 and BRCA2 genes. Finally, Myriad argues that the Patent and Trademark Office's (PTO) past practice of awarding gene patents is entitled to deference, citing *J. E. M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U. S. 124, a case where Congress had endorsed a PTO practice in subsequent legislation. There has been no such endorsement here, and the United States argued in the Federal Circuit and in this Court that isolated DNA was not patent eligible under § 101. Pp. 590–594.

(c) cDNA is not a "product of nature," so it is patent eligible under § 101. cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. Its creation results in an exons-only molecule, which is not naturally occurring. Its order of the exons may be dictated by nature, but the lab technician unquestionably creates something new when introns are removed from a DNA sequence to make cDNA. Pp. 594–595.

(d) This case, it is important to note, does not involve method claims, patents on new applications of knowledge about the BRCA1 and BRCA2 genes, or the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Pp. 595–596.

689 F. 3d 1303, affirmed in part and reversed in part.

THOMAS, J., delivered the opinion of the Court, in which ROBERTS, C. J., and KENNEDY, GINSBURG, BREYER, ALITO, SOTOMAYOR, and KAGAN, JJ., joined, and in which SCALIA, J., joined in part. SCALIA, J., filed an opinion concurring in part and concurring in the judgment, *post*, p. 596.

Christopher A. Hansen argued the cause for petitioners. With him on the briefs were *Sandra S. Park*, *Steven R. Shapiro*, *Aden J. Fine*, *Lenora M. Lapidus*, and *Daniel B. Ravicher*.

Solicitor General Verrilli argued the cause for the United States as *amicus curiae* urging affirmance in part and reversal in part. With him on the brief were *Principal Deputy Assistant Attorney General Delery*, *Deputy Solicitor General Stewart*, *Deputy Assistant Attorney General Brinkmann*, *Ginger D. Anders*, *Scott R. McIntosh*, and *Mark R. Freeman*.

Gregory A. Castanias argued the cause for respondents. With him on the brief were *Jennifer L. Swize*, *Brian M. Poissant*, *Laura A. Coruzzi*, *Israel Sasha Mayergoyz*, *Dennis Murashko*, *Benjamin G. Jackson*, and *Matthew S. Gordon*.*

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*Briefs of *amici curiae* urging reversal were filed for the Canavan Foundation et al. by *John L. Hendricks*, *Megan M. O'Laughlin*, and *John T. Tower*; for GeneDx et al. by *Aaron X. Fellmeth*; for Genformatic LLC by *Earl Landers Vickery* and *Daniel Binford Weaver*; for Knowledge Ecology International by *Krista L. Cox*; for the International Center for Technology Assessment et al. by *George A. Kimbrell*; for the National Women's Health Network et al. by *Debra Greenfield*; for Eileen M. Kane, by *Ms. Kane*, *pro se*; and for Kali N. Murray et al. by *Ms. Murray*, *pro se*. *Sarah M. Shalf* filed a brief for the Ethics & Religious Liberty Commission of the Southern Baptist Convention et al. as *amici curiae* urging vacatur.

Briefs of *amici curiae* urging affirmance were filed for the American Bar Association by *Laurel G. Bellows*, *John P. Elwood*, and *Stephen C. Stout*;

JUSTICE THOMAS delivered the opinion of the Court.

Respondent Myriad Genetics, Inc. (Myriad), discovered the precise location and sequence of two human genes, muta-

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for the American Intellectual Property Law Association by *Barbara R. Rudolph*, *Robert D. Litowitz*, *Erika Harmon Arner*, *Robert C. Stanley*, and *Jeffrey I. D. Lewis*; for the Animal Health Institute et al. by *Judy Jarecki-Black*, *Frank G. Smith*, and *Matthew W. Howell*; for the Association of American Physicians & Surgeons, Inc., et al. by *David P. Felsher* and *Andrew L. Schlafly*; for the Biotechnology Industry Organization by *Seth P. Waxman* and *Nicole Ries Fox*; for the Coalition for 21st Century Medicine by *Jeffrey A. Lamken* and *Michael G. Pattillo, Jr.*; for CropLife International by *Evan A. Young*; for the Federal Circuit Bar Association by *Claire Laporte* and *Terence P. Stewart*; for Genentech, Inc., et al. by *Mr. Waxman*, *Ms. Fox*, *Kevin A. Marks*, *Blair Elizabeth Taylor*, and *D. Michael Young*; for Gilead Sciences, Inc., et al. by *J. Timothy Keane* and *Rudolph A. Telscher*; for Immatics Biotechnologies, GmbH, by *Kristine L. Roberts*; for InHouse Patent Counsel, LLC, by *Rochelle K. Seide*; for the Intellectual Property Owners Association by *Paul H. Berghoff*, *Richard F. Phillips*, and *Kevin H. Rhodes*; for the NanoBusiness Commercialization Association by *Andrew S. Baluch*, *Harold C. Wegner*, and *Stephen B. Maebius*; for the National Venture Capital Association by *Lynn H. Pasahow*, *Michael J. Shuster*, and *Carolyn Chang*; for the New York Intellectual Property Law Association by *Matthew B. McFarlane*, *Ronald M. Daignault*, *Charles R. Macedo*, *Thomas J. Kowalski*, *Robert M. Isackson*, and *David F. Ryan*; for the Pharmaceutical Research and Manufacturers of America by *Kurt G. Calia*, *Alexa R. Hansen*, *Robert A. Long, Jr.*, and *Natalie M. Derzko*; for the University of Baltimore/Johns Hopkins University Center for Medicine & Law et al. by *Bruce D. Abramson* and *Miles J. Zaremski*; for Larry Geier et al. by *Matthew S. Hellman* and *Joshua M. Segal*; and for Jeffrey A. Lefstin by *Kevin B. Laurence*.

Briefs of *amici curiae* were filed for AARP by *Barbara Jones* and *Michael Schuster*; for Academics in Law et al. by *Roy I. Liebman*; for the American Medical Association et al. by *Lori B. Andrews*; for the Boston Patent Law Association by *Erik Paul Belt* and *Frank Porcelli*; for CLS Bank International by *Mark A. Perry* and *Brian M. Buroker*; for Fédération Internationale des Conseils en Propriété Intellectuelle by *Maxim H. Waldbaum* and *Robert D. Katz*; for Fifteen Law Professors by *Joshua D. Sarnoff, pro se*; for the Institute of Professional Representatives Before the European Patent Office by *Mr. Liebman*; for the Intellectual Property Amicus Brief Clinic of the Franklin Pierce Center for Intellectual Property, University of New Hampshire School of Law, by *Ann M. McCrackin*;

tions of which can substantially increase the risks of breast and ovarian cancer. Myriad obtained a number of patents based upon its discovery. This case involves claims from three of them and requires us to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U. S. C. § 101 by virtue of its isolation from the rest of the human genome. We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins. For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring. We, therefore, affirm in part and reverse in part the decision of the United States Court of Appeals for the Federal Circuit.

I

A

Genes form the basis for hereditary traits in living organisms. See generally *Association for Molecular Pathology* v. *United States Patent and Trademark Office*, 702 F. Supp. 2d 181, 192–211 (SDNY 2010). The human genome consists of approximately 22,000 genes packed into 23 pairs of chromosomes. Each gene is encoded as DNA, which takes

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for InVitae Corp. by *William P. Atkins*; for the Juhasz Law Firm, P. C., by *Paul R. Juhasz*; for Lynch Syndrome International by *Gideon A. Schor*; for MPEG LA, LLC, by *Daryl L. Joseffer*, *Kenneth H. Sonnenfeld*, and *Lawrence A. Horn*; for the Philadelphia Intellectual Property Law Association by *Paul F. Prestia* and *Brian S. Seal*; for Sigram Schindler Beteiligungsgesellschaft mbH by *Chidambaram S. Iyer*; for Target Discovery, Inc., by *David S. Forman*, *Courtney B. Casp*, *Victoria S. Lee*, and *Amelia F. Baur*; for Ananda Mohan Chakrabarty by *Jonathan E. Singer* and *Craig E. Countryman*; for Eric S. Lander by *Gideon A. Schor*; and for James D. Watson by *Matthew J. Dowd* and *James Wallace.*

the shape of the familiar "double helix" that Doctors James Watson and Francis Crick first described in 1953. Each "cross-bar" in the DNA helix consists of two chemically joined nucleotides. The possible nucleotides are adenine (A), thymine (T), cytosine (C), and guanine (G), each of which binds naturally with another nucleotide: A pairs with T; C pairs with G. The nucleotide cross-bars are chemically connected to a sugar-phosphate backbone that forms the outside framework of the DNA helix. Sequences of DNA nucleotides contain the information necessary to create strings of amino acids, which in turn are used in the body to build proteins. Only some DNA nucleotides, however, code for amino acids; these nucleotides are known as "exons." Nucleotides that do not code for amino acids, in contrast, are known as "introns."

Creation of proteins from DNA involves two principal steps, known as transcription and translation. In transcription, the bonds between DNA nucleotides separate, and the DNA helix unwinds into two single strands. A single strand is used as a template to create a complementary ribonucleic acid (RNA) strand. The nucleotides on the DNA strand pair naturally with their counterparts, with the exception that RNA uses the nucleotide base uracil (U) instead of thymine (T). Transcription results in a single strand RNA molecule, known as pre-RNA, whose nucleotides form an inverse image of the DNA strand from which it was created. Pre-RNA still contains nucleotides corresponding to both the exons and introns in the DNA molecule. The pre-RNA is then naturally "spliced" by the physical removal of the introns. The resulting product is a strand of RNA that contains nucleotides corresponding only to the exons from the original DNA strand. The exons-only strand is known as messenger RNA (mRNA), which creates amino acids through translation. In translation, cellular structures known as ribosomes read each set of three nucleotides, known as codons, in the mRNA. Each codon either tells the

ribosomes which of the 20 possible amino acids to synthesize or provides a stop signal that ends amino acid production.

DNA's informational sequences and the processes that create mRNA, amino acids, and proteins occur naturally within cells. Scientists can, however, extract DNA from cells using well-known laboratory methods. These methods allow scientists to isolate specific segments of DNA—for instance, a particular gene or part of a gene—which can then be further studied, manipulated, or used. It is also possible to create DNA synthetically through processes similarly well known in the field of genetics. One such method begins with an mRNA molecule and uses the natural bonding properties of nucleotides to create a new, synthetic DNA molecule. The result is the inverse of the mRNA's inverse image of the original DNA, with one important distinction: Because the natural creation of mRNA involves splicing that removes introns, the synthetic DNA created from mRNA also contains only the exon sequences. This synthetic DNA created in the laboratory from mRNA is known as cDNA.

Changes in the genetic sequence are called mutations. Mutations can be as small as the alteration of a single nucleotide—a change affecting only one letter in the genetic code. Such small-scale changes can produce an entirely different amino acid or can end protein production altogether. Large changes, involving the deletion, rearrangement, or duplication of hundreds or even millions of nucleotides, can result in the elimination, misplacement, or duplication of entire genes. Some mutations are harmless, but others can cause disease or increase the risk of disease. As a result, the study of genetics can lead to valuable medical breakthroughs.

B

This case involves patents filed by Myriad after it made one such medical breakthrough. Myriad discovered the precise location and sequence of what are now known as the BRCA1 and BRCA2 genes. Mutations in these genes can

dramatically increase an individual's risk of developing breast and ovarian cancer. The average American woman has a 12- to 13-percent risk of developing breast cancer, but for women with certain genetic mutations, the risk can range between 50 and 80 percent for breast cancer and between 20 and 50 percent for ovarian cancer. Before Myriad's discovery of the BRCA1 and BRCA2 genes, scientists knew that heredity played a role in establishing a woman's risk of developing breast and ovarian cancer, but they did not know which genes were associated with those cancers.

Myriad identified the exact location of the BRCA1 and BRCA2 genes on chromosomes 17 and 13. Chromosome 17 has approximately 80 million nucleotides, and chromosome 13 has approximately 114 million. *Association for Molecular Pathology* v. *United States Patent and Trademark Office*, 689 F. 3d 1303, 1328 (CA Fed. 2012). Within those chromosomes, the BRCA1 and BRCA2 genes are each about 80,000 nucleotides long. If just exons are counted, the BRCA1 gene is only about 5,500 nucleotides long; for the BRCA2 gene, that number is about 10,200. *Ibid.* Knowledge of the location of the BRCA1 and BRCA2 genes allowed Myriad to determine their typical nucleotide sequence.[1] That information, in turn, enabled Myriad to develop medical tests that are useful for detecting mutations in a patient's BRCA1 and BRCA2 genes and thereby assessing whether the patient has an increased risk of cancer.

Once it found the location and sequence of the BRCA1 and BRCA2 genes, Myriad sought and obtained a number of patents. Nine composition claims from three of those patents are at issue in this case.[2] See *id.*, at 1309, and n. 1 (noting

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[1] Technically, there is no "typical" gene because nucleotide sequences vary between individuals, sometimes dramatically. Geneticists refer to the most common variations of genes as "wild types."

[2] At issue are claims 1, 2, 5, 6, and 7 of U. S. Patent 5,747,282 (the '282 patent), claim 1 of U. S. Patent 5,693,473 (the '473 patent), and claims 1, 6, and 7 of U. S. Patent 5,837,492 (the '492 patent).

composition claims). Claims 1, 2, 5, and 6 from the '282 patent are representative. The first claim asserts a patent on "[a]n isolated DNA coding for a BRCA1 polypeptide," which has "the amino acid sequence set forth in SEQ ID NO:2." App. 822. SEQ ID NO:2 sets forth a list of 1,863 amino acids that the typical BRCA1 gene encodes. See *id.*, at 785–790. Put differently, claim 1 asserts a patent claim on the DNA code that tells a cell to produce the string of BRCA1 amino acids listed in SEQ ID NO:2.

Claim 2 of the '282 patent operates similarly. It claims "[t]he isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1." *Id.*, at 822. Like SEQ ID NO:2, SEQ ID NO:1 sets forth a long list of data, in this instance the sequence of cDNA that codes for the BRCA1 amino acids listed in claim 1. Importantly, SEQ ID NO:1 lists only the cDNA exons in the BRCA1 gene, rather than a full DNA sequence containing both exons and introns. See *id.*, at 779 (stating that SEQ ID NO:1's "MOLECULE TYPE:" is "cDNA"). As a result, the Federal Circuit recognized that claim 2 asserts a patent on the cDNA nucleotide sequence listed in SEQ ID NO:1, which codes for the typical BRCA1 gene. 689 F. 3d, at 1326, n. 9; *id.*, at 1337 (Moore, J., concurring in part); *id.*, at 1356 (Bryson, J., concurring in part and dissenting in part).

Claim 5 of the '282 patent claims a subset of the data in claim 1. In particular, it claims "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 1." App. 822. The practical effect of claim 5 is to assert a patent on any series of 15 nucleotides that exist in the typical BRCA1 gene. Because the BRCA1 gene is thousands of nucleotides long, even BRCA1 genes with substantial mutations are likely to contain at least one segment of 15 nucleotides that correspond to the typical BRCA1 gene. Similarly, claim 6 of the '282 patent claims "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 2." *Ibid.* This claim oper-

ates similarly to claim 5, except that it references the cDNA-based claim 2. The remaining claims at issue are similar, though several list common mutations rather than typical BRCA1 and BRCA2 sequences. See *ibid.* (claim 7 of the '282 patent); *id.*, at 930 (claim 1 of the '473 patent); *id.*, at 1028 (claims 1, 6, and 7 of the '492 patent).

C

Myriad's patents would, if valid, give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual's genome. The patents would also give Myriad the exclusive right to synthetically create BRCA cDNA. In Myriad's view, manipulating BRCA DNA in either of these fashions triggers its "right to exclude others from making" its patented composition of matter under the Patent Act. 35 U. S. C. § 154(a)(1); see also § 271(a) ("[W]hoever without authority makes . . . any patented invention . . . infringes the patent").

But isolation is necessary to conduct genetic testing, and Myriad was not the only entity to offer BRCA testing after it discovered the genes. The University of Pennsylvania's Genetic Diagnostic Laboratory (GDL) and others provided genetic testing services to women. Petitioner Dr. Harry Ostrer, then a researcher at New York University School of Medicine, routinely sent his patients' DNA samples to GDL for testing. After learning of GDL's testing and Ostrer's activities, Myriad sent letters to them asserting that the genetic testing infringed Myriad's patents. App. 94–95 (Ostrer letter). In response, GDL agreed to stop testing and informed Ostrer that it would no longer accept patient samples. Myriad also filed patent infringement suits against other entities that performed BRCA testing, resulting in settlements in which the defendants agreed to cease all allegedly

infringing activity. 689 F. 3d, at 1315. Myriad, thus, solidified its position as the only entity providing BRCA testing.

Some years later, petitioner Ostrer, along with medical patients, advocacy groups, and other doctors, filed this lawsuit seeking a declaration that Myriad's patents are invalid under 35 U. S. C. § 101. 702 F. Supp. 2d, at 186. Citing this Court's decision in *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U. S. 118 (2007), the District Court denied Myriad's motion to dismiss for lack of standing. *Association for Molecular Pathology* v. *United States Patent and Trademark Office*, 669 F. Supp. 2d 365, 385–392 (SDNY 2009). The District Court then granted summary judgment to petitioners on the composition claims at issue in this case based on its conclusion that Myriad's claims, including claims related to cDNA, were invalid because they covered products of nature. 702 F. Supp. 2d, at 220–237. The Federal Circuit reversed, *Association for Molecular Pathology* v. *United States Patent and Trademark Office*, 653 F. 3d 1329 (2011), and this Court granted the petition for certiorari, vacated the judgment, and remanded the case in light of *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U. S. 66 (2012). See *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 566 U. S. 902 (2012).

On remand, the Federal Circuit affirmed the District Court in part and reversed in part, with each member of the panel writing separately. All three judges agreed that only petitioner Ostrer had standing. They reasoned that Myriad's actions against him and his stated ability and willingness to begin BRCA1 and BRCA2 testing if Myriad's patents were invalidated were sufficient for Article III standing. 689 F. 3d, at 1323; *id.*, at 1337 (opinion of Moore, J.); *id.*, at 1348 (opinion of Bryson, J.).

With respect to the merits, the court held that both isolated DNA and cDNA were patent eligible under § 101. The central dispute among the panel members was whether the

act of *isolating* DNA—separating a specific gene or sequence of nucleotides from the rest of the chromosome—is an inventive act that entitles the individual who first isolates it to a patent. Each of the judges on the panel had a different view on that question. Judges Lourie and Moore agreed that Myriad's claims were patent eligible under § 101 but disagreed on the rationale. Judge Lourie relied on the fact that the entire DNA molecule is held together by chemical bonds and that the covalent bonds at both ends of the segment must be severed in order to isolate segments of DNA. This process technically creates new molecules with unique chemical compositions. See *id.*, at 1328 ("Isolated DNA . . . is a free-standing portion of a larger, natural DNA molecule. Isolated DNA has been cleaved (*i. e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule"). Judge Lourie found this chemical alteration to be dispositive, because isolating a particular strand of DNA creates a nonnaturally occurring molecule, even though the chemical alteration does not change the information-transmitting quality of the DNA. See *id.*, at 1330 ("The claimed isolated DNA molecules are distinct from their natural existence as portions of larger entities, and their informational content is irrelevant to that fact. We recognize that biologists may think of molecules in terms of their uses, but genes are in fact materials having a chemical nature"). Accordingly, he rejected petitioners' argument that isolated DNA was ineligible for patent protection as a product of nature.

Judge Moore concurred in part but did not rely exclusively on Judge Lourie's conclusion that chemically breaking covalent bonds was sufficient to render isolated DNA patent eligible. *Id.*, at 1341 ("To the extent the majority rests its conclusion on the chemical differences between [naturally occurring] and isolated DNA (breaking the covalent bonds), I cannot agree that this is sufficient to hold that the claims

to human genes are directed to patentable subject matter"). Instead, Judge Moore also relied on the United States Patent and Trademark Office's (PTO) practice of granting such patents and on the reliance interests of patent holders. *Id.*, at 1343. However, she acknowledged that her vote might have come out differently if she "were deciding this case on a blank canvas." *Ibid.*

Finally, Judge Bryson concurred in part and dissented in part, concluding that isolated DNA is not patent eligible. As an initial matter, he emphasized that the breaking of chemical bonds was not dispositive: "[T]here is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken." *Id.*, at 1351. Instead, he relied on the fact that "[t]he nucleotide sequences of the claimed molecules are the same as the nucleotide sequences found in naturally occurring human genes." *Id.*, at 1355. Judge Bryson then concluded that genetic "structural similarity dwarfs the significance of the structural differences between isolated DNA and naturally occurring DNA, especially where the structural differences are merely ancillary to the breaking of covalent bonds, a process that is itself not inventive." *Ibid.* Moreover, Judge Bryson gave no weight to the PTO's position on patentability because of the Federal Circuit's position that "the PTO lacks substantive rulemaking authority as to issues such as patentability." *Id.*, at 1357.

Although the judges expressed different views concerning the patentability of isolated DNA, all three agreed that patent claims relating to cDNA met the patent-eligibility requirements of § 101. *Id.*, at 1326, and n. 9 (recognizing that some patent claims are limited to cDNA and that such claims are patent eligible under § 101); *id.*, at 1337 (Moore, J., concurring in part); *id.*, at 1356 (Bryson, J., concurring in part and dissenting in part) ("cDNA cannot be isolated from nature, but instead must be created in the laboratory . . . because the introns that are found in the native gene are re-

moved from the cDNA segment").[3] We granted certiorari. 568 U. S. 1045 (2012).

II

A

Section 101 of the Patent Act provides:

> "Whoever invents or discovers any new and useful . . . composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U. S. C. § 101.

We have "long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable." *Mayo*, 566 U. S., at 70 (internal quotation marks and brackets omitted). Rather, "'they are the basic tools of scientific and technological work'" that lie beyond the domain of patent protection. *Id.*, at 71. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would "tie up" the use of such tools and thereby "inhibit future innovation premised upon them." *Id.*, at 86. This would be at odds with the very point of patents, which exist to promote creation. *Diamond* v. *Chakrabarty*, 447 U. S. 303, 309 (1980) (Products of nature are not created, and "'manifestations of . . . nature [are] free to all men and reserved exclusively to none'").

The rule against patents on naturally occurring things is not without limits, however, for "all inventions at some level

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[3] Myriad continues to challenge Dr. Ostrer's Declaratory Judgment Act standing in this Court. Brief for Respondents 17–22. But we find that, under the Court's decision in *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U. S. 118 (2007), Dr. Ostrer has alleged sufficient facts, "under all the circumstances, [to] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.*, at 127 (internal quotation marks omitted).

embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," and "too broad an interpretation of this exclusionary principle could eviscerate patent law." 566 U. S., at 71. As we have recognized before, patent protection strikes a delicate balance between creating "incentives that lead to creation, invention, and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention." *Id.*, at 92. We must apply this well-established standard to determine whether Myriad's patents claim any "new and useful . . . composition of matter," § 101, or instead claim naturally occurring phenomena.

B

It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this renders the genes patentable.

Myriad recognizes that our decision in *Chakrabarty* is central to this inquiry. Brief for Respondents 14, 23–27. In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. 447 U. S., at 305, and n. 1. The Court held that the modified bacterium was patentable. It explained that the patent claim was "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" *Id.*, at 309–310 (quoting *Hartranft* v. *Wiegmann*, 121 U. S. 609, 615 (1887); alteration in original). The *Chakrabarty* bacterium was new "with markedly different characteristics from any

found in nature," 447 U. S., at 310, due to the additional plasmids and resultant "capacity for degrading oil." *Id.*, at 305, n. 1. In this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.

Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry. In *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.*, 333 U. S. 127 (1948), this Court considered a composition patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants take nitrogen from the air and fix it in the soil. *Id.*, at 128–129. The ability of the bacteria to fix nitrogen was well known, and farmers commonly "inoculated" their crops with them to improve soil nitrogen levels. But farmers could not use the same inoculant for all crops, both because plants use different bacteria and because certain bacteria inhibit each other. *Id.*, at 129–130. Upon learning that several nitrogen-fixing bacteria did not inhibit each other, however, the patent applicant combined them into a single inoculant and obtained a patent. *Id.*, at 130. The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way. *Id.*, at 132 ("There is no way in which we could call [the bacteria mixture a product of invention] unless we borrowed invention from the discovery of the natural principle itself"). His patent claim thus fell squarely within the law of nature exception. So do Myriad's. Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes "new . . . composition[s] of matter," § 101, that are patent eligible.

Indeed, Myriad's patent descriptions highlight the problem with its claims. For example, a section of the '282 patent's Detailed Description of the Invention indicates that Myriad found the location of a gene associated with increased

risk of breast cancer and identified mutations of that gene that increase the risk. See App. 748–749.[4] In subsequent language Myriad explains that the location of the gene was unknown until Myriad found it among the approximately 8 million nucleotide pairs contained in a subpart of chromosome 17. See *ibid.*[5] The '473 and '492 patents contain similar language as well. See *id.*, at 854, 947. Many of Myriad's patent descriptions simply detail the "iterative process" of discovery by which Myriad narrowed the possible locations for the gene sequences that it sought.[6] See, *e. g.*, *id.*, at 750.

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[4] The full relevant text of the Detailed Description of the Invention is as follows:

"It is a discovery of the present invention that the BRCA1 locus which predisposes individuals to breast cancer and ovarian cancer, is a gene encoding a BRCA1 protein, which has been found to have no significant homology with known protein or DNA sequences. . . . It is a discovery of the present invention that mutations in the BRCA1 locus in the germline are indicative of a predisposition to breast cancer and ovarian cancer. Finally, it is a discovery of the present invention that somatic mutations in the BRCA1 locus are also associated with breast cancer, ovarian cancer and other cancers, which represents an indicator of these cancers or of the prognosis of these cancers. The mutational events of the BRCA1 locus can involve deletions, insertions and point mutations." App. 749.

Notwithstanding Myriad's repeated use of the phrase "present invention," it is clear from the text of the patent that the various discoveries *are* the "invention."

[5] "Starting from a region on the long arm of human chromosome 17 of the human genome, 17q, which has a size estimated at about 8 million base pairs, a region which contains a genetic locus, BRCA1, which causes susceptibility to cancer, including breast and ovarian cancer, has been identified." *Ibid.*

[6] Myriad first identified groups of relatives with a history of breast cancer (some of whom also had developed ovarian cancer); because these individuals were related, scientists knew that it was more likely that their diseases were the result of genetic predisposition rather than other factors. Myriad compared sections of their chromosomes, looking for shared genetic abnormalities not found in the general population. It was that process which eventually enabled Myriad to determine where in the genetic sequence the BRCA1 and BRCA2 genes reside. See, *e. g.*, *id.*, at 749, 763–775.

Myriad seeks to import these extensive research efforts into the § 101 patent-eligibility inquiry. Brief for Respondents 8–10, 34. But extensive effort alone is insufficient to satisfy the demands of § 101.

Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes (such as claims 1 and 2 of the '282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule.

Finally, Myriad argues that the PTO's past practice of awarding gene patents is entitled to deference, citing *J. E. M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U. S. 124 (2001). See Brief for Respondents 35–39, 49–50. We disagree. *J. E. M.* held that new plant breeds were eligible for utility patents under § 101 notwithstanding separate statutes providing special protections for plants, see 7 U. S. C. § 2321 *et seq.* (Plant Variety Protection Act); 35 U. S. C. §§ 161–164 (Plant Patent Act of 1930). After analyzing the text and structure of the relevant statutes, the Court mentioned that the Board of Patent Appeals and Interferences had determined that new plant breeds were patent eligible under § 101 and that Congress had recognized and

endorsed that position in a subsequent Patent Act amendment. 534 U. S., at 144–145 (citing *In re Hibberd*, 227 USPQ 443 (1985), and 35 U. S. C. § 119(f)). In this case, however, Congress has not endorsed the views of the PTO in subsequent legislation. While Myriad relies on Judge Moore's view that Congress endorsed the PTO's position in a single sentence in the Consolidated Appropriations Act of 2004, see Brief for Respondents 31, n. 8; 689 F. 3d, at 1346, that Act does not even mention genes, much less isolated DNA. § 634, 118 Stat. 101 ("None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism").

Further undercutting the PTO's practice, the United States argued in the Federal Circuit and in this Court that isolated DNA was *not* patent eligible under § 101, Brief for United States as *Amicus Curiae* 20–33, and that the PTO's practice was not "a sufficient reason to hold that isolated DNA is patent-eligible." *Id.*, at 26. See also *id.*, at 28–29. These concessions weigh against deferring to the PTO's determination.[7]

C

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring.[8]

[7] Myriad also argues that we should uphold its patents so as not to disturb the reliance interests of patent holders like itself. Brief for Respondents 38–39. Concerns about reliance interests arising from PTO determinations, insofar as they are relevant, are better directed to Congress. See *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U. S. 66, 88–90 (2012).

[8] Some viruses rely on an enzyme called reverse transcriptase to reproduce by copying RNA into cDNA. In rare instances, a side effect of a viral infection of a cell can be the random incorporation of fragments of the resulting cDNA, known as a pseudogene, into the genome. Such

Petitioners concede that cDNA differs from natural DNA in that "the non-coding regions have been removed." Brief for Petitioners 49. They nevertheless argue that cDNA is not patent eligible because "[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician." *Id.*, at 51. That may be so, but the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.[9]

III

It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents, "were well

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pseudogenes serve no purpose; they are not expressed in protein creation because they lack genetic sequences to direct protein expression. See J. Watson et al., Molecular Biology of the Gene 142, 144, fig. 7–5 (6th ed. 2008). Perhaps not surprisingly, given pseudogenes' apparently random origins, petitioners "have failed to demonstrate that the pseudogene consists of the same sequence as the BRCA1 cDNA." *Association for Molecular Pathology* v. *United States Patent and Trademark Office*, 689 F. 3d 1303, 1356, n. 5 (CA Fed. 2012). The possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.

[9] We express no opinion whether cDNA satisfies the other statutory requirements of patentability. See, *e. g.*, 35 U. S. C. §§ 102, 103, and 112; Brief for United States as *Amicus Curiae* 19, n. 5.

understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach," 702 F. Supp. 2d, at 202–203, and are not at issue in this case.

Similarly, this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, "[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications." 689 F. 3d, at 1349.

Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.

* * *

For the foregoing reasons, the judgment of the Federal Circuit is affirmed in part and reversed in part.

It is so ordered.

JUSTICE SCALIA, concurring in part and concurring in the judgment.

I join the judgment of the Court, and all of its opinion except Part I–A and some portions of the rest of the opinion going into fine details of molecular biology. I am unable to affirm those details on my own knowledge or even my own belief. It suffices for me to affirm, having studied the opinions below and the expert briefs presented here, that the portion of DNA isolated from its natural state sought to be patented is identical to that portion of the DNA in its natural state; and that complementary DNA (cDNA) is a synthetic creation not normally present in nature.